Amendment No. 365

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Senate Amendment to Senate Bill No. 37	(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	o Digest: Yes
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ASSEMBLY ACTION Initial and Date SENATE ACTION Ini	itial and Date
Adopted Lost Adopted Lost Adopted Lost	
Concurred In Not Concurred In Not	
Receded Not Receded Not	
Amend sec. 2, page 2, by deleting lines 17 through 20 and inserting: "2. In addition to the requirements of subsection 1, the applicant shall submit with his application a list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant. The Board may require any person on the applicant's list to submit a complete set of his fingerprints to the Board if the	
Board determines that the person has the".	
Bourd determines that the person has the .	
Amend sec. 3, page 3, by deleting lines 18 and 19 and inserting:	
"Sec. 3. 1. On a monthly basis, each licensed wholesaler shall submit to the Board an	
updated list of each employee, agent, independent contractor, consultant, guardian, personal".	
Amend sec. 3, page 3, by deleting lines 23 through 25 and inserting:	
SH/KP	Date: 4/18/2005

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

* A S B 3 7 3 6 5 *

"licensee as a wholesaler.".

Amend sec. 3, page 3, line 26, by deleting "the list" and inserting:

"an updated list".

Amend sec. 3, page 3, line 29, by deleting:

"that person shall" and inserting:

"the Board may require that person to".

Amend the bill as a whole by deleting sections 5 through 7, renumbering sections 8 through 13 as sections 7 through 12 and adding new sections designated sections 5 and 6, following sec. 4, to read as follows:

- "Sec. 5. As used in sections 5 to 8, inclusive, of this act, unless the context otherwise requires, "statement of prior sales" or "statement":
- 1. Means a statement of prior sales that must be used in a transaction involving the purchase or sale of a prescription drug by a wholesaler if required by the regulations adopted by the Board pursuant to section 6 of this act; and
- 2. Is synonymous with the term "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act."
 - Sec. 6. 1. The Board shall adopt regulations to provide for:
 - (a) The safe and efficient operation of wholesalers; and
- (b) The integrity and propriety of transactions involving the purchase and sale of prescription drugs by wholesalers.
- 2. The regulations adopted by the Board must include, without limitation, regulations establishing:

- (a) The circumstances and conditions under which a wholesaler must prepare, deliver, acquire and maintain a statement of prior sales regarding a transaction involving the purchase or sale of a prescription drug;
 - (b) The form and contents of a statement of prior sales; and
- (c) The process and procedures for verifying and certifying that the information contained in a statement of prior sales is complete and accurate.
- 3. In determining the circumstances and conditions under which a wholesaler must prepare, deliver, acquire and maintain a statement of prior sales regarding a transaction involving the purchase or sale of a prescription drug, the Board shall consider:
- (a) The need for verification to ensure that the transaction is a bona fide transaction pursuant to NRS 639.2615; and
- (b) The level of risk the transaction poses to public health and safety, including, without limitation, the potential that the transaction may involve the sale or purchase of a prescription drug that is:
 - (1) Counterfeit;
- (2) Deemed to be adulterated or misbranded in accordance with the provisions of chapter 585 of NRS;
 - (3) Mislabeled;
 - (4) Damaged or compromised by improper handling, storage or temperature control;
 - (5) From a foreign or unlawful source; or
- (6) Manufactured, packaged, labeled or shipped in violation of any state or federal law relating to prescription drugs.

- 4. If a statement of prior sales is required for a transaction involving the purchase or sale of a prescription drug by a wholesaler, the statement:
- (a) Must include the signature of the wholesaler or his designated representative certifying that the information contained in the statement is complete and accurate; and
 - (b) Except as otherwise provided in subsection 5, must be:
 - (1) In written or electronic form, if the transaction occurs before January 1, 2007; and
 - (2) In electronic form, if the transaction occurs on or after January 1, 2007.
- 5. The Board may extend the date for compliance with the requirement that the statement of prior sales must be in electronic form if the Board determines that the technology to provide such a statement in electronic form is not reasonably available or that the licensed wholesalers in this State otherwise require additional time to carry out the requirements of an electronic form. If the Board extends the deadline pursuant to this subsection, the Board shall ensure that all licensed wholesalers in this State are provided adequate notice of the extension.".

Amend sec. 8, pages 8 and 9, by deleting lines 41 through 45 on page 8 and lines 1 through 5 on page 9, and inserting:

"felony and shall be punished as provided in NRS 193.130 if, with the intent to defraud or deceive, he:

- 1. Fails to deliver to another person a complete and accurate statement of prior sales for a prescription drug, if such a statement is required, before selling or otherwise transferring the drug to that person.
- 2. Fails to acquire a complete and accurate statement of prior sales for a prescription drug, if such a statement is required, before obtaining the drug from another person.

3. Falsely swears or certifies that the information in a statement of prior sales is accurate and".

Amend sec. 9, page 9, by deleting lines 9 through 23 and inserting:

"felony and shall be punished as provided in NRS 193.130 if he knowingly:

- 1. Destroys, alters, conceals or fails to maintain a complete and accurate statement of prior sales for each prescription drug in his possession for wholesale distribution if such a statement is required.
- 2. Fails to authenticate information contained in a statement of prior sales for a prescription drug, if such a statement is required, and distributes or attempts to distribute that prescription drug.
 - 3. Forges, counterfeits or falsely creates a statement of prior sales.
- 4. Makes a false representation or assertion of any factual matter contained in a statement of prior sales.
 - 5. Fails to record material information required to be recorded in a statement of prior sales.".

 Amend sec. 12, page 11, line 30, by deleting:

"8 or 9" and inserting:

"7 or 8".

Amend the bill as a whole by deleting sections 14 and 15 and renumbering sec. 16 as sec. 13.

Amend sec. 16, page 13, lines 5 and 6, by deleting:

"10, inclusive, and 12 to 15, inclusive," and inserting:

"9, inclusive, and 11 and 12".

Amend sec. 16, page 13, line 7, by deleting "10" and inserting "9".

Amend sec. 16, page 13, line 18, by deleting "11" and inserting "10".

Amend the title of the bill to read as follows:

"AN ACT relating to prescription drugs; requiring an applicant for licensure as a wholesaler of prescription drugs to submit a set of his fingerprints to the State Board of Pharmacy for use by the Board in obtaining a report on the applicant's criminal history; authorizing the Board to require certain persons connected with the operations of a licensed wholesaler to submit a set of fingerprints to the Board for use by the Board in obtaining a report on the person's criminal history; requiring certain licensed wholesalers to file a bond or cash deposit conditioned upon compliance with the laws relating to wholesalers; requiring certain licensed wholesalers to prepare, deliver, acquire and maintain statements identifying prior sales of prescription drugs under certain circumstances; requiring the Board to adopt regulations regarding the use of such statements; providing penalties; and providing other matters properly relating thereto.".

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 a monthly 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 certain wholesalers to prepare, deliver, acquire and maintain statements identifying prior sales of prescription drugs under certain circumstances. The Board is required to adopt regulations regarding the use, form and contents of such statements. 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.