CHAPTER 151

PHARMACY

BOARD OF PHARMACY

151.01 DEFINITIONS.

Subdivision 1. **Words, terms, and phrases.** Unless the language or context clearly indicates that a different meaning is intended, the following words, terms, and phrases, for the purposes of this chapter, shall be given the meanings subjoined to them.

Subd. 2. **Pharmacy.** "Pharmacy" means an established place of business in which prescriptions, drugs, medicines, chemicals, and poisons are prepared, compounded, dispensed, vended, or sold to or for the use of patients and from which related clinical pharmacy services are delivered.

Subd. 3. **Pharmacist.** The term "pharmacist" means an individual with a currently valid license issued by the board of pharmacy to practice pharmacy.

Subd. 4. [Repealed, 1988 c 550 s 20]

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.

Subd. 6. **Medicine.** The term "medicine" means any remedial agent that has the property of curing, preventing, treating, or mitigating diseases, or that is used for that purpose.

Subd. 7. **Poisons.** The term "poisons" means any substance which, when introduced into the system, directly or by absorption, produces violent, morbid, or fatal changes, or which destroys living tissue with which it comes in contact.

Subd. 8. **Chemical.** The term "chemical" means all medicinal or industrial substances, whether simple or compound, or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.

Subd. 9. **Board or state board of pharmacy.** The term "board" or "state board of pharmacy" means the Minnesota state board of pharmacy.

Subd. 10. **Director.** The term "director" means the director of the Minnesota state board of pharmacy.

Subd. 11. **Person.** The term "person" means an individual, firm, partnership, company, corporation, trustee, association, agency, or other public or private entity.

Subd. 12. **Wholesale.** The term "wholesale" means and includes any sale for the purpose of resale.

Subd. 13. **Commercial purposes.** The phrase "commercial purposes" means the ordinary purposes of trade, agriculture, industry, and commerce, exclusive of the practices of medicine and pharmacy.

Subd. 14. **Manufacturing.** The term "manufacturing" except in the case of bulk compounding, prepackaging or extemporaneous compounding within a pharmacy, means and includes the production, quality control and standardization by mechanical, physical, chemical, or pharmaceutical means, packing, repacking, tableting, encapsulating, labeling, relabeling, filling or by any other process, of all drugs, medicines, chemicals, or poisons, without exception, for medicinal purposes.

Subd. 15. **Pharmacist intern.** The term "pharmacist intern" means (1) a natural person satisfactorily progressing toward the degree in pharmacy required for licensure, or (2) a graduate of the University of Minnesota college of pharmacy, or other pharmacy college approved by the board, who is registered by the state board of pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist, or (3) a qualified applicant awaiting examination for licensure.

Subd. 16. **Prescription.** The term "prescription" means a signed written order, or an oral order reduced to writing, given by a practitioner licensed to prescribe drugs for patients in the course of the practitioner's practice, issued for an individual patient and containing the following: the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, and the name and address of the prescriber.

Subd. 17. **Legend drug.** "Legend drug" means a drug which is required by federal law to bear the following statement, "Caution: Federal law prohibits dispensing without prescription."

Subd. 18. **Label.** "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug or medicine; and a requirement made by or under authority of Laws 1969, chapter 933 that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such drug or medicine, or is easily legible through the outside container or wrapper.

Subd. 19. **Package.** "Package" means any container or wrapping in which any drug or medicine is enclosed for use in the delivery or display of that article to retail purchasers, but does not include:

(a) shipping containers or wrappings used solely for the transportation of any such article in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors;

(b) shipping containers or outer wrappings used by retailers to ship or deliver any such article to retail customers if such containers and wrappings bear no printed matter pertaining to any particular drug or medicine.

Subd. 20. **Labeling.** "Labeling" means all labels and other written, printed, or graphic matter (a) upon a drug or medicine or any of its containers or wrappers, or (b) accompanying such article.

Subd. 21. **Federal act.** "Federal act" means the federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 301, et seq., as amended.

Subd. 22. **Pharmacist in charge.** "Pharmacist in charge" means a duly licensed pharmacist in the state of Minnesota who has been designated in accordance with the rules of the state board of pharmacy to assume professional responsibility for the operation of the pharmacy in compliance with the requirements and duties as established by the board in its rules.

Subd. 23. **Practitioner.** "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathy duly licensed to practice medicine, licensed doctor of dentistry, licensed podiatrist, or licensed veterinarian.

Subd. 24. **Brand name.** "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler or distributor.

Subd. 25. **Generic name.** "Generic name" means the established name or official name of a drug or drug product.

Subd. 26. **Finished dosage form.** "Finished dosage form" means that form of a drug which is or is intended to be dispensed or administered to the patient and requires no further manufacturing or processing other than packaging, reconstitution, or labeling.

Subd. 27. **Practice of pharmacy.** "Practice of pharmacy" means (1) the interpretation and evaluation of prescriptions or drug orders; (2) the compounding, dispensing, or labeling of drugs and devices (except labeling by a manufacturer or packager of nonprescription drugs or commercially packaged legend drugs and devices); (3) the participation in clinical interpretations of drug therapy for assurance of safe and effective use of drugs; (4) participation in drug selection and drug utilization reviews; (5) participation in the storage of drugs and the maintenance of records therefor; (6) the responsibility for advising on therapeutic values, content, hazards, and uses of drugs and devices; and (7) the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a pharmacy.

