SENATE BILL NO. 37-SENATOR WIENER

Prefiled February 4, 2005

Referred to Committee on Commerce and Labor

SUMMARY—Revises provisions governing wholesalers of prescription drugs. (BDR 54-13)

FISCAL NOTE: Effect on Local Government: No.

Effect on the State: Yes.

EXPLANATION - Matter in bolded italics is new; matter between brackets [omitted material] is material to be omitted.

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.

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.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

- **Section 1.** Chapter 639 of NRS is hereby amended by adding thereto the provisions set forth as sections 2 to 8, inclusive, of this act.
- Sec. 2. 1. In addition to the requirements for an application set forth in NRS 639.100, each applicant for a license to engage in wholesale distribution shall submit with his application a complete set of his fingerprints and written permission authorizing the Board to forward the fingerprints to the Central Repository for Nevada Records of Criminal History for submission to the Federal Bureau of Investigation for its report. If the applicant is a:
 - (a) Natural person, that person must submit his fingerprints.
 - (b) Partnership, each partner must submit his fingerprints.
- 13 (c) Corporation, each officer and director of the corporation 14 must submit his fingerprints.
 - (d) Sole proprietorship, that sole proprietor must submit his fingerprints.
 - 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 power to exercise significant influence over the operation of the applicant as a licensed wholesaler. The fingerprints must be submitted with written permission authorizing the Board to forward the fingerprints to the Central Repository for Nevada Records of Criminal History for submission to the Federal Bureau of Investigation for its report.

3. The Board may issue a provisional license to an applicant pending receipt of the reports from the Federal Bureau of Investigation if the Board determines that the applicant is

13 otherwise qualified.

 4. An applicant who is issued a license by the Board shall not allow a person who is required to submit his fingerprints pursuant to subsection 2 to act in any capacity in which he exercises significant influence over the operation of the wholesaler if the:

(a) Person does not submit a complete set of his fingerprints in

accordance with subsection 2; or

(b) Report of the criminal history of the person indicates that he has been convicted of, or entered a plea of guilty or nolo contendere to, a felony or offense involving moral turpitude or related to the qualifications, functions or duties of that person in connection with the operation of the wholesaler.

5. The Board shall not issue a license to an applicant if the

26 requirements of this section are not satisfied.

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 representative, lender or holder of indebtedness of the wholesaler who is employed by or otherwise contracts with the wholesaler for the provision of services in connection with the operation of the licensee as a wholesaler.

2. If a person identified on an undated list of the wholesaler is employed by or otherwise contracts with the wholesaler after the wholesaler is issued a license and that person did not submit his fingerprints pursuant to section 2 of this act, the Board may require that person to submit a complete set of his fingerprints to the Board if the Board determines that the person has the power to exercise significant influence over the operation of the licensee as a wholesaler. The fingerprints must be submitted within 30 days after being requested to do so by the Board and must include written permission authorizing the Board to forward the fingerprints to the Central Repository for Nevada Records of



Criminal History for submission to the Federal Bureau of Investigation for its report.

- 3. A wholesaler shall not allow a person who is required to submit his fingerprints pursuant to subsection 2 to act in any capacity in which he exercises significant influence over the operation of the wholesaler if the:
- (a) Person does not submit a complete set of his fingerprints in accordance with subsection 2; or
- (b) Report of the criminal history of the person indicates that he has been convicted of, or entered a plea of guilty or nolo contendere to, a felony or offense involving moral turpitude or related to qualifications, functions or duties of that person in connection with the operation of the wholesaler.
- Sec. 4. 1. Except as otherwise provided in this subsection, before the Board issues a license to engage in the wholesale distribution of prescription drugs, the applicant shall file with the Board a bond in the amount of \$100,000 executed by the applicant as principal, and by a corporation qualified under the laws of this State as surety, payable to this State and conditioned upon the compliance with the requirements of this chapter applicable to wholesalers. An applicant that is a publicly traded corporation is not required to file a bond or other security pursuant to this section.
- 2. In lieu of the bond required pursuant to subsection 1, an applicant may deposit with the Board a like amount of lawful money of the United States or any other form of security authorized by NRS 100.065. If security is provided in the form of a savings certificate, certificate of deposit or investment certificate, the certificate must state that the amount is not available for withdrawal except upon order of the Board.
- 3. The Board may, by agreement with a wholesaler who has been licensed with the Board for 5 consecutive years or more, allow a reduction in the amount of the bond or other security as provided in subsections 1 and 2, if the wholesaler has conducted business in accordance with the applicable provisions of this chapter for the immediately preceding 5 years, but no bond may be in an amount less than \$5,000. The Board may at any time thereafter require the licensee to increase the amount of the bond or other security if evidence is presented to the Board supporting this requirement.
- 4. The purpose of the bond and other security required by this section is to secure payment of any fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of a wholesaler that are imposed pursuant to NRS 622.400 or 622.410 which the licensee fails to pay within 30



