# Nevada State Board of Pharmacy

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June 11, 2020

## NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of
Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will hold a Public Hearing at 9:00 a.m. on Thursday, July 16, 2020, at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada. The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to Chapters 453 and/or 639 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

**Amendment of Nevada Administrative Code (NAC) Chapter 639.** The proposed regulation relates to the licensing and regulation of wholesalers.
(LCB File No. R040-20)

1. The need for and the purpose of the proposed regulation or amendment.

The proposed regulation amendments establish enhanced oversight of the licensing and regulation of wholesalers consistent with recommendations by the Executive Branch Audit Committee, Division of Internal Audit Report No. 20-05. The proposed regulations allow for wholesaler applicants to be sufficiently evaluated for licensure to protect the health, safety and welfare of the public.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no adverse economic impact from this regulation amendment on wholesalers or on the public. The regulation amendment has beneficial impact by decreasing the potential for counterfeit or adulterated drugs to be introduced into market.

(b) Both immediate and long-term effects.

Immediate or long-term economic effect on wholesalers and public will be negligible. Impact on industry and public is safer pharmaceuticals provided to patients.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation amendment.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The proposed regulation amendments are not more stringent then the requirements of federal law but rather conform to the requirements of 21 CFR 205.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

**Amendment of Nevada Administrative Code (NAC) Chapter 639.** The proposed regulation authorizes the Executive Secretary of the Board to require a person who submits an application appear before the Board if the application indicates that the applicant engaged in prohibited conduct. (LCB File No. R041-20)

1. The need for and the purpose of the proposed regulation or amendment.

The proposed regulation authorizes the Executive Secretary of the Board to require a person who submits an application for the issuance or renewal of a license, certificate or permit to appear before the Board if the application discloses that the applicant engaged in prohibited conduct. The regulation is necessary to allow applicants to be sufficiently evaluated for licensure to protect the health, safety and welfare of the public.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no adverse economic impact from this regulation amendment on the regulated entities or on the public beyond the expense of an applicant to appear before the board when required. The regulation has a beneficial impact on both the regulated entities and the public by improving the safety of pharmaceutical care.

(b) Both immediate and long-term effects.

Immediate or long-term economic effect on regulated entities will be negligible. Impact on public is safer pharmaceutical care.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation amendment.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation amendments of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments in written form to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521, or at e-mail address: shunting@pharmacy.nv.gov. Written submissions must be received by the Board at least fourteen days before the scheduled public hearing. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

A copy of this notice and the regulation to be adopted and amended will be on file at the State Library, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be adopted and amended will be available in all counties in which an office of the agency is not maintained, at the main public library, for inspection and copying by members of the public during business hours. The text of each regulation will include the entire text of any section of the Nevada Administrative Code which is proposed for amendment or repeal. This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary.

Upon adoption of any regulation, the agency, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at the following locations:

Nevada State Board of Pharmacy
Reno, Nevada

Nevada State Board of Pharmacy
Las Vegas, Nevada

Mineral County Courthouse
Hawthorne, Nevada

Elko County Courthouse
Elko, Nevada

Washoe County Courthouse
Reno, Nevada

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Existing regulations require an applicant for a license to engage in wholesale distribution of prescription drugs to submit any change in application information to the Board within 30 days of the change. (NAC 639.593) **Section 7** requires the applicant to submit a new application if the change is a change in ownership.

Existing regulations require certain applicants or licensed wholesalers to designate one natural person to be its representative. To qualify as a designated representative, existing regulations require the natural person to: (1) have been employed for at least 6,000 hours for a pharmacy or wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs; (2) have received a score of at least 75 percent on an examination provided by the Board; and (3) be at least 21 years of age. (NAC 639.5935) **Section 9** of this regulation removes the examination requirement.

Existing regulations also provide that if the designated representative leaves the employ of the wholesaler, it must notify the Board within 48 hours of the departure of the designated representative and cease all business operations until another designated representative is approved by the Board. (NAC 639.5935) **Section 9** removes the provisions that authorize a wholesaler to designate a new representative after the departure of its current designated representative, meaning that before there is a change in the designated representative: (1) the wholesaler must designate a new representative on a form provided by the Board; and (2) the Executive Secretary must approve the new designation.

