

**PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY**

LCB FILE NO. R085-201

**The following document is the initial draft regulation proposed
by the agency submitted on 06/16/2020**

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop

June 3, 2020

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

AUTHORITY: NRS 639.070; NRS 639.2177

Amendment of Nevada Administrative Code (NAC) 639.010, 639.200, 639.4992, 639.4996, 639.4998 and 639.750. The proposed amendments set forth the requirements for the licensing and regulation of recovery centers to dispense controlled substances and dangerous drugs if the Recovery Center is licensed by the State Board of Health pursuant to NRS 449.0303.

NAC 639.220 Schedule of fees; penalty for late renewal; exemptions from certain fees (NRS 639.070, 639.170)

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

	Actual cost of the examination
For the examination of an applicant for registration as a pharmacist.....	
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
<i>For the investigation or issuance of an original license to conduct a recovery center or surgical center for ambulatory patients licensed by the State Board of Health pursuant to NRS 449.0303</i>	500
<i>For the biennial renewal of a license to conduct a recovery center or surgical center for ambulatory patients licensed by the State Board of Health pursuant to NRS 449.0303</i>	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, <i>recovery center or</i> 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, <i>recovery center or</i> 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 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.

8. 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.

NAC 639.010 Definitions. (NRS 639.070) 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) 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.

12. “Recovery center” has the meaning ascribed to it in NRS 639.0144.

NAC 639.457 “Medical facility” defined. (NRS 639.070) “Medical facility” includes:

1. A surgical center for ambulatory patients;

2. An obstetric center;

3. An independent center for emergency medical care;

4. An agency to provide nursing in the home;

5. A facility for intermediate care;

6. A facility for skilled nursing;

7. A hospice;

8. A hospital;

9. A psychiatric hospital;

10. A facility for the treatment of irreversible renal disease; ~~and~~

11. A rural clinic; ~~and~~

12. A recovery center.

NAC 639.4992 Dispensing controlled substances or dangerous drugs: Registration and licensing required. (NRS 639.070, 639.071, **NRS 639.2177**) Each **recovery center** or surgical center for ambulatory patients shall **apply to the Board for a license to dispense controlled substances or dangerous drugs by submitting an application on a form prescribed by the Board and shall:**

1. Register with ~~the Board and~~ the Drug Enforcement Administration of the United States Department of Justice to dispense controlled substances;

2. Ensure that each practitioner who dispenses controlled substances *or dangerous drugs* in the *recovery center or* surgical center is registered with the Board and the Drug Enforcement Administration of the United States Department of Justice; and

3. Require each person employed to work in a pharmacy of the *recovery center or* surgical center for ambulatory patients and any person with whom the *recovery center or* surgical center for ambulatory patients has entered into a contract to provide pharmaceutical services to possess a current state license or certificate to provide such services.

4. A license to dispense controlled substances or dangerous drugs granted pursuant to this section is a revocable privilege, and no holder of such a license acquires any vested right therein or thereunder.

NAC 639.4996 Establishment and review of policies and procedures by pharmacist.
(NRS 639.070, 639.071, *NRS 639.2177*)

1. A *recovery center or* surgical center for ambulatory patients shall employ or enter into a contract with a pharmacist to establish policies and procedures which:

(a) Are consistent with the policies and procedures developed pursuant to NAC 639.477;

(b) Require the maintenance of records in accordance with the provisions of NAC 639.485 and 639.486;

(c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;

(d) Require maintenance of a perpetual inventory of all controlled substances;

(e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;

(f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;

(g) Ensure that the *recovery center or* surgical center dispenses drugs and investigational drugs *by chart orders and* in accordance with applicable state and federal laws; and

(h) Ensure that all compounding is:

(1) Performed by a registered pharmacist in accordance with the provisions of this chapter and chapter 639 of NRS; or

(2) If performed by an employee of the *recovery center or* surgical center, other than a registered pharmacist, performed:

(I) In accordance with the provisions of this chapter and chapter 639 of NRS;

(II) In a location designated for compounding that is clean and disinfected before each act of compounding; and

(III) By a person who has completed training for the type of compounding that will be performed.

