State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-EIGHTH SESSION

H. F. No. 1136

03/04/2013 Authored by Liebling
The bill was read for the first time and referred to the Committee on Health and Human Services Policy

A bill for an act

relating to health; changing licensing requirements for businesses regulated by the Board of Pharmacy; clarifying requirements for compounding; amending Minnesota Statutes 2012, sections 151.01, subdivisions 14, 30, by adding subdivisions; 151.19, subdivisions 1, 3; 151.44; 151.47, subdivision 1, by adding a subdivision; 151.49; proposing coding for new law in Minnesota Statutes, chapter 151; repealing Minnesota Statutes 2012, sections 151.19, subdivision 2; 151.25; 151.45; 151.47, subdivision 2; 151.48.

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

Section 1. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

Subd. 13a. **Manufacturer.** "Manufacturer" means anyone engaged in manufacturing.

Sec. 2. Minnesota Statutes 2012, section 151.01, subdivision 14, is amended to read:

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~~ preparation, propagation, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis. Manufacturing includes the packaging or repackaging of a drug, or the labeling or relabeling of the container of a drug, for resale by pharmacies, practitioners, or other persons. Manufacturing does not include the prepackaging, extemporaneous compounding, or bulk

compounding of a drug within a licensed pharmacy, nor the labeling of a container within a pharmacy for the purpose of dispensing a drug to a patient with a valid prescription.

Sec. 3. Minnesota Statutes 2012, section 151.01, subdivision 30, is amended to read:

Subd. 30. **Dispense or dispensing.** "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~~ interpretation, evaluation, and processing of a prescription drug order, including the preparation and delivery of a drug to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

Sec. 4. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

Subd. 35. **Compounding.** The term "compounding" means preparing, mixing, assembling, packaging, and labeling a drug for an identified individual patient as a result of a practitioner's prescription drug order, or for the purpose of, or incident to, research, teaching, or chemical analysis, and not for sale or dispensing. All compounding, regardless of the type of product, shall be done pursuant to a prescription drug order unless otherwise permitted in this chapter. Compounding also includes the preparation of drugs in which all bulk drug substances and components are nonprescription substances. Compounding does not include mixing or reconstituting a drug according to the product's labeling or the manufacturer's directions.

Sec. 5. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

Subd. 36. **Anticipatory compounding.** The term "anticipatory compounding" means the preparation by a pharmacy of a supply of a compounded drug product that is sufficient to meet the short-term anticipated need of the pharmacy for filling prescription drug orders. In the case of practitioners only, bulk compounding means the preparation of a supply of a compounded drug product that is sufficient to meet the practitioner's short-term anticipated need for dispensing or administering the drug to patients treated by the practitioner. Bulk compounding is not the preparation of a compounded drug product for wholesale distribution.

Sec. 6. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

Subd. 37. **Extemporaneous compounding.** The term "extemporaneous compounding" means compounding a drug product upon receipt of a prescription drug order for a specific patient.

Sec. 7. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

Subd. 38. **Compounded positron emission tomography drug.** (a) The term "compounded positron emission tomography drug" means a drug that:

(1) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(2) has been compounded by or on the order of a practitioner according to Minnesota Rules, chapters 4731 and 6800, for a patient or for research, teaching, or quality control.

(b) Compounded positron emission tomography drug includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program used in the preparation of a drug.

Sec. 8. Minnesota Statutes 2012, section 151.19, subdivision 1, is amended to read:

Subdivision 1. **Pharmacy ~~registration~~ licensure requirements.** ~~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 any applicable fee specified in section 151.065, 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.~~ (a) No person shall operate a pharmacy without first obtaining a license from the board and paying any applicable fee specified in section 151.065. The license shall be displayed in a conspicuous place in the pharmacy for which it is issued and expires on June 30 following the date of issue. It is unlawful for any person to operate a pharmacy unless the license has been issued to the person by the board.