Subd. 28. **Veterinary legend drug.** "Veterinary legend drug" means biosynthetic bovine somatotropin (BST) until June 12, 1992, 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."

Subd. 29. **Legend medical gas.** "Legend medical gas" means a liquid or gaseous substance used for medical purposes and that is required by federal law to bear the following statement: "Caution: Federal law prohibits dispensing without a prescription."

Subd. 30. **Dispense.** "Dispense or dispensing" means the preparation or delivery of a drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the drug.

History: *(5808-1) 1937 c 354 s 1; 1961 c 394 s 1; 1967 c 377 s 1,2; 1969 c 933 s 1-7; 1973 c 639 s 1,2; 1975 c 101 s 1; 1985 c 247 s 25; 1985 c 248 s 70; 1986 c 444; 1988 c 550 s 1-5; 1990 c 412 s 1,2; 1990 c 526 s 2; 1991 c 213 s 1*

151.02 STATE BOARD OF PHARMACY.

The Minnesota state board of pharmacy shall consist of two public members as defined by section 214.02 and five pharmacists actively engaged in the practice of pharmacy in this state. Each of said pharmacists shall have had at least five consecutive years of practical experience as a pharmacist immediately preceding appointment.

History: *(5808-2) 1937 c 354 s 2; 1973 c 638 s 27; 1976 c 239 s 58; 1986 c 444*

151.03 MEMBERSHIP.

Members of the board shall be appointed by the governor. The governor shall make appointments to the board that reflect the geography of the state. The board members who are pharmacists must, as a whole, reflect the broad mix of practice types of pharmacists practicing in Minnesota. Membership terms, compensation of members,

removal of members, the filling of membership vacancies, and fiscal year and reporting requirements shall be as provided in sections 214.07 to 214.09. The provision of staff, administrative services and office space; the review and processing of complaints; the setting of board fees; and other provisions relating to board operations shall be as provided in chapter 214. Any pharmacist on the board who, during incumbency, ceases to be actively engaged in the practice of pharmacy in this state shall be automatically disqualified from membership.

History: *(5808-3) 1937 c 354 s 3; 1973 c 638 s 28; 1975 c 136 s 29; 1976 c 149 s 32; 1976 c 222 s 80; 1986 c 444; 1991 c 199 art 1 s 45; 1992 c 389 s 1*

151.04 RECOMMENDED NAMES.

The Minnesota State Pharmaceutical Association and the Minnesota Society of Hospital Pharmacists may jointly recommend five names for each pharmacist to be appointed.

History: *(5808-4) 1937 c 354 s 4; 1973 c 638 s 29; 1988 c 550 s 6*

151.05 ELECTION OF OFFICERS.

The board shall annually elect one of its members as president and one of its members as vice-president, and a pharmacist, who may or may not be a member, as secretary.

History: *(5808-5) 1937 c 354 s 5*

151.06 POWERS AND DUTIES.

Subdivision 1. **Generally; rules.** (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;

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

(xiii) in the case of a pharmacist, aiding suicide or aiding attempted suicide in violation of section 609.215 as established by any of the following:

(A) a copy of the record of criminal conviction or plea of guilty for a felony in violation of section 609.215, subdivision 1 or 2;

(B) a copy of the record of a judgment of contempt of court for violating an injunction issued under section 609.215, subdivision 4;

(C) a copy of the record of a judgment assessing damages under section 609.215, subdivision 5; or

(D) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board shall investigate any complaint of a violation of section 609.215, subdivision 1 or 2;

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

(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. The board shall adopt rules regarding prospective drug utilization review and patient counseling by pharmacists. A pharmacist in the exercise of the pharmacist's professional judgment, upon the presentation of a new prescription by a patient or the patient's caregiver or agent, shall perform the prospective drug utilization review required by rules issued under this subdivision.

Subd. 1a. **Disciplinary action.** 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.

Subd. 2. **Application.** The provisions of subdivision 1 shall apply to an individual owner or sole proprietor and shall also apply to the following:

(1) In the case of a partnership, each partner thereof;

(2) In the case of an association, each member thereof;

(3) In the case of a corporation, each officer or director thereof and each shareholder owning 30 percent or more of the voting stock of such corporation.

Subd. 2a. [Repealed, 1988 c 550 s 20]

Subd. 3. **Application of administrative procedure act.** The board shall comply with the provisions of chapter 14, before it fails to issue, renew, suspends, or revokes any license or registration issued under this chapter.

Subd. 4. **Reinstatement.** Any license or registration which has been suspended or revoked may be reinstated by the board provided the holder thereof shall pay all costs of the proceedings resulting in the suspension or revocation, and, in addition thereto, pay a fee set by the board.

History: *(5808-6) 1937 c 354 s 6; 1941 c 78 s 1; 1955 c 847 s 16; 1969 c 933 s 8; 1973 c 722 s 2; 1975 c 136 s 30; 1976 c 222 s 81,82; 1982 c 424 s 130; 1985 c 248 s 70; 1988 c 550 s 7; 1990 c 526 s 3; 1990 c 568 art 2 s 18; 1992 c 513 art 7 s 10,11; 1992 c 577 s 5*

151.061 UNFAIR PRICE DISCRIMINATION.

Subdivision 1. Any person doing business in this state and engaged in the distribution (other than at retail) of any prescription drugs, who shall discriminate between purchasers by selling prescription drugs at a lower price or rate to one purchaser or association of purchasers than offered to another purchaser or association of purchasers within this state (other than at retail) after making allowance for the difference, if any, in the grade, quality, or quantity, and after equalizing the distance from the point of distribution and freight costs therefrom, shall be guilty of unfair discrimination. Unfair discrimination occurs when quantity discounts are not reasonably based on actual cost savings to all like purchasers. Unfair discrimination shall embrace any scheme of special rebates, collateral contracts, or any device of any nature which in substance violates the provisions of this subdivision. Nothing in this subdivision shall apply to purchases for their own use by schools, colleges, universities, public libraries, churches, hospitals or charitable institutions not operated for profit.

