Nevada State Board of Pharmacy

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Date Posted: January 19, 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 conduct a Public Hearing on Thursday, March 3, 2022, at 9:00 a.m. at the following location:

Pursuant to Governor Steve Sisolak's Emergency Directive 044 and AB 253, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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 of Nevada Administrative Code (NAC) 639.208. The proposed amendment to NAC 639.208 will amend the requirements necessary for an applicant to obtain a registration as a pharmacist by reciprocity. (LCB File R040-21)

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

NAC 639.208 was amended in 2014 when all states were considering increasing the required pharmacist intern hours from 1,500 to 1,740 as the national standard. Most states did not adopt the 1,740-hour requirement. The current 1,740-hour requirement poses a problem for pharmacists applying for a Nevada pharmacist registration by reciprocation. Most pharmacists have 1,500 hours of practical experience as required by their original state of licensure, which is 240 hours short of what is required by NAC 639.208. The proposed amendment removes the requirement that an applicant complete 1,740 hours of practical pharmaceutical experience, thereby requiring an applicant to complete not less than 1,500 hours of practical pharmaceutical experience consistent

with NRS 639.120. The amendment removes the 240-hour barrier for a pharmacist seeking registration by reciprocation in Nevada.

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. Pharmacists will benefit from removing the additional 240-hour requirement for a pharmacist seeking registration by reciprocation in Nevada, and the public will benefit from increased access to pharmaceutical care.

(b) Both immediate and long-term effects.

The Board anticipates that both the immediate and long-term effect on the public will be increased access to pharmaceutical care.

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

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

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

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

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

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

B. Amendment of Nevada Administrative Code (NAC) Chapter 639 authorizing the Board to require certain euthanasia technicians to register with the Board; increasing certain fees; revising requirements for certain applications; requiring an applicant for registration as a pharmacist, pharmaceutical technician or pharmaceutical technician in training to undergo a criminal background check; revising requirements for an outsourcing facility engaged in the compounding of sterile drugs. (LCB File R025-21)

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

The proposed amendment will implement the provisions of Senate Bill 408 requiring an applicant for registration as a pharmacist, pharmaceutical technician or pharmaceutical technician in training to undergo a criminal background check; increase the fees for the investigation or issuance or renewal of a license as a manufacturer or wholesaler; provide that an application for any certificate, license or permit issued by the Board is only valid for 1 year after the date it is received by the Board unless the Board extends its period of validity, and clarify the licensing requirements for an outsourcing facility or euthanasia technician. The benefits of the proposed amendments will result from protecting the health, safety and welfare of the public.

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

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

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

(a) Both adverse and beneficial effects.

There should be no adverse economic impact from this regulation amendment on the public. The regulation amendment will have an economic impact on manufacturers and wholesalers due to the increase in fees for the investigation or issuance or renewal of a license. The amendment will have a beneficial economic effect on regulated entities and the public by ensuring the delivery of safe and reliable pharmaceutical care.

(b) Both immediate and long-term effects.

The Board anticipates that there will be no immediate or long-term economic effect on the public, or that any such effects will be negligible. The amendment will have both an immediate and long-term beneficial economic effect on regulated entities and the public by ensuring the delivery of safe and reliable pharmaceutical care.

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

The regulation amendment increases the fees for the investigation or issuance or renewal of a license for manufacturers and wholesalers. The revenue generated from the fee increase will partially offset the costs of regulatory enforcement of this 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 amendment overlaps or duplicates.

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

This 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.

The regulation amendment increases the fees for the investigation or issuance or renewal of a license for manufacturers and wholesalers. The revenue generated from the fee increase will partially offset the costs of regulatory enforcement of this regulation incurred by the Board of Pharmacy.

C. **Amendment Of Nevada Administrative Code (NAC) 639.220, 639.715, 639.718 and 639 .720: Use of Mechanical Device to Dispense Prescription Drugs.**
(LCB File R013-21)

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

The proposed amendment will license the use of a mechanical device or an automated drug dispensing system to furnish a prescription drug to a patient at certain locations off the premises of the pharmacy; establishes certain fees relating to the use of a mechanical device or an automated drug dispensing system; and revise regulatory requirements for mechanical devices. The regulation is necessary to ensure the delivery of safe and reliable pharmaceutical care and will benefit 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 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 public. The amendment will have an economic impact on those pharmacies that wish to apply for licensure for a device. The amendment will have a beneficial economic effect on regulated entities and the public by ensuring the delivery of safe and reliable pharmaceutical care.