days after the fines or costs become due and payable. The Board may make a claim against a bond or other security pursuant to this subsection until 1 year after the license ceases to be valid or until 60 days after any administrative proceeding against the licensee conducted pursuant to NRS 639.241 to 639.2576, inclusive, is concluded.

- 5. Except as otherwise provided in this subsection, before renewing a license to engage in wholesale distribution, the Board shall require the licensee to file with the Board satisfactory evidence that his surety bond or other security is in full force. A licensee that is a publicly traded corporation is not required to maintain a bond or other security.
- 6. Failure of an applicant or licensee to file or maintain in full force the required bond or other security constitutes cause for the Board to deny, revoke, suspend or refuse to renew a license to engage in wholesale distribution.
- 7. All money received by the Board pursuant to this section must be deposited in accordance with NRS 639.081.
- 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
- 26 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
- 31 (b) The integrity and propriety of transactions involving the 32 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.
- 43 3. In determining the circumstances and conditions under 44 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;

- 10 (2) Deemed to be adulterated or misbranded in accordance 11 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:
- 25 (1) In written or electronic form, if the transaction occurs 26 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.
 - Sec. 7. A person who is licensed to engage in wholesale distribution pursuant to this chapter is guilty of a category C 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 complete.

Sec. 8. A person who is licensed to engage in wholesale distribution pursuant to this chapter is guilty of a category C 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.
- 18 3. Forges, counterfeits or falsely creates a statement of prior 19 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.
 - **Sec. 9.** NRS 639.180 is hereby amended to read as follows:
 - 639.180 1. Except as otherwise provided in this subsection, a certificate, license or permit issued by the Board pursuant to this chapter expires on October 31 of each even-numbered year. A certificate of registration as a pharmacist expires on October 31 of each odd-numbered year.
 - 2. Except as otherwise provided by NRS 639.137, 639.230 and 639.2328, each person to whom a certificate, license or permit has been issued may, if the certificate, license or permit has not been revoked, renew the certificate, license or permit biennially by:
 - (a) Filing an application for renewal;
 - (b) Paying the fee for renewal;
 - (c) Complying with the requirement of continuing professional education, if applicable; [and]
 - (d) If applicable, filing with the Board satisfactory evidence that his surety bond or other security required by section 4 of this act is in full force; and
 - (e) If the applicant is a natural person who is applying for the renewal of a certificate of registration as a pharmacist, intern pharmacist, pharmaceutical technician or pharmaceutical technician in training or a license issued pursuant to NRS 639.233, submitting the statement required pursuant to NRS 639.129.



3. The application for renewal, together with the fee for renewal and, if applicable, *the evidence of compliance with section* 4 of this act and the statement [,] required pursuant to NRS 639.129, must be delivered to the Executive Secretary of the Board on or before the expiration date of the certificate, license or permit, or the current renewal receipt thereof.

- 4. If a certificate, license or permit is renewed, it must be delivered to the applicant within a reasonable time after receipt of the application for renewal and the fee for renewal.
- 5. The Board may refuse to renew a certificate, license or permit if the applicant has committed any act proscribed by NRS 639.210.
- 6. If the application for renewal, [and] the fee for renewal and, if applicable, the evidence of compliance with section 4 of this act and the statement required pursuant to NRS 639.129, are not postmarked on or before the expiration date of the certificate, license or permit, or the current renewal receipt thereof, the registration is automatically forfeited.
 - **Sec. 10.** NRS 639.180 is hereby amended to read as follows:
- 639.180 1. Except as otherwise provided in this subsection, a certificate, license or permit issued by the Board pursuant to this chapter expires on October 31 of each even-numbered year. A certificate of registration as a pharmacist expires on October 31 of each odd-numbered year.
- 2. Except as otherwise provided by NRS 639.137, 639.230 and 639.2328, each person to whom a certificate, license or permit has been issued may, if the certificate, license or permit has not been revoked, renew the certificate, license or permit biennially by:
 - (a) Filing an application for renewal;
 - (b) Paying the fee for renewal; [and]
- (c) If applicable, filing with the Board satisfactory evidence that his surety bond or other security required by section 4 of this act is in full force; and
- (d) Complying with the requirement of continuing professional education, if applicable.
- 3. The application for renewal, together with the fee for renewal [.] and, if applicable, the evidence of compliance with section 4 of this act, must be delivered to the Executive Secretary of the Board on or before the expiration date of the certificate, license or permit, or the current renewal receipt thereof.
- 41 4. If a certificate, license or permit is renewed, it must be 42 delivered to the applicant within a reasonable time after receipt of 43 the application for renewal and the fee for renewal.



