



2005 SENATE BILL 599

February 13, 2006 - Introduced by Senators ROESSLER, HARSDORF and KANAVAS, cosponsored by Representatives MONTGOMERY, UNDERHEIM, KRAWCZYK, HINES, BIES, MURSAU, MUSSER, OTT, HUNDERTMARK, VOS, MOULTON, TOWNS and ALBERS. Referred to Committee on Health, Children, Families, Aging and Long Term Care.

1 **AN ACT** *to repeal* 450.07 (2) and 450.07 (3); *to amend* 450.01 (9) and 450.07
2 (title); and *to create* 450.01 (1m), 450.01 (2m), 450.01 (11m), 450.01 (11r),
3 450.01 (13r), 450.01 (14m), 450.01 (21m), 450.01 (23), 450.01 (24), 450.071,
4 450.072, 450.073 and 450.074 of the statutes; **relating to:** the wholesale
5 distribution of prescription drugs, granting rule-making authority, and
6 providing a penalty.

Analysis by the Legislative Reference Bureau

This bill regulates the wholesale distribution of prescription drugs. Under the bill, a "wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including but not limited to repackagers, own-label distributors, private label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, and drug wholesalers or distributors, independent wholesale drug traders, and retail pharmacies or chain pharmacy warehouses that conduct wholesale distribution. Wholesale distribution does not include: intracompany sales of prescription drugs; the administration, delivery, dispensing, sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons; the distribution of prescription drug samples by a manufacturer's representative; drug returns, when conducted by a hospital, health care facility, or charitable institution; the sale of minimal quantities of prescription drugs by retail

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franchises to licensed health care providers for office use; the practice of pharmacy; or the sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

The bill requires the Pharmacy Examining Board (the board) to license wholesale distributors, inspect wholesale distribution facilities, and investigate and approve the designated representative of a wholesale distributor. Once licensed, a wholesale distributor is required to create and maintain records of each prescription drug transaction it undertakes.

Each wholesale distributor shall establish and maintain an inventory and record (a pedigree) of all transactions regarding the receipt and distribution or other disposition of a prescription drug. A pedigree must contain all necessary identifying information concerning each sale or point of distribution in the chain of the distribution of the prescription drug from the manufacturer until final sale or distribution to a pharmacy or a person dispensing or distributing the prescription drug. Each pedigree must be maintained by the final recipient in the chain of distribution and by the wholesale distributor for three years from the date of sale or distribution.

Under the bill, a person who distributes a prescription drug without the appropriate licensure or without maintaining a proper pedigree is guilty of a Class E felony, and may be fined up to \$50,000 and imprisoned for up to 15 years or both. A person who intentionally does the same is guilty of a Class D felony and may be fined up to \$100,000 and imprisoned for up to 25 years or both.

Because this bill creates a new crime or revises a penalty for an existing crime, the Joint Review Committee on Criminal Penalties may be requested to prepare a report concerning the proposed penalty and the costs or savings that are likely to result if the bill is enacted.

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 450.01 (1m) of the statutes is created to read:

2 450.01 (1m) “Authentication” means verification, before distributing a
3 prescription drug, that each transaction listed on a pedigree has occurred.

4 **SECTION 2.** 450.01 (2m) of the statutes is created to read:

5 450.01 (2m) “Chain pharmacy warehouse” means a physical location for drugs
6 or devices that acts as a central warehouse and performs intracompany sales or

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1 transfers of the drugs or devices to a group of chain pharmacies that have the same
2 common ownership and control.

3 **SECTION 3.** 450.01 (9) of the statutes is amended to read:

4 450.01 (9) "Distributor" means a person licensed by the board under s. 450.07
5 ~~(2)~~ 450.071.

6 **SECTION 4.** 450.01 (11m) of the statutes is created to read:

7 450.01 (11m) "Facility" means a facility of a wholesale distributor where
8 prescription drugs are stored, handled, repackaged, or offered for sale.

9 **SECTION 5.** 450.01 (11r) of the statutes is created to read:

10 450.01 (11r) "Intracompany sales" means any transaction or transfer between
11 any division, subsidiary, parent, or affiliated or related company under common
12 ownership and control of a corporate entity.

13 **SECTION 6.** 450.01 (13r) of the statutes is created to read:

14 450.01 (13r) "Normal distribution channel" means a chain of custody for a
15 medication that goes from a manufacturer to a wholesale distributor to a pharmacy
16 or a chain pharmacy warehouse to a patient.

17 **SECTION 7.** 450.01 (14m) of the statutes is created to read:

18 450.01 (14m) "Pedigree" means a document or electronic file containing
19 information that records each distribution of a prescription drug within the
20 distribution channel.

21 **SECTION 8.** 450.01 (21m) of the statutes is created to read:

22 450.01 (21m) "Repackage" means to repack or otherwise change the container,
23 wrapper, or label of a prescription drug. Repackaging does not include the
24 administration, delivery, or distribution of a prescription drug by a pharmacist to a
25 patient.

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1 **SECTION 9.** 450.01 (23) of the statutes is created to read:

2 450.01 (23) “Wholesale distribution” does not include:

3 (a) Intracompany sales of prescription drugs.