Existing law requires applicants of a license to engage in wholesale distribution of prescription drugs to file a bond with the Board of not less than $25,000 and not more than $100,000, as determined by the Board. (NRS 639.515) Existing regulations authorize a wholesaler to provide a single bond for multiple sites: (1) of $100,000, if the net worth of the wholesaler is greater than $25,000,000 and the sites are owned by a common owner; or (2) in an amount determined by the Board, if the wholesaler only participates in transactions not considered wholesale transactions by the Board. (NAC 639.5938) **Section 10** of this regulation: (1) provides that the net worth of the wholesaler must be documented; and (2) removes the authority of the Board to determine the bond amount where the wholesaler only participates in transactions not considered wholesale transactions.

Existing regulations provide numerous avenues that a wholesaler can use to establish an ongoing relationship with a manufacturer. Existing regulations provide that one such avenue is when a wholesalers purchases at least 5,000 units of prescription drugs from the manufacturer in the immediate 12 months preceding the claim of the ongoing relationship and the Board or the wholesaler verify the purchase with the manufacturer. (NAC 639.594) **Section 11** of this regulation provides that all regulatory avenues for the establishment of the ongoing relationship must be documented. Additionally, **section 11** removes the requirement that the Board verify the sale of at least 5,000 units of prescription drugs, meaning that if a wholesaler documents its ongoing relationship via this avenue, the wholesaler itself must verify the purchase of the prescription drugs, not the Board. **Section 6** of this regulation makes a conforming change.

Existing regulations require licensed wholesalers to provide certain records to the Board relating to: (1) the separation and disposal of certain prescription drugs; (2) the inventory, receipt and distribution of prescription drugs; (3) a statement of prior sales; and (4) certain other records.

(NAC 639.601, 639.602, 639.603, 639.605) **Sections 12-15** of this regulation remove the requirement that these records be provided to the Board, and instead require the records to be readily retrievable.

**Section 1.** Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2, 3 and 4 of this regulation.

**Sec. 2.** ***"Person who exercises significant influence over the operation" means:***

***1. A partner in any form of partnership;***

***2. An officer or director of a corporation;***

***3. A sole proprietor;***

***4. A person designated as a representative pursuant to NAC 639.5935;***

***5. A person with a controlling interest of ownership;***

***6. Any person owning more than 10 percent of the corporate stock; or***

***7. Any other person identified by an applicant, licensed wholesaler or the Board.***

**Sec. 3.** ***Except as otherwise provided in NAC 639.593, each licensed wholesaler that provides an updated list pursuant to NRS 639.505 must submit to the Board:***

***1. A complete set of fingerprints from any person contained on the updated list who:***

***(a) Is a person who exercises significant influence over the operation of the licensed wholesaler; and***

***(b) Has not previously been required to submit a complete set of fingerprints pursuant to NRS 639.500 or NAC 639.593; and***

***2. Written permission from each person required to submit fingerprints pursuant to subsection 1, authorizing the Board to forward the complete set of fingerprints to the Central Repository for Nevada Records of Criminal History for submission to the Federal Bureau of Investigation for its report.***

**Sec. 4.** ***1. If a complete set of fingerprints from any person required to submit fingerprints pursuant to NRS 639.500 or NAC 639.593 or section 3 of this regulation is rejected by the Central Repository for Nevada Records of Criminal History, the person shall submit a second complete set of fingerprints and written permission authorizing the Board to forward the second complete set of fingerprints to the Central Repository for submission to the Federal Bureau of Investigation for its report.***

***2. If the second complete set of fingerprints of any person pursuant to subsection 1 is rejected by the Central Repository for Nevada Records of Criminal History, the Executive Secretary shall request a name-based background check of the person.***

**Sec. 5.** NAC 639.585 is hereby amended to read as follows:

639.585 As used in NAC 639.585 to 639.607, inclusive, ***and sections 2, 3 and 4 of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 639.587 to 639.592, inclusive, ***and section 2 of this regulation,*** have the meanings ascribed to them in those sections.

**Sec. 6.** NAC 639.589 is hereby amended to read as follows:

639.589 "Ongoing relationship" means a continuing business relationship in which a wholesaler distributes a manufacturer's prescription drugs which is ~~[established pursuant to]~~ ***documented in a manner prescribed in*** NAC 639.594.