(b) Application for a pharmacy license under this section shall be made in a manner specified by the board.

(c) No license shall be issued or renewed for a pharmacy located within the state unless the applicant agrees to operate the pharmacy in a manner prescribed by federal and state law and according to rules adopted by the board. No license shall be issued for a pharmacy located outside of the state unless the applicant agrees to operate the pharmacy in a manner prescribed by federal law and, when dispensing medications for residents of this state, the laws of this state and Minnesota Rules.

(d) No license shall be issued or renewed for a pharmacy that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of such licensure or registration.

(e) The board shall require a separate license for each pharmacy located within the state and for each pharmacy located outside of the state at which any portion of the dispensing process occurs for drugs dispensed to residents of this state.

(f) The board shall not issue an initial or renewed license for a pharmacy unless the pharmacy passes an inspection conducted by an authorized representative of the board. In the case of a pharmacy located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

(g) The board shall not issue an initial or renewed license for a pharmacy located outside of the state unless the applicant discloses and certifies:

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

(2) 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;

(3) that it agrees to cooperate with, and provide information to, the board concerning matters related to dispensing drugs to residents of this state;

(4) that, during its regular hours of operation, but no 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; and

(5) that, upon request of a resident of a long-term care facility located in this state, the resident's authorized representative, or a contract pharmacy or licensed health

care facility acting on behalf of the resident, the pharmacy will dispense medications prescribed for the resident in unit-dose packaging or, alternatively, comply with section 151.415, subdivision 5.

Sec. 9. Minnesota Statutes 2012, section 151.19, subdivision 3, is amended to read:

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 any applicable fee specified in section 151.065, 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.~~ (a) A person or establishment not licensed as a pharmacy or a practitioner shall not engage in the retail sale or distribution of federally restricted medical gases without first obtaining a registration from the board and paying the applicable fee specified in section 151.065. The registration shall be displayed in a conspicuous place in the business for which it is issued and expires 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.

(b) Application for a medical gas distributor registration under this section shall be made in a manner specified by the board.

(c) No registration shall be issued or renewed for a medical gas distributor located within the state unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board. No license shall be issued for a medical gas distributor located outside of the state unless the applicant agrees to operate in a manner prescribed by federal law and, when distributing medical gases for residents of this state, the laws of this state and Minnesota Rules.

(d) No registration shall be issued or renewed for a medical gas distributor that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of the licensure or registration. The board may, by rule, establish standards for the registration of a medical gas distributor that is not required to be licensed or registered by the state in which it is physically located.

(e) The board shall require a separate registration for each medical gas distributor located within the state and for each facility located outside of the state from which medical gases are distributed to residents of this state.

(f) The board shall not issue an initial or renewed registration for a medical gas distributor unless the medical gas distributor passes an inspection conducted by an authorized representative of the board. In the case of a medical gas distributor located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Sec. 10. **[151.251] PHARMACY COMPOUNDING.**

Subdivision 1. **Exemption from manufacturing licensure requirement.** Section 151.252 shall not apply to a pharmacy or a practitioner that compounds a drug product if the drug product is compounded for an identified individual patient based on receipt of a valid prescription drug order, as defined in section 151.01, subdivision 16a, on which the prescribing practitioner has indicated that compounding of the drug product is medically necessary for the patient, if the drug product meets the requirements of this section and is not sold at wholesale and if the compounding:

(1) is by a licensed pharmacist or a licensed practitioner, on the prescription order for the individual patient made by a licensed practitioner authorized to prescribe drugs; or

(2) is by a licensed pharmacist or licensed practitioner in limited quantities before the receipt of a valid prescription order for the individual patient and:

(i) is not dispensed or otherwise distributed in any manner prior to receipt of a valid prescription order; and

(ii) is based on a history of the licensed pharmacist or licensed practitioner receiving valid prescription orders for the compounding of the drug product, and those orders have been generated solely within an established relationship between the licensed pharmacist or licensed practitioner and the individual patient for whom the prescription order will be provided or the licensed practitioner who will write the prescription order.

