2007 Oc7 DRAFTING REQUEST

Senate Amendment (SA-SB1)

Received: **10/19/2007**

Received By: **csundber**

Wanted: **As time permits**

Identical to LRB:

For: **Legislative Fiscal Bureau**

By/Representing: **Renner**

This file may be shown to any legislator: **NO**

Drafter: **csundber**

May Contact:

Addl. Drafters:

Subject: **Occupational Reg. - prof lic**

Extra Copies:

Submit via email: **YES**

Requester's email:

Carbon copy (CC:) to: **christopher.sundberg@legis.wisconsin.gov**

Pre Topic:

LFB:.....Renner -

Topic:

Licensure and regulation of prescription drug wholesalers

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	csundber 10/19/2007	jdyer 10/19/2007		_____ _____			
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FE Sent For:

<END>

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✓ page numbers vs. special session SB-1

✓**Amendment 1 – Normal Distribution Channel**
(Source: NACDS)

Section 3526j (Pages 1460 – 1461) – Revise as follows:

450.01 (13r) (a) "Normal Distribution Channel" means a chain of custody *(including intracompany sales, transactions, or transfers)* for a prescription drug that runs, directly or by drop shipment, from a manufacturer of the drug, from that manufacturer to that manufacturer's co-licensed partner, from that manufacturer to that manufacturer's 3rd party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor, and continues as described in any of the following:

(1) To a pharmacy or to a person authorized to dispense or administer a drug to a patient; or
(2) To an authorized distributor of record, and then to a pharmacy or to a person authorized to dispense or administer a drug to a patient;
(3) To an authorized distributor of record, then to one other authorized distributor of record, then to an office-based practitioner;
(4) To a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, to either a patient, or other designated persons authorized by law to dispense or administer such drug to a patient; or
(5) To an authorized distributor of record to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, to either a patient, or other designated persons authorized by law to dispense or administer such drug to a patient;

✓**Amendment 2 – Definition of Pharmacy Warehouse – relates to amendment 1**
(Source: NACDS)

NEW Section (between Section 3526d Section 3526e, page 1459) – Insert new definition of pharmacy warehouse:

"Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales."

✓**Amendment 3 – Returns should be exempt from definition of "wholesale distribution"**
(Source: NACDS/Walgreens)

Section 3562o (page 1463) – Insert new distribution exemption from definition of wholesale distribution (l):

450.01 (23) "Wholesale distribution" means distribution of a prescription drug to a person other than a consumer or patient, but does not include any of the following:
...
(l) the transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, original wholesale distributor, or to a 3rd party returns processor or reverse distributor.

Amendment 4 –Returns authorized under any state law should be exempt from definition of "wholesale distribution"
(Source: Motion)

?

Section 3526o (page 1463) – Drug Returns

"(k) The donation or distribution of a prescription drug under s.255.056, *or drug returns that are authorized under any other state law."*

other WI law.

✓**Amendment 5 –Exempt blood from definition of prescription drug**
(Source: Pete Kammer for Baxter)

Language should be added to reflect that the definition of drug *"does not include blood, blood components, intended for transfusion, or biological products which are also medical devices."*

Rationale: Prevent the bill from unintentionally restricting the biotech industry and make this language compatible with federal law. Moreover, the blood components currently have stricter standards.

Amendment 6 – Provide additional flexibility to the Pharmacy Examining Board
(Source: Pharma)

Section 3530h (page 1472) – Additional flexibility for PEB

*"Not later than July 1, **2010**, the board shall determine the date on which the system will be implemented. The system may not be implemented before July 1, **2011**, and the board may delay the implementation date **in increments** if the board determines that the technology to implement the system is not yet universally available across the prescription drug supply chain **or the board determines patient safety cannot be adequately protected with existing technology.***

at the date when the electronic system would otherwise be implemented.

1248/1

2007 – 2008 LEGISLATURE

October 2007 Special Session

LRBb0255/2
CTS:wlj&kjf:sh

stays

LFB:.....Renner – Licensure and regulation of prescription drug wholesalers

FOR 2007–09 BUDGET -- NOT READY FOR INTRODUCTION

SENATE AMENDMENT ,

TO 2007 SENATE BILL 40

1

288

At the locations indicated, amend the bill as follows:

1. Page 333, line 9: after that line insert: 16

"**SECTION 217h.** 20.165 (1) (s) of the statutes is created to read:

20.165 **(1)** (s) *Wholesale drug distributor bonding.* As a continuing appropriation, all moneys received under s. 450.071 (5) and deposited in the fund created under s. 25.315, for securing payment of fees or costs that relate to the issuance of a license to engage in the wholesale distribution of prescription drugs.".

2. Page 463, line 8: after that line insert: 433 24

"**SECTION 678t.** 25.17 (1) (yn) of the statutes is created to read:

25.17 **(1)** (yn) Wholesale drug distributor bonding fund (s. 25.315);".

3. Page 465, line 12: after that line insert: 434 25

"**SECTION 686r.** 25.315 of the statutes is created to read:

25.315 Wholesale drug distributor bonding fund. There is established a separate nonlapsible trust fund designated as the wholesale drug distributor bonding fund to consist of moneys paid to the state under s. 450.071 (5) to secure payment of fees or costs that relate to the issuance of a license to engage in the wholesale distribution of prescription drugs.".

INS 2-11

4. Page 1543, line 2: after that line insert:

1361

"**SECTION 3462q.** 440.05 (intro.) of the statutes is amended to read:

440.05 Standard fees. (intro.) The following standard fees apply to all initial credentials, except as provided in ss. 440.42, 440.43, 440.44, 440.51, 444.03, 444.11, 446.02 (2) (c), 447.04 (2) (c) 2., 449.17 (1m) (d), ~~and~~ 449.18 (2) (d), and 450.071 (3):".

Fix component

5. Page 1548, line 23: ~~before that line insert~~: delete that line and substitute:

1363 18

"**SECTION 3465p.** 440.08 (2) (a) 28. of the statutes is repealed."

"**SECTION 3465q.** 440.08 (2) (a) 72. of the statutes is created to read:

440.08 **(2)** (a) 72. Wholesale distributor of prescription drugs: June 1 of each even–numbered year; $300, except that before June 1, 2010, the amount of the renewal fee is $350.".

INS 2-13

6. Page 1565, line 1: before that line insert:

1383 8

"**SECTION 3526a.** 450.01 (1p) of the statutes is created to read:

450.01 **(1p)** "Affiliated group" has the meaning given in section 1504 of the Internal Revenue Code.

SECTION 3526b. 450.01 (1t) of the statutes is created to read:

INS 2-17

450.01 **(1t)** "Authenticate" means to affirmatively verify, before wholesale distribution of a prescription drug occurs, that each transaction listed on a pedigree has occurred.

SECTION 3626c. 450.01 (1x) of the statutes is created to read:

450.01 **(1x)** "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. For purposes of this subsection, an ongoing relationship exists between a wholesale distributor and a manufacturer if all of the following apply:

(a) The wholesale distributor, including any affiliated group of the wholesale distributor, has in effect a written agreement with the manufacturer evidencing the ongoing relationship.

(b) The wholesale distributor, including any affiliated group of the wholesale distributor, is included in the manufacturer's current list of authorized distributors of record.

