Section 1, subdivision 2, and section 3, are effective the day following final enactment.

Presented to the governor April 24, 1990

Signed by the governor April 26, 1990, 10:37 p.m.

CHAPTER 525—S.F.No. 1750

An act relating to agriculture; extending the farmer-lender mediation act; appropriating money; amending Laws 1986, chapter 398, article 1, section 18, as amended.

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

Section 1. Laws 1986, chapter 398, article 1, section 18, as amended by Laws 1987, chapter 292, section 37, and Laws 1989, chapter 350, article 16, section 8, is amended to read:

Sec. 18. **REPEALER.**

Sections 1 to 17 and Minnesota Statutes, section 336.9-501, subsections (6) and (7), and sections 583.284, 583.285, and 583.305, are repealed on July 1, ~~1990~~ 1992.

Sec. 2. **APPROPRIATION.**

$100,000 is appropriated from the general fund to the Minnesota extension service for fiscal year 1991 for operation of the farmer-lender mediation program.

Presented to the governor April 24, 1990

Signed by the governor April 26, 1990, 11:34 p.m.

CHAPTER 526—S.F.No. 1758

An act relating to health; requiring the licensing of wholesale drug distributors; regulating the use of biosynthetic bovine somatotropin; providing penalties; amending Minnesota Statutes 1988, sections 151.01, subdivision 28; 151.06, subdivision 1; 151.15, subdivision 3; and 151.25; proposing coding for new law in Minnesota Statutes, chapter 151.

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

Section 1. **PURPOSE.**

The legislature finds that biosynthetic bovine somatotropin has not been fully researched to provide conclusive evidence about animal health effects. In the public interest, the legislature intends biosynthetic bovine somatotropin to be closely regulated and administered only in research or necessary medical circumstances for one year after the effective date of sections 2 and 4 of this act.

Sec. 2. Minnesota Statutes 1988, section 151.01, subdivision 28, is amended to read:

Subd. 28. **VETERINARY LEGEND DRUG.** "Veterinary legend drug" means biosynthetic bovine somatotropin (BST) until one year after the effective date of section 4 of this act or a drug that is required by federal law to bear the following statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

Sec. 3. Minnesota Statutes 1988, section 151.06, subdivision 1, is amended to read:

Subdivision 1. (a) **POWERS AND DUTIES.** The board of pharmacy shall have the power and it shall be its duty:

(1) to regulate the practice of pharmacy;

(2) to regulate the manufacture, wholesale, and retail sale of drugs within this state;

(3) to regulate the identity, labeling, purity, and quality of all drugs and medicines dispensed in this state, using the United States Pharmacopeia and the National Formulary, or any revisions thereof, or standards adopted under the federal act as the standard;

(4) to enter and inspect by its authorized representative any and all places where drugs, medicines, medical gases, or veterinary drugs or devices are sold, vended, given away, compounded, dispensed, manufactured, wholesaled, or held; it may secure samples or specimens of any drugs, medicines, medical gases, or veterinary drugs or devices after paying or offering to pay for such sample; it shall be entitled to inspect and make copies of any and all records of shipment, purchase, manufacture, quality control, and sale of these items provided, however, that such inspection shall not extend to financial data, sales data, or pricing data;

(5) to examine and license as pharmacists all applicants whom it shall deem qualified to be such;

(6) to license wholesale drug distributors;

(7) to deny, suspend, revoke, or refuse to renew any registration or license required under this chapter, to any applicant or registrant or licensee upon any of the following grounds:

(i) fraud or deception in connection with the securing of such license or registration;

(ii) in the case of a pharmacist, conviction in any court of a felony;

(iii) in the case of a pharmacist, conviction in any court of an offense involving moral turpitude;

(iv) habitual indulgence in the use of narcotics, stimulants, or depressant drugs; or habitual indulgence in intoxicating liquors in a manner which could cause conduct endangering public health;

(v) unprofessional conduct or conduct endangering public health;

(vi) gross immorality;

