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HOUSE BILL No. 4248

February 12, 2013, Introduced by Reps. Kivela, Dianda and Cavanagh and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled "Public health code,"

by amending sections 7220, 7340, and 17708 (MCL 333.7220, 333.7340, and 333.17708), section 7220 as amended by 1999 PA 144, section 7340 as added by 2006 PA 261, and section 17708 as amended by 2012 PA 209; and to repeal acts and parts of acts.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 7220. (1) The following controlled substances are included in schedule 5:

(a) The following drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

Loperamide

(b) Any compound, mixture, or preparation containing any of

- 1 the following limited quantities of narcotic drugs or salts of
- 2 narcotic drugs, which includes 1 or more nonnarcotic active
- 3 medicinal ingredients in sufficient proportion to confer upon the
- 4 compound, mixture, or preparation valuable medicinal qualities
- 5 other than those possessed by the narcotic drug alone:
- 6 (i) Not more than 200 milligrams of codeine, or any of its
- 7 salts, per 100 milliliters or per 100 grams and not more than 10
- 8 milligrams per dosage unit.
- 9 (ii) Not more than 100 milligrams of dihydrocodeine, or any of
- 10 its salts, per 100 milliliters or per 100 grams and not more than 5
- 11 milligrams per dosage unit.
- 12 (iii) Not more than 100 milligrams of ethylmorphine, or any of
- 13 its salts, per 100 milliliters or per 100 grams and not more than 5
- 14 milligrams per dosage unit.
- (iv) Not more than 2.5 milligrams of diphenoxylate and not less
- 16 than 25 micrograms of atropine sulfate per dosage unit.
- 17 (v) Not more than 100 milligrams of opium per 100 milliliters
- 18 or per 100 grams and not more than 5 milligrams per dosage unit.
- 19 (c) Except as otherwise provided in this subdivision,
- 20 ephedrine, a salt of ephedrine, an optical isomer of ephedrine, a
- 21 salt of an optical isomer of ephedrine, or a compound, mixture, or
- 22 preparation containing ephedrine, a salt of ephedrine, an optical
- 23 isomer of ephedrine, or a salt of an optical isomer of ephedrine.
- 24 However, the following are not included in schedule 5:
- 25 (i) A product containing ephedrine, a salt of ephedrine, an
- 26 optical isomer of ephedrine, or a salt of an optical isomer of
- 27 ephedrine if the drug product may lawfully be sold over the counter

- 1 without a prescription under federal law, is labeled and marketed
- 2 in a manner consistent with the pertinent OTC tentative final or
- 3 final monograph, is manufactured and distributed for legitimate
- 4 medical use in a manner that reduces or eliminates the likelihood
- 5 for abuse, and is not marketed, advertised, or labeled for an
- 6 indication of stimulation, mental alertness, energy, weight loss,
- 7 appetite control, or muscle enhancement and if the drug product is
- 8 1 of the following:
- 9 (A) A solid dosage form, including but not limited to a soft
- 10 gelatin caplet, that combines as active ingredients not less than
- 11 400 milligrams of guaifenesin and not more than 25 milligrams of
- 12 ephedrine per dose, packaged in blister packs with not more than 2
- 13 tablets or caplets per blister.
- 14 (B) An anorectal preparation containing not more than 5%
- 15 ephedrine.
- 16 (ii) A food product or a dietary supplement containing
- 17 ephedrine, if the food product or dietary supplement meets all of
- 18 the following criteria:
- 19 (A) It contains, per dosage unit or serving, not more than the
- 20 lesser of 25 milligrams of ephedrine alkaloids or the maximum
- 21 amount of ephedrine alkaloids provided in applicable regulations
- 22 adopted by the United States food and drug administration and
- 23 contains no other controlled substance.
- 24 (B) It contains no hydrochloride or sulfate salts of ephedrine
- 25 alkaloids.
- 26 (C) It is packaged with a prominent label securely affixed to
- 27 each package that states the amount in milligrams of ephedrine in a

- 1 serving or dosage unit; the amount of the food product or dietary
- 2 supplement that constitutes a serving or dosage unit; that the
- 3 maximum recommended dosage of ephedrine for a healthy adult human
- 4 is the lesser of 100 milligrams in a 24-hour period or the maximum
- 5 recommended dosage or period of use provided in applicable
- 6 regulations adopted by the United States food and drug
- 7 administration; and that improper use of the product may be
- 8 hazardous to a person's health.
- 9 (2) Inclusion of the substances described in subsection (1)(c)
- 10 into schedule 5 does not preclude prosecution for a crime involving
- 11 those schedule 5 substances under FORMER section 17766c.
- Sec. 7340. (1) A person shall not sell, distribute, deliver,
- 13 or otherwise furnish a product that contains any compound, mixture,
- 14 or preparation containing any detectable quantity of ephedrine or
- 15 pseudoephedrine, a salt or optical isomer of ephedrine or
- 16 pseudoephedrine, or a salt of an optical isomer of ephedrine or
- 17 pseudoephedrine to an individual if the sale is transacted through
- 18 use of the mail, internet, telephone, or other electronic means.
- 19 (2) This section does not apply to any of the following:
- 20 (a) A pediatric product primarily intended for administration
- 21 to children under 12 years of age according to label instructions.
- 22 (b) A product containing pseudoephedrine that is in a liquid
- 23 form if pseudoephedrine is not the only active ingredient.
- 24 (A) (c)—A product that the state board of pharmacy, upon
- 25 application of the manufacturer or certification by the United
- 26 States drug enforcement administration as inconvertible, exempts
- 27 from this section because the product has been formulated in such a