SECTION 3626d. 450.01 (2m) of the statutes is created to read:

450.01 **(2m)** "Colicensed" means, with respect to a partner or product, that 2 or more parties have the right to engage in marketing or manufacturing of a product consistent with the federal food and drug administration's implementation of the federal prescription drug marketing act.

SECTION 3526e. 450.01 (9m) of the statutes is created to read:

450.01 **(9m)** "Drop shipment" means a sale of a prescription drug to a wholesale distributor by the manufacturer of the drug, by the manufacturer's colicensed product partner, by the manufacturer's 3rd party logistics provider, or by the manufacturer's exclusive distributor, to which all of the following apply:

(a) The wholesale distributor or chain pharmacy warehouse takes title to, but not physical possession of, the drug.

(b) The wholesale distributor invoices a pharmacy, a chain pharmacy warehouse, or a person authorized to dispense or administer the drug to a patient.

(c) The pharmacy, chain pharmacy warehouse, or person authorized to dispense or administer the drug receives delivery of the drug directly from the manufacturer, the manufacturer's 3rd party logistics provider, or the manufacturer's exclusive distributor.

SECTION 3526f. 450.01 (11m) of the statutes is created to read:

450.01 **(11m)** "Facility" means a location where a wholesale distributor stores, handles, repackages, or offers for sale prescription drugs.

SECTION 3526g. 450.01 (11r) of the statutes is created to read:

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

SECTION 3526h. 450.01 (12) of the statutes is amended to read:

450.01 **(12)** "Manufacturer" means a person licensed ~~by the board under s. 450.07 (1)~~ <u>or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the federal food and drug administration's regulations and interpreted guidances implementing the federal prescription drug marketing act</u>.

SECTION 3526i. 450.01 (12m) of the statutes is created to read:

450.01 **(12m)** "Manufacturer's exclusive distributor" means a person that contracts with a manufacturer to provide or coordinate warehousing, distribution,

or other services on behalf of the manufacturer and who takes title to the manufacturer's prescription drug but who does not have general responsibility to direct the sale or disposition of the drug.

SECTION 3526j. 450.01 (13r) of the statutes is created to read:

450.01 **(13r)** (a) "Normal distribution channel" means a chain of custody for a prescription drug that runs, directly or by drop shipment, from the manufacturer of a drug, from the manufacturer to the manufacturer's colicensed partner, from the manufacturer to the manufacturer's 3rd–party logistics provider, or from the manufacturer to the manufacturer's exclusive distributor, and continues as described in any of the following:

INS 5-16

1. To a pharmacy or to a person authorized to dispense or administer a drug to a patient.

2. To an authorized distributor of record, and then to a pharmacy or to a person authorized to dispense or administer a drug to a patient.

3. To an authorized distributor of record, then to one other authorized distributor of record, then to an office–based practitioner.

(b) For purposes of this subsection, a distribution of a prescription drug to a warehouse or to another entity that redistributes the drug by intracompany sale to a pharmacy or to another person authorized to dispense or administer the drug constitutes a distribution to the pharmacy or to the person authorized to dispense or administer the drug.

SECTION 3526k. 450.01 (14m) of the statutes is created to read:

450.01 **(14m)** "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug.

SECTION 3526L. 450.01 (21e) of the statutes is created to read:

INS 5-24

1 450.01 **(21e)** "Repackage" means to repack or otherwise change the container,
2 wrapper, or label of a prescription drug, except that "repackage" does not include any
3 of the following:
4 (a) An action by a pharmacist with respect to a prescription drug that the
5 pharmacist is dispensing.
6 (b) An action by a pharmacist who receives a prescription drug or device that
7 the pharmacist dispensed to a patient, if, after altering the packaging or labeling of
8 the prescription drug or device, the pharmacist returns the prescription drug or
9 device to the patient.
10 **SECTION 3526m.** 450.01 (21m) of the statutes is created to read:
11 450.01 **(21m)** "Repackager" means a person that repackages.
12 **SECTION 3526n.** 450.01 (21s) of the statutes is created to read:
13 450.01 **(21s)** "Third party logistics provider" means a person that contracts
14 with a prescription drug manufacturer to provide or coordinate warehousing,
15 distribution, or other services on behalf of the manufacturer but that does not take
16 title to the manufacturer's prescription drug or have general responsibility to direct
17 the prescription drug's sale or disposition.
18 **SECTION 3526o.** 450.01 (23) of the statutes is created to read:
19 450.01 **(23)** "Wholesale distribution" means distribution of a prescription drug
20 to a person other than a consumer or patient, but does not include any of the
21 following:
22 (a) Intracompany sales of prescription drugs.
23 (b) The sale, purchase, distribution, trade, or transfer of a prescription drug or
24 offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency
25 medical reasons.

1 (c) The distribution of prescription drug samples, if the distribution is
2 permitted under 21 CFR 353 (d).
3 (d) Drug returns, when conducted by a hospital, health care entity, or
4 charitable institution as provided in 21 CFR 203.23.
5 (e) The sale of minimal quantities, as defined by the board in an administrative
6 rule, of prescription drugs by retail pharmacies to licensed practitioners for office
7 use.
8 (f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a
9 drug, or the dispensing of a drug pursuant to a prescription.
10 (g) The sale, transfer, merger, or consolidation of all or part of the business of
11 a pharmacy from or with another pharmacy, whether accomplished as a purchase
12 and sale of stock or business assets.
13 (h) The sale, purchase, distribution, trade, or transfer of a prescription drug
14 from one authorized distributor of record to one additional authorized distributor of
15 record, if the manufacturer states in writing to the receiving authorized distributor
16 of record that the manufacturer is unable to supply the drug and the supplying
17 authorized distributor of record states in writing that the drug has previously been
18 exclusively in the normal distribution channel.
19 (i) The delivery of, or offer to deliver, a prescription drug by a common carrier
20 solely in the common carrier's usual course of business of transporting prescription
21 drugs, if the common carrier does not store, warehouse, or take legal ownership of
22 the drug.
23 (j) A transaction excluded from the definition of "wholesale distribution" under
24 21 CFR 203.3 (cc).
25 (k) The donation or distribution of a prescription drug under s. 255.056.

INS 7-25

SECTION 3526p. 450.01 (24) of the statutes is created to read:

450.01 **(24)** "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including manufacturers, repackagers, own–label distributors, private label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, manufacturers' exclusive distributors, manufacturers' authorized distributors of record, prescription drug wholesalers and distributors, independent wholesale prescription drug traders, 3rd party logistics providers, retail pharmacies that conduct wholesale distribution, and chain pharmacy warehouses that conduct wholesale distribution.".

INS 8-12

Fix component

7. Page 1565, line 7: delete lines 7 to 17 and substitute: 1383 14 before that line insert

"**SECTION 3530a.** 450.07 (title) of the statutes is amended to read:

450.07 (title) **Manufacturers ~~and distributors~~; licensure.** ".

"**SECTION 3530b.** 450.07 (2) of the statutes is repealed.

SECTION 3530c. 450.07 (3) of the statutes is repealed.

SECTION 3530d. 450.07 (4) (c) of the statutes is created to read:

450.07 **(4)** (c) The rules adopted by the board under par. (b) shall require a manufacturer to maintain and to update at least once per month a list of the manufacturer's authorized distributors of record.