(b) Both immediate and long-term effects.

The Board anticipates that there will be no immediate or long-term economic effect on the public, or that any such effects will be negligible. The amendment will have both an immediate and long-term beneficial economic effect on regulated entities and the public by ensuring the delivery of safe and reliable pharmaceutical care.

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

The regulation adds fees for the licensing of an automated drug dispensing system and the certification of certain mechanical devices. The revenue generated from the fees will partially offset the costs of regulatory enforcement 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 amendment overlaps or duplicates.

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

This 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.

The regulation adds fees for the licensing of an automated drug dispensing system and the certification of certain mechanical devices. The revenue generated from the $500 registration or certification fee will partially offset the costs of regulatory enforcement of this regulation incurred by the Board of Pharmacy.

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 March 3, 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.

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 has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to Governor's Declaration of Emergency Directive 006.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R040-21

December 29, 2021

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

AUTHORITY: §§ 1 and 2, NRS 639.070, 639.120 and 639.134.

A REGULATION relating to the practice of pharmacy; revising the requirement that an applicant for a certificate as a registered pharmacist complete a certain number of hours of practical pharmaceutical experience as an intern pharmacist under the direct and immediate supervision of a registered pharmacist; revising the requirements for the issuance of a certificate as a registered pharmacist by reciprocity; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations governing the practice of pharmacy. (NRS 639.070, 639.120) Existing law requires an applicant for a certificate as a registered pharmacist to complete not less than 1,500 hours of practical pharmaceutical experience as an intern pharmacist under the direct and immediate supervision of a registered pharmacist. (NRS 639.120) Existing regulations establish that 1,740 hours of such practical pharmaceutical experience as an intern pharmacist are required to satisfy the requirement of not less than 1,500 hours of such practical pharmaceutical experience. (NAC 639.208) **Section 1** of this regulation removes the requirement that an applicant complete 1,740 hours of such practical pharmaceutical experience, thereby requiring an applicant to complete not less than 1,500 hours of such practical pharmaceutical experience pursuant to existing law.

Existing law authorizes the Board to grant an application for a certificate as a registered pharmacist, without requiring an examination, if the person (1) is registered as a pharmacist in another jurisdiction which requires the person to pass an examination in order to be registered in that jurisdiction; (2) produces evidence satisfactory to the Board that the person has the required secondary and professional education and training; and (3) is of good moral character. (NRS 639.120, 639.134) **Section 1** authorizes such an applicant to satisfy the requirement to provide evidence of having the required secondary and professional education and training by providing evidence that the applicant has satisfied the requirements of reciprocation of the Electronic Licensure Transfer Program of the National Association of Boards of Pharmacy.

Section 2 of this regulation establishes that the provisions of this regulation apply to any applicant who has submitted an application for a certificate as a registered pharmacist before the effective date of this regulation if the Board has not been approved or denied the application before the effective date of this regulation.

Section 1. NAC 639.208 is hereby amended to read as follows:

639.208 ~~[For the purposes of paragraph (d) of subsection 1 of NRS 639.120, an]~~ ***An*** applicant for a certificate as a registered pharmacist in this State ~~[must complete 1,740 hours of practical pharmaceutical experience as an intern pharmacist under the direct and immediate supervision of a registered pharmacist.]~~ ***by reciprocity pursuant to NRS 639.134 may provide evidence that the applicant has satisfied the requirements of paragraphs (b) and (d) of subsection 1 of NRS 639.120 by completing the requirements of reciprocation of the Electronic Licensure Transfer Program of the National Association of Boards of Pharmacy.***

Sec. 2. The amendatory provisions of this regulation apply to any applicant for a certificate as a registered pharmacist who has submitted an application for such a certificate to the State Board of Pharmacy before the effective date of this regulation if the Board has not approved or denied the application before the effective date of this regulation.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R025-21

September 30, 2021

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

AUTHORITY: §§ 1 and 4, NRS 639.070; § 2, NRS 453.226 and 639.070; § 3, NRS 639.070 and 639.127, as amended by section 5 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018; § 5, NRS 639.070 and 639.170, as amended by section 7 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1019; § 6, NRS 639.070 and 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018; §§ 7 and 9, NRS 639.070, 639.127, as amended by section 5 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018 and 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018; § 8, NRS 639.070 and 639.100, as amended by section 4 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1017.

