STEVE SISOLAK
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

Posted: August 5, 2022

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, September 8, 2022.

Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or in person at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

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:

A. Amendment to Nevada Administrative Code (NAC) 639. The proposed amendments relate to licensing and regulation of Medical Products Wholesalers as Wholesalers in order to conform the requirements of existing law. (LCB File No. R085-22)

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

The proposed amendment removes the separate fees for medical products wholesalers, thereby requiring medical products wholesalers to pay the same fees for the issuance and renewal of a license as other wholesalers and hold the same type of license as other wholesalers; authorizes a representative of a wholesaler to serve as an administrator of a medical products provider; authorizes a medical products provider and a medical products wholesaler operating out of a shared facility to also share a common administrator; provides that the Board may summarily suspend the license of a medical products wholesaler that is operating without a designated representative; allows a health professional who is not licensed, certified or registered as such in this State is eligible for licensure as a medical products provider or medical products wholesaler. The proposed amendments conform with existing statutory definitions of wholesale activity, removes unnecessary barriers, and streamlines the licensing process while still protecting public health, safety and welfare.

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

A copy of the proposed regulation 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 these regulation amendments on the regulated entities or on the public. The regulation amendments will have a beneficial effect on the regulated entities and on the public by streamlining the licensing process to provide expediency while continuing to uphold basic standards to protect public health, safety and welfare.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effects on regulated entities and on the public will be beneficial by removing unnecessary barriers in the licensing process while still protecting public health, safety and welfare.

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.

B. Amendment to Nevada Administrative Code (NAC) 453. The proposed amendments relate to controlled substances, provide for the registration of a law enforcement officer engaged in training a canine in drug detection, and add methoxetamine to the controlled substances listed in Schedule I. (LCB File No. R050-22)

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

The proposed amendment will authorize a law enforcement officer employed by the State or any of its political subdivisions or agencies to obtain a controlled substance registration issued by the Nevada State Board of Pharmacy, to then register for a Drug Enforcement Administration (DEA) license, to order and possess controlled substances in the course of training a canine to detect a controlled substance. This will ensure law enforcement officers are provided with the resources necessary to detect and investigate drug related crimes.

The proposed amendment will also add methoxetamine to the list of controlled substances listed in Schedule I in conformity with federal regulations of the Uniform Controlled Substances Act.

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

A copy of the proposed regulation 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 these regulation amendments on the regulated entities or on the public. The regulation amendments will have a beneficial effect on the regulated entities and on the public to ensure law enforcement officers are provided with the resources necessary to detect and investigate drug related crimes for the protection and safety of the public. The drugs proposed for addition to Schedule I have a high potential for abuse and no accepted medical use and the regulation amendment will benefit public health, safety and welfare.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effects on regulated entities and on the public will be beneficial to ensure law enforcement officers are provided with the resources necessary to detect and investigate drug related crimes for the protection and safety of the public. The regulation amendment will have both an immediate and long-term beneficial effect on the regulated entities and on the public since the drugs proposed for addition to Schedule I have a high potential for abuse and no accepted medical use, and the regulation amendment will benefit public health, safety and welfare.

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.

C. Amendment of Nevada Administrative Code (NAC) 453.540: Schedule IV. The proposed amendment to NAC 453.540 will add daridorexant to the list of controlled substances listed in Schedule IV. (LCB File No. R170-22)

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

The proposed amendment adds daridorexant to the list of controlled substances set forth in schedule IV of the Uniform Controlled Substances Act, consistent with federal regulations (21 C.F.R. § 1308.14). The amendment is needed to add such drug product to the list of controlled substances in schedule IV in conformity with federal regulations of the Uniform Controlled Substances Act.

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. The proposed amendment is needed to add daridorexant to the list of controlled substances in schedule IV in conformity with federal regulations of the Uniform Controlled Substances Act. The estimated economic effect on regulated entities is beneficial in that drugs classified as schedule IV have some potential for abuse and may lead to physical or psycho dependence.

(b) Both immediate and long-term effects.

Immediate or long-term economic effect on regulated entities and public from scheduling daridorexant should be reduced misuse.