Subd. 2. Any person injured by unfair discrimination as defined in subdivision 1 may bring a civil action and recover damages, together with costs and disbursements, including reasonable attorney's fees, and receive other equitable relief as determined by the court. The remedies provided by this section are cumulative and shall not be construed as restricting any remedy which is otherwise available.

History: *1973 c 722 s 1*

151.07 MEETINGS; EXAMINATION FEE.

The board shall meet at times as may be necessary and as it may determine to examine applicants for licensure and to transact its other business, giving reasonable notice of all examinations by mail to known applicants therefor. The secretary shall record the names of all persons licensed by the board, together with the grounds upon which the right of each to licensure was claimed. The fee for examination shall be in such amount as the board may determine, which fee may in the discretion of the board be returned to applicants not taking the examination.

History: *(5808-7) 1937 c 354 s 7; 1953 c 76 s 1; 1961 c 394 s 2; 1975 c 136 s 31; 1976 c 222 s 83*

151.08 [Repealed, 1975 c 136 s 77]

151.09 [Repealed, 1976 c 222 s 209]

151.095 INACTIVE STATUS LICENSE.

The board may, by rule, establish standards for an inactive status of licensure for

previously licensed pharmacists who have retired from active practice, have left the state, or have otherwise ceased to be actively engaged in the practice of pharmacy in this state.

History: *1988 c 550 s 8*

151.10 QUALIFICATIONS OF APPLICANTS.

Subdivision 1. **Graduates of schools in good standing.** To be entitled to examination by the board as a pharmacist the applicant shall be of good moral character, at least 18 years of age, and shall be a graduate of the college of pharmacy of the University of Minnesota or of a college or school of pharmacy in good standing of which the board shall be the judge and shall have completed internship requirements as prescribed by the board.

Subd. 2. **Graduates of schools outside the United States.** An applicant who is a graduate of a school or college of pharmacy located outside the United States, when that school or college of pharmacy has not been recognized by the board as a school in good standing, may be entitled to examination for licensure by the board if the applicant is of good moral character, at least 18 years of age, has completed the internship requirements prescribed by the board, has provided verification of the applicant's academic record and graduation, and has successfully passed examinations approved by the board to establish proficiency in English and equivalency of education with graduates of schools or colleges of pharmacy which the board has determined to be in good standing.

History: *(5808-10) 1937 c 354 s 10; 1941 c 78 s 2; 1973 c 639 s 3; 1973 c 725 s 20; 1976 c 222 s 84; 1984 c 426 s 1; 1986 c 444*

151.101 INTERNSHIP.

The board may license as an intern any natural persons who have satisfied the board that they are of good moral character, not physically or mentally unfit, and who have successfully completed the educational requirements for intern licensure prescribed by the board. The board shall prescribe standards and requirements for interns, pharmacist-preceptors, and internship training but may not require more than one year of such training.

The board in its discretion may accept internship experience obtained in another state provided the internship requirements in such other state are in the opinion of the board equivalent to those herein provided.

History: *1969 c 933 s 9; 1973 c 639 s 4; 1976 c 222 s 85; 1986 c 444; 1988 c 550 s 9*

151.11 [Repealed, 1988 c 550 s 20]

151.12 RECIPROCITY; LICENSURE.

The board may in its discretion grant licensure without examination to any pharmacist licensed by the board of pharmacy or a similar board of another state which accords similar recognition to licensees of this state; provided, the requirements for licensure in such other state are in the opinion of the board equivalent to those herein provided. The fee for licensure shall be in such amount as the board may determine by rule.

History: *(5808-12) 1937 c 354 s 12; 1961 c 394 s 4; 1973 c 639 s 5; 1976 c 222 s 87*

151.13 RENEWAL FEE; CONTINUING EDUCATION.

Subdivision 1. **Renewal fee.** Every person licensed by the board shall pay to the board a renewal fee to be fixed by it. The board may promulgate by rule a charge to be assessed for the delinquent payment of a fee. It shall be unlawful for any person licensed as a pharmacist who refuses or fails to pay such renewal fee to practice pharmacy in this state. Every certificate and license shall expire at the time therein prescribed.

Subd. 2. **Continuing education.** The board may appoint an advisory task force on continuing education, consisting of not more than ten members, to study continuing education programs and requirements and to submit its report and recommendations to the board. The task force shall expire, and the compensation and removal of members shall be as provided in section 15.059.

History: *(5808-13) 1937 c 354 s 13; 1961 c 394 s 5; 1969 c 486 s 1; 1973 c 655 s 1; 1976 c 222 s 88; 1983 c 260 s 38; 1990 c 412 s 3*

151.14 REINSTATEMENTS.

Any person who has been licensed by the board and has defaulted in the payment of the renewal fee may be reinstated within two years of such default without examination, upon payment of the arrears and upon compliance with the provisions of section 151.13, subdivision 2.