Subd. 2. **Compounded drug.** (a) A drug product may be compounded under this section if the licensed pharmacist or licensed practitioner:

(1) compounds the drug product using bulk drug substances, as defined in Code of Federal Regulations, title 21, section 207.3, subsection (a), paragraph (4), that:

(i) complies with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(ii) if a monograph does not exist, are drug substances that are components of drugs approved for use in this country by the United States Food and Drug Administration; or

(iii) if a monograph does not exist and the drug substance is not a component of a drug approved for use in this country by the United States Food and Drug Administration, appears on a list developed by the United States Food and Drug Administration through regulations issued by the Secretary of the United States Department of Health and Human Services pursuant to the Food, Drugs, and Cosmetic Act, section 503a, subsection (d) and:

(A) are manufactured by an establishment that is registered under the federal Food, Drug, and Cosmetic Act, section 360, including a foreign establishment registered under section 360, subsection (i) of the act; and

(B) are accompanied by valid certificates of analysis for each bulk drug substance; and

(2) compounds the drug product using ingredients, other than bulk drug substances, that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapters on pharmacy compounding.

(b) A licensed pharmacist or licensed practitioner, when compounding a drug product, is prohibited from using any product that appears on a list published by the secretary of the United States Department of Health and Human Services in the Federal Register of drug products that have been withdrawn or removed from the market because the drug products or components of the drug products have been found to be unsafe or not effective.

(c) A licensed pharmacist or licensed practitioner shall not compound any drug product that is essentially a copy of a commercially available drug product. For purposes of this paragraph, "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, that produces for that patient a sufficient difference between the compounded drug and the comparable commercially available drug product, as determined by the prescribing practitioner.

Subd. 3. **Exceptions.** (a) This section does not apply to:

(1) drugs compounded by a pharmacy licensed by the board for use by, or administration to, patients enrolled in a bona fide research study that is being conducted

pursuant to either an investigational new drug application approved by the United States Food and Drug Administration or that has been approved by an institutional review board;

(2) compounded positron emission tomography drugs as defined in section 151.01, subdivision 38; or

(3) radiopharmaceuticals.

(b) As used in this section, "compounding" does not include mixing, reconstituting, or other acts performed according to directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

Sec. 11. **[151.252] LICENSING OF DRUG MANUFACTURERS; FEES; PROHIBITIONS.**

Subdivision 1. **Requirements.** (a) No person shall act as a manufacturer without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(b) Application for a manufacturer license under this section shall be made in a manner specified by the board.

(c) No license shall be issued or renewed for a manufacturer unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

(d) No license shall be issued or renewed for a manufacturer that is required to be registered pursuant to United State Code, title 21, section 360, unless the applicant supplies the board with proof of registration. The board may establish by rule the standards for licensure of manufacturers that are not required to be registered under United States Code, title 21, section 360.

(e) No license shall be issued or renewed for a manufacturer that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of licensure or registration. The board may establish, by rule, standards for the licensure of a manufacturer that is not required to be licensed or registered by the state in which it is physically located.

(f) The board shall require a separate license for each facility located within the state at which manufacturing occurs and for each facility located outside of the state at which drugs that are shipped into the state are manufactured.

(g) The board shall not issue an initial or renewed license for a manufacturing facility unless the facility passes an inspection conducted by an authorized representative of the board. In the case of a manufacturing facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee

in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located or by the United States Food and Drug Administration, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Subd. 2. **Prohibition.** It is unlawful for any person engaged in manufacturing to sell legend drugs to anyone located in this state except as provided in this chapter.