SECTION 3530e. 450.071 of the statutes is created to read:

450.071 Wholesale distributors; licensure. (1) No person may engage in the wholesale distribution of a prescription drug in this state without obtaining a license from the board for each facility from which the person distributes prescription drugs. The board shall exempt a manufacturer that distributes prescription drugs or devises manufactured by the manufacturer from licensing and

1 other requirements under this section to the extent the license or requirement is not
2 required under federal law or regulation, unless the board determines that it is
3 necessary to apply a requirement to a manufacturer.

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

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

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

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

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

12 (e) If the applicant's wholesale distribution business is a partnership, the name
13 of each partner and the name of the partnership.

14 (f) If the applicant's wholesale distribution business is a corporation, the name
15 of each corporate officer and director, the name of the corporation, and the state of
16 incorporation.

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

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

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

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

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

1 2. The person's places of residence for the 7–year period immediately preceding
2 the date of the application.
3 3. The person's occupations, positions of employment, and offices held during
4 the 7–year period immediately preceding the date of the application.
5 4. The name and addresses for each business, corporation, or other entity listed
6 in subd. 3.
7 5. A statement indicating whether the person has been, during the 7–year
8 period immediately preceding the date of the application, the subject of any
9 proceeding for the revocation of any business or professional license and the
10 disposition of the proceeding.
11 6. A statement indicating whether the person has been, during the 7–year
12 period immediately preceding the date of the application, enjoined by a court, either
13 temporarily or permanently, from possessing, controlling, or distributing any
14 prescription drug, and a description of the circumstances surrounding the
15 injunction.
16 7. A description of any involvement by the person during the past 7 years with
17 any business, including investments other than the ownership of stock in a publicly
18 traded company or mutual fund, that manufactured, administered, prescribed,
19 distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits
20 in which such a business was named as a party.
21 8. A description of any misdemeanor or felony criminal offense of which the
22 person was, as an adult, found guilty, whether adjudication of guilt was withheld or
23 the person pleaded guilty or no contest. If the person is appealing a criminal
24 conviction, the application shall include a copy of the notice of appeal, and the

applicant shall submit a copy of the final disposition of the appeal not more than 15 days after a final disposition is reached.

9. A photograph of the person taken within the 12–month period immediately preceding the date of the application.

(k) A statement that each facility used by the applicant for the wholesale distribution of prescription drugs has been inspected in the 3–year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each such inspection.

(3) The board shall grant a license to the applicant to engage in the wholesale distribution of prescription drugs if all of the following apply:

(a) The applicant pays the fee under s. 440.05 (1) (a), except that before June 1, 2010, the amount of the initial fee is $350.

(b) The inspections conducted pursuant to sub. (2) (k) satisfy requirements adopted by the board for wholesale distribution facilities.

(c) All of the following apply to each person identified by the applicant as a designated representative:

1. The person is at least 21 years old.

2. The person has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs.

3. The person is employed by the applicant full time in a managerial level position.

1 4. The person is physically present at the wholesale prescription drug
2 distributor's facility during regular business hours and is involved in and aware of
3 the daily operation of the wholesale prescription drug distributor. This subdivision
4 does not preclude the designated representative from taking authorized sick leave
5 and vacation time or from being absent from the facility for other authorized
6 business or personal purposes.
7 5. The person is actively involved in and aware of the daily operations of the
8 wholesale distributor.
9 6. The person is a designated representative for only one applicant at any given
10 time. This subdivision does not apply if more than one wholesale distributor is
11 located at the facility and the wholesale distributors located at the facility are
12 members of an affiliated group.
13 7. The person has not been convicted of violating any federal, state, or local law
14 relating to wholesale or retail prescription drug distribution or distribution of a
15 controlled substance.
16 8. The person has not been convicted of a felony.
17 9. The person submits to the department 2 fingerprint cards, each bearing a
18 complete set of the applicant's fingerprints. The department of justice shall provide
19 for the submission of the fingerprint cards to the federal bureau of investigation for
20 the purposes of verifying the identity of the applicant and obtaining the applicant's
21 criminal arrest and conviction record. This subdivision does not apply to a person
22 accredited by the national association of boards of pharmacy's verified–accredited
23 wholesale distributor program.
24 **(3m)** Notwithstanding subs. (2) and (3), the board may grant a license to
25 engage in the wholesale distribution of prescription drugs to a person who is

domiciled in another state and is licensed to engage in the wholesale distribution of prescription drugs in another state, if the board determines that the standards for licensure in the state in which the person is licensed are at least as stringent as the standards for licensure under this section.

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

(5) (a) The board shall require every wholesale distributor to submit a surety bond acceptable to the board in an amount not to exceed $100,000 or other equivalent means of security acceptable to the board, except that the board shall not require submission of a bond or other security under this subsection by a chain pharmacy warehouse that is engaged only in intracompany transfers. A wholesale distributor that operates more than one facility is not required to submit a bond or other security under this paragraph for each facility.

(b) The bond or other security under this subsection shall be used to secure payment of fees or costs that relate to the issuance of a license under this section and that have not been paid within 30 days after the fees or costs have become final. No claim may be made against a wholesale distributor's bond or other security under this subsection more than one year after the date on which the wholesale distributor's license expires.

INS 13-22

(6) Applications for licensure under this section are not subject to inspection or copying under s. 19.35, and may not be disclosed to any person except as necessary for compliance with and enforcement of the provisions of this chapter.

SECTION 3530g. 450.072 of the statutes is created to read:

450.072 Wholesale distributors; restrictions on transactions. (1) A wholesale distributor shall receive prescription drug returns or exchanges from a

pharmacy, a person authorized to administer or dispense drugs, or a pharmacy's intracompany warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. A wholesale distributor that receives returns of expired, damaged, recalled, or otherwise nonsaleable prescription drugs may distribute the prescription drugs only to the original manufacturer of the products or to a 3rd party returns processor. Notwithstanding s. 450.073, returns or exchanges of saleable or nonsaleable prescription drugs, including any redistribution by a receiving wholesaler, are not subject to pedigree requirements under s. 450.073 if the returns or exchanges are exempt from the pedigree requirement under the federal food and drug administration's current guidance on the federal prescription drug marketing act. A person licensed under s. 450.071 or a pharmacy or other person authorized to administer or dispense drugs shall ensure that the person or pharmacy's return process is secure and does not permit the entry of adulterated and counterfeit products.

(2) (a) A manufacturer or wholesale distributor may not deliver prescription drugs to a person unless the person is licensed under s. 450.071, s. 450.06 or by the appropriate licensing authority of another state. A manufacturer or wholesale distributor may not deliver prescription drugs to a person that is not known to the manufacturer or wholesale distributor unless the manufacturer or wholesale distributor has verified with the board or with the licensing authority of the state in which the person in located that the person is licensed to receive prescription drugs.

