PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY

LCB FILE NO. R203-24I

The following document is the initial draft regulation proposed by the agency submitted on 12/9/2024

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – December 5, 2024

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; NRS 639.2327

Amendment of Nevada Administrative Code (NAC) Chapter 639. The proposed amendments set forth the requirements for the licensing and operation of a facility for intermediate care or facility for skilled nursing if the facility is licensed by the State Board of Health pursuant to NRS 449.0303.

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

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

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

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

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

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

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

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

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

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

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

For the investigation or issuance of an original license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303 500

For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303 500

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

For the biennial renewal of registration as a registered pharmacist.....200

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

For the initial registration of a pharmaceutical technician 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, 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, 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.....1,000

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

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

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

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

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

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

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

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

For the investigation or issuance of an original license to a facility for intermediate care or facility for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303.....500

For the biennial renewal of a license to a facility for intermediate care or facility for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303.....500

Sec. 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 through 4 of this regulation.

Sec 2.

1. ***Each facility for intermediate care or facility for skilled nursing, licensed by the State Board of Health pursuant to NRS 449.0303, which does not have a licensed pharmacy on the premises and who wishes to maintain a stock of drugs for emergency treatment of inpatients, must:***
    a. ***Apply to the Board for a license to maintain a stock of drugs for emergency treatment of inpatients by submitting an application on a form prescribed by the Board and pay the requisite fee. A license granted pursuant to this section is a revocable privilege, and no holder of such a license acquires any vested right therein or thereunder.***
    b. ***If the stock of drugs includes controlled substances listed in schedule II, III, IV and V, register with the Drug Enforcement Administration of the United States Department of Justice.***
2. ***The director for the facility for intermediate care or facility for skilled nursing must ensure that the facility for intermediate care or facility for skilled nursing adheres to the provisions in NRS 639.2327(2-6) pertaining to the stock of drugs for emergency treatment of inpatients.***

Sec. 3.

1. ***Each facility for intermediate care or facility for skilled nursing, licensed by the State Board of Health pursuant to NRS 449.0303, which does not have a licensed pharmacy on the premises and who wishes to maintain a stock of drugs for emergency treatment of inpatients, or to stock a supply of drugs pursuant to NAC 639.476, to stock a supply of drugs in a mechanical device pursuant to NAC 639.720, or receive a prescription drug filled on the chart order of a practitioner to administer to a patient at the facility for intermediate care or facility for skilled nursing pursuant to NAC 639.478, shall:***
    a. ***Enter into a contract with a licensed pharmacy to provide the stock of drugs for emergency treatment of inpatients, to stock a supply of drugs pursuant to NAC 639.476, to stock a supply of drugs in a mechanical device pursuant to NAC 639.720, or to process and fill a prescription drug on the chart order of a practitioner to administer to a patient at the facility for intermediate care or facility for skilled nursing pursuant to NAC 639.478; and***
    b. ***Employ or enter into a contract with a pharmacist to establish policies and procedures which:***

i. *Are consistent with the policies and procedures developed pursuant to NAC 639.477;*

ii. *Require the maintenance of records in accordance with the provisions of NAC 639.485 and 639.486;*

iii. *Address the purchase, storage, maintenance of records of drugs purchases, administered;*

iv. *Require maintenance of a perpetual inventory of all controlled substances;*

v. *Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;*

vi. *Require the storage of drugs in accordance with specifications of the manufacturer;*

vii. *Require that the stock of drugs for emergency treatment of inpatients is stored pursuant to NRS 639.2327(2), stock of supply of drugs pursuant to NAC 639.476 and prescription drugs filled on the chart order of a practitioner for administration is secured and stored in a locked cabinet or room; and*

viii. *Ensure that the facility for intermediate care or facility for skilled nursing administers drugs pursuant to chart orders and in accordance with applicable state and federal laws; and*

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

d. *The pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing pursuant to subsection 1b may establish the policies and procedures required pursuant to that subsection with the assistant of the director of the facility for intermediate care or facility for skilled nursing.*

Sec 4.