A REGULATION relating to pharmacy; requiring certain euthanasia technicians to register with the State Board of Pharmacy; revising requirements for certain applications with the Board; increasing certain fees; clarifying that an applicant for registration as a pharmacist or pharmaceutical technician is required to undergo a criminal background check in certain circumstances; revising requirements for an outsourcing facility that is engaged in the compounding of sterile drugs; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires every practitioner or other person who dispenses any controlled substance within this State or who proposes to engage in the dispensing of any controlled substance within this State to obtain a registration issued by the State Board of Pharmacy in accordance with its regulations. (NRS 453.226) Existing regulations prescribe the prerequisites for a euthanasia technician to possess and administer sodium pentobarbital, including registering with the Board. (NAC 638.510) **Section 2** of this regulation requires a euthanasia technician who possesses or administers or who proposes to possess or administer sodium pentobarbital within this State to obtain a registration issued by the Board.

Existing law provides that an application for registration as a pharmacist is only valid for 1 year after the date it is received by the Board. (NRS 639.127) Existing regulations require an applicant for a certificate as a registered pharmacist to provide all information and make all appearances required by the Board within 1 year after passing the North American Pharmacist

Licensure Examination. (NAC 639.205) **Section 3** of this regulation provides that an application for any certificate, license or permit issued by the Board is only valid for 1 year after the application is received by the Board.

Senate Bill No. 408 of the 2021 Legislative Session increased the maximum fees that the Board is authorized to impose for the investigation or issuance or the renewal of a license as a manufacturer or wholesaler from $500 to $1,000. (section 7 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1019) **Section 5** of this regulation amends existing regulations to increase those fees from $500 to $1,000.

Existing law requires an applicant for registration as a pharmacist or a pharmaceutical technician to submit his or her fingerprints to the Board for the purpose of conducting criminal background check. (NRS 639.127, as amended by section 5 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018, NRS 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1019)

Section 6 of this regulation makes a conforming change to clarify in the Nevada Administrative Code that an applicant for registration as a pharmaceutical technician is required to comply with this requirement. **Section 4** of this regulation makes a conforming change to account for changes in numbering made by **section 6. Section 7** of this regulation authorizes an applicant for registration as a pharmacist or a pharmaceutical technician to submit his or her fingerprints electronically to the Board. **Section 9** of this regulation requires an applicant for registration as a pharmacist or pharmaceutical technician to submit a second set of fingerprints if his or her first set of fingerprints is rejected by the Central Repository for Nevada Records of Criminal History.

Existing regulations prescribe certain duties for an outsourcing facility that is engaged in the compounding of sterile drugs in this State or for shipment into this State. (NAC 639.6915) **Section 8** of this regulation requires such a facility to submit an application for a license as a manufacturer in accordance with existing law on a form prescribed by the Board.

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

Sec. 2. ***1. A euthanasia technician who possesses or administers or proposes to possess or administer sodium pentobarbital pursuant to NAC 638.510 must apply to the Board on a form prescribed by the Board for a certificate of registration pursuant to NRS 453.226.***

2. Any certificate of registration issued pursuant to subsection 1 is a revocable privilege and no holder of such a certificate acquires any vested right therein or thereunder.

3. As used in this section, "euthanasia technician" has the meaning ascribed to it in NRS 638.005.

Sec. 3. ***Except as otherwise provided in NAC 639.205, an application for any certificate, license or permit issued by the Board is valid for 1 year after the date on which the application is received by the Board unless the Board extends the period of validity for the application. An applicant who fails to provide all required information or make all required appearances within 1 year after that date must submit a new application for the applicable certificate, license or permit.***

Sec. 4. NAC 639.010 is hereby amended to read as follows:

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

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

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

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

4. "Direct supervision" means the direction given by a supervising pharmacist 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.

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

6. "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.

7. "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 ~~[(e)]~~ *(f)* 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.

8. "Practitioner" has the meaning ascribed to it in NRS 639.0125.

9. "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.

10. "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.

11. "Surgical center for ambulatory patients" has the meaning ascribed to it in NRS 449.019.