History: *(5808-14) 1937 c 354 s 14; 1973 c 655 s 2; 1976 c 222 s 89*

151.15 COMPOUNDING DRUGS UNLAWFUL UNDER CERTAIN CONDITIONS.

Subdivision 1. **Location.** It shall be unlawful for any person to compound, dispense, vend, or sell drugs, medicines, chemicals, or poisons in any place other than a pharmacy, except as provided in this chapter.

Subd. 2. **Proprietors of pharmacies.** No proprietor of a pharmacy shall permit the compounding or dispensing of prescriptions except by a pharmacist or by a pharmacist intern under the personal supervision of a pharmacist; or the vending or selling of drugs, medicines, chemicals, or poisons in the proprietor's pharmacy except under the personal supervision of a pharmacist.

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 June 12, 1992, 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.

Subd. 4. **Unlicensed persons; legend drugs.** It shall be unlawful for any person other than a licensed practitioner or pharmacist to compound or dispense legend drugs except as provided in this chapter.

History: *(5808-16) 1937 c 354 s 16; 1967 c 377 s 3; 1986 c 444; 1988 c 550 s 10; 1990 c 526 s 4; 1991 c 213 s 2*

151.16 VIOLATION A GROSS MISDEMEANOR.

Every person who violates any of the provisions of section 151.15, when the death of a human being results from such violation shall be guilty of a gross misdemeanor. This section is supplementary to existing laws relating to homicide and not a repeal thereof.

History: *(5808-17) 1937 c 354 s 17*

151.17 UNLAWFUL USE OF "PHARMACIST."

It shall be unlawful for any person to falsely assume or pretend to the title of pharmacist.

History: *(5808-18) 1937 c 354 s 18*

151.18 UNLAWFUL TO USE MISLEADING NAME.

It is unlawful for any person to carry on, conduct, or transact a retail business under a name which contains as a part thereof the words "drugs," "drug store," "pharmacy," "medicine," "apothecary," or "chemist shop," or any abbreviation, translation,

extension, or variation thereof; or in any manner by advertisement, circular, or poster, sign or otherwise, describe or refer to the place of business conducted by such person by such term, abbreviation, translation, extension, or variation unless the place so conducted is a pharmacy.

History: *(5808-19) 1937 c 354 s 19*

151.19 REGISTRATION; FEES.

Subdivision 1. **Pharmacy registration.** The board shall require and provide for the annual registration of every pharmacy now or hereafter doing business within this state. Upon the payment of a fee to be set by the board, the board shall issue a registration certificate in such form as it may prescribe to such persons as may be qualified by law to conduct a pharmacy. Such certificate shall be displayed in a conspicuous place in the pharmacy for which it is issued and expire on the 30th day of June following the date of issue. It shall be unlawful for any person to conduct a pharmacy unless such certificate has been issued to the person by the board.

Subd. 2. **Nonresident pharmacies.** The board shall require and provide for an annual nonresident special pharmacy registration for all pharmacies located outside of this state that regularly dispense medications for Minnesota residents and mail, ship, or deliver prescription medications into this state. Nonresident special pharmacy registration shall be granted by the board upon the disclosure and certification by a pharmacy:

(1) that it is licensed in the state in which the dispensing facility is located and from which the drugs are dispensed;

(2) the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing drugs to residents of this state;

(3) that it complies with all lawful directions and requests for information from the board of pharmacy of all states in which it is licensed or registered, except that it shall respond directly to all communications from the board concerning emergency circumstances arising from the dispensing of drugs to residents of this state;

(4) that it maintains its records of drugs dispensed to residents of this state so that the records are readily retrievable from the records of other drugs dispensed;

(5) that it cooperates with the board in providing information to the board of pharmacy of the state in which it is licensed concerning matters related to the dispensing of drugs to residents of this state; and

(6) that during its regular hours of operation, but not less than six days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patients' records; the toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this state.

Subd. 3. **Sale of federally restricted medical gases.** The board shall require and provide for the annual registration of every person or establishment not licensed as a pharmacy or a practitioner engaged in the retail sale or distribution of federally restricted medical gases. Upon the payment of a fee to be set by the board, the board shall issue a registration certificate in such form as it may prescribe to those persons or places that may be qualified to sell or distribute federally restricted medical gases. The certificate shall be displayed in a conspicuous place in the business for which it is issued and expire on the date set by the board. It is unlawful for a person to sell or distribute federally restricted medical gases unless a certificate has been issued to that person by the board.

History: *(5808-20) 1937 c 354 s 20; 1953 c 76 s 3; 1961 c 394 s 6; 1969 c 486 s 2; 1976 c 222 s 90; 1986 c 444; 1988 c 550 s 11; 1989 c 314 s 1*

151.20 [Repealed, 1969 c 933 s 22]

151.21 SUBSTITUTION.

Subdivision 1. Except as provided in subdivision 2, it shall be unlawful for any

pharmacist, assistant pharmacist, or pharmacist intern who dispenses prescriptions, drugs, and medicines to substitute an article different from the one ordered, or deviate in any manner from the requirements of an order or prescription without the approval of the prescriber.