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 than federal, state or local standards regulating the same activity.

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 Board at pharmacy@pharmacy.nv.gov or to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521. Written submissions must be received by the Board on or before September 8, 2022. 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.

Members of the public who are disabled and require special accommodations or assistance at the meeting are requested to notify the Nevada State Board of Pharmacy in writing at 985 Damonte Ranch Pkwy., #206, Reno, Nevada 89521, or by calling (775) 850-1440. Please notify us at least one (1) week prior to the scheduled meeting date to allow time to secure any necessary equipment or provisions prior to the meeting.

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.

Pursuant to NRS 233B.064(1), upon adoption of any regulation, the Board, 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

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R085-22

July 19, 2022

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

AUTHORITY: § 1, NRS 639.070 and 639.170; § 2, NRS 639.070 and 639.100; §§ 3-8, NRS 639.070.

A REGULATION relating to pharmacy; revising certain types of licenses and fees; revising various provisions regarding administrators; revising various definitions; revising certain licensing criteria; revising certain conditions for the suspension of certain licenses; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law establishes the maximum fees the State Board of Pharmacy may charge for the issuance and renewal of licenses. (NRS 639.170) Existing regulations prescribe different fees for the issuance and renewal of a license as a medical products wholesaler and a wholesaler. (NAC 639.220) **Section 1** of this regulation removes the separate fees for medical products wholesalers, thereby requiring medical products wholesalers to pay the same fees for the issuance and renewal of a license as other wholesalers. **Section 3** of this regulation provides that medical products wholesalers hold the same type of license as other wholesalers.

Existing regulations require an applicant for a license to operate as a wholesaler to designate at least one natural person to serve as the representative of the wholesaler. (NAC 639.5935) Existing regulations also require each medical products provider or medical products wholesaler to employ an administrator at all times. (NAC 639.694). **Section 2** of this regulation authorizes a representative of a wholesaler to serve as an administrator of a medical products provider. **Section 4** of this regulation authorizes a medical products provider and a medical products wholesaler operating out of a shared facility to also share a common administrator. **Section 8** of this regulation provides that the Board may summarily suspend the license of a medical products wholesaler that is operating without a designated representative.

Existing regulations provide that the Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to a practicing health professional. (NAC 639.6943) **Section 5** of this regulation limits the applicability of this provision to health professionals who are licensed, certified or registered in this State, thereby clarifying that a health professional who is not licensed, certified or registered as such in this State is eligible for licensure as a medical products provider or medical products wholesaler.

Existing regulations establish requirements concerning the premises of a medical products provider and the maintenance of records by a medical products provider. (NAC

639.6946, 639.6949, 639.695) **Section 6** of this regulation prohibits a medical products provider from operating out of the same location as another medical products provider. **Section 7** of this regulation requires a medical products provider to maintain certain records relating to its inventory of medical products separate from the records of any medical products wholesaler.

Section 1. NAC 639.220 is hereby amended to read as follows:

639.220 1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist ..... Actual cost of the examination

For the investigation or registration of an applicant as a registered pharmacist.....$200

For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....200

For the investigation or issuance of an original license to conduct a retail pharmacy 500

For the biennial renewal of a license to conduct a retail pharmacy 500

For the investigation or issuance of an original license to conduct an institutional pharmacy 500

For the biennial renewal of a license to conduct an institutional pharmacy 500

For the investigation or issuance of an original license to conduct a pharmacy in a correctional institution 500

For the biennial renewal of a license to conduct a pharmacy in a correctional institution.....500

For the investigation or issuance of an original license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed pursuant to chapter 449 of NRS 500

For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed pursuant to chapter 449 of NRS 500

For the issuance of an original or duplicate certificate of registration as a registered pharmacist 50

For the biennial renewal of registration as a registered pharmacist 200

For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of lapse) 100

For the initial registration of a pharmaceutical technician or pharmaceutical technician in training 50

For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in training 50

For the investigation or registration of an intern pharmacist 40

For the biennial renewal of registration as an intern pharmacist 40

For the investigation or registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances 80