**Sec. 7.** NAC 639.593 is hereby amended to read as follows:

639.593 1. Each applicant for a license to engage in the wholesale distribution of prescription drugs must submit an application to the Board. The application must be made on a form furnished by the Board. The application must include:

(a) The name, business address and telephone number of the applicant and the address of the facility, if different from the address of the applicant;

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

(c) The address, telephone number and name of the person who manages the facility;

(d) The type of ownership or operation of the facility;

(e) Except as otherwise provided in subsection ~~[7.]~~ *6:*

(1) A complete set of fingerprints from each person required to submit fingerprints pursuant to *subsection 1 of* NRS 639.500; ~~[and]~~

(2) *A complete set of fingerprints from any person contained on the list provided by the applicant pursuant to subsection 2 of NRS 639.500, if the person qualifies as a person who exercises significant influence over the operations of the applicant; and*

*(3)* Written permission from each person who ~~[submitted]~~ *is required to submit* fingerprints *pursuant to subparagraphs (1) or (2),* 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; and

(f) If the applicant is a:

(1) Natural person, the name of the person.

(2) Partnership, the name of the partnership and the name of each partner.

(3) Corporation ~~[, the]~~ *:*

*(I) The* name and title of each officer and director of the corporation ~~[, the]~~ *documented with the registration entity in the state of incorporation;*

*(II) The* corporate name and the state of incorporation *;* ~~[,]~~ and ~~[the]~~

*(III) The* name of the parent company, if any.

(4) Sole proprietorship, the name of the sole proprietor and the name of the business entity.

2. If a wholesaler distributes prescription drugs from more than one facility, the wholesaler must obtain a license for each facility.

3. The Board will not consider the sale or distribution of a prescription drug to be a wholesale transaction if the sale, distribution or other transaction involving the prescription drug is a sale, distribution or other transaction in which:

(a) A wholesaler licensed by the Board or the relevant authority of another state sells, distributes or otherwise provides a prescription drug to a wholesaler or pharmacy licensed by the Board;

(b) Both the transferring wholesaler and the transferee are wholly owned by a common owner; and

(c) The common owner is a publicly traded corporation.

➥ For the purposes of this subsection, a wholesaler whose transaction does not comply with the provisions of paragraphs (a), (b) and (c) may apply to the Board to consider the transaction of the wholesaler not to be a wholesale transaction if the wholesaler provides proof that is satisfactory to the Board that the proposed transaction will not endanger the public and is not proposed for the purpose of evading the provisions of this chapter and chapter 639 of NRS. The Board will consider such a transaction to be a wholesale transaction until the Board approves the application of the wholesaler.

4. An applicant shall submit to the Board any change in the information required by this section within 30 days after the change occurs. ***The applicant shall submit a new application to the Board if the change is a change in ownership.***

5. A license issued by the Board is not transferable.

6. ~~[Except as otherwise provided in subsection 7, each wholesaler applying for renewal of a license to engage in the wholesale distribution of prescription drugs must submit:~~

~~(a) A complete set of fingerprints from each person required to submit fingerprints pursuant to NRS 639.500; and~~

~~(b) Written permission from each person who submitted fingerprints 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.~~

~~7.]~~ Unless the Board otherwise requires, a wholesaler is not required to submit fingerprints pursuant to ***subparagraph (2) of paragraph (e) of*** subsection ~~[6]~~ ***1 or section 3 of this regulation*** if:

(a) The wholesaler's securities are publicly traded and regulated by the Securities Exchange Act of 1934, as amended, 15 U.S.C. §§ 78a et seq.;

(b) The wholesaler is owned by a corporation whose securities are publicly traded and regulated by the Act;

(c) The wholesaler is accredited by the National Association of Boards of Pharmacy under the ***Drug Distributor Accreditation program, formerly the*** Verified-Accredited Wholesale Distributors program;

(d) The wholesaler is a manufacturer of prescription drugs; or

(e) The wholesaler is a facility that distributes prescription drugs manufactured by a single manufacturer.

**Sec. 8.** NAC 639.5931 is hereby amended to read as follows:

639.5931 A person who is required to submit a complete set of his or her fingerprints to the Board pursuant to NRS 639.500 or 639.505 or NAC 639.593 ~~[must]~~ ***or section 3 of this regulation may*** submit the fingerprints electronically in a format prescribed by the Board.