Sec. 5. 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..... Actual cost pharmacist..... of the examination

..... For the investigation or registration of an applicant as a registered pharmacist.....$180

.. For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....180

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

..... For the biennial renewal of registration as a registered pharmacist.....180

.... 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 40

For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in training 40

.....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, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances 80

.....For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances.....80

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

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

..... For the investigation or issuance of an original license to a manufacturer or wholesaler .....~~[500]~~

1,000 ..... For the biennial renewal of a license for a manufacturer or wholesaler.....~~[500]~~

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 each location where the practitioner will dispense controlled substances or dangerous drugs, or both 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 each location where the practitioner will dispense controlled substances or dangerous drugs, or both.....300

.....For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both.....150

..For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both.....150

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 health center:

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, 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 the fee for the collective certification of advanced practice registered nurses in the employ of a public or nonprofit agency as set forth in subsection 1.

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

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, 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.

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

Sec. 6. NAC 639.240 is hereby amended to read as follows:

639.240 1. No person may perform the duties of a pharmaceutical technician until the person has been issued a certificate of registration.

2. An applicant for registration as a pharmaceutical technician must:

(a) Be 18 years of age or older;

(b) Be a high school graduate or the equivalent;

(c) Not have been convicted of any felony or a misdemeanor involving moral turpitude, dishonesty or the unlawful possession, sale or use of drugs;

(d) Have no history of drug abuse; ~~[and]~~

(e) ***Have complied with the requirements of subsection 4 of NRS 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018; and***

(f) Have complied with one of the following requirements:

(1) The successful completion of a program of training for pharmaceutical technicians, including, but not limited to, a program of training offered by a postsecondary school, that is approved by the Board pursuant to NAC 639.256.

(2) Registration in another state as a pharmaceutical technician, if the requirements for registration in that state are equivalent to the requirements of this State, and the successful completion of at least 240 hours of employment as a pharmaceutical technician in a pharmacy in that state, which must be verified by the managing pharmacist of the pharmacy.

(3) If the state in which the applicant has been employed does not offer registration, licensure or certification as a pharmaceutical technician:

(I) The successful completion of at least 1,500 hours of experience in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371 during the 3 years immediately preceding the date on which his or her application was submitted;

(II) The successful completion of at least 350 hours of employment in a pharmacy in this State; and

(III) The acquisition of a written statement to the Board from the managing pharmacist of the pharmacy referred to in sub-subparagraph (II) stating that the applicant, during his or her employment, demonstrated competence to perform the tasks assigned to him or her.

➥ Such an applicant must register as a pharmaceutical technician in training before he or she completes the requirements of sub-subparagraph (II).

(4) The successful completion of at least 1,500 hours of training and experience as a pharmaceutical technician in training. A pharmaceutical technician in training may accumulate certified hours of training from each place of employment.

(5) The successful completion of a program of training for pharmaceutical technicians conducted by a branch of the Armed Forces of the United States, the Indian Health Service of the United States Department of Health and Human Services or the United States Department of Veterans Affairs.

(6) Certification by the Pharmacy Technician Certification Board or the National Healthcareer Association as a pharmacy technician if:

(I) The applicant successfully completes a program of training for pharmaceutical technicians conducted by a postsecondary school in another state;

(II) The program is accredited or otherwise approved by the appropriate regulatory authority in that state; and

(III) The applicant successfully completes at least 240 hours of employment as a pharmaceutical technician in training in a pharmacy in another state, which must be verified by the managing pharmacist of the pharmacy.

3. An applicant who attended a school outside the United States must submit to an organization which evaluates educational credentials a copy of the transcript of his or her academic record from that school for a determination of whether the grades the applicant received are substantially equivalent to the grades required for an applicant who attended a school, or a program of training for pharmaceutical technicians that is accredited by the American Society of Health-System Pharmacists, in the United States. The applicant must ensure that a copy of the organization's evaluation of the transcript is submitted to the Board.

4. Upon receipt of an application and the required fee, the Executive Secretary shall, unless he or she has good cause to deny the registration, issue a certificate of registration to the pharmaceutical technician.

Sec. 7. NAC 639.5931 is hereby amended to read as follows:

639.5931 A person who is required to submit a complete set of his or her fingerprints to the Board pursuant to ***subsection 2 of NRS 639.127, as amended by section 5 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018, subsection 4 of NRS 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018,*** NRS 639.500 or 639.505 or NAC 639.593 or section 3 of LCB File No. R040-20 may submit the fingerprints electronically in a format prescribed by the Board.