Subd. 2. A pharmacist who receives a prescription for a brand name legend drug may, with the written or verbal consent of the purchaser, dispense any drug having the same generic name as the brand name drug prescribed if the prescriber has not personally written in handwriting "dispense as written" or "D.A.W." on the prescription or, when an oral prescription is given, has not expressly indicated the prescription is to be dispensed as communicated. A pharmacist who receives a prescription marked "D.A.W." or "dispense as written", or an oral prescription indicating that the prescription is to be dispensed as communicated, may substitute for the prescribed brand name drug a generically equivalent drug product which is manufactured in the same finished dosage form having the same active ingredients and strength by the same manufacturer as the prescribed brand name drug. A pharmacist may also substitute pursuant to the oral instructions of the prescriber. A pharmacist may not substitute a generically equivalent drug product unless, in the pharmacist's professional judgment, the substituted drug is therapeutically equivalent and interchangeable to the prescribed drug. A pharmacist shall notify the purchaser if the pharmacist is dispensing a drug other than the brand name drug prescribed.

Subd. 3. A pharmacist dispensing a drug under the provisions of subdivision 2 shall not dispense a drug of a higher retail price than that of the brand name drug prescribed. Any difference between acquisition cost to the pharmacist of the drug dispensed and the brand name drug prescribed shall be passed on to the purchaser.

History: *(5808-22) 1937 c 354 s 22; 1969 c 933 s 10; 1975 c 101 s 2; 1986 c 444*

151.211 RECORDS OF PRESCRIPTIONS.

All prescriptions dispensed shall be kept on file at the location in which such dispensing occurred for a period of at least two years. No prescription shall be refilled except with the written or verbal consent of the prescriber. The date of such refill must be recorded and initialed upon the original prescription or within the electronically maintained record of the original prescription by the pharmacist, pharmacist intern, or practitioner who refills the prescription.

History: *1969 c 933 s 11; 1973 c 639 s 6; 1986 c 444; 1988 c 550 s 12*

151.212 LABEL OF PRESCRIPTION DRUG CONTAINERS.

Subdivision 1. **Prescription drugs.** Drugs dispensed pursuant to a prescription shall bear a label permanently affixed to the immediate container in which the drug is dispensed and which is received by the purchaser. The label shall bear the name of the manufacturer or distributor of the finished dosage form of the drug and all other information required by law and by rules of the board.

Subd. 2. **Controlled substances.** In addition to the requirements of subdivision 1, when the use of any drug containing a controlled substance, as defined in chapter 152, or any other drug determined by the board, either alone or in conjunction with alcoholic beverages, may impair the ability of the user to operate a motor vehicle, the board shall require by rule that notice be prominently set forth on the label or container. Rules promulgated by the board shall specify exemptions from this requirement when there is evidence that the user will not operate a motor vehicle while using the drug.

Subd. 3. **Veterinary drugs.** Drugs dispensed, sold, or distributed in any manner pursuant to the order of a licensed veterinarian shall bear a label permanently affixed to the container in which the drug is dispensed and which is received by the purchaser. The label shall bear the name of the manufacturer or distributor of the finished dosage form of the drug and all other information required by law and the rules of the board.

History: *1969 c 933 s 12; 1975 c 101 s 3; 1975 c 356 s 1; 1976 c 338 s 5; 1985 c 248 s 70; 1988 c 550 s 13,14*

151.213 COPIES OF PRESCRIPTIONS.

Prescriptions on file in a pharmacy are not a public record. A person having custody of or access to such prescription orders shall not divulge the contents thereof or provide a copy thereof to anyone except to:

(1) The patient for whom the prescription was issued, the patient's agent, or another pharmacist acting on behalf of the patient or the patient's agent;

(2) The licensed practitioner who issued the prescription;

(3) The licensed practitioner who is then treating the patient;

(4) A member, inspector, or investigator of the board or any federal, state, county, or municipal officer whose duty it is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug;

(5) An agency of government charged with the responsibility of providing medical care for the patient;

(6) An insurance carrier or attorney on receipt of written authorization signed by the patient or the patient's legal representative, authorizing the release of such information;

(7) Any person duly authorized by a court order.

Such copies furnished shall bear on the face thereof the statement "Copy for information only," and may be filed to account for the dispensing of a drug only if such dispensing is authorized in writing or orally by the prescriber and communicated to the pharmacist dispensing and filing such copy.

History: *1969 c 933 s 13; 1986 c 444*

151.22 LIABILITY FOR QUALITY OF DRUGS.

Every pharmacist in charge or proprietor of a pharmacy shall be responsible for the quality of all drugs, medicines, chemicals, and poisons procured for use and sold therein, except proprietary medicines or other articles sold in the original package of the manufacturer.

History: *(5808-23) 1937 c 354 s 23; 1969 c 933 s 14*

151.23 POISONS MUST BE LABELED.

It shall be unlawful for any person to sell at retail any poison without affixing to the package or receptacle containing the same a label conspicuously bearing the word "poison," and the name and the business address of the seller, and being satisfied that such poison is to be legitimately used. This section shall not apply to the sale of poison on a physician's written prescription or in the original package of the manufacturer.

History: *(5808-24) 1937 c 354 s 24; 1986 c 444*

151.24 SALE OF POISONS MUST BE RECORDED.

It shall be unlawful:

(1) For any person, either acting independently or while in the employ of another, to sell or give away any poison, as designated by the board, without first recording in a book to be kept for that purpose with an indelible pencil or ink the date, the name and address of the person to whom, and the amount and kind of poison, delivered, except when such poison is sold on the written prescription of a physician;

(2) To give a false name to be recorded;

(3) For any person having custody of any such record book to refuse to produce it on demand for the inspection of any authorized agent of the board or other duly authorized officer.