**Sec. 9.** NAC 639.5935 is hereby amended to read as follows:

639.5935 1. Except as otherwise provided in this subsection, an applicant for a license, or a licensee with a license, to operate as a wholesaler shall designate at least one natural person to serve as the representative of the wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a wholesaler pursuant to this section unless the Executive Secretary determines that the designated natural person meets the qualifications set forth in subsection 2 and approves that natural person to be the designated representative of the wholesaler. The requirement to designate a representative set forth in this subsection does not apply to:

(a) An applicant that is a publicly traded corporation; or

(b) An applicant in which a majority interest of the applicant is owned by a pharmacist who is:

(1) Licensed by the Board;

(2) A resident of this State; and

(3) Not an owner of any interest in a pharmacy licensed by the Board.

2. Except as otherwise provided in subsection 3, the Board will approve a natural person as the representative of a wholesaler if the applicant for a license to operate as a wholesaler or the licensee presents proof satisfactory to the Executive Secretary that the natural person:

(a) Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs; ***and***

(b) ~~[Has received a score of at least 75 percent on an examination given by the Board regarding federal and state laws and wholesaler practices; and~~

~~(c)]~~ Is at least 21 years of age.

3. The Board may, based upon any of the grounds set forth in NRS 639.210, refuse to approve a natural person for service as the representative of a wholesaler, regardless of whether the person is otherwise qualified.

4. A representative of a wholesaler designated pursuant to this section:

(a) Must be actively involved in and aware of the actual daily operation of the wholesaler;

(b) Must be employed full-time in a managerial level position with the wholesaler;

(c) Must be physically present at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leave, vacation leave and other authorized absences; and

(d) May serve in this representative capacity for only one wholesaler at a time.

5. A wholesaler that is required to designate a natural person as its representative pursuant to this section shall not open or operate a facility unless that representative is actually employed full-time in the operation of the wholesaler and is physically present at the facility of the wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. ~~[If the natural person designated as the representative of a wholesaler leaves the employ of the wholesaler, thus leaving the wholesaler without a representative in violation of this section, the wholesaler shall:~~

~~(a) Immediately cease conducting business until another qualified natural person is approved by the Board to serve as the representative of the wholesaler; and~~

~~(b) Not later than 48 hours after that person leaves its employ, notify the Board that the person designated as the representative of the wholesaler has left the employ of the wholesaler.]~~

6. ~~[Before a wholesaler that is in violation of this section because the natural person designated as the representative of the wholesaler left the employ of the wholesaler may continue conducting business:]~~ ***Before there is a change in the natural person designated as the representative pursuant to this section:***

(a) The wholesaler must designate, on a form provided by the Board, a new natural person to serve as the representative of the wholesaler; and

(b) The Executive Secretary must approve the natural person so designated.

7. A wholesaler that operates without a representative in violation of this section is subject to the immediate suspension of its license ***and the wholesaler shall cease conducting business*** until it employs a qualified natural person to be its representative. The Executive Secretary may take such action as deemed necessary to secure the facility of the wholesaler and to ensure that the wholesaler does not conduct business during the period of the suspension.

**Sec. 10.** NAC 639.5938 is hereby amended to read as follows:

639.5938 Upon application from a wholesaler, the Board may allow a single bond ~~[:~~

~~1. Of]~~ ***of*** $100,000 to serve as the bond required pursuant to NRS 639.515, for multiple sites if all sites are owned by a common owner who has a ***documented*** net worth of more than $25,000,000. ~~[The owner must provide evidence satisfactory to the Board demonstrating adequate net worth~~

~~2. In an amount determined by the Board to serve as the bond required pursuant to NRS 639.515, for multiple sites where the wholesaler participates exclusively in transactions that the Board considers not to be a wholesale transaction pursuant to subsection 3 of NAC 639.593.]~~

**Sec. 11.** NAC 639.594 is hereby amended to read as follows:

639.594 1. An ongoing relationship between a wholesaler and a manufacturer must be ~~[established]~~ ***documented*** by:

(a) A written franchise, license or other agreement between a manufacturer and wholesaler to distribute prescription drugs;

