SENATE
STATE OF MINNESOTA
EIGHTY-EIGHTH SESSION

S.F. No. 2028

(SENATE AUTHORS: REINERT, Miller, Sieben, Ruud and Housley)

DATE	D-PG	OFFICIAL STATUS
02/27/2014	5885	Introduction and first reading Referred to Health, Human Services and Housing
03/03/2014	5939	Authors added Miller; Sieben
03/04/2014	5964	Author added Ruud
03/06/2014	6008	Author added Housley
03/19/2014	6298	Comm report: To pass and re-referred to Judiciary
03/26/2014	6848a	Comm report: To pass as amended and re-refer to State and Local Government
03/27/2014		Comm report: To pass as amended and re-refer to Finance

A bill for an act

relating to public safety; granting the Board of Pharmacy cease and desist authority to prevent the sale of synthetic drugs; modifying laws governing misbranding drugs, adulterated drugs; expanding the definition of drug; repealing the sunset and legislative reporting requirement for the Board of Pharmacy's emergency drug scheduling authority; providing training and expert support in the prosecution of synthetic drug cases; establishing a public education plan; appropriating money; amending Minnesota Statutes 2012, sections 151.01, subdivision 5; 151.06, subdivision 1a, by adding a subdivision; 151.26, subdivision 1; 151.34; 151.35; 151.36; 152.02, subdivision 8b.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2012, section 151.01, subdivision 5, is amended to read:

Subd. 5. **Drug.** The term "drug" means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, and all substances and preparations, other than food, intended to affect the structure or any function of the bodies of humans or other animals. The term drug shall also mean any compound, substance, or derivative that is not approved for human consumption by the United States Food and Drug Administration or specifically permitted for human consumption under Minnesota law, and when introduced into the body induces an effect similar to that of a Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance is marketed for the purpose of human consumption.

EFFECTIVE DATE. This section is effective August 1, 2014.

Sec. 2. Minnesota Statutes 2012, section 151.06, subdivision 1a, is amended to read:

Subd. 1a. **~~Disciplinary action~~ Cease and desist orders.** ~~It shall be grounds for disciplinary action by the Board of Pharmacy against the registration of the pharmacy if the Board of Pharmacy determines that any person with supervisory responsibilities at the pharmacy sets policies that prevent a licensed pharmacist from providing drug utilization review and patient counseling as required by rules adopted under subdivision 1. The Board of Pharmacy shall follow the requirements of chapter 14 in any disciplinary actions taken under this section.~~ (a) Whenever it appears to the board that a person has engaged in an act or practice constituting a violation of a law, rule, or other order related to the duties and responsibilities entrusted to the board, the board may issue and cause to be served upon the person an order requiring the person to cease and desist from violations.

(b) The cease and desist order must state the reasons for the issuance of the order and must give reasonable notice of the rights of the person to request a hearing before an administrative law judge. A hearing must be held not later than ten days after the request for the hearing is received by the board. After the completion of the hearing, the administrative law judge shall issue a report within ten days. Within 15 days after receiving the report of the administrative law judge, the board shall issue a further order vacating or making permanent the cease and desist order. The time periods provided in this provision may be waived by agreement of the executive director of the board and the person against whom the cease and desist order was issued. If the person to whom a cease and desist order is issued fails to appear at the hearing after being duly notified, the person is in default, and the proceeding may be determined against that person upon consideration of the cease and desist order, the allegations of which may be considered to be true. Unless otherwise provided, all hearings must be conducted according to chapter 14. The board may adopt rules of procedure concerning all proceedings conducted under this subdivision.

(c) If no hearing is requested within 30 days of service of the order, the cease and desist order will become permanent.

(d) A cease and desist order issued under this subdivision remains in effect until it is modified or vacated by the board. The administrative proceeding provided by this subdivision, and subsequent appellate judicial review of that administrative proceeding, constitutes the exclusive remedy for determining whether the board properly issued the cease and desist order and whether the cease and desist order should be vacated or made permanent.

EFFECTIVE DATE. This section is effective August 1, 2014, and applies to violations occurring on or after that date.

Sec. 3. Minnesota Statutes 2012, section 151.06, is amended by adding a subdivision to read:

Subd. 1b. **Enforcement of violations of cease and desist orders.** (a) Whenever the board under subdivision 1a seeks to enforce compliance with a cease and desist order that has been made permanent, the allegations of the cease and desist order are considered conclusively established for purposes of proceeding under subdivision 1a for permanent or temporary relief to enforce the cease and desist order. Whenever the board under subdivision 1a seeks to enforce compliance with a cease and desist order when a hearing or hearing request on the cease and desist order is pending, or the time has not yet expired to request a hearing on whether a cease and desist order should be vacated or made permanent, the allegations in the cease and desist order are considered conclusively established for the purposes of proceeding under subdivision 1a for temporary relief to enforce the cease and desist order.