1. *A pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing shall:*

a. *Visit the facility for intermediate care or facility for skilled nursing at least once a month to:*

i. *Evaluate the effectiveness of the policies and procedures established in section 3; and*

ii. *Confirm that the facility for intermediate care or facility for skilled nursing is complying with those policies and procedures, the provisions of this section and Section 3;*

b. Maintain documentation of each visit that the pharmacist makes pursuant to subsection 1;

c. Conduct an audit at least once each month using sufficient number of records of the facility for intermediate care or facility for skilled nursing, including, without limitation, records of patients and records relating to the purchasing, storing, and administration of drugs, which must be randomly selected to determine whether:

i. The records indicate that the drugs are administered in a safe and effective manner in accordance with accepted standards of practice and the specification of the manufacturer;

ii. The records demonstrate:

1. That a discrepancy does not exist in the number or quantity of drug dispensed on the order of a practitioner to the number or quantity of drug remaining;

2. The employees of the facility for intermediate care or facility for skilled nursing maintain accurate records relating to drugs; and

3. The employees of the facility for intermediate care or facility for skilled nursing properly monitor and maintain the perpetual inventory required pursuant to subparagraph 4 of paragraph b of subsection 1 of section 3; 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 facility for intermediate care or facility for skilled nursing 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 actual quantity of a controlled substance in the possession of the facility for intermediate care or facility for skilled nursing and the amount of the controlled substance that should be in the possession of the facility for intermediate care or facility for skilled nursing according to the records of the facility, including, without limitation:

i. Purchase orders and invoices for the controlled substance;

ii. Records which indicate the removal of the controlled substance from the storage area;

iii. Patient records;

iv. Records which indicate the return of the controlled substance to the manufacturer;

v. Records which indicate that the controlled substance was destroyed; and

vi. Any other record for the controlled substance;

c. The facility for intermediate care or facility for skilled nursing has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to Section 3.

d. The facility for intermediate care or facility for skilled nursing is administering a drug in violation of accepted standards of practice or the specifications of the manufacturer; or

e. The facility for intermediate care or facility for skilled nursing is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the facility for intermediate care or facility for skilled nursing.

NAC 639.498

1. Except as otherwise provided in subsection 2:

(a) At least once each month, the director or ***the pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing*** ~~***a licensed consulting pharmacist***~~ shall destroy, on the premises of the facility, the controlled substances described in subsection 1 of NAC 639.050.

(b) If the director destroys the controlled substances, the ***pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing*** ~~***licensed consulting pharmacist***~~ shall witness the destruction of the controlled substances. If the ***pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing*** ~~***licensed consulting pharmacist***~~ destroys the controlled substances, the director shall witness the destruction of the controlled substances.

2. The director may designate a nurse licensed pursuant to chapter 632 of NRS to carry out his or her duties pursuant to this section. The ***pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing*** ~~***licensed consulting pharmacist***~~ may designate a pharmacist licensed pursuant to chapter 639 of NRS to carry out his or her duties pursuant to this section.

3. The controlled substances must be destroyed in accordance with 21 C.F.R. Parts 1300, 1301, 1304, 1305, 1307 and 1317 and any other provision of federal law governing the destruction or disposal of controlled substances.

Statutes and regulations referenced when drafting this proposed regulation:

NRS 639.004 "Chart order" defined. "Chart order" means an order entered on the chart of a patient in a hospital, recovery center, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

NAC 639.478 Limitations on distribution of drugs. (NRS 639.070**,** 639.071**,** 639.072**)**

1. A drug may be given to a patient in a medical facility or correctional institution only on the order of a practitioner or an agent of the practitioner.
2. A drug may be distributed in a medical facility or correctional institution only from the original or a direct copy of the practitioner's order for medication.
3. A controlled substance listed in schedule II may be distributed to outpatients only pursuant to a written prescription.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NRS 639.2327 Maintenance of stocks of drugs by certain facilities. A facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services and is registered with the Board pursuant to this chapter may maintain a stock of drugs for emergency treatment of inpatients, subject to the following conditions:

1. The Board shall by regulation determine the specific drugs and the quantities thereof which may be maintained.
2. The emergency stock of drugs must be maintained at all times in a solid, sealed container and the seal must remain intact except when the drugs are needed for emergency treatment of a patient in the facility. The sealed container must be stored at all times in a locked compartment on the premises of the facility.
3. All drugs delivered to a facility must be signed for by the nurse or other person in charge. An inventory of the stock of drugs must be appended to the sealed container. Immediately after the drugs are needed, the physician or registered nurse who breaks the seal shall enter on the inventory sheet the following information:
   (a) The date and time the sealed container is opened;
   (b) The name of the patient for whom the drugs are to be used;
   (c) The name of the patient's physician or the physician who directs the administration of the drugs, if different;
   (d) An itemization of the drugs removed; and
   (e) The signature of the person who opened the sealed container.
4. When the drugs have been removed and the information required by subsection 3 has been entered on the inventory, the physician or registered nurse shall immediately replace the container in a locked compartment and shall notify the pharmaceutical consultant, as soon as it is practical to do so, that the container has been opened.