(vii) employing, assisting, or enabling in any manner an unlicensed person to practice pharmacy;

(viii) conviction of theft of drugs, or the unauthorized use, possession, or sale thereof;

(ix) violation of any of the provisions of this chapter or any of the rules of the state board of pharmacy;

(x) in the case of a pharmacy license, operation of such pharmacy without a pharmacist present and on duty;

(xi) in the case of a pharmacist, physical or mental disability which could cause incompetency in the practice of pharmacy; or

(xii) in the case of a pharmacist, the suspension or revocation of a license to practice pharmacy in another state;

~~(7)~~ (8) to employ necessary assistants and make rules for the conduct of its business; and

~~(8)~~ (9) to perform such other duties and exercise such other powers as the provisions of the act may require.

(b) **TEMPORARY SUSPENSION.** In addition to any other remedy provided by law, the board may, without a hearing, temporarily suspend a license for not more than 60 days if the board finds that a pharmacist has violated a statute or rule that the board is empowered to enforce and continued practice by the pharmacist would create an imminent risk of harm to others. The suspension shall take effect upon written notice to the pharmacist, specifying the statute or rule violated. At the time it issues the suspension notice, the board shall schedule a disciplinary hearing to be held under the administrative procedure act. The pharmacist shall be provided with at least 20 days notice of any hearing held under this subdivision.

(c) **RULES.** For the purposes aforesaid it shall be the duty of the board to make and publish uniform rules not inconsistent herewith for carrying out and enforcing the provisions of this chapter.

Sec. 4. Minnesota Statutes 1988, section 151.15, subdivision 3, is amended to read:

Subd. 3. **UNLICENSED PERSONS; VETERINARY LEGEND DRUGS.** It shall be unlawful for any person other than a licensed veterinarian or pharmacist to compound or dispense veterinary legend drugs except as provided in this chapter. Until one year after the effective date of section 4 of this act, a veterinarian or veterinarian's assistant may use biosynthetic bovine somatotropin (BST) for medical or research purposes only. Biosynthetic bovine somatotropin (BST) may not be dispensed to, used by, or administered by a person who is not a licensed veterinarian or a veterinarian's assistant under the veterinarian's supervision.

Sec. 5. Minnesota Statutes 1988, section 151.25, is amended to read:

151.25 **REGISTRATION OF MANUFACTURERS OR WHOLESALERS; FEE; PROHIBITIONS.**

The board shall require and provide for the annual registration of every person engaged in manufacturing ~~or selling at wholesale~~ drugs, medicines, chemicals, or poisons for medicinal purposes, now or hereafter doing business with accounts in this state. Upon a payment of a fee as set by the board, the board shall issue a registration certificate in such form as it may prescribe to such manufacturer ~~or wholesaler~~. Such registration certificate shall be displayed in a conspicuous place in such manufacturer's or wholesaler's place of business for which it is issued and expire on the date set by the board. It shall be unlawful for any person to manufacture ~~or sell at wholesale~~ drugs, medicines, chemicals, or poisons for medicinal purposes unless such a certificate has been issued to the person by the board. It shall be unlawful for any person engaged in the manufacture ~~or selling at wholesale~~ of drugs, medicines, chemicals, or poisons for medicinal purposes, or the person's agent, to sell legend drugs or biosynthetic bovine somatotropin (BST) until one year after the effective date of section 2 of this act to other than a pharmacy, except as provided in this chapter.

Sec. 6. **[151.42] SCOPE.**

Sections 6 to 14 apply to any person, partnership, corporation, or other business enterprise engaging in the wholesale distribution of prescription drugs within the state.

Sec. 7. **[151.43] DEFINITIONS.**

As used in sections 6 to 14, the following terms have the meanings given in paragraphs (a) to (f):

(a) "Wholesale drug distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) a sale between a division, subsidiary, parent, affiliated, or related company under the common ownership and control of a corporate entity;

(2) the purchase or other acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug for its own use from the organization or from other hospitals or health care entities that are members of such organizations;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986, as amended through December 31, 1988, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale, purchase, or trade of a drug or offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(5) the sale, purchase, or trade of a drug or offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) the transfer of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(8) the distribution of prescription drug samples by manufacturers representatives; or

(9) the sale, purchase, or trade of blood and blood components.