Sec. 8. NAC 639.6915 is hereby amended to read as follows:

639.6915 An outsourcing facility that is engaged in the compounding of sterile drugs in this State or for shipment into this State shall:

1. Obtain a license from the Board as a manufacturer in accordance with NRS 639.100, ***as amended by section 4 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1017,*** and ***NRS*** 639.233 ~~[.]~~ ***by submitting an application on a form prescribed by the Board;***

2. Comply with the provisions of NAC 639.609 to 639.619, inclusive; and

3. Comply with all the requirements of 21 U.S.C. § 353b.

Sec. 9. Section 4 of LCB File No. R040-20 is hereby amended to read as follows:

1. If a complete set of fingerprints from any person required to submit fingerprints pursuant to ***subsection 2 of NRS 639.127, as amended by section 5 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018, subsection 4 of NRS 639.1371, as amended by section 6 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1018,*** NRS 639.500 ***or 639.505*** or NAC 639.593 or section 3 of LCB File No. R040-20 is rejected by the Central Repository for Nevada Records of Criminal History, the person shall submit a second complete set of fingerprints and written permission authorizing the Board to forward the second complete

set of fingerprints to the Central Repository for submission to the Federal Bureau of Investigation for its report.

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

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R013-21

October 28, 2021

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

AUTHORITY: § 1, NRS 639.070; § 2, NRS 639.070 and 639.2655.

A REGULATION relating to pharmacy; establishing certain fees relating to the use of an automated drug dispensing system or a mechanical device at certain locations; authorizing a pharmacy to dispense prescription drugs to a patient using an automated drug dispensing system under certain circumstances; 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 practice of pharmacy as necessary for the protection of the public. Existing law authorizes the Board to adopt regulations governing the dispensing, recordkeeping, storage and handling of drugs. Additionally, existing law authorizes the Board to charge and collect fees for any incidental service the Board provides. (NRS 639.070) Existing law further allows a pharmacist to use computerized mechanical equipment to perform work that a pharmacist is authorized to perform by law in accordance with the regulations adopted by the Board. (NRS 639.2655)

Under existing regulations, the Board has adopted a schedule of fees for certain applications, licenses and registrations. (NAC 639.220) **Section 1** of this regulation adds fees for the licensing of an automated drug dispensing system and the certification of certain mechanical devices to the schedule of fees. **Section 1** also makes a conforming change by removing a reference to a previously deleted fee.

Existing regulations authorize pharmacies and medical facilities to use mechanical devices to dispense drugs to a patient. (NAC 639.718, 639.720) **Section 2** of this regulation establishes certain requirements that a pharmacy must follow to use an automated drug dispensing system. **Section 2** requires an automated drug dispensing system to track who uses the system, what drugs are in the system, the temperature of the system and other information to ensure that the drugs in the system are safely stored and only dispensed to a person authorized to receive the dispensed drug. **Section 2** of this regulation further requires the Board to issue a license to a pharmacy for an automated drug dispensing system upon approval of an application for a license by the Board and payment of the requisite fee.

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 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, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances 200

For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances 200

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

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

For the investigation or issuance of an original license to a manufacturer or wholesaler 500

For the biennial renewal of a license for a manufacturer or wholesaler 500

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 certificate 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 certificate 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 health center:~~

~~(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, 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 the fee for the collective certification of advanced practice registered nurses in the employ of a public or nonprofit agency as set forth in subsection 1.~~

~~6.]~~ A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, 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.

~~[7.]~~ ***6.*** A practitioner who is exempt from the payment of a fee pursuant to subsection 6 shall notify the Board in writing of each change of address or additional address, or both.

~~[8.]~~ ***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. 2. NAC 639.718 is hereby amended to read as follows:

639.718 1. Except as otherwise provided in this section, a pharmacy may use ~~[a mechanical device to furnish]~~ ***an automated drug dispensing system to dispense*** a prescription drug to a patient ***if the pharmacy obtained a license from the Board for the automated drug dispensing system.***

2. The Board will provide to a pharmacy an application for a license for an automated drug dispensing system upon request. The Board will issue a license for an automated drug dispensing system if the application for a license is approved and the requisite fee is paid. A license must be:

(a) Issued for each automated drug dispensing system at a designated location; and

(b) Posted on the system so that the license is visible to the public.