(b) The presence of the wholesaler on a list of distributors with which the manufacturer does business, created by the manufacturer and located on a publicly accessible website maintained by the manufacturer; or

(c) The existence of the purchase by the wholesaler of at least 5,000 sales units of prescription drugs from the manufacturer within the 12 months immediately preceding the transaction for which the wholesaler claims to have an ongoing relationship and:

(1) ~~[The Board or a]~~ ***A*** purchasing wholesaler verifying the purchase with the manufacturer at its main corporate office in the United States; or

(2) The wholesaler maintaining invoices showing that the purchase was made directly from the manufacturer which include an account number assigned by the manufacturer to the wholesaler's address of record on file with the Board.

2. The records ~~[establishing]~~ ***documenting*** an ongoing relationship between a wholesaler and a manufacturer must be:

(a) If the facility is located within this State, maintained at the facility of the wholesaler throughout the period that such a relationship exists;

(b) Maintained for 3 years after the termination of any such relationship; and

(c) Available for review and copying by the Board or by any authorized representative of a federal, state or local agency.

3. An ongoing relationship between a wholesaler and a manufacturer may be attributed to an affiliated wholesaler if:

(a) The affiliated wholesaler is licensed by the Board or the relevant authority of another state;

(b) The wholesaler who has the ongoing relationship with the manufacturer and the affiliated wholesaler are wholly owned by a common owner; and

(c) The common owner is a publicly traded corporation.

4. As used in this section, "sales unit" means any standard container or unit of packaging used by the manufacturer for the prescription drug.

**Sec. 12.** NAC 639.601 is hereby amended to read as follows:

639.601 1. A prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated must be separated from other prescription drugs until it is destroyed or returned to the supplier.

2. A prescription drug whose immediate or sealed outer or secondary container has been opened or used must be identified as such and separated from other prescription drugs until it is destroyed or returned to the supplier.

3. If a prescription drug is returned to a wholesaler by a purchaser or purchasing wholesaler under conditions which cast doubt on the prescription drug's safety, identity, strength, quality or purity, the wholesaler shall destroy the prescription drug or return it to the supplier unless, after conducting an examination, testing or other investigation, the wholesaler determines that the

prescription drug complies with the appropriate standards of safety, identity, strength, quality and purity as prescribed in the package insert as approved by the Food and Drug Administration or in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670. The wholesaler shall keep a ***readily retrievable*** record of any examination, testing or other investigation conducted and make any records available for inspection by the Board.

4. Unless the reason a prescription drug must be destroyed or returned to the supplier is related to the expiration date of the prescription drug, a wholesaler that is required to destroy a prescription drug or return it to the supplier pursuant to subsection 3 shall ~~[provide to the Board a written notice]~~ ***maintain a readily retrievable record*** that includes:

(a) The name of the prescription drug;

(b) The lot number and expiration date of the prescription drug;

(c) The quantity of the prescription drug;

(d) The name and address of the business that returned the prescription drug to the wholesaler;

(e) Whether the wholesaler will:

(1) Return the prescription drug to the supplier; or

(2) Destroy the prescription drug; and

(f) The reason for the action taken by the wholesaler. ~~[~~

~~5. Within 48 hours after receipt by the Board of a notice required pursuant to subsection 4, a member of the staff of the Board shall inspect the prescription drug at the facility of the wholesaler and may impound or remove the prescription drug. If the member of the staff of the~~

~~Board does not impound or remove the prescription drug, the wholesaler may return the prescription drug to the supplier or destroy the prescription drug.]~~

**Sec. 13.** NAC 639.602 is hereby amended to read as follows:

639.602 1. Each wholesaler shall make and maintain a ***readily retrievable*** record of its inventory and of each transaction relating to the receipt and distribution or other disposition of a prescription drug. The record must include, without limitation:

(a) The purchase order, correspondence and any other document evidencing that the wholesaler ordered the prescription drug from the supplier;

(b) The invoice or other document provided to the wholesaler by the supplier concerning the purchase of the prescription drug;

(c) The shipping record, which may be a manifest, shipping label, shipping bill or any similar document, evidencing the shipment of the prescription drug from the supplier to the wholesaler;

(d) The purchase order, correspondence and any other document evidencing that the purchaser or purchasing wholesaler ordered the prescription drug from the wholesaler;

