JOE LOMBARDO
Governor

HELEN PARK
President

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Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

Posted: August 8, 2023

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 conduct a Public Hearing on Thursday, September 7, 2023, at 9:00 a.m. at the following location:

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 the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto. (LCB File No. R196-22)

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

The purpose of the proposed amendment provides for the licensing and regulation for a facility for treatment with narcotics to dispense controlled substances or dangerous drugs and prescribes fees for the licensing of such

facility. The regulation also requires dispensing practitioners at a facility for treatment with narcotics to obtain informed consent for reporting information to the Prescription Monitoring Program (PMP) to track controlled substance prescriptions. The regulation is necessary to expand patient access to treatment and ensure the delivery of safe and reliable pharmaceutical care which will benefit public health, safety, and welfare.

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 Either the terms or the substance of the regulations to be adopted, amended or repealed.

A copy of the proposed regulation is attached to this notice; however, please note that the proposed regulation posted at www.bop.nv.gov 3 working days before the hearing will be the regulation considered.

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 on the public. The beneficial effects will be expanded patient access to treatment to improve the delivery of safe and reliable pharmaceutical care which will benefit public health, safety, and welfare.

Facilities for treatment with narcotics centers that wish to dispense controlled substances or dangerous drugs must first apply to the Board of Pharmacy for a certificate of registration. The regulation will have an economic impact on those facilities for treatment with narcotics that pay the $80.00 registration fee and $80.00 biennial license renewal fee.

(b) Both immediate and long-term effects.

Immediate and long-term economic effects on regulated entities will be negligible. The immediate and long-term economic effects will be improved pharmaceutical care for the public.

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

The revenue generated from the registration fee will partially offset the costs of enforcement of this new regulation incurred by the Board of Pharmacy.

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 overlaps or duplicates.

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

The proposed 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 of the same activity in which the proposed state regulation is more stringent.

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

This proposed 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 teambc@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 7, 2023. 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. R196-22

June 30, 2023

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

AUTHORITY: §§ 1, 2 and 4, NRS 453.221, 639.070 and 639.2177; § 3, NRS 639.070 and 639.170.

A REGULATION relating to pharmacy; requiring a facility for treatment with narcotics to obtain a license to administer opioid agonist treatment medication; requiring a dispensing practitioner at such a facility to obtain informed consent before reporting certain information; prescribing certain fees; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations relating to the registration and control of the dispensing of controlled substances in Nevada. (NRS 453.221) Existing law further authorizes the Board to adopt regulations that: (1) are necessary for the protection of the public relating to the practice of pharmacy; (2) authorize the Executive Secretary of the Board to issue certificates, licenses and permits required for the practice of pharmacy or for the dispensing of controlled substances; and (3) govern the dispensing of poisons, drugs, chemicals and medicines. (NRS 639.070) Existing regulations require a facility for treatment with narcotics, which is a facility certified by the federal government to treat addiction to narcotics using other narcotics, to be licensed by the Division of Public and Behavioral Health of the Department of Health and Human Services. (NAC 449.15445) **Section 1** of this regulation additionally requires a facility for treatment with narcotics to obtain a license from the Board to administer opioid agonist treatment medication and sets forth the requirements to obtain such a license. **Section 1** also requires dispensing practitioners at a facility for treatment with narcotics to obtain informed consent for the reporting of information to a program that tracks prescriptions of certain controlled substances. **Section 2** of this regulation defines certain terms.

Existing regulations prescribe fees for the issuance and biennial renewal of authorization of a facility for treatment with narcotics to prescribe or possess controlled substances. (NAC 639.220) **Section 3** of this regulation clarifies that such fees apply to the investigation or issuance and biennial renewal of a license to administer opioid agonist treatment medication. **Section 4** of this regulation authorizes a facility for treatment with narcotics that is operating on the effective date of this regulation to continue to do so without obtaining such a license until 6 months after that date.

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

1. A person or public or private facility shall not operate or provide the services of a facility for treatment with narcotics unless the person or facility holds a license to administer opioid agonist treatment medication issued by the Board pursuant to this section.

2. A person or public or private facility may apply to the Board for a license to administer opioid agonist treatment medication by submitting an application to the Board on a form prescribed by the Board. The Board shall issue such a license if the applicant meets the requirements sets forth in subsection 3 and pays the fee required by NAC 639.220.

3. An applicant for a license pursuant to subsection 2 must:

(a) Be certified by the Substance Abuse and Mental Health Services Administration of the United States Department of Health and Human Services pursuant to 42 C.F.R. § 8.11;

(b) Hold a license issued by the Division of Public and Behavioral Health of the Department of Health and Human Services pursuant to NAC 449.154 to 449.15485, inclusive, to operate a facility for treatment with narcotics;

(c) Be certified by the Division of Public and Behavioral Health of the Department of Health and Human Services pursuant to NRS 458.025; and

(d) Ensure that each practitioner who dispenses opioid agonist treatment medication at the facility is registered with the Board pursuant to NRS 453.231 and the Drug Enforcement Administration of the United States Department of Justice to dispense controlled substances.

4. Any license issued pursuant to this section is a revocable privilege and a holder of such a license does not acquire any vested right in such a license.

5. Each dispensing practitioner practicing at a facility for treatment with narcotics shall, to the extent required by 42 C.F.R. § 2.36, obtain informed consent for the reporting of information to the computerized program to track prescriptions for controlled substances established pursuant to NRS 453.162.

Sec. 2. NAC 639.010 is hereby amended to read as follows:

639.010 As used in this chapter, unless the context otherwise requires:

1. "Automated drug dispensing system" means a system that performs operations, other than compounding or administration, related to the storage and dispensing of drugs.

2. "Board" means the State Board of Pharmacy.

