## 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 cos
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	
nharmagist	190

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	
	0.0

	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	<del>[500]</del>
1,000	For the biennial renewal of a license for a manufacturer or	
	wholesaler	<del>[500]</del>
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

- 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.