4 (b) The administration, delivery, dispensing, sale, purchase, distribution,
5 trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade,
6 or transfer a prescription drug for emergency medical reasons.

7 (c) The distribution of prescription drug samples by a manufacturer’s
8 representative.

9 (d) Drug returns, when conducted by a hospital, health care facility, or
10 charitable institution.

11 (e) The sale of minimal quantities of prescription drugs by retail franchises to
12 licensed health care providers for office use.

13 (f) The practice of pharmacy.

14 (g) The sale, transfer, merger, or consolidation of all or part of the business of
15 a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether
16 accomplished as a purchase and sale of stock or business assets.

17 **SECTION 10.** 450.01 (24) of the statutes is created to read:

18 450.01 (24) “Wholesale distributor” means a person engaged in the wholesale
19 distribution of prescription drugs, including but not limited to repackagers,
20 own-label distributors, private label distributors, jobbers, brokers, warehouses,
21 including manufacturers’ and distributors’ warehouses, and drug wholesalers or
22 distributors, independent wholesale drug traders, and retail pharmacies or chain
23 pharmacy warehouses that conduct wholesale distribution.

24 **SECTION 11.** 450.07 (title) of the statutes is amended to read:

25 **450.07 (title) Manufacturers and distributors; licensure.**

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1 **SECTION 12.** 450.07 (2) of the statutes is repealed.

2 **SECTION 13.** 450.07 (3) of the statutes is repealed.

3 **SECTION 14.** 450.071 of the statutes is created to read:

4 **450.071 Wholesale distributors; licensure. (1)** No person may engage in
5 the wholesale distribution of a prescription drug in this state without obtaining a
6 license from the board. The board shall exempt manufacturers from licensing and
7 other requirements under this section to the extent the license or requirement is not
8 required under federal law or regulation or unless the board determines that it is
9 necessary to apply a requirement to a manufacturer.

10 **(2)** An applicant shall submit a form provided by the board showing all of the
11 following and swear or affirm the truthfulness of each item in the application:

12 (a) The name, business address, and telephone number of the applicant.

13 (b) All trade or business names used by the applicant.

14 (c) Names, addresses, and telephone numbers of contact persons for all
15 facilities used by the applicant for the storage, handling, and distribution of
16 prescription drugs.

17 (d) The type of ownership or operation for the applicant's business.

18 (e) If the applicant's wholesale distribution business is a partnership, the
19 name, address, title, and telephone number of each partner, and the name of the
20 partnership.

21 (f) If the applicant's wholesale distribution business is a corporation, the name,
22 address, title, and telephone number of each corporate officer and director, the name
23 of the corporation, and the state of incorporation.

24 (g) If the applicant's wholesale distribution business is a sole proprietorship,
25 the name of the sole proprietor and the name of the business entity.

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1 (h) A list of all licenses and permits issued to the applicant by any other state
2 that authorizes the applicant to purchase or possess prescription drugs.

3 (i) The name, address, and telephone number of a designated representative.

4 (j) For the person listed in par. (i), a personal information statement that
5 contains all of the following:

6 1. The person's date and place of birth.

7 2. The person's places of residence for the past 7 years.

8 3. The person's occupations, positions of employment, and offices held during
9 the past 7 years.

10 4. The name and addresses for each business, corporation, or other entity listed
11 in subd. 3.

12 5. A statement regarding whether the person has been, during the past 7 years,
13 the subject of any proceeding for the revocation of any license or been prosecuted for
14 any criminal offense, and the disposition of the proceeding or prosecution.

15 6. A statement regarding whether the person has been, during the past 7 years,
16 enjoined, either temporarily or permanently, from possessing, controlling, or
17 distributing any prescription drug, and a description of the circumstances
18 surrounding the injunction.

19 7. A description of any involvement by the person with any business, including
20 investments, other than the ownership of stock in a publicly traded company or
21 mutual fund, during the past 7 years, that manufactured, administered, prescribed,
22 distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits
23 in which such a business was named as a party.

24 8. A photograph of the person taken within the previous 30 days.

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1 **(3)** Upon receipt of the application and information required in sub. (2), the
2 board shall conduct a physical inspection of the facility from which the applicant
3 intends to engage in the wholesale distribution of prescription drugs.

4 **(4)** The board shall grant a license to the applicant to engage in the wholesale
5 distribution of prescription drugs if the inspection conducted pursuant to sub. (3)
6 satisfies requirements adopted by the board for wholesale distribution facilities and
7 if the designated representative listed by applicant:

8 (a) Is at least 21 years old.

9 (b) Has been employed full time for at least 3 years in a pharmacy or with a
10 wholesale prescription drug distributor in a capacity related to the administration,
11 dispensing, and distribution of, and record keeping related to, prescription drugs.

12 (c) Has received a score of 75 percent or more on an examination designed and
13 administered by the board that tests the applicant's knowledge of state and federal
14 laws regarding the wholesale distribution of prescription drugs.

15 (d) Is employed by the applicant full time in a managerial level position.