History: *(5808-25) 1937 c 354 s 25; 1986 c 444*

151.25 REGISTRATION OF MANUFACTURERS; FEE; PROHIBITIONS.

The board shall require and provide for the annual registration of every person engaged in manufacturing 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. 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 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 of drugs, medicines, chemicals, or poisons for medicinal purposes, or the person's agent, to sell legend drugs or biosynthetic bovine somatotropin (BST) until June 12, 1992, to other than a pharmacy, except as provided in this chapter.

History: *(5808-26) 1937 c 354 s 26; 1953 c 76 s 4; 1961 c 394 s 7; 1973 c 639 s 7; 1976 c 222 s 91; 1986 c 444; 1988 c 550 s 15; 1990 c 526 s 5; 1990 c 568 art 2 s 19; 1991 c 213 s 3*

151.26 EXCEPTIONS.

Subdivision 1. 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.

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. 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.

Subd. 2. [Repealed, 1973 c 639 s 11]

History: *(5808-27) 1937 c 354 s 27; 1953 c 76 s 5; 1969 c 627 s 1; 1971 c 192 s 1; 1973 c 639 s 8; 1Sp1981 c 4 art 1 s 82; 1986 c 444; 1988 c 550 s 16*

151.27 EXPENSES.

The expenses of administering sections 151.01 to 151.40 shall be paid from the appropriations made to the state board of pharmacy.

History: *(5808-28) 1937 c 354 s 28; 1973 c 638 s 30; 1976 c 222 s 92*

151.28 [Repealed, 1988 c 550 s 20]

151.29 VIOLATION A MISDEMEANOR.

Any person violating any of the provisions of this chapter, or rules hereunder, shall be guilty of a misdemeanor, unless otherwise provided.

History: *(5808-30) 1937 c 354 s 30; 1985 c 248 s 70*

151.30 COUNTY ATTORNEY TO PROSECUTE.

It shall be the duty of the county attorney of the county wherein any offense under this chapter is committed to prosecute the offender, except that when offenses hereunder are committed in cities of the first class it shall be the duty of the city attorney thereof to prosecute the offender. Such prosecutor is authorized to examine the books of any manufacturer or wholesale dealer within the state for the purpose of acquiring information to aid in the prosecution.

History: *(5808-31) 1937 c 354 s 31*

151.31 [Repealed, 1988 c 550 s 20]

151.32 CITATION.

The title of sections 151.01 to 151.40 shall be the pharmacy practice act of 1988.

History: *(5808-35) 1937 c 354 s 35; 1988 c 550 s 17*

151.33 CARELESS DISTRIBUTION OF DRUGS.

Subdivision 1. **Prohibited.** No person, directly or indirectly, by agent or otherwise, shall scatter, distribute, or give away any samples of any medicine, drugs, or medical compounds, salve, or liniment of any kind unless the same is delivered into the hands of an adult person, or mailed to such persons through the regular mail service.

Subd. 2. **Penalty.** Any person violating any provision of this section shall be guilty of a misdemeanor.

History: *(10275, 10276) 1905 c 33 s 1,2; 1971 c 23 s 15*

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 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 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.

History: *1969 c 933 s 15; 1971 c 25 s 35; 1988 c 550 s 18; 1989 c 314 s 2; 1990 c 412 s 4*

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, 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.

History: *1969 c 933 s 16*

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, 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.

History: *1969 c 933 s 17*

151.361 MANUFACTURER DISCLOSURE.

Subdivision 1. The manufacturer, packager, or distributor of any human use legend drug sold, delivered, or offered for sale in the state of Minnesota after January 1, 1976 must have printed on the label on the immediate container of the drug the name and address of the manufacturer of the finished dosage form of the drug.

Subd. 2. (a) No legend drug in solid oral dosage form may be manufactured, packaged or distributed for sale in this state after January 1, 1983 unless it is clearly marked or imprinted with a symbol, number, company name, words, letters, national drug code or other mark uniquely identifiable to that drug product. An identifying mark or imprint made as required by federal law or by the federal Food and Drug Administration shall be deemed to be in compliance with this section.

(b) The board of pharmacy may grant exemptions from the requirements of this section on its own initiative or upon application of a manufacturer, packager, or distributor indicating size or other characteristics which render the product impractical for the imprinting required by this section.

(c) The provisions of clauses (a) and (b) shall not apply to any of the following:

(1) Drugs purchased by a pharmacy, pharmacist, or licensed wholesaler prior to January 1, 1983, and held in stock for resale.

(2) Drugs which are manufactured by or upon the order of a practitioner licensed by law to prescribe or administer drugs and which are to be used solely by the patient for whom prescribed.

Subd. 3. Failure to comply with the requirements of this section shall subject a drug to embargo in accordance with section 151.38.

History: *1975 c 101 s 4; 1981 c 206 s 1*

151.37 LEGEND DRUGS, WHO MAY PRESCRIBE, POSSESS.

Subdivision 1. Except as otherwise provided in this chapter, it shall be unlawful for any person to have in possession, or to sell, give away, barter, exchange, or distribute a legend drug.

Subd. 2. (a) A licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug, and may cause the same to be administered by a nurse or intern under the practitioner's direction and supervision, and may cause a person who is an appropriately certified and licensed health care professional to prescribe and administer the same within the expressed legal scope of the person's practice as defined in Minnesota Statutes.