For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances 80

For authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, facility for treatment with narcotics, researcher, instructional user or any other authorized person, except a practitioner who is a medical intern or resident physician, to prescribe or possess controlled substances 200

For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, facility for treatment with narcotics, researcher, instructional user or any other authorized person, except a practitioner who is a medical intern or resident physician, to prescribe or possess controlled substances 200

For authorization of a practitioner who is a medical intern or resident physician to prescribe or possess controlled substances 80

For the biennial renewal of authorization of a practitioner who is a medical intern or resident physician to prescribe or possess controlled substances 80

For the investigation or issuance of an original license to engage in business as an authorized warehouse ~~[,]~~ *or* medical products provider ~~[or medical products wholesaler]~~ 500

For the biennial renewal of a license to engage in business as an authorized warehouse ~~[,]~~ *or* medical products provider ~~[or medical products wholesaler]~~ 500

For the investigation or issuance of an original license to a manufacturer or wholesaler.....1,000

For the biennial renewal of a license for a manufacturer or wholesaler 1,000

For the reissuance of a license issued to a pharmacy, when no change of ownership is involved, but the license must be reissued because of a change in the information required thereon.....50

For authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption.....300

For the biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption.....300

For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....150

For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....150

For the investigation or issuance of an original license for an automated drug dispensing system.....500

For the biennial renewal of a license for an automated drug dispensing system 500

For the investigation or issuance of an original license to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy 250

For the biennial renewal of a license to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy 250

2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection 6 of NRS 639.170, is 50 percent of the renewal fee for each period of delinquency in addition to the renewal fee for each period of delinquency.

3. Any person who has been registered as a pharmacist in this State for at least 50 years is not required to pay the fee for the biennial renewal of a certificate of registration as a registered pharmacist.

4. The provisions of this section concerning the fee for the biennial renewal of the authorization to dispense controlled substances or dangerous drugs do not apply to an advanced practice registered nurse who is required to pay a fee pursuant to NAC 639.870.

5. A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally-qualified health center that provides health care primarily to medically underserved persons in a community; and

(b) Which is not a medical facility as defined in NRS 449.0151,

➥ is not required to pay a fee to the Board for a change of address or for an additional address at which the practitioner dispenses drugs.

6. A practitioner who is exempt from the payment of a fee pursuant to subsection 5 shall notify the Board in writing of each change of address or additional address, or both.

7. In addition to any other fees paid by an applicant for a certificate, license or permit issued pursuant to chapter 639 of NRS, the Board may require that the applicant pay any costs of inspection incurred by the Board.

Sec. 2. 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) 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 ~~[.]~~ ***; and***

(e) May serve as an administrator of a medical products provider pursuant to NAC 639.694.

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.

6. 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 in Nevada 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. 3. NAC 639.6937 is hereby amended to read as follows:

639.6937 1. "Medical products wholesaler" means a person licensed *as a wholesaler* pursuant to ~~[NAC 639.693 to 639.6958, inclusive, to sell, lease]~~ *chapter 639 of NRS who sells, leases* or otherwise ~~[provide]~~ *provides* medical products to a health care facility, agency, practitioner or provider in this State.

2. The term does not include:

(a) A person who sells, leases or otherwise provides medical products to a consumer; or

(b) An installer of medical gas systems, as that term is defined in NAC 477.137, who is registered pursuant to chapter 477 of NAC.

Sec. 4. NAC 639.694 is hereby amended to read as follows:

639.694 1. Except as otherwise provided in subsection 4, each medical products provider or medical products wholesaler shall employ an administrator at all times. The administrator must:

(a) Be a natural person;

(b) Have a high school diploma or its equivalent;

(c) Have:

(1) At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or

(2) An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;

(d) Be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and

(e) Be approved by the Board.

2. The administrator shall ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

3. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after the beginning of the employment.

4. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

5. A medical products provider and medical products wholesaler operating out of a shared facility may share a common administrator.