- 1 way as to effectively prevent the conversion of the active
- 2 ingredient into methamphetamine.
- **3 (B)** (d) A person who dispenses a product described in
- 4 subsection (1) pursuant to a prescription.
- 5 (C) (e) A person who, in the course of his or her business,
- 6 sells or distributes products described in subsection (1) to either
- 7 of the following:
- 8 $\frac{(i)}{A}$ A person licensed by this state to manufacture, deliver,
- 9 dispense, or possess with intent to manufacture or deliver a
- 10 controlled substance, prescription drug, or other drug.
- 11 (ii) A person who orders those products described in subsection
- 12 (1) for retail sale pursuant to a license issued under the general
- 13 sales tax act, 1933 PA 167, MCL 205.51 to 205.78.
- 14 (D) (f)—A manufacturer or distributor who donates product
- 15 samples to a nonprofit charitable organization that has tax-exempt
- 16 status pursuant to UNDER section 501(c)(3) of the internal revenue
- 17 code of 1986, 26 USC 501, a licensed practitioner, or a
- 18 governmental entity.
- 19 (3) A person who violates this section is guilty of a felony
- 20 punishable by imprisonment for not more than 4 years or a fine of
- 21 not more than \$5,000.00, or both.
- Sec. 17708. (1) "Preceptor" means a pharmacist approved by the
- 23 board to direct the training of an intern in an approved pharmacy.
- 24 (2) "Prescriber" means a licensed dentist, a licensed doctor
- 25 of medicine, a licensed doctor of osteopathic medicine and surgery,
- 26 a licensed doctor of podiatric medicine and surgery, a licensed
- 27 optometrist certified under part 174 to administer and prescribe

- 1 therapeutic pharmaceutical agents, a licensed veterinarian, or
- 2 another licensed health professional acting under the delegation
- 3 and using, recording, or otherwise indicating the name of the
- 4 delegating licensed doctor of medicine, or licensed doctor of
- 5 osteopathic medicine and surgery, OR LICENSED DOCTOR OF PODIATRIC
- 6 MEDICINE AND SURGERY.
- 7 (3) "Prescription" means an order by a prescriber to fill,
- 8 compound, or dispense a drug or device written and signed; written
- 9 or created in an electronic format, signed, and transmitted by
- 10 facsimile; or transmitted electronically or by other means of
- 11 communication. An order transmitted in other than written or hard-
- 12 copy form shall be electronically recorded, printed, or written and
- 13 immediately dated by the pharmacist, and that record constitutes
- 14 the original prescription. In a health facility or agency licensed
- 15 under article 17 or other medical institution, an order for a drug
- 16 or device in the patient's chart constitutes for the purposes of
- 17 this definition the original prescription. Subject to section
- 18 17751(2) and (5), prescription includes, but is not limited to, an
- 19 order for a drug, not including a controlled substance as defined
- 20 in section 7104 except under circumstances described in section
- 21 17763(e), written and signed; written or created in an electronic
- 22 format, signed, and transmitted by facsimile; or transmitted
- 23 electronically or by other means of communication by a physician
- 24 prescriber or dentist prescriber licensed to practice dentistry,
- 25 medicine, or osteopathic medicine and surgery in a state other than
- 26 Michigan.
- 27 (4) "Prescription drug" means 1 or more of the following:

- 1 (a) A drug dispensed pursuant to a prescription.
- 2 (b) A drug bearing the federal legend "CAUTION: federal law
- 3 prohibits dispensing without prescription" or "Rx only".
- 4 (c) A drug designated by the board as a drug that may only be
- 5 dispensed pursuant to a prescription.
- 6 (D) EPHEDRINE, A SALT OF EPHEDRINE, AN OPTICAL ISOMER OF
- 7 EPHEDRINE, A SALT OF AN OPTICAL ISOMER OF EPHEDRINE, OR A COMPOUND,
- 8 MIXTURE, OR PREPARATION CONTAINING EPHEDRINE, A SALT OF EPHEDRINE,
- 9 AN OPTICAL ISOMER OF EPHEDRINE, OR A SALT OF AN OPTICAL ISOMER OF
- 10 EPHEDRINE.
- 11 Enacting section 1. Sections 7340a, 17766c, 17766e, and 17766f
- 12 of the public health code, 1978 PA 368, MCL 333.7340a, 333.17766c,
- 13 333.17766e, and 333.17766f, are repealed.
- 14 Enacting section 2. This amendatory act takes effect January
- **15** 1, 2014.

01078'13 Final Page KKR