(b) "Wholesale drug distributor" means anyone engaged in wholesale drug distribution, including but not limited to, manufacturers; repackers; own-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and pharmacies that conduct wholesale drug distribution. A wholesale drug distributor does not include a common carrier or individual hired primarily to transport prescription drugs.

(c) "Manufacturer" means anyone who is engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(d) "Prescription drug" means a drug required by federal or state law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to United States Code, title 21, sections 811 and 812.

(e) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(f) "Blood components" means that part of blood separated by physical or mechanical means.

Sec. 8. **[151.44] WHOLESALE DRUG DISTRIBUTOR ADVISORY TASK FORCE.**

The board shall appoint a wholesale drug distributor advisory task force composed of five members, to be selected and to perform duties and responsibilities as follows:

(a) One member must be a pharmacist who is neither a member of the board nor a board employee.

(b) Two members must be representatives of wholesale drug distributors as defined in section 7, paragraph (b).

(c) One member must be a representative of drug manufacturers.

(d) One member must be a public member as defined by section 214.02.

(e) The advisory task force shall review and make recommendations to the board on the merit of all rules dealing with wholesale drug distributors and drug manufacturers that are proposed by the board; and no rule affecting wholesale drug distributors proposed by the board may be adopted without first being submitted to the task force for review and comment.

(f) In making advisory task force appointments, the board shall consider recommendations received from each of the wholesale drug distributor, pharmacist, and drug manufacturer classes cited in paragraphs (a) to (c), and shall adopt rules that provide for solicitation of the recommendations.

Sec. 9. **[151.45] PROHIBITED DRUG PURCHASES OR RECEIPT.**

It is unlawful for any person to knowingly purchase or receive a prescription drug from a source other than a person or entity licensed under the laws of the state, except where otherwise provided. Licensed wholesale drug distributors other than pharmacies may not dispense or distribute prescription drugs directly to patients. A person violating the provisions of this section is guilty of a misdemeanor.

Sec. 10. **[151.46] WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENTS.**

Subdivision 1. **REQUIREMENTS.** All wholesale drug distributors are subject to the requirements in paragraphs (a) to (e).

(a) No person or distribution outlet may act as a wholesale drug distributor without first obtaining a license from the board and paying the required fee.

(b) No license may be issued or renewed for a wholesale drug distributor to operate unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board.

(c) The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within the state, or for a parent entity with divisions, subsidiaries, or affiliate companies within the state, when operations are conducted at more than one location and joint ownership and control exists among all the entities.

(d) As a condition for receiving and retaining a wholesale drug distributor license issued under sections 6 to 14, an applicant shall satisfy the board that it has and will continuously maintain:

(1) adequate storage conditions and facilities;

(2) minimum liability and other insurance as may be required under any applicable federal or state law;

(3) a viable security system that includes an after hours central alarm, or comparable entry detection capability; restricted access to the premises; comprehensive employment applicant screening; and safeguards against all forms of employee theft;

(4) a system of records describing all wholesale drug distributor activities set forth in section 7 for at least the most recent two-year period, which must be reasonably accessible as defined by board regulations in any inspection authorized by the board;

(5) principals and persons, including officers, directors, primary shareholders, and key management executives who must at all times demonstrate and maintain their capability of conducting business in conformity with sound financial practices as well as state and federal law;

(6) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, about each wholesale drug distributor to be licensed, including all pertinent corporate licensee information, if applicable, or other ownership, principal, key personnel, and facilities information found to be necessary by the board;

(7) written policies and procedures that assure reasonable wholesale drug distributor preparation for, protection against, and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or product shipping and receiving, outdated product or other unauthorized product control, appropriate disposition of returned goods, and product recalls;

(8) sufficient inspection procedures for all incoming and outgoing product shipments; and

(9) operations in compliance with all federal requirements applicable to wholesale drug distribution.