(e) The invoice or other document provided by the wholesaler when the purchaser or purchasing wholesaler purchased the prescription drug;

(f) The shipping record evidencing the shipment of the prescription drug from the wholesaler to the purchaser or purchasing wholesaler;

(g) A copy of the license of the supplier that sold the prescription drug to the wholesaler;

(h) If the supplier has an ongoing relationship with a manufacturer, a copy of the records maintained pursuant to NAC 639.594 which must be obtained by the wholesaler before the wholesaler may sell a prescription drug received from the supplier; and

(i) One or more of the documents required by NAC 639.5977 as reasonable assurance that the purchasing wholesaler is in compliance with subparagraph (2) of paragraph (c) of subsection 2 of NRS 639.595.

2. The wholesaler shall maintain the records described in subsection 1 for at least 3 years after the receipt, distribution or other disposition of the prescription drug. The records must be made available for copying and inspection by any person authorized to inspect those records.

3. Except as otherwise provided in this subsection, a wholesaler shall maintain the records required by this section at the facility. If the records are maintained by a computer, the records must be immediately retrievable and readily available for inspection.

4. If the records are not maintained at the facility because the facility is located outside of this State and are not immediately retrievable by computer, the records must be made available for inspection within 2 working days after a request is made by a person authorized to examine those records.

**Sec. 14.** NAC 639.603 is hereby amended to read as follows:

639.603 1. Except as otherwise provided in paragraph (a) of subsection 6 of NAC 639.5975 and NAC 639.6035, each wholesaler shall provide a statement of prior sales identifying each sale of a prescription drug before the prescription drug is sold to another wholesaler or to a pharmacy when supplying prescription drugs if the wholesaler:

(a) Has not established an ongoing relationship with the manufacturer from whom the prescription drug was purchased; or

(b) Purchased the prescription drug from another wholesaler.

2. The statement of prior sales must:

(a) Be in writing and bear the title "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act";

(b) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or wholesaler;

(c) Accompany all prescription drugs purchased from a wholesaler, even if they are resold to another distributor;

(d) Include the business name and address of the person from whom the prescription drug was purchased;

(e) Include the date of the sale; and

(f) Include the:

(1) Name of the prescription drug;

(2) Strength of the prescription drug;

(3) Size of the container;

(4) Number of containers;

(5) Lot number of the prescription drug; and

(6) Name of the manufacturer of the finished dosage form.

3. Each statement of prior sales must be:

(a) Maintained by the buyer and the wholesaler for 3 years;

(b) Except as otherwise provided in subsection 4, available for copying or inspection upon a request by an authorized representative of any federal, state or local agency, a manufacturer of prescription drugs or a pharmacist or practitioner who purchases prescription drugs from the wholesaler; and

(c) Maintained by the wholesaler at its facility.

4. If a wholesaler cannot provide a statement of prior sales upon request made pursuant to paragraph (b) of subsection 3 because the wholesaler purchased a prescription drug with a particular lot number from more than one source, the wholesaler must provide:

(a) Copies of all of the "Statements Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act," as described in subsection 2, that relate to the prescription drug with the particular lot number; or

(b) A statement certifying how much of a prescription drug the wholesaler purchased directly from the drug's manufacturer and how much of the prescription drug the wholesaler purchased from other wholesalers, which must accurately account for the wholesaler's purchases of a prescription drug for the 12 months immediately preceding the request and may be made in the form of a percentage, ratio or per unit accounting. The wholesaler must provide, upon request, all "Statements Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" that were the basis for the statement made pursuant to this paragraph.

5. ~~[Beginning February 15, 2007, a]~~ ***A*** wholesaler shall ~~[transmit to]~~ ***make a record of any statement of prior sale readily retrievable for inspection by*** the Board. ~~[, on or before the 15th day of each month, the information collected pursuant to subsection 2 for all statements of prior sales made for the immediately preceding month regarding the sale of a prescription drug to:~~

~~(a) Each customer in Nevada; and~~

~~(b) Each wholesaler located in Nevada.~~

~~The information required by this subsection must be transmitted by electronic mail to the Board or to a website established by the Board in a format required by the Board.]~~

**Sec. 15.** NAC 639.605 is hereby amended to read as follows:

639.605 1. Each wholesaler shall establish written policies and procedures for the receipt, security, storage, inventory and distribution of prescription drugs.

