Regulatory Analysis Form

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REVIEW COMMISSION

IRRC Number: 2135

(1) Agency

PA Department of Health

(2) I.D. Number (Governor's Office Use)

10-163

(3) Short Title

Amending the schedules of controlled substances.

(4) PA Code Cite

28 PA Code § 25.72

(5) Agency Contacts & Telephone Numbers

Primary Contact: John Hair (717) 783-8665

Secondary Contact: Janice Staloski (717) 783-1379

(6) Type of Rulemaking (check one)

Proposed Rulemaking
√ Final Order Adopting Regulation
Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

✓ No
Yes: By the Attorney General
Yes: By the Governor

(8) Briefly explain the regulation in clear and non technical language.

The Department amends the schedule of controlled substances at 28 PA Code §25.72. These regulations contain five schedules of controlled substances which categorize substances according to different potentials for abuse and medical use. A controlled substance is placed in Schedule II when there is: (1) a high potential for abuse; (2) currently accepted medical use in the United States and (3) abuse may lead to severe psychic or physical dependence. A controlled substance is placed in Schedule III when there is: (1) a potential for abuse less than the substances listed in Schedule I or Schedule 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 regulation reschedules dronabinol from a Schedule II to Schedule III controlled substance. This action permits patients to obtain prescription refills and possibly reduce trips to physicans offices. This action allows pharmacies to accept telephoned or fascimiled prescriptions from physicans rather than mandated written prescriptions. This action allows pharmacies to obtain the drug product more quickly for patients.

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The amendment to the Schedules of controlled substances follows similar actions by the Federal Drug Enforcement Agency (DEA).

The amendment to the regulation at 28 PA Code Chapter 25 was approved by the Pennsylvania Drug, Device, and Cosmetic Board on December 9,1999.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The amendment to the schedules of controlled substances are made pursuant to Sections 3 and 4 of the Controlled Substance, Drug Device and Cosmetics Act (Act), (P.L. 233, No. 64), (35 P.S. §780-101 et seq.), which authorizes 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.

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

This action permits patients with serious illnesses to obtain prescription refills and reduce trips to physicians' offices. This action allows pharmacies to accept telephoned or fascimiled prescriptions from physicians rather than mandated written prescriptions. This action also allows pharmacies to order the drug more quickly for patients.

Dronabinol has been available in the United States since 1986. Since that time, drug diversion, misuse, and abuse have been minimal. Thus, rescheduling of dronabinol will reduce patient burdens without any increase risk of public health, safety, or general public welfare.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

No known risks associated with not amending the schedule. However see (11) for benefit.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Patients with AIDS and patients who are receiving chemotherapy and achieve benefits from the drug dronabinol will be able to obtain prescriptions with refills and possibly reduce the number of actual visits to the physician's office. This regulation allows pharmacies to order the drug more quickly for patients.

Because of increased flexibility in prescribing, sales of dronabinol might increase and result in increased profits for drug manufacturers.

Regulatory Analysis Form

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

None known

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

All pharmacies and pharmacists in the Commonwealth, physicians, hospitals, and certain health clinics and drug distributors, manufacturers and distributors who are already complying with the schedule II regulations.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The Drug, Device, and Cosmetic Board convened a public hearing on the matter. Comments were provided for the hearing in the form of a letter from Commonwealth physicians supporting the rescheduling of dronabinol from a schedule III controlled substance to a schedule II controlled substance.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures that may be required.

This order does not affect costs or savings by the regulated community. This order does not require any legal, accounting, or consulting procedures not already being undertaken by the regulated community.

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(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures that may be required.

The amendment has no measurable fiscal impact on local government, because a system exists for the oversight of controlled substances.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures that may be required.

The amendment has no measurable fiscal impact on the state government. An administrative paperwork system is already in place and does not measurably change with the rescheduling of a controlled substance.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$N/A	$	$	$	$	$
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

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(20a) Explain how the cost estimates listed above were derived.

There will be no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public.

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
N/A				

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The benefits are described above. There are no apparent adverse effects and costs.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

There are no alternative nonregulatory approaches.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

There are no alternative regulatory approaches.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

No

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The amendment to reschedule follows similar action by the DEA. At least half of the other states have also rescheduled. More states may follow in this action. This amendment does not put Pennsylvania at a competitive disadvantage with other states.

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(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

No public hearings or informational meetings are scheduled at this time. Prior to publication as proposed rulemaking the Drug Device and Cosmetic Board convened a public hearing on the matter. Comments were provided for the hearing in the form of a letter from Commonwealth physicians supporting the rescheduling of dronabinol from a schedule III controlled substance to a schedule II controlled substance. The Department determined that public hearings or informational meetings were not needed.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements?

Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

While there may be some change associated with moving a substance from schedule II to schedule III, there are no measurable change in existing reporting, record keeping or other paperwork requirements.

