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36A

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop
March 19, 2020

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: §1, NRS 639.070

A REGULATION relating to controlled substances; adding certain substances to the controlled substances listed in Schedule II; and providing other matters properly relating thereto.

NAC 453.520 Schedule II. (NRS 453.146, 453.2182, 639.070)

1. Schedule II consists of the drugs listed in this section, by whatever official, common, usual, chemical or trade name designated.

2. Unless specifically excepted or unless listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis, is hereby enumerated in schedule II:

(a) Opium and opiate, and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone and naltrexone, and their respective salts, but including:

Codeine;
Diprenorphine;
Ethylmorphine;
Etorphine hydrochloride;
Granulated opium;
Hydrocodone;
Hydrocodone combination product (meaning any product that contains hydrocodone in combination with any other active ingredient);
Hydromorphone;
Metopon;
Morphine;
Opium extracts;
Opium fluid;
Powdered opium;
Raw opium;
Oxycodone;
Oxymorphone;
Thebaine; and
Tincture of opium.

(b) Any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (a) if they do not include the isoquinoline alkaloids of opium.

(c) Opium poppy and poppy straw.

(d) Cocaine hydrochloride salt prepared by a registered chemical or pharmaceutical manufacturer of the Drug Enforcement Administration of the Department of Justice which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Drug Enforcement Administration.

(e) Benzolyecgonine or ecgonine.

(f) Concentrate of poppy straw (meaning the crude extract of poppy straw in either liquid, solid or powder form and containing the phenanthrene alkaloids of the opium poppy).

3. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (dextrorphan and levopropoxyphene excepted), are hereby enumerated on schedule II:

Alfentanil;
Alphaprodine;
Anileridine;
4-Anilino-N-Phenethyl-4-Piperidine (ANPP) (some trade or other names: 4-ANPP; despropionyl fentanyl);
Bezitramide;
Bulk dextropropoxyphene (in nondosage forms);
Carfentanil;
Dihydrocodeine;
Diphenoxylate;
Fentanyl;
Isomethadone;
Levo-alphacetylmethadol (some trade or other names: levo-alpha-acetylmethadol; levomethadyl acetate; LAAM);
Levomethorphan;
Levorphanol;
Metazocine;
Methadone;
Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenylbutane;
Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;
Pethidine (meperidine);
Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;
Pethidine-Intermediate-B, ethyl-4-phenylpiperdine-4-carboxylate;
Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
Phenazocine;
Piminodine;
Racemethorphan;
Racemorphan;
Ramifentanil;

Sufentanil; or
Tapentadol.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system is hereby enumerated on schedule II:

(a) Amphetamine, its salts, optical isomers and salts of optical isomers;

(b) Phenmetrazine and its salts;

(c) Unless specifically excepted, any preparation which contains any quantity of methamphetamine, including its salts, isomers and salts of isomers, prepared by a registered chemical or pharmaceutical manufacturer of the Drug Enforcement Administration of the Department of Justice, which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Drug Enforcement Administration;

(d) Methylphenidate; or

(e) Lisdexamfetamine.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation, is hereby enumerated on schedule II:

Amobarbital;
Glutethimide;
Pentobarbital; or
Secobarbital.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances is hereby enumerated on schedule II:

(a) Immediate precursors to phencyclidine (PCP):

1-Phenylcyclohexylamine; or
1-piperidinocyclohexanecarbonitrile (PCC).

(b) Immediate precursors to amphetamine and methamphetamine:

Phenylacetone (some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone).

7. Any material, compound, mixture or preparation which contains any quantity of Nabilone (commonly referred to as: (+)-trans-3-(1,1-dimethylheptyl)-6, 6a, 7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H- dibenzol[b,d]pyran-9-one) is hereby enumerated on schedule II.

8. Dronabinol oral solution in a drug product approved by the Food and Drug Administration (some trade or other names: (6aR,10aR)-6a,7,8,10a-Tetrahydro-6,6,9-

trimethyl-3-pentyl-6H-dibenzo[b,d]-pyran-1-ol; (-)-delta-9-trans-tetrahydrocannabinol; Syndros) is hereby enumerated on schedule II.

36B

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop - March 19, 2020

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS 639.100; NRS 639.500

A REGULATION relating to the wholesale distribution of prescription drugs; and providing other matters properly relating thereto.