Sec. 5. NAC 639.6943 is hereby amended to read as follows:

639.6943 1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

(a) A practicing health professional; or

(b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who ~~[performs]~~ ***:***

(a) Is licensed, certified or registered to practice his or her profession in this State; and

(b) Performs services within the scope of his or her licensure, ***certification*** or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Sec. 6. NAC 639.6946 is hereby amended to read as follows:

639.6946 1. Except as otherwise provided in NAC 639.6945, a medical products provider shall:

(a) Provide services for all medical products sold, leased or otherwise provided by the medical products provider, including, without limitation, set up, repair and maintenance.

(b) Employ an administrator and other employees sufficient to provide the services described in paragraph (a).

(c) Ensure that each employee is trained to:

(1) Use, set up, repair and maintain the medical products sold, leased or otherwise provided by the medical products provider that an employee is authorized to sell, lease or otherwise provide to a consumer; and

(2) Instruct consumers concerning the use, set up and maintenance of the medical products sold, leased or otherwise provided by the medical products provider that an employee is authorized to sell, lease or provide to a consumer.

(d) Maintain an inventory of medical products that is adequate to serve the needs of the consumers served by the medical products provider.

(e) Maintain a suitable physical location, other than a residence, at which the medical products provider can:

(1) Store inventory;

(2) Repair or service any equipment which the medical products provider sells, leases or otherwise provides; and

(3) Keep all current records related to the business of the medical products provider.

(f) Have a functioning restroom containing a toilet and a sink with hot and cold water at the place of business of the medical products provider.

(g) Maintain the place of business of the medical products provider in a clean, orderly and sanitary condition.

(h) Ensure that the place of business complies at all times with applicable federal, state and local laws, regulations and rules, including, without limitation, applicable occupational safety rules, fire codes, building codes and health codes.

(i) Maintain liability insurance of at least $1,000,000, which must include product liability insurance if the medical products provider:

(1) Designs, fabricates or manufactures medical products; or

(2) Substantially modifies commercially available medical products.

(j) Maintain a log or other record regarding all repairs made to a medical product provided by the medical products provider. For a medical product repaired by the medical products provider, the log or record must identify:

(1) The type of medical product;

(2) The manufacturer;

(3) The model or model number;

(4) The serial number;

(5) The date of the repair;

(6) The specific repair made;

(7) The name of the person or company who performed the repair; and

(8) A certification that the medical product has been returned to the specifications of the manufacturer as a result of the repair.

2. If the medical products provider cannot certify that the repaired medical product has been returned to the specifications of the manufacturer as a result of the repair, the medical products provider must:

(a) Determine whether the medical product can be safely and effectively used for a limited purpose, in which case the medical products provider must note that the medical product must only be used for a limited purpose and must ensure that the medical product is only used for such a limited purpose; or

(b) Ensure that the medical product is removed from service and is not sold, leased or otherwise provided to any person without a written statement acknowledging that the medical product:

(1) Was repaired;

(2) Could not be repaired to the specifications of the manufacturer; and

(3) Cannot be used by the consumer for the purposes for which the medical product was intended.

3. Any device used by a medical products provider to calibrate or test equipment must be accurate and must be maintained according to the directions and specifications of the manufacturer. The scales used to weigh reservoirs of liquid oxygen must be accurate and must be certified annually by the State Sealer of Consumer Equitability.

4. The business premises of any medical products provider must be open and accessible to the public and the Board at all times during regular hours of operation.

5. ***A medical products provider shall not operate at the same location as another medical products provider.***

6. A medical products provider shall develop and use a written procedure for addressing consumer complaints, including, without limitation, procedures for maintaining a complaint file that documents all complaints from consumers and the resolution of each complaint.

Sec. 7. NAC 639.695 is hereby amended to read as follows:

639.695 The records made or kept pursuant to NAC 639.6949 must be:

1. Kept in a file, chart or other storage system allowing the record to be retrieved by reference to the name of the consumer, the name of the practitioner, the date the product was provided or the type of medical product;

2. Retained for at least 5 years from the date the records are made or received;

3. Kept at the physical location of the business; ~~[and]~~

4. ***Maintained separately from the records of any medical products wholesaler; and***

5. Readily retrievable upon request by a member of the Board, or a person conducting an inspection or investigation on behalf of the Board.