(b) A licensed practitioner that dispenses for profit a legend drug that is to be administered orally, is ordinarily dispensed by a pharmacist, and is not a vaccine, must file with the practitioner's licensing board a statement indicating that the practitioner dispenses legend drugs for profit, the general circumstances under which the practitioner dispenses for profit, and the types of legend drugs generally dispensed. It is unlawful to dispense legend drugs for profit after July 31, 1990, unless the statement has been filed with the appropriate licensing board. For purposes of this paragraph,

"profit" means (1) any amount received by the practitioner in excess of the acquisition cost of a legend drug for legend drugs that are purchased in prepackaged form, or (2) any amount received by the practitioner in excess of the acquisition cost of a legend drug plus the cost of making the drug available if the legend drug requires compounding, packaging, or other treatment. The statement filed under this paragraph is public data under section 13.03. This paragraph does not apply to a licensed doctor of veterinary medicine or a registered pharmacist.

Subd. 2a. A supervising physician may delegate to a physician assistant who is registered with the board of medical practice and certified by the National Commission on Certification of Physician Assistants and who is under the supervising physician's supervision, the authority to prescribe and administer legend drugs and medical devices, subject to the requirements in section 147.34 and other requirements established by the commissioner of health in rules.

Subd. 3. A licensed doctor of veterinary medicine, in the course of professional practice only and not for use by a human being, may personally prescribe, administer, and dispense a legend drug, and may cause the same to be administered or dispensed by an assistant under the doctor's direction and supervision.

Subd. 4. Any qualified person may use legend drugs in the course of a bona fide research project, but cannot administer or dispense such drugs to human beings unless such drugs are prescribed, dispensed, and administered by a person lawfully authorized to do so.

Subd. 5. Nothing in this chapter shall prohibit the sale to, or the possession of, a legend drug by licensed drug wholesalers, licensed manufacturers, registered pharmacies, local detoxification centers, licensed hospitals, bona fide hospitals wherein animals are treated, or licensed pharmacists and licensed practitioners while acting within the course of their practice only.

Subd. 6. Nothing in this chapter shall prohibit the possession of a legend drug by an employee, agent, or sales representative of a registered drug manufacturer, or an employee or agent of a registered drug wholesaler, or registered pharmacy, while acting in the course of employment.

Subd. 7. Nothing in this chapter shall prohibit the possession of a legend drug by a person for that person's use when it has been dispensed to the person in accordance with a written or oral prescription by a practitioner.

Subd. 8. It is unlawful for a person to procure, attempt to procure, possess, or control a legend drug by any of the following means:

(1) deceit, misrepresentation, or subterfuge;

(2) using a false name; or

(3) falsely assuming the title of, or falsely representing a person to be a manufacturer, wholesaler, pharmacist, practitioner, or other authorized person for the purpose of obtaining a legend drug.

Subd. 9. Nothing in this chapter shall prohibit the possession of a legend drug by an employee or agent of a registered analytical laboratory while acting in the course of laboratory employment.

Subd. 10. **Purchase of drugs for communicable diseases.** The commissioner of health, in carrying out the duties of section 144.05, may purchase and distribute antituberculosis drugs, biologics, and vaccines to treat and prevent communicable disease.

History: *1969 c 933 s 18; 1973 c 639 s 9; 1974 c 369 s 1; 1976 c 222 s 93,94; 1976 c 338 s 6; 1986 c 444; 1988 c 440 s 2; 1988 c 550 s 19; 1990 c 489 s 1; 1990 c 524 s 2; 1991 c 30 s 11; 1991 c 106 s 6*

151.38 EMBARGOES.

(1) Whenever a duly authorized agent of the board finds or has probable cause to believe that any drug or medicine is adulterated, or so misbranded as to be dangerous or fraudulent, or is being sold, delivered, or offered for sale in violation of section

151.361, the agent shall affix thereto an appropriate marking, giving notice that the article is, or is suspected of being, adulterated, misbranded or sold, delivered, or offered for sale in violation of section 151.361 and has been embargoed, and warning that it is unlawful for any person to remove or dispose of the embargoed article by sale or otherwise without permission from the agent or the court.

(2) When an embargoed article has been found by the agent to be adulterated or misbranded, or is being sold, delivered, or offered for sale in violation of section 151.361, the board shall, within 30 days, petition the district court in whose jurisdiction the article is embargoed for an order of condemnation. When an embargoed article is not so found by the agent , the agent shall remove the marking.

(3) If the court finds that an embargoed article is adulterated or misbranded, or is being sold, delivered, or offered for sale in violation of section 151.361, the article shall be destroyed at the expense of the claimant thereof, who shall also pay all court costs and fees, storage and other proper expenses. If the adulteration or misbranding, or lack of manufacturer disclosure as required by section 151.361 can be corrected by proper labeling or processing of the article, or by filing the proper documents with the court, the court, after the costs, fees, and expenses have been paid and a sufficient bond has been executed, may order that the article be delivered to the claimant for labeling, processing or filing under supervision of an agent of the board. The expense of the supervision shall be paid by claimant. The bond shall be returned to the claimant on the representation to the court by the board that the article is no longer in violation of this chapter and that the expenses of supervision have been paid.

History: *1969 c 933 s 19; 1975 c 101 s 5; 1986 c 444*

151.39 DISTRESSED DRUGS.

Subdivision 1. Distressed drugs shall mean drugs or medicines which have been subjected to accident, fire, flood, adverse temperatures, or other physical influences which could affect the potency, quality, purity, or efficacy of such drug or medicine could otherwise cause the drug or medicine to be adulterated or misbranded within the meaning of the provisions of this chapter.