(b) A manufacturer or wholesale distributor may distribute a prescription drug only to the premises listed on the person's license or authorization, except that a manufacturer or wholesale distributor may distribute the prescription drugs to an

1 authorized agent of the person at the premises of the manufacturer or wholesale
2 distributor if all of the following are true:
3 1. The manufacturer or wholesale distributor documents the authorized
4 agent's name and address.
5 2. Distribution to an authorized agent is necessary to promote or protect the
6 immediate health or safety of the authorized agent's patient.
7 (c) A manufacturer or wholesale distributor may distribute a prescription drug
8 to a hospital pharmacy receiving area if a licensed pharmacist or another authorized
9 recipient signs, at the time of the distribution, a receipt that shows the type and
10 quantity of prescription drugs distributed. If there is a discrepancy between the type
11 and quantity of prescription drugs indicated on the receipt and the type and quantity
12 of prescription drugs received at the hospital pharmacy receiving area, the
13 discrepancy shall be reported to the manufacturer or wholesale distributor that
14 distributed the prescription drugs no later than the day immediately following the
15 date on which the prescription drugs were distributed to the hospital pharmacy
16 receiving area.
17 (d) No manufacturer or wholesale distributor may accept payment for, or allow
18 the use of, a person's credit to establish an account for the purchase of a prescription
19 drug from any person other than the owner of record, the chief executive officer, or
20 the chief financial officer identified on the license or authorization of a person who
21 may receive prescription drugs. Any account established for the purchase of
22 prescription drugs shall bear the name of the licensed or authorized person.
23 **SECTION 3530h.** 450.073 of the statutes is created to read:
24 **450.073 Wholesale distributors; pedigree. (1)** A wholesale distributor
25 shall establish and maintain a pedigree for each prescription drug that leaves, or has

ever left, the normal distribution channel. Before a wholesale distribution of a prescription drug leaves the normal distribution channel, a wholesale distributor shall provide a copy of the pedigree to the person receiving the drug. This section does not apply to a retail pharmacy or pharmacy intracompany warehouse unless the pharmacy or pharmacy intracompany warehouse engages in the wholesale distribution of prescription drugs.

(2) A pedigree shall contain all necessary identifying information concerning each sale in the chain of the distribution of the prescription drug from the manufacturer of the prescription drug or the manufacturers 3rd–party logistics provider, colicensed product partner, or exclusive distributor until final sale or distribution to a pharmacy or a person dispensing or distributing the prescription drug. The pedigree shall include all of the following:

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

(b) The name and address of each facility from which the prescription drug was distributed, if different from the address provided in par. (a).

(c) The date of each distribution.

(d) A certification that every recipient has authenticated the pedigree before distribution of the prescription drug to the next point in the chain of distribution.

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

(3) The board shall promulgate rules implementing an electronic track and trace pedigree system. Not later than July 1, 2009, the board shall determine the date on which the system will be implemented. The system may not be implemented

2010

in increments

before July 1, 2010, and the board may delay the implementation date by one or more periods of one year if the board determines that the technology to implement the system is not yet universally available across the prescription drug supply chain.

2011

INS 17-3

(4) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager but not including the original manufacturer of the prescription drug, who possesses a pedigree for the prescription drug, and who intends to further distribute the prescription drug, shall verify that each transaction recorded on the pedigree has occurred before the person may distribute the prescription drug.

(5) (a) A pedigree shall be maintained by a person who purchases prescription drugs identified in the pedigree and by a wholesale distributor who distributes prescription drugs identified in the pedigree for not less than 3 years from the date of sale or distribution.

(b) A person maintaining a pedigree under par. (a) shall make the pedigree available for inspection or use by a law enforcement officer within 7 days after the law enforcement officer's request.

SECTION 3530i. 450.074 of the statutes is created to read:

450.074 Wholesale distributors; prohibited actions, enforcement, penalties. (1) If the board finds that there is a reasonable probability that a wholesale distributor, other than a manufacturer, has done any of the following, that continued distribution of a prescription drug involved in the occurrence could cause death or serious adverse health consequences, and that additional procedures would result in an unreasonable delay, the board shall issue an order requiring that distribution of a prescription drug in this state cease immediately:

(a) Violated a provision of ss. 450.071 to 450.073.

1 (b) Falsified a pedigree or sold, distributed, transferred, manufactured,
2 repackaged, handled, or held a counterfeit prescription drug intended for human
3 use.

4 **(2)** If the board issues an order under sub. (1), the board shall provide the
5 person who is the subject of the order an opportunity for an informal hearing not
6 more than 10 days after the date on which the order is issued. If, after a hearing, the
7 board determines that the order was issued without sufficient grounds, the board
8 shall vacate the order.

9 **(3)** Any person who knowingly does any of the following is guilty of a Class H
10 felony:

11 (a) Fails to obtain a license required under s. 450.071.

12 (b) Purchases or otherwise receives a prescription drug from a pharmacy in
13 violation of s. 450.072 (1).

14 (c) Violates s. 450.072 (2) (a), if the person is required to obtain a license under
15 s. 450.071.

16 (d) Violates s. 450.072 (2) (b).

17 (e) Violates s. 450.072 (2) (d).

18 (f) Violates s. 450.073.

19 (g) Provides false or fraudulent records to, or makes a false or fraudulent
20 statement to, the board, a representative of the board, or a federal official.

21 (h) Obtains or attempts to obtain a prescription drug by fraud, deceit, or
22 misrepresentation, or engages in misrepresentation or fraud in the distribution of
23 a prescription drug.

24 (i) Manufactures, repackages, sells, transfers, delivers, holds, or offers for sale
25 a prescription drug that is adulterated, misbranded, counterfeit, suspected of being

counterfeit, or otherwise unfit for distribution, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(j) Adulterates, misbrands, or counterfeits a prescription drug, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(k) Receives a prescription drug that has been adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeited, or suspected of being counterfeited, and delivers or proffers such a drug.

(L) Alters, mutilates, destroys, obliterates, or removes any part of the labeling of a prescription drug or commits another act that results in the misbranding of a prescription drug.

(4) Subsection (3) does not apply to a prescription drug manufacturer or an agent of a prescription drug manufacturer, if the manufacturer or agent is obtaining or attempting to obtain a prescription drug for the sole purpose of testing the authenticity of the prescription drug.".

8. Page 1703, line 12: after that line insert:

"(1j) WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS. Using the procedure under section 227.24 of the statutes, the department of regulation and licensing shall promulgate rules necessary to administer sections 450.071, 450.072, 450.073, and 450.074 of the statutes, as created by this act, for the period before the effective date of permanent rules necessary to administer sections 450.071, 450.072, 450.073, and 450.074 of the statutes. Notwithstanding section 227.24 (1) (c) and (2) of the statutes,

emergency rules promulgated under this subsection remain in effect until March 1, 2008, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding section 227.24 (1) (a) and (3) of the statutes, the department is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.".

9. Page 1742, line 14: after that line insert:

"(1j) WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS. The treatment of sections 440.08 (2) (a) 28., 440.08 (2) (a) 72., 450.01 (12), 450.07 (title), (2), (3), and (4) (c), 450.071, 450.072, 450.073, and 450.074 of the statutes takes effect on June 1, 2008.".

(END)

#. Page 1612, line 1: delete "450.07 (1),".

Insert 2-11:

1. Page 1361, line 15: delete "28." and substitute "27m.".

Insert 2-13:

2. Page 1366, line 24: after that line insert:

Insert 2-17:

SECTION 3465s. 440.08 (2) (a) 72. of the statutes, as created by 2007 Wisconsin Act .... (this act), is amended to read:

440.08 **(2)** (a) 72. Wholesale distributor of prescription drugs: June 1 of each even-numbered year~~; $300, except that before June 1, 2010, the amount of the renewal fee is $350~~.".

Insert ~~5-15~~: 5-16

4. To a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

5. To an authorized distributor of record, then to a pharmacy warehouse, then to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

Insert 5-24:

SECTION 3526km. 450.01 (15m) of the statutes is created to read:

450.01 **(15m)** "Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales.

SECTION 3526kr. 450.01 (20) of the statutes is amended to read:

450.01 **(20)** "Prescription drug" means all of the following, but does not include blood, blood components intended for transfusion, or biological products that are also medical devices:

(a) ~~Any~~ A drug, drug product, or drug-containing preparation ~~which~~ that is subject to 21 USC 353 (b) or 21 CFR 201.105.

(b) ~~Any~~ A controlled substance included in schedules II to V of ch. 961, whether by statute or rule, except ~~substances which~~ a substance that by law may be dispensed without the prescription order of a practitioner. Controlled substances are included within this definition for purposes of s. 450.11 (3), (4) (a), and (8) only and for violations thereof punishable under s. 450.11 (9).

History: 1985 a. 146; 1987 a. 65; 1991 a. 114; 1995 a. 448; 1997 a. 27, 68; 1997 a. 237 s. 727m; 2005 a. 187.

Insert 7-25:

(L) The transfer from a retail pharmacy or pharmacy warehouse of an expired, damaged, returned, or recalled prescription drug to the original manufacturer or original wholesale distributor or to a 3rd-party returns processor or reverse distributor.

(m) The return of a prescription drug, if the return is authorized by the law of this state.

Insert 8-12:

3. Page 1383, line 18: after that line insert:

Insert 13-22:

SECTION 3530eg. 450.071 (3) (a) of the statutes, as created by 2007 Wisconsin Act .... (this act), is amended to read:

450.071 **(3)** (a) The applicant pays the fee under s. 440.05 (1) (a)~~, except that before June 1, 2010, the amount of the initial fee is $350~~.

(end ins 13-22)

Insert 17-3:

NO ¶ or is not capable of adequately protecting patient safety. NO ¶

State of Wisconsin
2007 - 2008 LEGISLATURE
October 2007 Special Session

LRBb1248/1
CTS:wlj/kjf/jld:jf

LFB:.....Renner – Licensure and regulation of prescription drug wholesalers

FOR 2007-09 BUDGET -- NOT READY FOR INTRODUCTION

SENATE AMENDMENT ,

TO SENATE BILL 1

At the locations indicated, amend the bill as follows:

1. Page 288, line 16: after that line insert:

"**SECTION 217h.** 20.165 (1) (s) of the statutes is created to read:

20.165 **(1)** (s) *Wholesale drug distributor bonding.* As a continuing appropriation, all moneys received under s. 450.071 (5) and deposited in the fund created under s. 25.315, for securing payment of fees or costs that relate to the issuance of a license to engage in the wholesale distribution of prescription drugs.".

2. Page 433, line 24: after that line insert:

"**SECTION 678t.** 25.17 (1) (yn) of the statutes is created to read:

25.17 **(1)** (yn) Wholesale drug distributor bonding fund (s. 25.315);".

3. Page 434, line 25: after that line insert:

"**SECTION 686r.** 25.315 of the statutes is created to read:

25.315 Wholesale drug distributor bonding fund. There is established a separate nonlapsible trust fund designated as the wholesale drug distributor bonding fund to consist of moneys paid to the state under s. 450.071 (5) to secure payment of fees or costs that relate to the issuance of a license to engage in the wholesale distribution of prescription drugs.".

4. Page 1361, line 2: after that line insert:

"**SECTION 3462q.** 440.05 (intro.) of the statutes is amended to read:

440.05 Standard fees. (intro.) The following standard fees apply to all initial credentials, except as provided in ss. 440.42, 440.43, 440.44, 440.51, 444.03, 444.11, 446.02 (2) (c), 447.04 (2) (c) 2., 449.17 (1m) (d), ~~and~~ 449.18 (2) (d), and 450.071 (3):".

5. Page 1361, line 15: delete "28." and substitute "27m.".

6. Page 1363, line 18: delete that line and substitute:

"**SECTION 3465p.** 440.08 (2) (a) 28. of the statutes is repealed.".

7. Page 1366, line 24: after that line insert:

"**SECTION 3465q.** 440.08 (2) (a) 72. of the statutes is created to read:

440.08 **(2)** (a) 72. Wholesale distributor of prescription drugs: June 1 of each even-numbered year; $300, except that before June 1, 2010, the amount of the renewal fee is $350.

SECTION 3465s. 440.08 (2) (a) 72. of the statutes, as created by 2007 Wisconsin Act .... (this act), is amended to read:

440.08 **(2)** (a) 72. Wholesale distributor of prescription drugs: June 1 of each even-numbered year~~; $300, except that before June 1, 2010, the amount of the renewal fee is $350~~.".

1 **8.** Page 1383, line 8: before that line insert:

2 "**SECTION 3526a.** 450.01 (1p) of the statutes is created to read:

3 450.01 **(1p)** "Affiliated group" has the meaning given in section 1504 of the
4 Internal Revenue Code.

5 **SECTION 3526b.** 450.01 (1t) of the statutes is created to read:

6 450.01 **(1t)** "Authenticate" means to affirmatively verify, before wholesale
7 distribution of a prescription drug occurs, that each transaction listed on a pedigree
8 has occurred.

9 **SECTION 3526c.** 450.01 (1x) of the statutes is created to read:

10 450.01 **(1x)** "Authorized distributor of record" means a wholesale distributor
11 with whom a manufacturer has established an ongoing relationship to distribute the
12 manufacturer's prescription drug. For purposes of this subsection, an ongoing
13 relationship exists between a wholesale distributor and a manufacturer if all of the
14 following apply:

15 (a) The wholesale distributor, including any affiliated group of the wholesale
16 distributor, has in effect a written agreement with the manufacturer evidencing the
17 ongoing relationship.

18 (b) The wholesale distributor, including any affiliated group of the wholesale
19 distributor, is included in the manufacturer's current list of authorized distributors
20 of record.

21 **SECTION 3526d.** 450.01 (2m) of the statutes is created to read:

22 450.01 **(2m)** "Colicensed" means, with respect to a partner or product, that 2
23 or more parties have the right to engage in marketing or manufacturing of a product

consistent with the federal food and drug administration's implementation of the federal prescription drug marketing act.

SECTION 3526e. 450.01 (9m) of the statutes is created to read:

450.01 **(9m)** "Drop shipment" means a sale of a prescription drug to a wholesale distributor by the manufacturer of the drug, by the manufacturer's colicensed product partner, by the manufacturer's 3rd party logistics provider, or by the manufacturer's exclusive distributor, to which all of the following apply:

(a) The wholesale distributor or chain pharmacy warehouse takes title to, but not physical possession of, the drug.

(b) The wholesale distributor invoices a pharmacy, a chain pharmacy warehouse, or a person authorized to dispense or administer the drug to a patient.

(c) The pharmacy, chain pharmacy warehouse, or person authorized to dispense or administer the drug receives delivery of the drug directly from the manufacturer, the manufacturer's 3rd party logistics provider, or the manufacturer's exclusive distributor.

SECTION 3526f. 450.01 (11m) of the statutes is created to read:

450.01 **(11m)** "Facility" means a location where a wholesale distributor stores, handles, repackages, or offers for sale prescription drugs.

SECTION 3526g. 450.01 (11r) of the statutes is created to read:

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

SECTION 3526h. 450.01 (12) of the statutes is amended to read:

450.01 **(12)** "Manufacturer" means a person licensed ~~by the board under s. 450.07 (1)~~ or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the federal food and drug administration's regulations and interpreted guidances implementing the federal prescription drug marketing act.

SECTION 3526i. 450.01 (12m) of the statutes is created to read:

450.01 **(12m)** "Manufacturer's exclusive distributor" means a person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer and who takes title to the manufacturer's prescription drug but who does not have general responsibility to direct the sale or disposition of the drug.

SECTION 3526j. 450.01 (13r) of the statutes is created to read:

450.01 **(13r)** (a) "Normal distribution channel" means a chain of custody for a prescription drug that runs, directly or by drop shipment, from the manufacturer of a drug, from the manufacturer to the manufacturer's colicensed partner, from the manufacturer to the manufacturer's 3rd–party logistics provider, or from the manufacturer to the manufacturer's exclusive distributor, and continues as described in any of the following:

1. To a pharmacy or to a person authorized to dispense or administer a drug to a patient.

2. To an authorized distributor of record, and then to a pharmacy or to a person authorized to dispense or administer a drug to a patient.

3. To an authorized distributor of record, then to one other authorized distributor of record, then to an office–based practitioner.

4. To a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

5. To an authorized distributor of record, then to a pharmacy warehouse, then to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

(b) For purposes of this subsection, a distribution of a prescription drug to a warehouse or to another entity that redistributes the drug by intracompany sale to a pharmacy or to another person authorized to dispense or administer the drug constitutes a distribution to the pharmacy or to the person authorized to dispense or administer the drug.

SECTION 3526k. 450.01 (14m) of the statutes is created to read:

450.01 **(14m)** "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug.

SECTION 3526km. 450.01 (15m) of the statutes is created to read:

450.01 **(15m)** "Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales.

SECTION 3526kr. 450.01 (20) of the statutes is amended to read:

450.01 **(20)** "Prescription drug" means <u>all of the following, but does not include blood, blood components intended for transfusion, or biological products that are also medical devices</u>:

(a) ~~Any~~ <u>A</u> drug, drug product<u>,</u> or drug-containing preparation ~~which~~ <u>that</u> is subject to 21 USC 353 (b) or 21 CFR 201.105.

1 (b) ~~Any~~ A controlled substance included in schedules II to V of ch. 961, whether
2 by statute or rule, except ~~substances which~~ a substance that by law may be dispensed
3 without the prescription order of a practitioner. Controlled substances are included
4 within this definition for purposes of s. 450.11 (3), (4) (a), and (8) only and for
5 violations thereof punishable under s. 450.11 (9).

6 **SECTION 3526L.** 450.01 (21e) of the statutes is created to read:

7 450.01 **(21e)** "Repackage" means to repack or otherwise change the container,
8 wrapper, or label of a prescription drug, except that "repackage" does not include any
9 of the following:

10 (a) An action by a pharmacist with respect to a prescription drug that the
11 pharmacist is dispensing.

12 (b) An action by a pharmacist who receives a prescription drug or device that
13 the pharmacist dispensed to a patient, if, after altering the packaging or labeling of
14 the prescription drug or device, the pharmacist returns the prescription drug or
15 device to the patient.

16 **SECTION 3526m.** 450.01 (21m) of the statutes is created to read:

17 450.01 **(21m)** "Repackager" means a person that repackages.

18 **SECTION 3526n.** 450.01 (21s) of the statutes is created to read:

19 450.01 **(21s)** "Third party logistics provider" means a person that contracts
20 with a prescription drug manufacturer to provide or coordinate warehousing,
21 distribution, or other services on behalf of the manufacturer but that does not take
22 title to the manufacturer's prescription drug or have general responsibility to direct
23 the prescription drug's sale or disposition.

24 **SECTION 3526o.** 450.01 (23) of the statutes is created to read:

1 450.01 **(23)** "Wholesale distribution" means distribution of a prescription drug
2 to a person other than a consumer or patient, but does not include any of the
3 following:
4 (a) Intracompany sales of prescription drugs.
5 (b) The sale, purchase, distribution, trade, or transfer of a prescription drug or
6 offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency
7 medical reasons.
8 (c) The distribution of prescription drug samples, if the distribution is
9 permitted under 21 CFR 353 (d).
10 (d) Drug returns, when conducted by a hospital, health care entity, or
11 charitable institution as provided in 21 CFR 203.23.
12 (e) The sale of minimal quantities, as defined by the board in an administrative
13 rule, of prescription drugs by retail pharmacies to licensed practitioners for office
14 use.
15 (f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a
16 drug, or the dispensing of a drug pursuant to a prescription.
17 (g) The sale, transfer, merger, or consolidation of all or part of the business of
18 a pharmacy from or with another pharmacy, whether accomplished as a purchase
19 and sale of stock or business assets.
20 (h) The sale, purchase, distribution, trade, or transfer of a prescription drug
21 from one authorized distributor of record to one additional authorized distributor of
22 record, if the manufacturer states in writing to the receiving authorized distributor
23 of record that the manufacturer is unable to supply the drug and the supplying
24 authorized distributor of record states in writing that the drug has previously been
25 exclusively in the normal distribution channel.

1 (i) The delivery of, or offer to deliver, a prescription drug by a common carrier
2 solely in the common carrier's usual course of business of transporting prescription
3 drugs, if the common carrier does not store, warehouse, or take legal ownership of
4 the drug.
5 (j) A transaction excluded from the definition of "wholesale distribution" under
6 21 CFR 203.3 (cc).
7 (k) The donation or distribution of a prescription drug under s. 255.056.
8 (L) The transfer from a retail pharmacy or pharmacy warehouse of an expired,
9 damaged, returned, or recalled prescription drug to the original manufacturer or
10 original wholesale distributor or to a 3rd-party returns processor or reverse
11 distributor.
12 (m) The return of a prescription drug, if the return is authorized by the law of
13 this state.
14 **SECTION 3526p.** 450.01 (24) of the statutes is created to read:
15 450.01 **(24)** "Wholesale distributor" means a person engaged in the wholesale
16 distribution of prescription drugs, including manufacturers, repackagers, own-label
17 distributors, private label distributors, jobbers, brokers, warehouses, including
18 manufacturers' and distributors' warehouses, manufacturers' exclusive
19 distributors, manufacturers' authorized distributors of record, prescription drug
20 wholesalers and distributors, independent wholesale prescription drug traders, 3rd
21 party logistics providers, retail pharmacies that conduct wholesale distribution, and
22 chain pharmacy warehouses that conduct wholesale distribution.".
23 **9.** Page 1383, line 14: before that line insert:
24 "**SECTION 3530a.** 450.07 (title) of the statutes is amended to read:

1 **450.07** (title) **Manufacturers ~~and distributors~~; licensure.**".

2 **10.** Page 1383, line 18: after that line insert:

3 "**SECTION 3530b.** 450.07 (2) of the statutes is repealed.

4 **SECTION 3530c.** 450.07 (3) of the statutes is repealed.

5 **SECTION 3530d.** 450.07 (4) (c) of the statutes is created to read:

6 450.07 **(4)** (c) The rules adopted by the board under par. (b) shall require a
7 manufacturer to maintain and to update at least once per month a list of the
8 manufacturer's authorized distributors of record.

9 **SECTION 3530e.** 450.071 of the statutes is created to read:

10 **450.071 Wholesale distributors; licensure. (1)** No person may engage in
11 the wholesale distribution of a prescription drug in this state without obtaining a
12 license from the board for each facility from which the person distributes
13 prescription drugs. The board shall exempt a manufacturer that distributes
14 prescription drugs or devises manufactured by the manufacturer from licensing and
15 other requirements under this section to the extent the license or requirement is not
16 required under federal law or regulation, unless the board determines that it is
17 necessary to apply a requirement to a manufacturer.

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

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

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

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

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

2 (e) If the applicant's wholesale distribution business is a partnership, the name
3 of each partner and the name of the partnership.

4 (f) If the applicant's wholesale distribution business is a corporation, the name
5 of each corporate officer and director, the name of the corporation, and the state of
6 incorporation.

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

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

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

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

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

15 2. The person's places of residence for the 7-year period immediately preceding
16 the date of the application.

17 3. The person's occupations, positions of employment, and offices held during
18 the 7-year period immediately preceding the date of the application.

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

21 5. A statement indicating whether the person has been, during the 7-year
22 period immediately preceding the date of the application, the subject of any
23 proceeding for the revocation of any business or professional license and the
24 disposition of the proceeding.

1 6. A statement indicating whether the person has been, during the 7-year
2 period immediately preceding the date of the application, enjoined by a court, either
3 temporarily or permanently, from possessing, controlling, or distributing any
4 prescription drug, and a description of the circumstances surrounding the
5 injunction.

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

11 8. A description of any misdemeanor or felony criminal offense of which the
12 person was, as an adult, found guilty, whether adjudication of guilt was withheld or
13 the person pleaded guilty or no contest. If the person is appealing a criminal
14 conviction, the application shall include a copy of the notice of appeal, and the
15 applicant shall submit a copy of the final disposition of the appeal not more than 15
16 days after a final disposition is reached.

17 9. A photograph of the person taken within the 12-month period immediately
18 preceding the date of the application.

19 (k) A statement that each facility used by the applicant for the wholesale
20 distribution of prescription drugs has been inspected in the 3-year period
21 immediately preceding the date of the application by the board, a pharmacy
22 examining board of another state, the National Association of Boards of Pharmacy,
23 or another accrediting body recognized by the board, with the date of each such
24 inspection.

1 **(3)** The board shall grant a license to the applicant to engage in the wholesale
2 distribution of prescription drugs if all of the following apply:
3 (a) The applicant pays the fee under s. 440.05 (1) (a), except that before June
4 1, 2010, the amount of the initial fee is $350.
5 (b) The inspections conducted pursuant to sub. (2) (k) satisfy requirements
6 adopted by the board for wholesale distribution facilities.
7 (c) All of the following apply to each person identified by the applicant as a
8 designated representative:
9 1. The person is at least 21 years old.
10 2. The person has been employed full time for at least 3 years in a pharmacy
11 or with a wholesale prescription drug distributor in a capacity related to the
12 dispensing and distribution of, and record keeping related to, prescription drugs.
13 3. The person is employed by the applicant full time in a managerial level
14 position.
15 4. The person is physically present at the wholesale prescription drug
16 distributor's facility during regular business hours and is involved in and aware of
17 the daily operation of the wholesale prescription drug distributor. This subdivision
18 does not preclude the designated representative from taking authorized sick leave
19 and vacation time or from being absent from the facility for other authorized
20 business or personal purposes.
21 5. The person is actively involved in and aware of the daily operations of the
22 wholesale distributor.
23 6. The person is a designated representative for only one applicant at any given
24 time. This subdivision does not apply if more than one wholesale distributor is

1 located at the facility and the wholesale distributors located at the facility are
2 members of an affiliated group.

3 7. The person has not been convicted of violating any federal, state, or local law
4 relating to wholesale or retail prescription drug distribution or distribution of a
5 controlled substance.

6 8. The person has not been convicted of a felony.

7 9. The person submits to the department 2 fingerprint cards, each bearing a
8 complete set of the applicant's fingerprints. The department of justice shall provide
9 for the submission of the fingerprint cards to the federal bureau of investigation for
10 the purposes of verifying the identity of the applicant and obtaining the applicant's
11 criminal arrest and conviction record. This subdivision does not apply to a person
12 accredited by the national association of boards of pharmacy's verified-accredited
13 wholesale distributor program.

14 **(3m)** Notwithstanding subs. (2) and (3), the board may grant a license to
15 engage in the wholesale distribution of prescription drugs to a person who is
16 domiciled in another state and is licensed to engage in the wholesale distribution of
17 prescription drugs in another state, if the board determines that the standards for
18 licensure in the state in which the person is licensed are at least as stringent as the
19 standards for licensure under this section.

20 **(4)** The board may set, by rule, continuing education requirements for
21 designated representatives under this section.

22 **(5)** (a) The board shall require every wholesale distributor to submit a surety
23 bond acceptable to the board in an amount not to exceed $100,000 or other equivalent
24 means of security acceptable to the board, except that the board shall not require
25 submission of a bond or other security under this subsection by a chain pharmacy

warehouse that is engaged only in intracompany transfers. A wholesale distributor that operates more than one facility is not required to submit a bond or other security under this paragraph for each facility.

(b) The bond or other security under this subsection shall be used to secure payment of fees or costs that relate to the issuance of a license under this section and that have not been paid within 30 days after the fees or costs have become final. No claim may be made against a wholesale distributor's bond or other security under this subsection more than one year after the date on which the wholesale distributor's license expires.

(6) Applications for licensure under this section are not subject to inspection or copying under s. 19.35, and may not be disclosed to any person except as necessary for compliance with and enforcement of the provisions of this chapter.

SECTION 3530eg. 450.071 (3) (a) of the statutes, as created by 2007 Wisconsin Act .... (this act), is amended to read:

450.071 **(3)** (a) The applicant pays the fee under s. 440.05 (1) (a)~~, except that before June 1, 2010, the amount of the initial fee is $350~~.

SECTION 3530g. 450.072 of the statutes is created to read:

450.072 Wholesale distributors; restrictions on transactions. (1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy, a person authorized to administer or dispense drugs, or a pharmacy's intracompany warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. A wholesale distributor that receives returns of expired, damaged, recalled, or otherwise nonsaleable prescription drugs may distribute the prescription drugs only to the original manufacturer of the products or to a 3rd party returns processor.

1 Notwithstanding s. 450.073, returns or exchanges of saleable or nonsaleable
2 prescription drugs, including any redistribution by a receiving wholesaler, are not
3 subject to pedigree requirements under s. 450.073 if the returns or exchanges are
4 exempt from the pedigree requirement under the federal food and drug
5 administration's current guidance on the federal prescription drug marketing act.
6 A person licensed under s. 450.071 or a pharmacy or other person authorized to
7 administer or dispense drugs shall ensure that the person or pharmacy's return
8 process is secure and does not permit the entry of adulterated and counterfeit
9 products.

10 **(2)** (a) A manufacturer or wholesale distributor may not deliver prescription
11 drugs to a person unless the person is licensed under s. 450.071 or 450.06 or by the
12 appropriate licensing authority of another state. A manufacturer or wholesale
13 distributor may not deliver prescription drugs to a person that is not known to the
14 manufacturer or wholesale distributor unless the manufacturer or wholesale
15 distributor has verified with the board or with the licensing authority of the state in
16 which the person in located that the person is licensed to receive prescription drugs.

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

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

24 2. Distribution to an authorized agent is necessary to promote or protect the
25 immediate health or safety of the authorized agent's patient.

1 (c) A manufacturer or wholesale distributor may distribute a prescription drug
2 to a hospital pharmacy receiving area if a licensed pharmacist or another authorized
3 recipient signs, at the time of the distribution, a receipt that shows the type and
4 quantity of prescription drugs distributed. If there is a discrepancy between the type
5 and quantity of prescription drugs indicated on the receipt and the type and quantity
6 of prescription drugs received at the hospital pharmacy receiving area, the
7 discrepancy shall be reported to the manufacturer or wholesale distributor that
8 distributed the prescription drugs no later than the day immediately following the
9 date on which the prescription drugs were distributed to the hospital pharmacy
10 receiving area.

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

17 **SECTION 3530h.** 450.073 of the statutes is created to read:

18 **450.073 Wholesale distributors; pedigree. (1)** A wholesale distributor
19 shall establish and maintain a pedigree for each prescription drug that leaves, or has
20 ever left, the normal distribution channel. Before a wholesale distribution of a
21 prescription drug leaves the normal distribution channel, a wholesale distributor
22 shall provide a copy of the pedigree to the person receiving the drug. This section
23 does not apply to a retail pharmacy or pharmacy intracompany warehouse unless the
24 pharmacy or pharmacy intracompany warehouse engages in the wholesale
25 distribution of prescription drugs.

1 **(2)** A pedigree shall contain all necessary identifying information concerning
2 each sale in the chain of the distribution of the prescription drug from the
3 manufacturer of the prescription drug or the manufacturers 3rd-party logistics
4 provider, colicensed product partner, or exclusive distributor until final sale or
5 distribution to a pharmacy or a person dispensing or distributing the prescription
6 drug. The pedigree shall include all of the following:
7 (a) The name, address, telephone number, and, if available, electronic mail
8 address of each recipient or distributor of the prescription drug in the chain of
9 distribution, until the final sale or distribution described in sub. (2) (intro.).
10 (b) The name and address of each facility from which the prescription drug was
11 distributed, if different from the address provided in par. (a).
12 (c) The date of each distribution.
13 (d) A certification that every recipient has authenticated the pedigree before
14 distribution of the prescription drug to the next point in the chain of distribution.
15 (e) The name, dosage strength, size and number of containers, lot number, and
16 name of the manufacturer for each prescription drug.
17 **(3)** The board shall promulgate rules implementing an electronic track and
18 trace pedigree system. Not later than July 1, 2010, the board shall determine the
19 date on which the system will be implemented. The system may not be implemented
20 before July 1, 2011, and the board may delay the implementation date in increments
21 if the board determines that the technology to implement the system is not yet
22 universally available across the prescription drug supply chain or is not capable of
23 adequately protecting patient safety.
24 **(4)** A person who is engaged in the wholesale distribution of a prescription
25 drug, including a repackager but not including the original manufacturer of the

prescription drug, who possesses a pedigree for the prescription drug, and who intends to further distribute the prescription drug, shall verify that each transaction recorded on the pedigree has occurred before the person may distribute the prescription drug.

(5) (a) A pedigree shall be maintained by a person who purchases prescription drugs identified in the pedigree and by a wholesale distributor who distributes prescription drugs identified in the pedigree for not less than 3 years from the date of sale or distribution.

(b) A person maintaining a pedigree under par. (a) shall make the pedigree available for inspection or use by a law enforcement officer within 7 days after the law enforcement officer's request.

SECTION 3530i. 450.074 of the statutes is created to read:

450.074 Wholesale distributors; prohibited actions, enforcement, penalties. (1) If the board finds that there is a reasonable probability that a wholesale distributor, other than a manufacturer, has done any of the following, that continued distribution of a prescription drug involved in the occurrence could cause death or serious adverse health consequences, and that additional procedures would result in an unreasonable delay, the board shall issue an order requiring that distribution of a prescription drug in this state cease immediately:

(a) Violated a provision of ss. 450.071 to 450.073.

(b) Falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use.

(2) If the board issues an order under sub. (1), the board shall provide the person who is the subject of the order an opportunity for an informal hearing not

more than 10 days after the date on which the order is issued. If, after a hearing, the board determines that the order was issued without sufficient grounds, the board shall vacate the order.

(3) Any person who knowingly does any of the following is guilty of a Class H felony:

(a) Fails to obtain a license required under s. 450.071.

(b) Purchases or otherwise receives a prescription drug from a pharmacy in violation of s. 450.072 (1).

(c) Violates s. 450.072 (2) (a), if the person is required to obtain a license under s. 450.071.

(d) Violates s. 450.072 (2) (b).

(e) Violates s. 450.072 (2) (d).

(f) Violates s. 450.073.

(g) Provides false or fraudulent records to, or makes a false or fraudulent statement to, the board, a representative of the board, or a federal official.

(h) Obtains or attempts to obtain a prescription drug by fraud, deceit, or misrepresentation, or engages in misrepresentation or fraud in the distribution of a prescription drug.

(i) Manufactures, repackages, sells, transfers, delivers, holds, or offers for sale a prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or otherwise unfit for distribution, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(j) Adulterates, misbrands, or counterfeits a prescription drug, except for wholesale distribution by a manufacturer of a prescription drug that has been

1 delivered into commerce pursuant to an application approved by the federal food and
2 drug administration.
3 (k) Receives a prescription drug that has been adulterated, misbranded, stolen,
4 obtained by fraud or deceit, counterfeited, or suspected of being counterfeited, and
5 delivers or proffers such a drug.
6 (L) Alters, mutilates, destroys, obliterates, or removes any part of the labeling
7 of a prescription drug or commits another act that results in the misbranding of a
8 prescription drug.
9 **(4)** Subsection (3) does not apply to a prescription drug manufacturer or an
10 agent of a prescription drug manufacturer, if the manufacturer or agent is obtaining
11 or attempting to obtain a prescription drug for the sole purpose of testing the
12 authenticity of the prescription drug.".
13 **11.** Page 1567, line 22: after that line insert:
14 "(1j) WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS. Using the procedure under
15 section 227.24 of the statutes, the department of regulation and licensing shall
16 promulgate rules necessary to administer sections 450.071, 450.072, 450.073, and
17 450.074 of the statutes, as created by this act, for the period before the effective date
18 of permanent rules necessary to administer sections 450.071, 450.072, 450.073, and
19 450.074 of the statutes. Notwithstanding section 227.24 (1) (c) and (2) of the statutes,
20 emergency rules promulgated under this subsection remain in effect until March 1,
21 2008, or the date on which permanent rules take effect, whichever is sooner.
22 Notwithstanding section 227.24 (1) (a) and (3) of the statutes, the department is not
23 required to provide evidence that promulgating a rule under this subsection as an
24 emergency rule is necessary for the preservation of the public peace, health, safety,

1 or welfare and is not required to provide a finding of emergency for a rule
2 promulgated under this subsection.".

3 **12.** Page 1611, line 14: after that line insert:

4 "(1j) WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS. The treatment of sections
5 440.08 (2) (a) 28., 440.08 (2) (a) 72., 450.01 (12), 450.07 (title), (2), (3), and (4) (c),
6 450.071, 450.072, 450.073, and 450.074 of the statutes takes effect on June 1, 2008.".

7 **13.** Page 1612, line 1: delete "450.07 (1),".

8 **(END)**