(b) Notwithstanding this subdivision or subdivision 1a, the person against whom the cease and desist order is issued and who has requested a hearing under subdivision 1a may, within 15 days after service of the cease and desist order, bring an action in Ramsey County District Court for issuance of an injunction to suspend enforcement of the cease and desist order pending a final decision of the board under subdivision 1a to vacate or make permanent the cease and desist order. The court shall determine whether to issue such an injunction based on traditional principles of temporary relief.

EFFECTIVE DATE. This section is effective August 1, 2014, and applies to violations occurring on or after that date.

Sec. 4. Minnesota Statutes 2012, section 151.26, subdivision 1, is amended to read:

Subdivision 1. **Generally.** Nothing in this chapter shall subject a person duly licensed in this state to practice medicine, dentistry, or veterinary medicine, to inspection by the State Board of Pharmacy, nor prevent the person from administering drugs, medicines, chemicals, or poisons in the person's practice, nor prevent a duly licensed practitioner from furnishing to a patient properly packaged and labeled drugs, medicines, chemicals, or poisons as may be considered appropriate in the treatment of such patient; unless the person is engaged in the dispensing, sale, or distribution of drugs and the board provides reasonable notice of an inspection.

Except for the provisions of section 151.37, nothing in this chapter applies to or interferes with the dispensing, in its original package and at no charge to the patient, of a legend drug, other than a controlled substance, that was packaged by a manufacturer and provided to the dispenser for distribution as a professional sample.

Nothing in this chapter shall prevent the sale of drugs, medicines, chemicals, or poisons at wholesale to licensed physicians, dentists and veterinarians for use in their practice, nor to hospitals for use therein.

Nothing in this chapter shall prevent the sale of drugs, chemicals, or poisons either at wholesale or retail for use for commercial purposes, or in the arts, nor interfere with the sale of insecticides, as defined in Minnesota Statutes 1974, section 24.069, and nothing in this chapter shall prevent the sale of common household preparations and other drugs, chemicals, and poisons sold exclusively for use for nonmedicinal purposes; provided that this exception does not apply to any compound, substance, or derivative that is not approved for human consumption by the United States Food and Drug Administration or specifically permitted for human consumption under Minnesota law, and when introduced into the body induces an effect similar to that of a Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance is marketed for the purpose of human consumption.

Nothing in this chapter shall apply to or interfere with the vending or retailing of any nonprescription medicine or drug not otherwise prohibited by statute which is prepackaged, fully prepared by the manufacturer or producer for use by the consumer, and labeled in accordance with the requirements of the state or federal Food and Drug Act; nor to the manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature, for use for nonmedicinal purposes; provided that this exception does not apply to any compound, substance, or derivative that is not approved for human consumption by the United States Food and Drug Administration or specifically permitted for human consumption under Minnesota law, and when introduced into the body induces an effect similar to that of a Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance is marketed for the purpose of human consumption. Nothing in this chapter shall prevent the sale of drugs or medicines by licensed pharmacists at a discount to persons over 65 years of age.

EFFECTIVE DATE. This section is effective August 1, 2014.

Sec. 5. Minnesota Statutes 2012, section 151.34, is amended to read:

151.34 PROHIBITED ACTS.

It shall be unlawful to:

(1) manufacture, sell or deliver, hold or offer for sale any drug that is adulterated or misbranded;

(2) adulterate or misbrand any drug;

(3) receive in commerce any drug that is adulterated or misbranded, and to deliver or proffer delivery thereof for pay or otherwise;

(4) refuse to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record as authorized by this chapter;

(5) remove or dispose of a detained or embargoed article in violation of this chapter;

(6) alter, mutilate, destroy, obliterate, or remove the whole or any part of the labeling of, or to do any other act with respect to a drug, if such act is done while such drug is held for sale and results in such drug being adulterated or misbranded;

(7) use for a person's own advantage or to reveal other than to the board or its authorized representative or to the courts when required in any judicial proceeding under this chapter any information acquired under authority of this chapter concerning any method or process ~~which~~ that is a trade secret and entitled to protection;

(8) use on the labeling of any drug any representation or suggestion that an application with respect to such drug is effective under the federal act or that such drug complies with such provisions;