3. The ~~[device]~~ ***automated drug dispensing system*** must conform to all of the following provisions:

(a) The ~~[device]~~ ***system*** must contain only prescription drugs:

(1) Approved for use in the system by a registered pharmacist employed by the pharmacy;

~~[(1)]~~ ***(2)*** For which counseling is not required pursuant to NAC 639.707~~[;]~~, ***unless the system uses user-based access technology that includes, without limitation, an audio-visual***

function that allows the patient to communicate, in real time, with a registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708; and

~~[(2)]~~ ***(3)*** For which the prescriptions have been processed, verified and completed in the same manner as prescriptions for drugs that are delivered manually by the pharmacy, including the provision of printed medication guides and any other information required pursuant to NAC 639.707.

(b) The ~~[device]~~ ***system*** must not contain ***:***

(1) ~~[controlled]~~ ***Controlled*** substances included in schedule II ~~[.]~~ ***; or***

(2) Controlled substances included in schedules III, IV and V unless authorized by the Drug Enforcement Administration of the United States Department of Justice to dispense such substances.

(c) The ~~[device]~~ ***system*** must***:*** ~~[be designed to ensure that the device:]~~

(1) ~~[Is located such that access to the device:~~

~~(I) For]~~***Control and track access to the system for*** stocking, cleaning, maintenance or any other purpose ***so that access to the system*** can be obtained only by a pharmacist or a member of the staff of the pharmacy from within a secured area of the pharmacy ***using user-based access technology.***~~[; and~~

~~(II) Is]~~

(2) Be secure from unauthorized access to and removal of prescription drugs***.*** ~~[from the device.~~

~~(2) Records the name of each person at the pharmacy who authorizes access to the device.~~

~~(3) Cannot be used by a patient:~~

~~(I) Outside the physical location of the pharmacy.~~

~~(II) Unless the~~]

(3) Be owned or leased by the pharmacy who obtained the license for the automated drug dispensing system and operated under the supervision and control of that pharmacy.

(4) Monitor the temperature of the system or be able to have a device installed to monitor the temperature of the system, including, without limitation, an alarm that records when the temperature of the system reaches a level outside the range compatible with the proper storage of a prescription drug and a method to notify the pharmacy of the temperature change.

(5) Create and maintain a complete, accurate and readily retrievable record of all transactions. The record must include, without limitation:

(I) The name, strength, quantity and form of dosage of each prescription drug stocked, inventoried, removed or dispensed from the system;

(II) Each day and time the system is accessed;

(III) An inventory of the prescription drugs stored in the system; and

(IV) The identity of each person who accesses the system.

(6) Restrict access to a patient ***who*** previously has indicated to the pharmacy that the patient desires that his or her prescription drugs be ~~[furnished]~~ ***dispensed*** by the ~~[mechanical device.]~~ ***system.***

~~[(4) Provides]~~ ***(7) Provide*** a method to identify the patient and ~~[furnishes]~~ ***dispense*** a prescription drug only to the patient or to an authorized agent of the patient.

~~[(5) Can furnish]~~ ***(8) Dispense*** one, any combination or all of the prescription drugs available to a patient at the option of the patient at the time that the patient removes the prescription drugs from the ~~[device.]~~ ***system.***

~~[(6) Records]~~ ***(9) Record*** the date and time that the patient removes the prescription drugs from the ~~[device.]~~ ***system.***

~~[(7) Informs]~~ ***(10) Inform*** a patient:

(I) That a prescription drug is not available to be ~~[furnished]~~ ***dispensed*** by the ~~[device]~~ ***system*** if the pharmacist wishes to counsel the patient regarding the prescription drug.

(II) If the patient is using the ~~[device]~~ ***system*** at the time that the pharmacy is open, that the patient may discuss questions and concerns regarding the prescription drug with a pharmacist at the pharmacy ~~[.]~~ ***or through user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate, in real time, with a registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.***

(III) If the patient is using the ~~[device]~~ ***system*** at the time that the pharmacy is closed, that the patient may discuss questions and concerns regarding the prescription drug ~~[using a toll-free telephone number at which a pharmacist at a pharmacy licensed by the Board will respond at all hours when the pharmacy at which the device is located is closed. A pharmacist who responds to questions or concerns pursuant to this sub-subparagraph must have access by computer to the same information regarding the patient that a pharmacist would have using the computer system of the pharmacy at which the device is located.]~~ ***through user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate,***

in real time, with a registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.

