6-29

Secretary of State
Certificate and Order for Filing

PERMANENT ADMINISTRATIVE RULES

I certify that the attached copies* are true, full and correct copies of the PERMANENT Rule(s) adopted on June 16, 2010 by the
Date prior to or same as filing date

Oregon Board of Pharmacy — OAR Chapter 855
Agency and Division — Administrative Rules Chapter Number

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to become effective June 29, 2010 (Date upon filing or later) Rulemaking Notice was published in the May 2010 (Month and Year) *Oregon Bulletin.***

BP 8-2010

RULE CAPTION

Reschedule methamphetamine in Controlled Substance Schedule 1 and marijuana in Controlled Substance Schedule II.

RULEMAKING ACTION

List each rule number separately, 000-000-0000.

ADOPT:

AMEND: 855-080-0020, 855-080-0021, 855-080-0022, 855-080-0028, 855-080-0055, 855-080-0085, 855-080-0105

REPEAL:

RENUMBER: Secure approval of rule numbers with the Administrative Rules Unit prior to filing.

AMEND & RENUMBER:

FILED
JUN 29 2010
ARCHIVES DIVISION
SECRETARY OF STATE

ORS 475.035, 689.205
Stat. Auth.

Other Authority

ORS 475.059, 475.065
Stats. Implemented

RULE SUMMARY

ORS 475.059 requires the Board to reschedule marijuana from Controlled Substance Schedule I to Schedule II, III, IV or V. In accordance with ORS 475.035, the Board has reviewed a spectrum of the scientific knowledge available regarding marijuana with specific reference to its pharmacological effects, the patterns of use and misuse, and the potential consequences of abuse. The Board reviewed an extensive collection of scientific and sociological material relating to marijuana, as well as comments from members of the public, some of whom have extensive training and experience with marijuana. The Board decided that Schedule II is the most appropriate schedule. Under ORS 475.065, the Board is also required to reschedule methamphetamine, except for accepted medical use, as a Schedule I drug. The other amendments correct errors and update rules in accordance with changes in federal regulations.

Authorized Signer — Gary A. Schnabel (Printed name) — 6/25/2010 (Date)

*With this original, file one photocopy of certificate, one paper copy of rules listed in Rulemaking Actions, and electronic copy of rules.
**The *Oregon Bulletin* is published on the 1st of each month and updates the rule text found in the Oregon Administrative Rules Compilation. Notice forms must be submitted to the Administrative Rules Unit, Oregon State Archives, 800 Summer Street NE, Salem, Oregon 97310 by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a Saturday, Sunday or legal holiday when Notice forms are accepted until 5:00 pm on the preceding workday.

BOARD OF PHARMACY

DIVISION 80

SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0020

Schedules

Pursuant to ORS 475.005(6) those drugs and their immediate precursors classified in Schedules I through V under the Federal Controlled Substances Act, 21 U.S.C. Sections 811 to 812 and as amended by the Board pursuant to ORS 475.035 are the controlled substances for purposes of regulation and control under the Act. Those schedules are set out in OAR 855-080-0021 through 855-080-0026.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035

855-080-0021

Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21CFR part 1308.11, and unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) Benzylfentanyl;

(b) Thenylfentanyl;

(c) N-Benzylpiperazine (BZP);

(d) 1,4-butanediol.

(e) Methamphetamine, except as listed in OAR 855-080-0022.

(2) Exceptions. The following are exceptions to subsection (1) of this rule:

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals.

(b) 1,4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products.

(c) Marijuana.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035, 475.059, 475.065, 475.940

855-080-0022

Schedule II

Schedule II consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.12 and any quantity of the following substances:

(a) Marijuana;

(b) Methamphetamine, when in the form of an FDA approved product containing methamphetamine, its salts, isomers and salts of its isomers as an active ingredient for the purposes of currently accepted medical use.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035, 475.059, 475.065

855-080-0028

Excluded Substances

The following drugs and their generic equivalents are excepted from the schedules in OAR 855-080-0021 through 855-080-0026:

(1) Benzedrex inhaler (Propylhexedrine).

(2) Vicks -- Vapor inhaler (Levmetamfetamine).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155

855-080-0055

Separate Registration for Independent Activities

The manufacturing and distributing of controlled substances are deemed activities independent of each other. A separate registration is required for each activity; however, a person registered to manufacture may distribute or dispense any controlled substance which they are registered to manufacture, provided that, unless specifically exempted, they comply with all requirements and duties prescribed by statute and rules for persons registered to distribute or dispense as applicable.

Stat. Auth.: 689.205
Stats. Implemented: ORS 475.125, 689.155

Controlled Substances Prescriptions

855-080-0085

Prescription Requirements

(1) Except as provided in sections (2) and (3) of this rule, the provisions of 21 CFR 1306.01 through 1306.27 and 1304.03(d) shall be complied with by the registrants, practitioners and pharmacists as specified therein in the issuance, preparation, labeling dispensing, recordkeeping and filing of prescriptions for controlled substances. An electronic prescription is permitted for any substance listed in OAR 855-080-0022 through 855-080-0026 when so permitted by federal regulations.

(2) The provisions of 21 CFR 1306.11(a) under section (1) of this rule are amended by deleting "which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act."

(3) The provisions of 21 CFR 1306.21 through 1306.27 under section (1) of this rule shall be deemed to apply also to controlled substances listed in Schedule V.

(4) Controlled substances in Schedules III, IV, and V which are prescription drugs determined by the Board pursuant to ORS 475.185(3) are those prescription drugs as determined under the Federal Food, Drug, and Cosmetic Act. Such drugs are "Legend Drugs" and bear the legend "Caution: Federal law prohibits dispensing without a prescription", or an equivalent legend. In addition, any preparation containing any amount of codeine or its salts, opium, or paregoric in Schedules III, IV, or V is a prescription drug as determined by the Board pursuant to ORS 475.185(3).

(5) "Emergency Situations" as referred to in ORS 475.185(2) mean the same as specified in 21 CFR 290.10.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.185, 475.188

855-080-0105

Disposal of Drugs

(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Controlled substances which are expired, deteriorated or unwanted shall be disposed of in conformance with **21 CFR 1307.21**.

(3) Expired, deteriorated, discontinued, or unwanted controlled substances in a long-term care facility shall be destroyed and the destruction jointly witnessed on the premises by any two of the following:

(a) The consultant pharmacist or registered nurse designee.

(b) The Director of Nursing Services or supervising nurse designee

(c) The administrator of the facility or an administrative designee

(d) A Registered Nurse employed by the facility

(4) The destruction shall be documented and signed by the witnesses and the document retained at the facility for a period of at least three years. Copies of the document shall be sent to the consultant pharmacist. Any destruction of controlled substances deviating from this procedure must be approved by the Board prior to implementation.

(5) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public heath or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.305