2. The policies and procedures established pursuant to subsection 1 must be maintained, reviewed at least annually, and dated upon adoption and amendment.

3. The pharmacist employed by or contracted with a *recovery center or* surgical center for ambulatory patients pursuant to subsection 1 may establish the policies and procedures required pursuant to that subsection with the assistance of a practitioner or an employee or contractor of the *recovery center or* surgical center.

NAC 639.4998 Duties of pharmacist who establishes policies and procedures. (NRS 639.070, 639.071, *NRS 639.2177*) A pharmacist employed by or contracted with a *recovery center or* surgical center for ambulatory patients pursuant to NAC 639.4996 shall:

1. Visit the *recovery center or* surgical center at least once each month to:
 - (a) Evaluate the effectiveness of the policies and procedures established pursuant to NAC 639.4996; and
 - (b) Confirm that the *recovery center or* surgical center is complying with those policies and procedures, the provisions of this section and NAC 639.4996;
2. Maintain documentation of each visit that the pharmacist makes pursuant to subsection 1;
3. Conduct an audit at least once each month using a sufficient number of records of the *recovery center or* surgical center, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
 - (a) The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
 - (b) Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
 - (c) The records demonstrate:
 - (1) That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
 - (2) That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
 - (d) The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
 - (e) The employees of the *recovery center or* surgical center properly maintain accurate records relating to drugs and investigational drugs; and
 - (f) The employees of the *recovery center or* surgical center properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
4. Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
 - (a) The *recovery center or* surgical center is violating a state or federal law which affects the care and safety of a patient;
 - (b) There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the *recovery center or* surgical center and the amount of the controlled substance that should be in the possession of the *recovery center or* surgical center according to the records of the *recovery center or* surgical center, including, without limitation:
 - (1) Purchase orders and invoices for the controlled substance;
 - (2) Records which indicate the removal of the controlled substance from the storage area;
 - (3) Patient records;
 - (4) Records which indicate the return of the controlled substance to the manufacturer;
 - (5) Records which indicate that the controlled substance was destroyed; and
 - (6) Any other record for the controlled substance;

- (c) The *recovery center or* surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
- (d) The *recovery center or* surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
- (e) The *recovery center or* surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the *recovery center or* surgical center.

NAC 639.750 Dispensing of medication at certain locations when local retail pharmacy is closed. (NRS 639.070)

1. If the services of a local retail pharmacy are not available, the practitioner in charge of the emergency room of a hospital, *of a recovery center* or of a surgical center for ambulatory patients may dispense medication in an amount adequate to treat patients in the emergency room, *recovery center* or surgical center for ambulatory patients during the hours that the local retail pharmacy is closed.

2. If a practitioner dispenses medication at the emergency room of a hospital, *at a recovery center* or at a surgical center for ambulatory patients:

(a) The following information must be maintained for each medication dispensed:

(1) The name of the patient and, if not readily available from the records of the hospital, the address of the patient;

(2) The name, strength and quantity of the medication;

(3) The name of the prescribing practitioner and the classification of his or her license;

(4) The registration number of the prescribing practitioner that is issued by the Drug Enforcement Administration of the United States Department of Justice, if the medication is a controlled substance;

(5) The signature of the practitioner who dispenses the medication;

(6) The directions for using the medication;

(7) The date the medication is dispensed; and

(8) The signature of the prescribing practitioner.

(b) The medication must be dispensed in a container in accordance with NAC 639.740.

(c) A label that contains the following information must be affixed to the container:

(1) The date;

(2) The name of the prescribing practitioner;

(3) The name of the patient;

(4) The number of dosage units;

(5) Specific directions for use;

(6) The expiration date of the medication;

(7) The proprietary or generic name of the medication;

(8) The strength of the medication;

(9) The initials of the practitioner who dispenses the medication; and

(10) The following warning:

Caution: Do not use with alcohol or nonprescription drugs without consulting the prescribing practitioner.