

Minnesota Statutes 2004, Table of ChaptersTable of contents for Chapter 151**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.

HIST: 1990 c 526 s 7; 1990 c 568 art 2 s 22

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Minnesota Statutes 2004, Table of ChaptersTable of contents for Chapter 151**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.

HIST: 1993 c 345 art 5 s 11

Minnesota Statutes 2004, Table of ChaptersTable of contents for Chapter 151**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.

**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.

HIST: 1990 c 526 s 10; 1990 c 568 art 2 s 25; 1993 c 345 art 5  
s 12

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