(IV) That the patient may choose not to purchase the prescription drug from the system at any time before the system dispenses the prescription drug.

(11) Dispense all prescription drugs in containers labeled in conformance with NRS 639.2801.

(12) Be installed in such a place and manner that a person is unable to remove the system from its location and any attempts to obtain access to the device without authorization are visible to the pharmacist of the pharmacy either through the system being in view of the pharmacist or by real-time audio-visual communication technology or audio-visual recording technology.

(13) Be located in a:

(I) Pharmacy;

(II) Medical facility, as defined in subsections 1 to 14, inclusive, or 16 of NRS 449.0151; or

(III) Practice site of one or more practitioners of medicine.

(14) Be approved for use by the Board upon determination that the system:

(I) Dispenses prescription drugs accurately; and

(II) Otherwise satisfies the provisions of this section.

~~[2. A pharmacy shall not use a mechanical device to furnish a prescription drug to a patient until the pharmacy has notified the Board in writing of:~~

~~(a) The type of device that will be used; and~~

~~(b) The anticipated date that the device will first be used.]~~

4. A pharmacy that dispenses prescription drugs by an automated drug dispensing system pursuant to this section shall maintain a written policy that sets forth:

(a) The duties of all persons who are authorized to access the system; and

(b) The procedures for:

(1) Maintaining the security of the prescription drugs stored in the system during the maintenance and repair of the system;

(2) The preparation of an inventory of the prescription drugs stored in the system; and

(3) Stocking the system with prescription drugs.

5. A pharmacy that dispenses prescription drugs through an automated drug dispensing system pursuant to this section shall comply with all applicable federal and state recordkeeping requirements and shall maintain those records in a readily retrievable manner separate from other pharmacy records.

6. Prescription drugs stored in an automated drug dispensing system pursuant to this section shall be deemed part of the inventory and the responsibility of the pharmacy that was issued the license for the system. Prescription drugs dispensed from the system shall be considered to have been dispensed by that pharmacy.

~~[3.]~~ *7.* The Board may prohibit a pharmacy from using a ~~[mechanical device]~~ *system* to furnish a prescription drug to a patient if the Board determines that the ~~[device]~~ *system* or the pharmacy's use of the ~~[device]~~ *system* does not comply with this section.

~~[4.]~~ *8.* The provisions of this section do not prohibit the use of a ~~[mechanical device]~~ *system* to furnish a drug or device that is approved by the Food and Drug Administration for sale over the counter without a prescription if the pharmacy using the ~~[mechanical device]~~ *system* is otherwise authorized to use the ~~[mechanical device]~~ *system* pursuant to this section.

9. As used in this section:

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

(b) "User-based access technology" means software or hardware that restricts access to the system to authorized users by requiring two-factor authentication. Authentication factors may include, without limitation, knowledge, hardware tokens or biometric information.

function that allows the patient to communicate, in real time, with a registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708; and

~~[(2)]~~ ***(3)*** For which the prescriptions have been processed, verified and completed in the same manner as prescriptions for drugs that are delivered manually by the pharmacy, including the provision of printed medication guides and any other information required pursuant to NAC 639.707.

(b) The ~~[device]~~ ***system*** must not contain ***:***

(1) ~~[controlled]~~ ***Controlled*** substances included in schedule II ~~[.]~~ ***; or***

(2) Controlled substances included in schedules III, IV and V unless authorized by the Drug Enforcement Administration of the United States Department of Justice to dispense such substances.

(c) The ~~[device]~~ ***system*** must***:*** ~~[be designed to ensure that the device:]~~

(1) ~~[Is located such that access to the device:~~

~~(I) For~~***Control and track access to the system for*** stocking, cleaning, maintenance or any other purpose ***so that access to the system*** can be obtained only by a ***registered*** pharmacist ~~[or a member of the staff of the pharmacy from within a secured area of]~~ ***, pharmaceutical technician, or intern pharmacist employed by*** the pharmacy ***using user-based access technology.***~~[; and~~

~~(II) Is]~~

(2) Be secure from unauthorized access to and removal of prescription drugs ***.*** ~~[from the device.~~

~~(2) Records the name of each person at the pharmacy who authorizes access to the device.~~

~~(3) Cannot be used by a patient:~~