16 (e) Is physically present at the wholesale prescription drug distributor's facility
17 during regular business hours and is involved in and aware of the daily operation of
18 the wholesale prescription drug distributor. This paragraph does not preclude the
19 designated representative from taking authorized sick leave and vacation time or
20 from being absent from the facility for other authorized business or personal
21 purposes.

22 (f) Is a designated representative for only one applicant at any given time.

23 (g) Has not been convicted of violating any federal, state, or local law relating
24 to wholesale or retail prescription drug distribution or distribution of a controlled
25 substance.

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1 (h) Has not been convicted of a felony.

2 (i) Submits to the department 2 fingerprint cards, each bearing a complete set
3 of the applicant's fingerprints. The department of justice may provide for the
4 submission of the fingerprint cards to the federal bureau of investigation for the
5 purposes of verifying the identification of the applicant and obtaining the applicant's
6 criminal arrest and conviction record.

7 (5) The board may set, by rule, continuing education requirements for
8 designated representatives under this section.

9 (6) The board shall require every wholesale distributor to submit a surety bond
10 acceptable to the board of at least \$100,000 or other equivalent means of security
11 acceptable to the board.

12 **SECTION 15.** 450.072 of the statutes is created to read:

13 **450.072 Wholesale distributors; restrictions on transactions.** (1) A
14 wholesale distributor shall receive prescription drug returns or exchanges from a
15 pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the
16 agreement between the wholesale distributor and the pharmacy or chain pharmacy
17 warehouse. Returns or exchanges made under this section shall not be subject to the
18 requirements of s. 450.073, but no wholesale distributor shall permit the entry of
19 adulterated or counterfeit product during a return or exchange of product.

20 (2) (a) A manufacturer or wholesale distributor may distribute a prescription
21 drug only to the premises listed on the person's license or authorization, except that
22 a manufacturer or wholesale distributor may distribute the prescription drugs to an
23 authorized agent of the person at the premises of the manufacturer or wholesale
24 distributor if all of the following are true:

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1 1. The manufacturer or wholesale distributor documents the authorized
2 agent's name and address.

3 2. This method of distribution is necessary to promote or protect the immediate
4 health or safety of the authorized agent's patient.

5 (b) A manufacturer or wholesale distributor may distribute a prescription drug
6 to a hospital pharmacy receiving area if a licensed pharmacist or another authorized
7 recipient signs, at the time of the distribution, a receipt that shows the type and
8 quantity of prescription drugs distributed.

9 (c) No manufacturer or wholesale distributor may accept payment for, or allow
10 the use of, a person's credit to establish an account for the purchase of a prescription
11 drug from any person other than the owner of record, the chief executive officer, or
12 the chief financial officer listed on the license or authorization of a person who may
13 receive prescription drugs. Any account established for the purchase of prescription
14 drugs shall bear the name of the licensed or authorized person.

15 **SECTION 16.** 450.073 of the statutes is created to read:

16 **450.073 Wholesale distributors; pedigree. (1)** Each wholesale distributor
17 shall establish and maintain an inventory and record of all transactions regarding
18 the receipt and distribution or other disposition of a prescription drug. The records
19 shall include a pedigree for each prescription drug that leaves the normal
20 distribution channel. This section does not apply to a retail pharmacy or a chain
21 pharmacy warehouse unless the pharmacy or chain pharmacy warehouse engages
22 in the wholesale distribution of prescription drugs. This section also does not apply
23 to a transfer from a manufacturer's warehouse to a wholesale distributor.

24 **(2)** A pedigree shall contain all necessary identifying information concerning
25 each sale or point of distribution in the chain of the distribution of the prescription

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1 drug from the manufacturer until final sale or distribution to a pharmacy or a person
2 dispensing or distributing the prescription drug. At a minimum, the pedigree shall
3 include:

4 (a) The name, address, telephone number, and, if available, electronic mail
5 address of each recipient or distributor of the prescription drug in the chain of
6 distribution, until the final sale or distribution that is described in sub. (2) (intro.).

7 (b) The address of each location from which the prescription drug was
8 distributed, if different from the address provided in par. (a).

9 (c) The date of each distribution.

10 (d) Certification that each recipient authenticated the pedigree before
11 distribution of the prescription drug to the next point in the chain of distribution.

12 (e) The name, dosage strength, size and number of containers, lot number, and
13 name of the manufacturer for each prescription drug.

14 **(3)** The board may require, after December 31, 2007, wholesale distributors to
15 maintain an electronic pedigree. The board may determine, after consultation with
16 prescription drugs manufacturers, wholesale distributors, and pharmacies, when to
17 require all wholesale distributors to maintain an electronic pedigree.

18 **(4)** Each person who is engaged in the wholesale distribution of a prescription
19 drug, including a repackager but not including the original manufacturer of the
20 prescription drug, and who possesses a pedigree for the prescription drug shall verify
21 that each transaction recorded on the pedigree has occurred before the person may
22 distribute the prescription drug.

23 **(5)** Each pedigree shall be maintained by the final recipient in the chain of
24 distribution and by the wholesale distributor for 3 years from the date of sale or
25 distribution.