- 5. The Board may refuse to renew a certificate, license or permit if the applicant has committed any act proscribed by NRS 639.210.
- 6. If the application for renewal, [and] the fee for renewal and, if applicable, the evidence of compliance with section 4 of this act are not postmarked on or before the expiration date of the certificate, license or permit, or the current renewal receipt thereof, the registration is automatically forfeited.
 - **Sec. 11.** NRS 639.210 is hereby amended to read as follows:
- 639.210 The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant:
 - 1. Is not of good moral character;

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- 2. Is guilty of habitual intemperance;
- 3. Becomes or is intoxicated or under the influence of liquor, any depressant drug or a controlled substance, unless taken pursuant to a lawfully issued prescription, while on duty in any establishment licensed by the Board;
- 4. Is guilty of unprofessional conduct or conduct contrary to the public interest;
 - 5. Is addicted to the use of any controlled substance;
 - 6. Has been convicted of a violation of any law or regulation of the Federal Government or of this or any other state related to controlled substances, dangerous drugs, drug samples, or the wholesale or retail distribution of drugs;
 - 7. Has been convicted of:
 - (a) A felony relating to holding a certificate, license, registration or permit pursuant to this chapter; [or]
 - (b) A felony pursuant to section 7 or 8 of this act; or
- 31 (c) Other crime involving moral turpitude, dishonesty or 32 corruption;
- 8. Has been convicted of violating any of the provisions of NRS 616D.200, 616D.220, 616D.240 or 616D.300 to 616D.440, inclusive:
 - 9. Has willfully made to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of this chapter;
 - 10. Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent;
 - 11. Has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs;



12. Has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit;

- 13. Has failed to renew his certificate, license or permit by failing to submit the application for renewal or pay the renewal fee therefor:
- 14. Has had his certificate, license or permit suspended or revoked in another state on grounds which would cause suspension or revocation of a certificate, license or permit in this State;
- 15. Has, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he presides, or has knowingly allowed a violation of any provision of this chapter or other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his supervision;
- 16. Has repeatedly been negligent, which may be evidenced by claims of malpractice settled against him; [or]
- 17. Has failed to maintain and make available to a state or federal officer any records in accordance with the provisions of this chapter or chapter 453 or 454 of NRS : or
- 18. Has failed to file or maintain a bond or other security if required by section 4 of this act.
- **Sec. 12.** A person who possesses a license to engage in the wholesale distribution of prescription drugs issued by the State Board of Pharmacy before October 1, 2005, must, as a condition to renewal of that license, file a bond or other security required by section 4 of this act.
- **Sec. 13.** 1. This section and sections 1 to 9, inclusive, and 11 and 12 of this act become effective on October 1, 2005.
- 2. Section 9 of this act expires by limitation on the date on which the provisions of 42 U.S.C. § 666 requiring each state to establish procedures under which the state has authority to withhold or suspend, or to restrict the use of professional, occupational and recreational licenses of persons who:
- (a) Have failed to comply with a subpoena or warrant relating to a proceeding to determine the paternity of a child or to establish or enforce an obligation for the support of a child; or



- (b) Are in arrears in the payment for the support of one or more 2 children.
 - → are repealed by the Congress of the United States.

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- 3. Section 10 of this act becomes effective on the date on which the provisions of 42 U.S.C. § 666 requiring each state to establish procedures under which the state has authority to withhold or suspend, or to restrict the use of professional, occupational and recreational licenses of persons who:
- (a) Have failed to comply with a subpoena or warrant relating to a proceeding to determine the paternity of a child or to establish or enforce an obligation for the support of a child; or
- (b) Are in arrears in the payment for the support of one or more 13 children,
 - → are repealed by the Congress of the United States.