Sec. 8. NAC 639.6958 is hereby amended to read as follows:

639.6958 1. The Executive Secretary may summarily suspend the license of a medical products provider or medical products wholesaler upon receiving evidence sufficient to cause the Executive Secretary to reasonably believe that a medical products provider or medical products wholesaler is:

(a) Operating without liability insurance;

(b) Operating without a license;

(c) Operating without a business administrator or a facility administrator; ~~[or]~~

(d) ***Operating without a designated representative in the case of a medical products wholesaler; or***

(e) Engaging in practices that are fraudulent or deceitful.

2. The Executive Secretary shall immediately provide written notice to the medical products provider or medical products wholesaler that informs the medical products provider or medical products wholesaler of:

(a) The factual and legal reasons for the summary suspension; and

(b) The right of the medical products provider or medical products wholesaler to provide the Board with any evidence or information that would show that either the factual or legal reasons for the summary suspension are incorrect.

3. The Executive Secretary may take whatever action he or she deems reasonably necessary to secure the medical products and premises, and to ensure that the medical products provider or medical products wholesaler does not conduct business during the summary suspension.

4. The Executive Secretary shall release the medical products provider or medical products wholesaler from the summary suspension upon receiving evidence satisfactory to the Executive Secretary from the medical products provider or medical products wholesaler that the deficiency noted in the written notice has been remedied.

5. Within 10 days after summarily suspending the license of a medical products provider or medical products wholesaler, the Executive Secretary shall serve upon the medical products provider or medical products wholesaler an accusation pursuant to NRS 639.241. A hearing on the accusation must be set for the next regularly scheduled meeting of the Board.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R050-22

May 20, 2022

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

AUTHORITY: §§ 1 and 2, NRS 453.221, 453.226 and 639.070; § 3, NRS 453.146 and 639.070.

A REGULATION relating to controlled substances; authorizing certain law enforcement officers to register with the State Board of Pharmacy to possess controlled substances; adding methoxetamine to the controlled substances listed in schedule I; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

The federal Controlled Substances Act requires every person who manufactures or distributes any controlled substance to obtain an annual registration issued by the Attorney General of the United States. (21 U.S.C. § 822) However, the requirement for such registration is waived for any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and who is duly authorized to possess controlled substances in the course of his or her official duties. (21 C.F.R § 1301.24) Similarly, existing state law requires certain persons to obtain a registration from the State Board of Pharmacy in order to possess, dispense or conduct research with any controlled substance in this State. (NRS 453.226) Existing regulations: (1) exempt from the requirements of registration any person who is exempted from federal registration by federal laws or regulations; and (2) waive the requirement of registration for an officer or employee of this State or any of its political subdivisions or agencies who is engaged in the enforcement of any state or local law relating to controlled substances and is authorized to possess controlled substances in the course of his or her official duties. (NAC 453.100, 453.150)

Section 1 of this regulation authorizes a law enforcement officer who is employed by the State or any of its political subdivisions or agencies to register with the Board for the purpose of possessing controlled substances in the course of training canines to detect a controlled substance. **Section 1** further provides that a law enforcement officer is not required to register before possessing such controlled substances or engaging in certain other conduct which the law enforcement officer is otherwise authorized to perform without a registration.

Existing regulations: (1) provide that certain groups of activities related to controlled substances are deemed to be independent of each other; and (2) require, with certain exceptions, a person who engages in more than one group of independent activities to obtain a separate registration for each group of activities. (NAC 453.110) **Section 2** of this regulation provides that if a law enforcement officer is registered pursuant to **section 1**, possessing a controlled substance

in the course of training a canine to detect a controlled substance is also an activity that is deemed to be independent. Thus, such a law enforcement officer who is registered to possess controlled substances in the course of training a canine is not authorized to engage in certain other activities involving controlled substances.