Sec. 12. Minnesota Statutes 2012, section 151.44, is amended to read:

151.44 DEFINITIONS.

As used in sections 151.43 to 151.51, the following terms have the meanings given in paragraphs (a) to (h):

(a) "Wholesale drug distribution" means distribution of prescription or nonprescription drugs to persons other than a consumer or patient or reverse distribution of such drugs, 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 or nonprescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(8) the distribution of prescription or nonprescription 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~~ repackagers; 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 or nonprescription drugs.

(c) "Manufacturer" ~~means anyone who is engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug~~ has the meaning provided in section 151.01, subdivision 13a.

(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.

(g) "Reverse distribution" means the receipt of prescription or nonprescription drugs received from or shipped to Minnesota locations for the purpose of returning the drugs to their producers or distributors.

(h) "Reverse distributor" means a person engaged in the reverse distribution of drugs.

Sec. 13. Minnesota Statutes 2012, section 151.47, subdivision 1, is amended to read:

Subdivision 1. **Requirements.** (a) All wholesale drug distributors are subject to the requirements ~~in paragraphs (a) to (f)~~ of this subdivision.

~~(a)~~ (b) No person or distribution outlet shall act as a wholesale drug distributor without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(c) Application for a wholesale drug distributor license under this section shall be made in a manner specified by the board.

~~(b)~~ (d) 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.~~

(e) No license may be issued or renewed for a drug wholesale distributor that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of licensure or registration. The board may establish, by rule, standards for the licensure of a drug wholesale distributor that is not required to be licensed or registered by the state in which it is physically located.

(f) The board shall require a separate license for each drug wholesale distributor facility located within the state and for each drug wholesale distributor facility located outside of the state from which drugs are shipped into the state or to which drugs are reverse distributed.

(g) The board shall not issue an initial or renewed license for a drug wholesale distributor facility unless the facility passes an inspection conducted by an authorized representative of the board. In the case of a drug wholesale distributor facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

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

~~(f) A wholesale drug distributor shall file with the board an annual report, in a form and on the date prescribed by the board, identifying all payments, honoraria, reimbursement or other compensation authorized under section 151.461, clauses (3) to (5), paid to practitioners in Minnesota during the preceding calendar year. The report shall identify the nature and value of any payments totaling $100 or more, to a particular practitioner during the year, and shall identify the practitioner. Reports filed under this provision are public data.~~

Sec. 14. Minnesota Statutes 2012, section 151.47, is amended by adding a subdivision to read:

Subd. 3. **Prohibition.** It is unlawful for any person engaged in wholesale drug distribution to sell drugs to anyone located within the state or to receive drugs in reverse distribution from anyone located within the state except as provided in this chapter.

Sec. 15. Minnesota Statutes 2012, section 151.49, is amended to read:

151.49 LICENSE RENEWAL APPLICATION PROCEDURES.

Application blanks or notices for renewal of a license required by sections 151.42 to 151.51 shall be mailed or otherwise provided 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 and supporting documents is not made before the expiration date, the existing license or renewal shall lapse and become null and void upon the date of expiration.

Sec. 16. **REPEALER.**

Minnesota Statutes 2012, sections 151.19, subdivision 2; 151.25; 151.45; 151.47, subdivision 2; and 151.48, are repealed.

151.19 REGISTRATION; FEES.

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 payment of any applicable fee specified in section 151.065 and 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;

(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; and

(7) that, upon request of a resident of a long-term care facility located within the state of Minnesota, the resident's authorized representative, or a contract pharmacy or licensed health care facility acting on behalf of the resident, the pharmacy will dispense medications prescribed for the resident in unit-dose packaging or, alternatively, comply with the provisions of section 151.415, subdivision 5.

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 any applicable fee specified in section 151.065, 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 to other than a pharmacy, except as provided in this chapter.

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.

151.47 WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENTS.

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.

151.48 OUT-OF-STATE WHOLESALE DRUG DISTRIBUTOR LICENSING.

(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 any applicable fee specified in section 151.065.

(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) 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.

(d) 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.