Subd. 2. No person shall sell, barter, vend, give away, or exchange distressed drugs until the board has determined that such drugs are not adulterated or misbranded within the meaning of this chapter.

Subd. 3. Every person who owns or controls distressed drugs shall immediately notify the board of the existence of such drugs and the location thereof and the board shall promptly cause an inspection and examination to be made of such drugs.

Subd. 3a. No person may import distressed drugs into this state without notification to the board of the source, destination, kind and quantity of such drugs. Such drugs may not be sold or offered for sale without written approval of the board. The board shall grant such approval when the applicant has clearly demonstrated that such distressed drugs were inspected on the site within a reasonable period after the occurrence set forth in subdivision 1 by an agency of the foreign state satisfactory to the board and the furnishing of a written certification by such agency in such form as is satisfactory to the board indicating that there is no reasonable cause to believe the drugs are not adulterated or misbranded. Nothing herein shall be construed to prevent the board from exerting its authority and rights set forth in section 151.38 after such drugs have entered this state.

Subd. 4. The board shall, within 30 days of such notification, indicate whether or not it has probable cause to believe that such drugs are adulterated or misbranded within the meaning of this chapter. If the board determines that no such probable cause exists, it shall furnish the owner or person having control of such drugs a written certificate to that effect. If the board has probable cause to believe that the drugs are adulterated or misbranded, it shall follow the procedure set forth in section 151.38.

History: *1969 c 933 s 20; 1971 c 24 s 14; 1973 c 639 s 10; 1986 c 444*

151.40 POSSESSION AND SALE OF HYPODERMIC SYRINGES AND NEEDLES.

It shall be unlawful for any person to possess, control, manufacture, sell, furnish, dispense, or otherwise dispose of hypodermic syringes or needles or any instrument or implement which can be adapted for subcutaneous injections, except by the following persons when acting in the course of their practice or employment: licensed practitioners, registered pharmacies and their employees or agents, licensed pharmacists, licensed doctors of veterinary medicine or their assistants, registered nurses, registered medical technologists, medical interns, licensed drug wholesalers, their employees or agents, licensed hospitals, licensed nursing homes, bona fide hospitals where animals are treated, licensed morticians, syringe and needle manufacturers, their dealers and agents, persons engaged in animal husbandry, clinical laboratories, persons engaged in bona fide research or education or industrial use of hypodermic syringes and needles provided such persons cannot use hypodermic syringes and needles for the administration of drugs to human beings unless such drugs are prescribed, dispensed, and administered by a person lawfully authorized to do so, persons who administer drugs pursuant to an order or direction of a licensed doctor of medicine or of a licensed doctor of osteopathy duly licensed to practice medicine.

History: *1969 c 933 s 21; 1976 c 222 s 95; 1986 c 444*

151.41 [Repealed, 1981 c 323 s 4; 1983 c 312 art 1 s 27]

WHOLESALE DRUG DISTRIBUTION LICENSING ACT

151.42 CITATION.

Sections 151.42 to 151.51 may be cited as the "wholesale drug distribution licensing act of 1990."

History: *1990 c 568 art 2 s 20*

151.43 SCOPE.

Sections 151.42 to 151.51 apply to any person, partnership, corporation, or business firm engaging in the wholesale distribution of prescription drugs within the state.

History: *1990 c 526 s 6; 1990 c 568 art 2 s 21*

151.44 DEFINITIONS.

As used in sections 151.43 to 151.51, 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.

History: *1990 c 526 s 7; 1990 c 568 art 2 s 22*

151.45 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 shall be a pharmacist who is neither a member of the board nor a board employee.

(b) Two members shall be representatives of wholesale drug distributors as defined in section 151.44, paragraph (b).

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

(d) One member shall 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 shall 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.

History: *1990 c 526 s 8; 1990 c 568 art 2 s 23*

151.46 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 shall not dispense or distribute prescription drugs directly to patients. A person violating the provisions of this section is guilty of a misdemeanor.

History: *1990 c 526 s 9; 1990 c 568 art 2 s 24*

151.47 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 shall act as a wholesale drug distributor without first obtaining a license from the board and paying the required fee.

(b) No license shall 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 151.42 to 151.51, 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 151.44 for at least the most recent two-year period, which shall 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 shall 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 shall control.

History: *1990 c 526 s 10; 1990 c 568 art 2 s 25*

151.48 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 shall be made on a form furnished by the board.

(c) The issuance of a license under sections 151.42 to 151.51 shall not change or 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.

History: *1990 c 526 s 11; 1990 c 568 art 2 s 26*

151.49 LICENSE RENEWAL APPLICATION PROCEDURES.

Application blanks for renewal of a license required by sections 151.42 to 151.51 shall be mailed to each licensee on or before the first day of the month prior to 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 shall lapse and become null and void upon the date of expiration.

History: *1990 c 526 s 12; 1990 c 568 art 2 s 27*

151.50 RULES.

The board shall adopt rules to carry out the purposes and enforce the provisions of sections 151.42 to 151.51. All rules adopted under this section shall 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 shall control.

History: *1990 c 526 s 13; 1990 c 568 art 2 s 28*

151.51 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 shall 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.

History: *1990 c 526 s 14; 1990 c 568 art 2 s 29*