Existing law authorizes the Board to add, delete or reschedule substances listed as controlled substances in schedules I, II, III, IV and V of the Uniform Controlled Substances Act by regulation. (NRS 453.146) Existing regulations set forth the drugs and substances that are enumerated in schedule I. (NAC 453.510) **Section 3** of this regulation adds methoxetamine to the list of controlled substances set forth in schedule I.

Section 1. Chapter 453 of NAC is hereby amended by adding thereto a new section to read as follows:

1. Notwithstanding the exemption from registration set forth in NAC 453.100 and the waiver of the requirement of registration set forth in NAC 453.150, a law enforcement officer who is employed by the State or any of its political subdivisions or agencies may register pursuant to this chapter for the purpose of possessing controlled substances in the course of training a canine to detect a controlled substance.

2. Nothing in this section shall be construed to require a law enforcement officer to register before:

(a) Possessing a controlled substance in order to train a canine to detect the controlled substance; or

(b) Engaging in any other conduct for which the law enforcement officer is otherwise authorized to perform without a registration.

Sec. 2. NAC 453.110 is hereby amended to read as follows:

453.110 1. For the purpose of registration under this chapter, the following groups of activities are deemed to be independent of each other:

(a) Manufacturing any controlled substance;

(b) Distributing any controlled substance;

(c) Dispensing, prescribing, conducting research, except for the research described in paragraph (d), and conducting instructional activities with any controlled substance listed in schedules II through V, inclusive;

(d) Conducting research with any narcotic drug listed in schedules II to V, inclusive, for the purpose of continuing the dependence of a person on the drug in the course of conducting an authorized clinical investigation in the development of a program for rehabilitation of narcotic addicts pursuant to a Notice of Claimed Investigational Exemption for a New Drug approved by the Food and Drug Administration;

(e) Conducting research and instructional activities with any controlled substances listed in schedule I; ~~[and]~~

(f) Conducting chemical analysis with a controlled substance listed in any schedule ~~[.]~~ ***; and***

(g) Possessing a controlled substance in the course of training canines to detect a controlled substance, if a law enforcement officer is registered pursuant to section 1 of this regulation.

2. A person who engages in more than one group of independent activities must obtain a separate registration for each group of activities except as provided in NAC 453.120.

3. Except as provided in subsection 4, a single registration to engage in any group of independent activities may include one or more of the controlled substances listed in the schedules which are authorized for that group.

4. A person registered to conduct research with the controlled substances listed in schedule I may conduct research with any substance listed in schedule I for which he or she has filed and had approved a research protocol.

Sec. 3. NAC 453.510 is hereby amended to read as follows:

453.510 1. Schedule I consists of the drugs and other substances 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 opiates, including, without limitation, 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:

Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Acetylmethadol;

Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other names: acryloylfentanyl);

Allylprodine;

Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-acetylmethadol, levomethadyl acetate or "LAAM");

Alphameprodine;

Alphamethadol;

Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Benzethidine;

Betacetylmethadol;

Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxythiofentanyl (trade or other names: N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

Betameprodine;

Betamethadol;

Betaprodine;

Butyryl fentanyl (trade or other names: N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Clonitazene;

Cyclopentyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

Cyclopropyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambutene;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine);

Fentanyl carbamate (Ethyl-(1-phenethylpiperidin-4-yl)(phenyl)carbamate);

Fluoro furanyl fentanyl;

Fluoroacryl fentanyl;

Fluorobutyryl fentanyl;

Fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);

Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

Furethidine;

Hydroxypethidine;

Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Methoxyacetyl fentanyl;

Methyl acetyl fentanyl;

Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl));

Methylfentanyl;

Methylthiofentanyl;

Morpheridine;

MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

Noracymethadol;

Norlevorphanol;

Normethadone;

N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluro 2'-fluorofentanyl);

Norpipanone;

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;

Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Phenyl fentanyl (some trade or other names: benzoyl fentanyl);

Phenylpropanoyl fentanyl;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl);

Tilidine; or

Trimeperidine; or

Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide).