(9) in the case of a manufacturer, packer, or distributor offering legend drugs for sale within this state, fail to maintain for transmittal or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter ~~which~~ that is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under provisions of this chapter;

(10) conduct a pharmacy without a pharmacist in charge;

(11) dispense a legend drug without first obtaining a valid prescription for that drug;

(12) conduct a pharmacy without proper registration with the board;

(13) practice pharmacy without being licensed to do so by the board; ~~or~~

(14) sell at retail federally restricted medical gases without proper registration with the board except as provided in this chapter.; or

(15) sell any compound, substance, or derivative that is not approved for human consumption by the United States Food and Drug Administration or specifically permitted for human consumption under Minnesota law, and when introduced into the body induces an effect similar to that of a Schedule I or Schedule II controlled substance listed in

section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance is marketed for the purpose of human consumption.

EFFECTIVE DATE. This section is effective August 1, 2014, and applies to sales on or after that date.

Sec. 6. Minnesota Statutes 2012, section 151.35, is amended to read:

151.35 DRUGS, ADULTERATION.

A drug shall be deemed to be adulterated:

(1) if it consists in whole or in part of any filthy, putrid or decomposed substance; or if it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been rendered injurious to health, or whereby it may have been contaminated with filth; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice as required under the federal act to assure that such drug is safe and has the identity, strength, quality, and purity characteristics, which it purports or is represented to possess; or the facility in which it was produced was not registered by the United States Food and Drug Administration or licensed by the board; or, its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the federal act, or it is a color additive, the intended use of which in or on drugs is for the purposes of coloring only, and is unsafe within the meaning of the federal act;

(2) if it purports to be or is represented as a drug the name of which is recognized in the United States Pharmacopoeia or the National Formulary, and its strength differs from, or its quality or purity falls below, the standard set forth therein. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act. No drug defined in the United States Pharmacopoeia or the National Formulary shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label;

(3) if it is not subject to the provisions of paragraph (2) of this section and its strength differs from, or its purity or quality differs from that which it purports or is represented to possess;

(4) if any substance has been mixed or packed therewith so as to reduce its quality or strength, or substituted wholly or in part therefor.

EFFECTIVE DATE. This section is effective August 1, 2014.

Sec. 7. Minnesota Statutes 2012, section 151.36, is amended to read:

151.36 DRUGS, MISBRANDING.

A drug shall be deemed to be misbranded:

(1) if its labeling is false or misleading in any particular;

(2) if in package form and not dispensed pursuant to a prescription unless it bears a label containing (a) the name and place of business of the manufacturer, packer, or distributor, (b) a statement of ~~identity~~ ingredients, and (c) an accurate statement of the net quantity of the contents in terms of weight, measure, or numerical count, provided, however, that under (c) reasonable variations shall be permitted, and exceptions as to small packages shall be allowed in accordance with the federal act;

(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if it otherwise fails to meet the labeling requirements of the federal act.

EFFECTIVE DATE. This section is effective August 1, 2014.

Sec. 8. Minnesota Statutes 2012, section 152.02, subdivision 8b, is amended to read:

Subd. 8b. **Board of Pharmacy; expedited scheduling of additional substances.** ~~(a)~~ The state Board of Pharmacy may, by rule, add a substance to Schedule I provided that it finds that the substance has a high potential for abuse, has no currently accepted medical use in the United States, has a lack of accepted safety for use under medical supervision, has known adverse health effects, and is currently available for use within the state. For the purposes of this subdivision only, the board may use the expedited rulemaking process under section 14.389. ~~The scheduling of a substance under this subdivision expires the day after the adjournment of the legislative session immediately following the substance's scheduling unless the legislature by law ratifies the action.~~

~~(b) If the board schedules a substance under this subdivision, the board shall notify in a timely manner the chairs and ranking minority members of the senate and house of representatives committees having jurisdiction over criminal justice and health policy~~

~~and finance of the action and the reasons for it. The notice must include a copy of the administrative law judge's decision on the matter.~~

~~(c) This subdivision expires August 1, 2014.~~

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 9. **MINNESOTA DEPARTMENT OF HUMAN SERVICES.**

$50,000 in fiscal year 2014 and $50,000 in fiscal year 2015 are appropriated from the general fund to the Department of Human Services for increasing public awareness of the dangers of synthetic drugs. The educational awareness campaign should be designed to reach a broad audience but contain targeted messages for students and young adults. The commissioners of education, health, and human services shall cooperate in the formulation and implementation of the educational awareness campaign. If the appropriation for either year is insufficient, the appropriation for the other year is available for it.

EFFECTIVE DATE. This section is effective the day following final enactment.