3. "Controlled substances" has the meaning ascribed to it in NRS 0.031.

4. "Dangerous drug" has the meaning ascribed to it in NRS 454.201.

5. "Direct supervision" means the direction given by a supervising pharmacist or dispensing practitioner who is:

(a) On the premises of the pharmacy or telepharmacy at all times when the person he or she is supervising is working at the pharmacy or telepharmacy or at a remote site or satellite consultation site; and

(b) Aware of the activities of that person related to the preparation and dispensing of medications, including the maintenance of appropriate records.

6. "Dispensing practitioner" means:

(a) A practitioner to whom the Board has issued a certificate of registration pursuant to NAC 639.742 to dispense controlled substances or dangerous drugs, or both, for human consumption; or

(b) A licensed veterinarian to whom the Board has issued a certificate of registration pursuant to NAC 639.7423 to dispense controlled substances or dangerous drugs, or both, not for human consumption.

7. "Dispensing technician" means a person who performs technical services in a pharmacy under the direct supervision of a dispensing practitioner and is registered with the Board pursuant to NAC 639.7425.

8. "Dispensing technician in training" means a person who is registered with the Board pursuant to section 1 of LCB File No. R178-22 in order to obtain the training and experience required to be a dispensing technician pursuant to subparagraph (1) of paragraph (c) of subsection 2 of NAC 639.7425.

9. "Executive Secretary" means the Executive Secretary employed by the Board pursuant to NRS 639.040.

10. ***"Facility for treatment with narcotics" has the meaning ascribed to it in NAC 449.1542.***

11. "Federally-qualified health center" has the meaning ascribed to it in 42 U.S.C. § 1396d(l)(2)(B).

~~[11.]~~ ***12.*** "Federally-qualified health center vehicle" means a vehicle that meets the requirements of paragraph (c) of subsection 1 of section 3 of LCB File No. R004-19.

~~[12.]~~ ***13.*** "Licensed veterinarian" has the meaning ascribed to it in NRS 638.007.

~~[13.]~~ ***14.*** "Oncology group practice" means two or more dispensing practitioners who practice oncology in a group practice.

~~[14.]~~ ***15. "Opioid agonist treatment medication" has the meaning ascribed to it in 42 C.F.R. § 8.2.***

16. "Pharmaceutical technician" means a person who performs technical services in a pharmacy under the direct supervision of a pharmacist and is registered with the Board pursuant to NAC 639.240.

~~[15.]~~ ***17.*** "Pharmaceutical technician in training" means a person who is registered with the Board pursuant to NAC 639.242 in order to obtain the training and experience required to be a pharmaceutical technician pursuant to subparagraph (3) of paragraph (d) of subsection 2 of NAC 639.240, or who is enrolled in a program of training for pharmaceutical technicians that is approved by the Board.

~~[16.]~~ ***18.*** "Practitioner" has the meaning ascribed to it in NRS 639.0125.

~~[17.]~~ ***19.*** "Prescription drug" means a drug or medicine as defined in NRS 639.007 which:

(a) May be dispensed only upon a prescription order that is issued by a practitioner; and

(b) Is labeled with the symbol "Rx only" pursuant to federal law or regulation.

~~[18.]~~ ***20.*** "Public or nonprofit agency" means a health center as defined in 42 U.S.C. § 254b(a) which:

(a) Provides health care primarily to medically underserved persons in a community;

(b) Is receiving a grant issued pursuant to 42 U.S.C. § 254b or, although qualified to receive such a grant directly from the Federal Government, is receiving money from such a grant under a contract with the recipient of that grant; and

(c) Is not a medical facility as defined in NRS 449.0151.

~~[19.]~~ ***21.*** "Reproductive healthcare center" means a health facility owned and operated by a nonprofit corporation or a public health center, as defined in subsection 8 of NRS 449.260, principally engaged in providing family planning services and reproductive healthcare,

including, without limitation, the testing, diagnosis and treatment of, or providing of medication to prevent, a sexually transmitted infection or other infection of the urogenital system.

~~[20.]~~ ***22.*** "Surgical center for ambulatory patients" has the meaning ascribed to it in NRS 449.019.

~~[21.]~~ ***23.*** "User-based access technology" means software or hardware that restricts access to an automated drug dispensing system to authorized users by requiring two-factor authentication. Authentication factors may include, without limitation, knowledge, hardware tokens or biometric information.

Sec. 3. 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 by the State Board of Health pursuant to NRS 449.0303 500

For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303 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, pharmaceutical technician in training, dispensing technician or dispensing technician in training 50

For the biennial renewal of registration of a pharmaceutical technician, pharmaceutical technician in training, dispensing technician or dispensing 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 500

For the biennial renewal of a license to engage in business as an authorized warehouse or medical products provider 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 to furnish drugs and medications for administration to patients at a medical facility.....250

For the biennial renewal of a license to a pharmacy authorizing the use of a mechanical device to furnish drugs and medications for administration to patients at a medical facility.....250

For the investigation or issuance of an original license for a facility for treatment with narcotics to administer opioid agonist treatment medication.....80

For the biennial renewal of a license for a facility for treatment with narcotics to administer opioid agonist treatment medication.....80

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 actual costs of inspection incurred by the Board.

Sec. 4. 1. Notwithstanding the provisions of section 1 of this regulation, a person or public or private facility who is operating or providing the services of a facility for treatment with narcotics on the effective date of this regulation may continue to operate or provide the services of such a facility without obtaining a license to administer opioid agonist treatment medication pursuant to section 1 of this regulation until 6 months after the effective date of this regulation.

2. As used in this section:

(a) "Facility for treatment with narcotics" has the meaning ascribed to it in NAC 449.1542.

(b) "Opioid agonist treatment medication" has the meaning ascribed to it in 42 C.F.R. § 8.2.