3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, 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:

Acetorphine;

Acetyl fentanyl;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except hydrochloride salt);

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine; or

Thebacon.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, including, without limitation, 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:

Adinazolam (some trade or other names: 8-chloro-1-((dimethylamino)methyl)-6-phenyl - 4H-s-triazolo(4,3-a)(1,4)benzodiazepine; adinazolamum; Deracyn);

Alpha-ethyltryptamine (some trade or other names: ET, Trip);

Alpha-methyltryptamine (some trade or other names: AMT);

Bromazolam (some trade or other names: 8-bromo-1-methyl-6-phenyl-4H[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; XLI-268);

1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);

4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);

1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);

4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine (some trade or other names: Etizolam);

Clonazolam (some trade or other names: 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; clonitrazolam);

1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18; BTM-8; RCS-8);

Diclazepam (some trade or other names: 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepin-2-one; 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one; 2'-chlorodiazepam; Chlorodiazepam; Ro 5-3448);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA);

2,5-dimethoxy-4-ethylamphet-amine (some trade or other names: DOET);

2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);

2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivative thereof (some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N-o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-NBOMe; 25D-NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);

2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);

3-[(2-Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy-N, N-dimethyltryptamine;4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT);

5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or other names: CP-47,497);

5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other names: cannabicyclohexanol; CP-47,497 C8 homologue);

Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4-ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);

Flualprazolam (some trade or other names: 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4h-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; 2'-fluoro alprazolam; ortho-fluoro alprazolam);

Flubromazepam (some trade or other names: 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-Bromo-5-(2-fluorophenyl)-1H-benzo[e][1,4]diazepin-2(3H)-one; 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one);

Flubromazolam (some trade or other names: 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine);

Flunitrazolam (some trade or other names: 6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

(1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);

[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluorpentyl JWH-018 indazole);

[1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);

[1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophyenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);

(1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);

1-(5-fluoropentyl)-N-(tricyclo[3.3.1.13,7]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA;

1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22);

Flutoprazepam (some trade or other names: 7-chloro-1-(cyclopropylmethyl)-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

Meclonazepam (some trade or other names: (3S)-5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one; Ro 11-3128);

Methoxetamine (some trade or other names: MXE; 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone)

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-methylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine (some trade or other names: MMDA);

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; "STP");

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-122);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-ADB; 5F-MDMB-PINACA);

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine(MDMA);

Methylenedioxy-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-200);

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other names: ADB-CHMINACA; MAB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (trade or other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trade or other name: AB-FUBINACA);

N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other name: AB-CHMINACA);

N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);

Nifoxipam (some trade or other names: 5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7-nitro-2H-1,4-benzodiazepin-2-one; 1,3-Dihydro-5-(2-fluorophenyl)-3-hydroxy-7-nitro-2H-1,4-benzodiazepin-2-one; 3-hydroxydesmethylflunitrazepam; DP 370);

Nitrazolam (some trade or other names: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Norflurazepam (some trade or other names: 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; nor-Flurazepam; N-Desalkylflurazepam; Desalkylflurazepam; Ro 5-3367);

1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);

1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);

1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);

1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);

(1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: UR-144);

1-pentyl-N-(tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);

1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC);

Phenazepam (some trade or other names: 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-bromo-5-(2-chlorophenyl)-1,2-dihydro-3H-1,4-benzodiazepin-2-one; BD 98; Fenazepam; Elzepam; Phezipam; Phenorelaxan; Phenzitat);

Pyrazolam (some trade or other names: 8-bromo-1-methyl-6-(2-pyridinyl)-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine; 8-bromo-1-methyl-6-(pyridin-2-yl)-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; Pirazolam);

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);

Gamma hydroxy butyric acid (some trade or other names: GHB);

Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; *Tabernanthe iboga*);

Lysergic acid diethylamide;

Marijuana;

Mescaline;

Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP, 3-MeOPP, 4-MeOPP);

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as *Lophophora williamsii Lemaire*, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzo[f]isochromene-7-carboxylate);

Ethylamine analog of phencyclidine (some trade or other names: N-ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidine (some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine; TFMPP).