Section. 1. NAC Chapter 639 of NAC is hereby amended by adding thereto the following provisions:

NAC 639.589X "Person who exercises significant influence over the operation" defined. (NRS 639.070, 639.100, 639.500) ***"Person who exercises significant influence over the operation" means:***

1. ***A general or limited partner of a 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(1);***
5. ***Any person with a controlling interest in ownership;***
6. ***Any person holding more than 10 percent of the corporate stock; and***
7. ***Any other person identified by an applicant, a licensed wholesaler, or the Board.***

Section. 2. NAC Chapter 639 of NAC is hereby amended by adding thereto the following provisions:

NAC 639.5XXX Rejection of fingerprints by the Central Repository for Nevada Records of Criminal History; name check. (NRS 639.070, 639.100, 639.500)

1. ***If a set of fingerprints from a person required to submit fingerprints pursuant to NRS 639.500 is rejected by the Central Repository for Nevada Records of Criminal History, the person must submit a second complete set of fingerprints.***
2. ***If, after resubmission of a second set of fingerprints from a person required to submit fingerprints pursuant to NRS 639.500, the second set of fingerprints is rejected by the Central Repository for Nevada Records of Criminal History, the Executive Secretary shall request a name-based background check for that person.***

Section. 3. NAC Chapter 639 of NAC is hereby amended by adding thereto the following provisions:

NAC 639.5XXX Submission of additional fingerprints; prohibitions. (NRS 639.070, 639.505) ***Each licensed wholesaler submitting to the Board an updated list pursuant to NRS 639.505 must submit:***

1. A complete set of fingerprints from any person identified on the updated list who exercises significant influence over the operation as defined in NAC 639.589X who has not previously submitted fingerprints pursuant to NRS 639.500*; and*

2. 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.

Section. 4. NAC 639.593 is hereby amended as follows:

NAC 639.593 Licensing requirements; consideration of transaction as wholesale transaction; transferability and renewal of license. (NRS 639.070, 639.100, 639.500)

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:

(1) A complete set of fingerprints from each person *who exercises significant influence over the operation as defined in NAC 639.589X and* required to submit fingerprints pursuant to NRS 639.500; and

(2) 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; 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 name and title of each officer and director of the corporation *from the domicile business registration agency*, the corporate name and the state of incorporation, and 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.

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 subsection 6*~~ 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*** 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.

Section. 5. NAC 639.5931 is hereby amended as follows:

NAC 639.5931 Submission of fingerprints: Required method. (NRS 639.070, 639.500, 639.505) 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*~~ ***may*** submit the fingerprints electronically in a format prescribed by the Board.

Section. 6. NAC 639.5935 is hereby amended as follows:

NAC 639.5935 Representative of wholesaler: General requirements; exceptions; approval; enforcement. (NRS 639.070, 639.100)

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 change in the designated representative:*** ~~***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***~~:

(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 must cease operations in this State*** 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.

Section. 7. NAC 639.5938 is hereby amended as follows:

NAC 639.5938 Filing of single bond for multiple sites. (NRS 639.070, 639.515) Upon application from a wholesaler, the Board may allow a single bond~~:~~

~~1. O~~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.*~~

Section. 8. NAC 639.594 is hereby amended as follows:

NAC 639.594 Establishment of ongoing relationship. (NRS 639.070, 639.100, 639.595)

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.

Section. 9. NAC 639.601 is hereby amended as follows:

NAC 639.601 Prescription drugs: Separation and disposal of certain drugs. (NRS 639.070)

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.***~~

Section. 10. NAC 639.602 is hereby amended as follows:

NAC 639.602 Prescription drugs: Records. (NRS 639.070, 639.595)

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.

Section. 11. NAC 639.603 is hereby amended as follows:

NAC 639.603 Prescription drugs: Requirements regarding statements of prior sales. (NRS 639.070, 639.595)

1. Except as otherwise provided in paragraph (a) of subsection 6 of NAC 639.5975 and NAC 639.6035, each wholesaler shall ~~*provide*~~ ***maintain as a readily retrievable record*** 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 wholesaler shall transmit to 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*~~ ***The wholesaler shall make any records of each statement of prior sales available for inspection by the Board.***

Section. 12. NAC 639.605 is hereby amended as follows:

NAC 639.605 Establishment and maintenance of policies and procedures regarding prescription drugs. (NRS 639.070, 639.595)

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 ***readily retrievable*** records required pursuant to NRS 639.234 and NAC 639.585 to 639.607, inclusive.

(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.

36D

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Workshop - March 19, 2020

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AUTHORITY: NRS 639.070

A REGULATION relating to the licensing and regulation of the practice of pharmacy; and providing other matters properly relating thereto.

Section. 1. NAC Chapter 639 of NAC is hereby amended by adding thereto the following provisions:

NAC 639.XXX Appearance on application for certificate, license or permit. (NRS 639.070; NRS 639.180)

1. The Executive Secretary may require a person submitting an application for any certificate, license or permit required by chapter 453, 454 or 639 of NRS, or an application for renewal of any certificate, license or permit to appear at the next regular meeting of the Board if the application discloses any information that would be grounds for discipline under NRS 453.236 or NRS 639.210 or for action under NRS 639.2895.

2. Any person required to appear at the next regular meeting of the Board pursuant to this section must be given written notice in compliance with NRS 241.033 and NRS 241.034.