(e) An agent or employee of any licensed wholesale drug distributor need not seek licensure under this section.

Subd. 2. **REQUIREMENTS MUST CONFORM WITH FEDERAL LAW.** All requirements set forth in this section must conform to wholesale drug distributor licensing guidelines formally adopted by the United States Food and Drug Administration; and in case of conflict between a wholesale drug distributor licensing requirement imposed by the board and a Food and Drug Administration wholesale drug distributor guideline, the latter controls.

Sec. 11. **[151.47] OUT-OF-STATE WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENTS.**

(a) It is unlawful for an out-of-state wholesale drug distributor to conduct business in the state without first obtaining a license from the board and paying the required fee.

(b) Application for an out-of-state wholesale drug distributor license under this section must be made on a form furnished by the board.

(c) The issuance of a license under sections 6 to 14 does not affect tax liability imposed by the department of revenue on any out-of-state wholesale drug distributor.

(d) No person acting as principal or agent for any out-of-state wholesale drug distributor may sell or distribute drugs in the state unless the distributor has obtained a license.

(e) The board may adopt regulations that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity to the extent that an out-of-state wholesale drug distributor:

(1) possesses a valid license granted by another state under legal standards comparable to those that must be met by a wholesale drug distributor of this state as prerequisites for obtaining a license under the laws of this state; and

(2) can show that the other state would extend reciprocal treatment under its own laws to a wholesale drug distributor of this state.

Sec. 12. **[151.48] LICENSE RENEWAL APPLICATION PROCEDURES.**

The board shall mail application blanks for renewal of a license required by sections 6 to 14 to each licensee on or before the first day of the month before the month in which the license expires and, if application for renewal of the license with the required fee is not made before the expiration date, the existing license or renewal lapses and becomes null and void upon the date of expiration.

Sec. 13. **[151.49] RULES.**

The board shall adopt rules to carry out the purposes and enforce the provisions of sections 6 to 14. All rules adopted under this section must conform to wholesale drug distributor licensing guidelines formally adopted by the United States Food and Drug Administration; and in case of conflict between a rule adopted by the board and a Food and Drug Administration wholesale drug distributor guideline, the latter controls.

Sec. 14. **[151.50] BOARD ACCESS TO WHOLESALE DRUG DISTRIBUTOR RECORDS.**

Wholesale drug distributors may keep records at a central location apart from the principal office of the wholesale drug distributor or the location at which the drugs were stored and from which they were shipped, provided that the records must be made available for inspection within two working days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription drugs record keeping.

Sec. 15. **EFFECTIVE DATE.**

Sections 3, and 5 to 14 are effective on January 1, 1991.

Sections 2 and 4 and the portion of section 5 that relates to biosynthetic bovine somatotropin (BST) are effective 30 days after the commissioner of agriculture publishes notice in the State Register that (a) the states of Minnesota and Wisconsin, or (b) states having 40 percent or more of milk production as determined by the United States Department of Agriculture statistics for the most recent available calendar year, including Minnesota, have adopted provisions that restrict general use of biosynthetic bovine somatotropin (BST). Notwithstanding this section and sections 2 and 4 and the portion of section 5 that relates to biosynthetic bovine somatotropin, restrictions on the general use of biosynthetic bovine somatotropin, remain in effect only so long as restrictions are effective in the state of Wisconsin or in states having 40 percent or more of milk production, including Minnesota. On the date that restrictions on the general use of biosynthetic bovine somatotropin are no longer in effect in the state of Wisconsin and in states having 40 percent or more of milk production, including Minnesota, sections 2 and 4 and the portion of section 5 that relates to biosynthetic bovine somatotropin have no effect and biosynthetic bovine somatotropin may be sold for general use.

Presented to the governor April 24, 1990

Signed by the governor April 26, 1990, 3:33 p.m.