(29) Please list any special provisions that have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The amendment to current regulation is based on established procedures to protect the health and welfare of the public in general and not affected groups or persons.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The amendment will become effective upon publication as final in the Pennsylvania Bulletin.

(31) Provide the schedule for continual review of the regulation.

The amendment will be effective immediately upon final adoption. The schedules of controlled substances are continually monitored and updated as needed.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

2135

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REVIEW COMMISSION

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or independent Agencies.
BY _____ DEPUTY ATTORNEY GENERAL	DEPARTMENT OF HEALTH (AGENCY)	BY _____
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-163	1/24/01 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) (~~Chief Counsel, Independent Agency~~) (Strike inapplicable title)
	BY _____ Robert S. Zimmerman, Jr.	
9 Check if applicable. Copy not approved. Objections attached.	TITLE: Secretary of Health	9 Check if applicable. No Attorney General approval or objection within 30 days after submission.

DEPARTMENT OF HEALTH

FINAL RULEMAKING

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASE

[28 Pa. Code Chapter 25]

The Department of Health (Department) hereby adopts amendments to 28 Pa. Code § 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) (P. L. 233, No. 64) (35 P.S. §780-101 et seq.) 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 met on December 9, 1999. The meeting notice was published in the Pennsylvania Bulletin 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 Fed. Reg. 59,751). Both 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 Drug, Device and Cosmetic 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 rulemaking amends 28 Pa. Code § 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. Such benefits, however, are not quantifiable.

PAPER 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 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 pursuant to 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 _____. 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.

These final-form regulations were deemed approved by the House Health and Human Services Committee and the Senate Public Health and Welfare Committee on _____. IRRC met on _____, and approved the regulation in accordance with Section 5.1(e) of the Regulatory Review Act. The Office of Attorney General approved the regulations on _____.

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, Pennsylvania 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 (i.e. large print, audio tape or Braille) may contact Mr. Hair so that necessary arrangements may be made.

FINDINGS

The Department finds:

1. Public notice of intention to adopt the regulations 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 regulations is necessary and appropriate.

ORDER

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

(a) A regulation of the Department, 28 Pa. Code § 25.72, is amended by rescheduling dronabinol from Schedule II to Schedule III as set forth in 30 Pa.B. 3945 and Annex A hereto.

(b) The Secretary of Health 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 of Health shall submit this order, Annex A 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 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*.

ANNEX A

DEPARTMENT OF HEALTH

TITLE 28 – HEALTH AND SAFETY

* * *

PART III. PREVENTION OF DISEASES

CHAPTER 25. CONTROLLED SUBSTANCES, DRUGS, DEVICES AND COSMETICS

* * *

§25.72. Schedules of controlled substances.

* * *

(c) Schedule II. In determining that a substance comes within this schedule, the Secretary will find: a high potential for abuse; currently acceptable 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 substances are included in this schedule:

* * *

(5) A material, compound, mixture or preparation, unless specifically excepted, which contains a quantity of:

* * *

[(iv) Dronabinol-synthetic-in sesame oil and encapsulated in a soft gelatin capsule but only those drug products approved by the United States Food and Drug Administration.]
[(v)] (iv) Nabilone.

* * *

(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 Schedule 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:

* * *

(9) A material, compound, mixture or preparation, unless specifically excepted, which contains a quantity of Dronabinol-synthetic-in sesame oil encapsulated in a soft gelatin capsule but only those drug products approved by the United States Food and Drug Administration.

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

ROBERT S. ZIMMERMAN, JR., MPH
SECRETARY OF HEALTH

February 5, 2001

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, PA 17101

Re: Department of Health Final-Form Regulations
Schedule of Controlled Substances
No. 10-163

Dear Mr. Nyce:

Enclosed is a copy of the final-form regulations for review by the Commission pursuant to the Regulatory Review Act (Act) (71 P.S. §§745.1-745.15). Section 5.1(a) of the Act provides that, upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Commission and the standing committee, a copy of the agency's response to the comments received, the names and addresses of commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

The Department did not receive any comments to the proposed rulemaking.

Section 5.1(e) of the Act provides that within ten (10) days following the expiration of the standing committee review period, or at its next regularly scheduled meeting, the Commission shall approve or disapprove the final-form regulations.

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Deborah Griffiths, Director, Office of Legislative Affairs, (717) 783-3985.

Sincerely,

Robert S. Zimmerman, Jr.

Enclosures
RSZ/KBF/kad

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

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REVIEW COMMISSION

I.D. NUMBER:	10-163
SUBJECT:	Prevention of Disease
AGENCY:	Department of Health

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
2/5	Lauraine Calvert	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
2/5	Lila J. Burns	
2/5	Kristi Knoiser	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
2/5	E. Pagan	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU