Amendment No. 878

Assembly Amendment to Senate Bill No. 37 First Reprint	(BDR 54-13)
Proposed by: Committee on Commerce and Labor	
Amendment Box:	
Resolves Conflicts with: N/A	
Amends: Summary: No Title: Yes Preamble: No Joint Sponsorship: No Digest: Yes	

ASSEMBLY ACTION	Initial and Date	SENATE ACTION	Initial and Date
Adopted ☐ Lost ☐		Adopted ☐ Lost ☐	
Concurred In ☐ Not ☐		Concurred In ☐ Not ☐	
Receded ☐ Not ☐		Receded ☐ Not ☐	

Amend section 1, page 2, line 2, by deleting "8," and inserting "12,".

Amend sec. 2, page 3, line 9, after "***report.***" by inserting:

"***The provisions of this subsection do not apply to a:***

(a) Lender or holder of indebtedness of an applicant who is a commercial bank, bank holding company, subsidiary or affiliate of a bank holding company, personal property broker, consumer finance lender, commercial finance lender or insurer, or any other person engaged in the business of extending credit, who is regulated by an officer or agency of the State or the Federal Government.

(b) Common motor carrier or other delivery service that delivers a drug at the direction of a manufacturer.".

KCR/BJE Date: 5/26/2005

S.B. No. 37—Revises provisions governing wholesalers of prescription drugs.

Amend the bill as a whole by adding a new section designated sec. 2.5, following sec. 2, to read as follows:

"**Sec. 2.5.** ***The Board shall implement and maintain reasonable security measures to protect the information obtained by the Board pursuant to section 2 of this act and all other information related to an application for a license to engage in wholesale distribution to protect the information from unauthorized access, acquisition, destruction, use, modification or disclosure. The provisions of this section do not prohibit the Board from disclosing and providing such information to other state and federal agencies involved in the regulation of prescription drugs to the extent deemed necessary by the Board.***".

Amend sec. 3, page 3, line 27, by deleting "***a monthly***" and inserting "***an annual***".

Amend sec. 3, page 3, line 33, after "***wholesaler.***" by inserting:

"***Any changes to the list must be submitted to the Board not later than 30 days after the change is made.***".

Amend sec. 3, page 4, line 2, after "***report.***" by inserting:

"***The provisions of this subsection do not apply to a:***

(a) Lender or holder of indebtedness of a wholesaler who is a commercial bank, bank holding company, subsidiary or affiliate of a bank holding company, personal property broker, consumer finance lender, commercial finance lender or insurer, or any other person engaged in the business of extending credit, who is regulated by an officer or agency of the State or the Federal Government.

(b) Common motor carrier or other delivery service that delivers a drug at the direction of a manufacturer.".

Amend sec. 4, page 4, line 17, by deleting:

"***the amount of $100,000***" and inserting:

"***an amount not less than $25,000 and not more than $100,000, as determined by the Board,***".

Amend sec. 5, page 5, by deleting lines 24 and 25 and inserting:

"***by a wholesaler, if required; and***".

Amend sec. 6, page 5, by deleting lines 29 through 34 and inserting:

"**Sec. 6.** ***1. The Board shall ensure the safe and efficient operation of wholesalers and the integrity and propriety of transactions involving the purchase and sale of prescription drugs by wholesalers, including, without limitation, ensuring:***".

Amend sec. 6, page 5, line 43, by deleting:

"***3. In determining***" and inserting:

"***2. In ensuring***".

Amend sec. 6, page 6, line 18, by deleting "***4.***" and inserting "***3.***".

Amend sec. 6, page 6, line 24, by deleting "***5,***" and inserting "***4,***".

Amend sec. 6, page 6, line 29, by deleting "***5.***" and inserting "***4.***".

Amend the bill as a whole by adding a new section designated sec. 6.5, following sec. 6, to read as follows:

"**Sec. 6.5.** ***If a statement of prior sales indicates that more than 3 prior sales of a prescription drug have occurred, including, without limitation, a sale involving an authorized distributor of record, a person who is licensed to engage in wholesale distribution pursuant to this chapter shall not sell that prescription drug to another wholesaler.***".

Amend the bill as a whole by renumbering sections 9 through 11 as sections 14 through 16 and adding new sections designated sections 9 through 13, following sec. 8, to read as follows:

"**Sec. 9.** ***A person who is licensed to engage in wholesale distribution pursuant to this chapter shall maintain the following information, updated annually, concerning each wholesaler from whom the licensee purchases a prescription drug or to whom the licensee sells a prescription drug:***

1. A list that identifies each state in which the wholesaler is domiciled and each state into which the wholesaler ships prescription drugs.

2. Copies of each state and federal regulatory license and registration held by the wholesaler, including, without limitation, the numbers accompanying each license and registration.

3. Copies of formation documents, business licenses and other documents related to the company of the wholesaler and its operations.

4. Copies of the wholesaler's most recent site inspection report by state or federal agencies.

5. If the licensee receives a prescription drug from the wholesaler, a copy of the wholesaler's product liability insurance policy that includes the licensee as an additional insured for at least $1,000,000.

6. A list that includes the name and address of:

(a) If the wholesaler is a partnership, limited-liability partnership or limited-liability corporation, the partners or shareholders, as applicable.

(b) If the wholesaler is a private corporation, the officers, directors and shareholders.

(c) If the wholesaler is a public corporation, the officers and directors.

7. Evidence of due diligence in accordance with section 10 of this act.

8. A copy of the wholesaler's policy or procedure for internal operations, including, without limitation, the procedures related to handling counterfeit, misbranded or adulterated prescription drugs.

9. A listing of all manufacturers with whom the wholesaler claims status as an authorized distributor of record and the applicable account numbers.

Sec. 10. ***1. A person who is licensed to engage in wholesale distribution pursuant to this chapter shall maintain the following evidence regarding due diligence concerning each wholesaler with whom the licensee does business in accordance with any applicable requirements of the Fair Credit Reporting Act, 15 U.S.C. §§ 1681 et seq.:***

(a) A copy of the driver's license of:

(1) If the wholesaler is a sole proprietor, the owner.

(2) If the wholesaler is a partnership, limited-liability partnership or limited-liability corporation, each partner or shareholder, as applicable.

(3) If the wholesaler is a private corporation, each officer and director.

(b) Proof that the licensee has checked to determine if civil or criminal litigation or both exists against the company, its owners, partners, officers or directors and whether any disciplinary action has been taken or is pending against the company, its owners, partners, officers or directors by a state or federal agency.

2. A person who is licensed to engage in wholesale distribution pursuant to this chapter shall not maintain a business relationship with any company if any of the owners, partners, officers or directors have been convicted of a felony related to the wholesale distribution of prescription drugs.

Sec. 11. ***1. A person who is licensed to engage in wholesale distribution pursuant to this chapter shall, within 30 days after beginning a business relationship with another wholesaler, conduct an on-site inspection of each facility of the wholesaler to verify that the wholesaler complies with federal requirements for the storage of prescription drugs and the operation of the facilities where prescription drugs are stored.***

2. After the date of the inspection pursuant to subsection 1, the licensee shall conduct an on-site inspection biannually.

3. Each on-site inspection conducted pursuant to this section must include:

(a) An assessment of the authority, training and experience of persons who are responsible for receiving, inspecting, storing, handling and shipping prescription drugs at the facility;

(b) An assessment of the operational conditions of each facility of the wholesaler, including, without limitation, security, climate control and cleanliness;

(c) An assessment of compliance with:

(1) The Federal Prescription Drug Marketing Act;

(2) Appropriate recordkeeping measures;

(3) The Drug Enforcement Administration recordkeeping requirements if the wholesaler maintains a federal controlled substance registration; and

(4) Temperature monitoring and documentation requirements; and

(d) An assessment of the procedures of the wholesaler for detecting adulterated, misbranded or counterfeit prescription drugs.

4. For each inspection pursuant to this section, the licensee shall obtain and maintain the signature of the appropriate representative of the wholesaler verifying the accuracy of the inspection.

5. Each licensee shall enter into an agreement with each wholesaler with whom the licensee enters into a business relationship providing that the wholesaler will comply with all applicable federal and state laws and regulations relating to the purchase and sale of prescription drugs and requiring the wholesaler to notify the licensee of any material change regarding the integrity or legal status of prescription drugs received by the licensee or any other material change regarding the legal status of the wholesaler.

Sec. 12. ***A person who is licensed to engage in wholesale distribution pursuant to this chapter shall certify a claim by another wholesaler that the wholesaler is an authorized distributor of record from whom the licensee purchases a prescription drug. Such certification includes a statement signed by a representative of the wholesaler certifying the claim that the wholesaler is an authorized distributor of record for a specified manufacturer and:***

1. A copy of the written agreement currently in effect with the manufacturer;

2. A copy of a letter from the manufacturer endorsing the wholesaler as an authorized distributor of record;

3. Copies of applicable invoices from the manufacturer demonstrating the purchase by the wholesaler of at least 1,000 sales units of prescription drugs from the manufacturer within the 12 months immediately preceding the current month;

4. Copies of applicable invoices from the manufacturer from each of the previous 12 months;

5. Copies of applicable invoices from the manufacturer specific to the given transaction; or

6. Verification from the manufacturer's website that the wholesaler is an authorized distributor of record.

Sec. 13. NRS 639.040 is hereby amended to read as follows:

639.040 1. The Board shall elect a President and a Treasurer from among its members.

2. The Board shall employ an Executive Secretary, who ~~[must not be]~~ ***is not*** a member of the Board. ***The Executive Secretary must have experience as a licensed pharmacist in this State or in another state with comparable licensing requirements.*** The Executive Secretary shall keep a complete record of all proceedings of the Board and of all certificates issued, and shall perform such other duties as the Board may require, for which services he is entitled to receive a salary to be determined by the Board.".

Amend the bill as a whole by renumbering sections 12 and 13 as sections 19 and 20 and adding new sections designated sections 17 and 18, following sec. 11, to read as follows:

"**Sec. 17.** NRS 639.2615 is hereby amended to read as follows:

639.2615 1. A wholesaler may sell a prescription drug only ~~[to:~~

~~(a) A pharmacy or practitioner; or~~

~~(b) Another wholesaler if:~~

~~(1) The wholesaler who purchases the drug is licensed by the Board or the board or other relevant authority of another state; and~~

~~(2) The]~~ ***if the*** sale is a bona fide transaction.

2. A wholesaler may purchase a prescription drug only from:

(a) A manufacturer; ~~[or]~~

(b) ***A pharmacy or practitioner if that pharmacy or practitioner maintains a valid license in the State in which the pharmacy or practitioner is domiciled; or***

(c) Another wholesaler if:

(1) The wholesaler who sells the drug is licensed by the Board; and

(2) The sale is a bona fide transaction.

3. ***A wholesaler may receive a prescription drug from a pharmacy or practitioner only if the wholesaler does not pay the pharmacy or practitioner an amount, either in cash or credit, that is more than the price for which the wholesaler sells such prescription drugs to other pharmacies or practitioners at the time of return and:***

(a) The prescription drug was originally shipped to the pharmacy or practitioner by the wholesaler; or

(b) The prescription drug could not be returned by the pharmacy or practitioner to the original wholesaler.

➥ If a wholesaler receives a prescription drug pursuant to this subsection and the wholesaler subsequently sells the prescription drug to another wholesaler, the prescription drug must be accompanied by a statement of prior sales as defined in section 5 of this act.

4. The Board shall not limit the quantity of prescription drugs a wholesaler may purchase, sell, distribute or otherwise provide to another wholesaler, distributor or manufacturer.

~~[4.]~~ ***5.*** For the purposes of this section:

(a) A purchase shall be deemed a bona fide transaction if:

(1) The wholesaler purchased the drug:

(I) Directly from the manufacturer of the drug; or

(II) With a reasonable belief that the drug was originally purchased directly from the manufacturer of the drug;

(2) The circumstances of the purchase reasonably indicate that the drug was not purchased from a source prohibited by law;

(3) Unless the drug is purchased by the wholesaler from the manufacturer, before the wholesaler sells the drug to another wholesaler, the wholesaler who sells the drug conducts a reasonable visual examination of the drug to ensure that the drug is not:

(I) Counterfeit;

(II) Deemed to be adulterated or misbranded in accordance with the provisions of chapter 585 of NRS;

(III) Mislabeled;

(IV) Damaged or compromised by improper handling, storage or temperature control;

(V) From a foreign or unlawful source; or

(VI) Manufactured, packaged, labeled or shipped in violation of any state or federal law relating to prescription drugs;

(4) The drug is shipped directly from the wholesaler who sells the drug to the wholesaler who purchases the drug; and

(5) The documents of the shipping company concerning the shipping of the drug are attached to the invoice for the drug and are maintained in the records of the wholesaler.

(b) A sale shall be deemed a bona fide transaction if ~~[~~~~there is a reasonable assurance by the wholesaler that purchases the drug that the wholesaler will sell the drug directly and~~~~]~~ ***the wholesaler sells the prescription drug*** only to ~~[~~~~a~~~~]~~ ***:***

(1) A pharmacy or practitioner ~~[.]~~ ***if that pharmacy or practitioner maintains a valid license in the state in which the pharmacy or practitioner is domiciled.***

(2) Another wholesaler who maintains a valid license in the state in which he is domiciled if the wholesaler who sells the prescription drug has complied with sections 9, 10 and 11 of this act.

(c) The purchase or sale of a prescription drug includes, without limitation, the distribution, transfer, trading, bartering or any other provision of a prescription drug to another person by a wholesaler. A transfer of a prescription drug from a wholesale facility of a wholesaler to another wholesale facility of the wholesaler shall not be deemed a purchase or sale of a prescription drug pursuant to this section if the wholesaler is a corporation whose securities are publicly traded and regulated by the Securities Exchange Act of 1934.

Sec. 18. NRS 639.2801 is hereby amended to read as follows:

639.2801 Unless specified to the contrary in writing on the prescription by the prescribing practitioner, all prescriptions filled by any practitioner must be dispensed in a container to which is affixed a label or other device which clearly shows:

1. The date.

2. The name, address and prescription serial number of the practitioner who filled the prescription.

3. The names of the prescribing practitioner and of the person for whom prescribed.

4. The number of dosage units.

5. Specific directions for use given by the prescribing practitioner.

6. The expiration date of the effectiveness of the drug or medicine dispensed, if that information is ~~[required to be]~~ included on the original label of the manufacturer of ~~[the]~~ ***that*** drug or medicine.

~~[The practitioner shall not specify on the label or other device for the drug or medicine an expiration date that is earlier than]~~ ***If*** the expiration date specified by the manufacturer ~~[on the original label.]~~ ***is not less than 1 year after the date of dispensing, the practitioner may use a date that is 1 year after the date of dispensing as the expiration date.***

7. The proprietary or generic name of the drug or medicine as written by the prescribing practitioner.

8. The strength of the drug or medicine.

➥ The label must contain the warning:

Caution: Do not use with alcohol or nonprescribed drugs without consulting the prescribing practitioner.".

Amend sec. 13, page 10, by deleting lines 34 and 35 and inserting:

"**Sec. 20.** 1. This section and sections 1 to 14, inclusive, and 16 to 19, inclusive, of this act become effective on October 1, 2005.".

Amend sec. 13, page 10, line 36, by deleting "9" and inserting "14".

Amend sec. 13, page 11, line 4, by deleting "10" and inserting "15".

Amend the title of the bill by deleting the eleventh through fifteenth lines and inserting:

"with the laws relating to wholesalers; requiring the State Board of Pharmacy to ensure the safe and efficient operation of wholesalers and the integrity and propriety of transactions involving wholesalers; revising provisions governing the sale and purchase of prescription drugs by wholesalers;".

If this amendment is adopted, the Legislative

Counsel's Digest will be changed to read as follows:

Legislative Counsel's Digest:

Existing law provides for the licensure of wholesalers of prescription drugs and the regulation of the practice of the wholesale distribution of prescription drugs. (Chapter 639 of NRS)

This bill requires an applicant for a license as a wholesaler to submit a complete set of his fingerprints to the State Board of Pharmacy for a criminal background check. In addition, if the Board determines that an employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of an applicant has the power to exercise significant influence over the operation of the applicant as a licensed wholesaler, the Board may require such a person to submit a complete set of his fingerprints for a criminal background check.

This bill requires each wholesaler to submit, on an annual basis, an updated list of employees, agents, independent contractors, consultants, guardians, personal representatives, lenders and holders of indebtedness. The Board may require persons identified on the updated list to submit a complete set of fingerprints for a criminal background check if the Board determines that such a person has the power to exercise significant influence over the operation of the wholesaler.

This bill requires an applicant for an initial license or renewal of a license as a wholesaler to file a bond or other form of security. This requirement does not apply to publicly traded corporations.

This bill requires the Board to ensure the safe and efficient operation of wholesalers and the integrity and propriety of transactions involving wholesalers, including, without limitation, ensuring the circumstances under which a wholesaler must prepare, deliver, acquire and maintain a statement

identifying prior sales. Before January 1, 2007, the statement must be in either written or electronic form. On and after January 1, 2007, the statement must be in electronic form unless the Board determines that the technology is not reasonably available or that the wholesalers require additional time to provide the statements in electronic form.

This bill provides penalties if a wholesaler fails to comply with the requirements related to the statement identifying prior sales of prescription drugs and if the wholesaler knowingly destroys, fails to authenticate, forges or falsifies a statement or fails to record material information in such a statement. A wholesaler who violates these provisions is guilty of a category C felony.

Existing law requires the Board to employ an Executive Secretary. (NRS 639.040)

This bill amends existing law to require the Executive Secretary employed by the Board to have experience as a licensed pharmacist in this State or in another state with comparable licensing requirements.

Existing law governs transactions involving wholesalers, including the sale and purchase of prescription drugs. (NRS 639.2615)

This bill amends existing law to revise the descriptions of a “bona fide sale” and a “bona fide purchase” in transactions involving wholesalers.