For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

5. All parts of the plant presently classified botanically as *Datura*, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound, manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone or methaqualone having a depressant effect on the central nervous system, including, without limitation, 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.

7. 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, including, without limitation, their salts, isomers and salts of isomers:

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one, alpha-pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha-pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: alpha-PHP);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one, β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alpha-aminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,Ndimethylcathinone; N,N-dimethyl MDCATH; N,N-dimethyl-3,4- methylenedioxycathinone; N,N-dimethyl-β-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one; bk-MDDMA);

N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA);

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade or other names: ephylone);

Fenethylline;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4-FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-2(methylamino)propan-1-one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-methylcathinone, 1-(2-fluorophenyl)-2-(methylamino)propan-1-one, 2-FMC);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone, 4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N-Methylcathinone, cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

4'-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);

4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-Methylenedioxypyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2(pyrrolidin-1-yl)pentan-1-one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482);

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one, α-methylaminovalerophenone); or

Pentylone (trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolylpentanamine; bk-MBDP; bk-methyl-K).

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or

identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule, Tetrahydrocannabinols (natural or synthetic equivalents of substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances, derivatives and their isomers with a similar chemical structure; and

Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

10. Unless specifically listed in another schedule and except as otherwise provided in subsection 11, any material, compound, mixture or preparation which contains any quantity of

CBD (natural or synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity).

11. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight,

↳ is not a controlled substance.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R170-22

August 2, 2022

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

AUTHORITY: § 1, NRS 453.146, 453.2182 and 639.070.

A REGULATION relating to controlled substances; adding daridorexant to the controlled substances listed in schedule IV of the Uniform Controlled Substances Act; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to add, delete or reschedule substances listed as controlled substances in schedules I, II, III, IV and V of the Uniform Controlled Substances Act by regulation. (NRS 453.146) Existing law also provides that if a substance is designated, rescheduled or deleted as a controlled substance pursuant to federal law, the Board is required, with certain exceptions, to similarly treat the substance under the Uniform Controlled Substances Act. (NRS 453.2182) This regulation adds daridorexant to the list of controlled substances set forth in schedule IV of the Uniform Controlled Substances Act, consistent with federal regulations. (21 C.F.R. § 1308.14)

Section 1. NAC 453.540 is hereby amended to read as follows:

453.540 1. Schedule IV consists of the drugs and other substances 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 material, compound, mixture or preparation containing any of the following narcotic drugs, including, without limitation, their salts, calculated as the free anhydrous base of alkaloid, is hereby enumerated on schedule IV, in quantities:

(a) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit; or

(b) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxy-butane).

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including, without limitation, their salts, isomers and salts of isomers, is hereby enumerated on schedule IV, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Alprazolam;

Barbital;

Bromazepam;

Butorphanol;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

Clotiazepam;

Cloxazolam;

Daridorexant;

Delorazepam;

Diazepam;

Dichloralphenazone;

Eluxadoline;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Halazepam;

Haloxazolam;

Ketazolam;

Lemborexant;

Loprazolam;

Lorazepam;

Lorcaserin;

Lormetazepam;

Mebutamate;

Medazepam;

Meprobamate;

Methohexital;

Methylphenobarbital (mephobarbital);

Midazolam;

Nimetazepam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Remimazolam;

Suvorexant;

Temazepam;

Tetrazepam;

Tramadol (2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol);

Triazolam;

Zaleplon;

Zolpidem; or

Zopiclone.

4. Any material, compound, mixture or preparation which contains any quantity of fenfluramine, including, without limitation, its salts, isomers and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible, is hereby enumerated on schedule IV. For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

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 stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, is hereby enumerated on schedule IV:

Cathine ((+)-norpseudoephedrine);

Diethylpropion;

Fencamfamin;

Fenproporex;

Mazindol;

Mefenorex;

Modafinil;

Pemoline (including organometallic complexes and chelates thereof);

Phentermine;

Pipradrol;

Sibutramine; or

SPA ((-)-dimethylamino-1,2,diphenylethane).

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of pentazocine, including, without limitation, its salts, is hereby enumerated on schedule IV.