2. The written policies and procedures must include:

(a) A procedure for identifying, recording and reporting any losses or thefts of prescription drugs.

(b) A procedure for correcting any errors or inaccuracies concerning the wholesaler's inventory.

(c) A procedure that requires the oldest approved stock of a prescription drug to be distributed first. The procedure may allow deviation from that requirement if the deviation is temporary and appropriate.

(d) A procedure relating to the recall or withdrawal of a prescription drug because of:

(1) Any action taken at the request of the Food and Drug Administration or other federal agency or state or local law enforcement agency or other governmental agency, including the Board;

(2) Any voluntary action taken by a manufacturer to remove defective or potentially defective drugs from the market; or

(3) Any action taken by a manufacturer to promote public health and safety by the replacement of existing prescription drugs with an improved product or new design of a package.

(e) A procedure for the operation of a facility in the event of a strike, fire, flood or other natural disaster or emergency.

(f) A procedure to ensure that any outdated prescription drug is separated from other drugs that are not outdated and is destroyed or returned to the manufacturer. The procedure must provide for the establishment and maintenance of written records of the disposition of each

outdated prescription drug. The wholesaler shall keep the records for 3 years after the disposition of the prescription drug.

(g) A procedure to gather, make and maintain all records required pursuant to NRS 639.234 and NAC 639.585 to 639.607, inclusive ~~.~~ ***, and sections 2, 3 and 4 of this regulation, including a procedure to make records readily retrievable, as applicable.***

(h) A procedure to ensure that all prescription drugs received are examined pursuant to NAC 639.599 and 639.601.

(i) A procedure to ensure that the prescription drugs are not contraband drugs or counterfeit drugs.

3. As used in this section:

(a) "Contraband drug" means a prescription drug that is offered for sale by a purchaser to a wholesaler in violation of an agreement to which the purchaser is a party or is otherwise in privity of contract that would prohibit or otherwise disallow such a sale or resale.

(b) "Counterfeit drug" means a prescription drug that is adulterated, mislabeled or misbranded pursuant to chapter 585 of NRS.

**PROPOSED REGULATION OF THE**

**STATE BOARD OF PHARMACY**

**LCB File No. R041-20**

May 14, 2020

EXPLANATION – Matter in *italics* is new; matter in brackets [~~omitted material~~] is material to be omitted.

AUTHORITY: §1, NRS 639.070 and 639.180.

A REGULATION relating to pharmacy; authorizing the Executive Secretary of the State Board of Pharmacy to require certain applicants for the issuance or renewal of certain licenses to appear before the Board; and providing other matters properly relating thereto.

**Legislative Counsel's Digest:**

Existing law authorizes the State Board of Pharmacy to adopt regulations that authorize the Executive Secretary of the Board to issue certificates, licenses and permits pursuant to chapters 453, 454 and 639 of NRS. (NRS 639.070) Existing law authorizes a holder of a certificate, license or permit to apply for the renewal of such certificate, license or permit. (NRS 639.180) Existing law authorizes the Board to suspend or revoke a registration to dispense a controlled substance in certain circumstances. (NRS 453.236) Existing law also authorizes the Board to suspend or revoke any certificate, license, registration or permit issued pursuant to chapter 639 of NRS in certain circumstances. (NRS 639.210) Existing law further authorizes the Board to issue a cease and desist order or a citation to a person who practices or offers to practice without a license, certificate or permit issued pursuant to chapter 639 of NRS. (NRS 639.2895)

**Section 1** of this regulation authorizes the Executive Secretary of the Board to require a person who submits an application for the issuance or renewal of a license, certificate or permit required by chapter 453, 454 or 639 of NRS to appear before the next regular meeting of the Board if the application contains any information that indicates the applicant engaged in prohibited conduct.

**Section 1.** Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

***The Executive Secretary may require a person who submits an application for the issuance of a license, certificate or permit pursuant to chapter 453, 454 or 639 of NRS or an application for the renewal of any such license, certificate or permit to appear at the next regular meeting***

*of the Board if the application contains any information that indicates the applicant engaged in conduct which would be prohibited pursuant to NRS 453.236, 639.210 or 639.2895.*