CHAPTER 151

PHARMACY

151.01 DEFINITIONS.

[For text of subds 1 to 22, see M.S.1992]

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

[For text of subds 24 to 30, see M.S.1992]

History: *1993 c 121 s 10*

151.21 SUBSTITUTION.

Subdivision 1. Except as provided in this section, 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. MS 1992 [Renumbered subd 3]

Subd. 2. When a pharmacist receives a written prescription on which the prescriber has personally written in handwriting "dispense as written" or "D.A.W.," or an oral prescription in which the prescriber has expressly indicated that the prescription is to be dispensed as communicated, the pharmacist shall dispense the brand name legend drug as prescribed.

Subd. 3. MS 1992 [Renumbered subd 4]

Subd. 3. When a pharmacist receives a written prescription on which the prescriber has not personally written in handwriting "dispense as written" or "D.A.W.," or an oral prescription in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated, and there is available in the pharmacist's stock a less expensive generically equivalent drug that, in the pharmacist's professional judgment, is safely interchangeable with the prescribed drug, then the pharmacist shall, after disclosing the substitution to the purchaser, dispense the generic drug, unless the purchaser objects. 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. 4. A pharmacist dispensing a drug under the provisions of subdivision 3 shall not dispense a drug of a higher retail price than that of the brand name drug prescribed. If more than one safely interchangeable generic drug is available in a pharmacist's stock, then the pharmacist shall dispense the least expensive alternative. 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.

Subd. 5. Nothing in this section requires a pharmacist to substitute a generic drug if the substitution will make the transaction ineligible for third-party reimbursement.

Subd. 6. When a pharmacist dispenses a brand name legend drug and, at that time,

a less expensive generically equivalent drug is also available in the pharmacist's stock, the pharmacist shall disclose to the purchaser that a generic drug is available.

Subd. 7. This section does not apply to prescription drugs dispensed to persons covered by a health plan that covers prescription drugs under a managed care formulary or similar practices.

Subd. 8. The following drugs are excluded from this section: coumadin, dilantin, lanoxin, premarin, theophylline, synthroid, tegretol, and phenobarbital.

History: *1993 c 345 art 5 s 10*

151.37 LEGEND DRUGS, WHO MAY PRESCRIBE, POSSESS.

[For text of subds 1 to 10, see M.S.1992]

Subd. 11. **Complaint reporting.** The board of pharmacy shall report on a quarterly basis to the board of optometry any complaints received regarding the prescription or administration of topical legend drugs under section 148.576.

History: *1993 c 121 s 11*

151.461 GIFTS TO PRACTITIONERS PROHIBITED.

It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner. A medical device manufacturer that distributes drugs as an incidental part of its device business shall not be considered a manufacturer, a wholesale drug distributor, or agent under this section. As used in this section, "gift" does not include:

(1) professional samples of a drug provided to a prescriber for free distribution to patients;

(2) items with a total combined retail value, in any calendar year, of not more than $50;

(3) a payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;

(4) reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;

(5) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project;

(6) publications and educational materials; or

(7) salaries or other benefits paid to employees.

History: *1993 c 345 art 5 s 11*

151.47 WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENTS.

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

(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.

(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.

[For text of subd 2, see M.S.1992]

History: *1993 c 345 art 5 s 12*