5. The sealed container and its contents at all times remain the responsibility of the pharmaceutical consultant. Upon being notified that the sealed container has been opened, or on the next business day if notification is not received during business hours, but in no event more than 48 hours following receipt of the notification, the pharmaceutical consultant shall:

(a) Examine the inventory sheet;

(b) Replace the drugs removed;

(c) Secure a written prescription for the drugs replaced, if one is required by law;

(d) Enter the name and quantity of the drugs so replaced on the inventory sheet, together with the date and time of replacement;

(e) Reseal the container; and

(f) Sign the inventory sheet.

6. No person other than a licensed physician or registered nurse may open the container or remove any drugs from the container.

7. The Board, its agents and inspectors may at all times have access to the premises of the facility to determine compliance with this section.

NRS 639.23275 Delivery of controlled substance or dangerous drug to hospital, recovery center, facility for intermediate care or facility for skilled nursing which does not have pharmacy on premises.

1. Except as otherwise provided in NRS 453.256, no pharmacy may deliver a controlled substance or dangerous drug for a specific patient to a hospital, recovery center, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services which does not have a pharmacy on the premises except pursuant to a prescription given:

(a) Directly from the prescribing practitioner to a pharmacist;

(b) Indirectly by means of an order signed by the prescribing practitioner; or

(c) By an oral order transmitted by an agent of the prescribing practitioner.

2. If an order for entry on a chart is given by a prescribing practitioner, the chart order must be signed by the practitioner who authorized the administration of the drug within 48 hours after the order is given by that practitioner.

NRS 639.2589 Form for prescription required to contain line for practitioner's signature; substitutions in filling prescriptions in certain facilities; substitutions in filling prescriptions ordered on patient's chart in hospital.

1. The form used for any prescription which is issued or intended to be filled in this state must contain a line for the signature of the practitioner.

2. Substitutions may be made in filling prescriptions contained in the orders of a physician, or of an advanced practice registered nurse who is a practitioner, in a facility for skilled nursing or facility for intermediate care.

3. Substitutions may be made in filling prescriptions for drugs ordered on a patient's chart in a hospital if the hospital's medical staff has approved a formulary for specific generic substitutions.

4. Substitutions may be made in filling prescriptions for biological products ordered on a patient's chart in a hospital if the hospital's medical staff has approved a formulary for specific interchangeable biological products.

NRS 639.267 Return, reissuance or transfer of unused drugs: Drugs packaged in unit doses generally; regulations.

1. As used in this section, "unit dose" means that quantity of a drug which is packaged as a single dose.

2. A pharmacist who provides a regimen of drugs in unit doses to a patient in a facility for skilled nursing or facility for intermediate care as defined in chapter 449 of NRS may credit the person or agency

which paid for the drug for any unused doses. The pharmacist may return the drugs to the dispensing pharmacy, which may reissue the drugs to fill other prescriptions or transfer the drugs in accordance with the provisions of NRS 449.2485.

3. Except schedule II drugs specified in or pursuant to chapter 453 of NRS and except as otherwise provided in NRS 433.801, 435.700, 449.2485, 638.200, 639.2675 and 639.2676, unit doses packaged in ampules or vials which do not require refrigeration may be returned to the pharmacy which dispensed them. The Board shall, by regulation, authorize the return of any other type or brand of drug which is packaged in unit doses if the Food and Drug Administration has approved the packaging for that purpose.

NRS 449.0151 "Medical facility" defined. [Effective January 1, 2022.] "Medical facility" includes:

1. A surgical center for ambulatory patients;
2. A freestanding birthing 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 facility for hospice care;
8. A hospital;
9. A psychiatric hospital;
10. A facility for the treatment of irreversible renal disease;
11. A rural clinic;
12. A nursing pool;
13. A facility for modified medical detoxification;
14. A facility for refractive surgery;
15. A mobile unit; and
16. A community triage center.

NRS 449.0038 "Facility for intermediate care" defined. "Facility for intermediate care" means an establishment operated and maintained to provide 24-hour personal and medical supervision, for a person who does not have illness, disease, injury or other condition that would require the degree of care and treatment which a hospital or facility for skilled nursing is designed to provide.

NRS 449.0039 "Facility for skilled nursing" defined.

1. "Facility for skilled nursing" means an establishment which provides continuous skilled nursing and related care as prescribed by a physician to a patient in the facility who is not in an acute episode of illness and whose primary need is the availability of such care on a continuous basis.
2. "Facility for skilled nursing" does not include a facility which meets the requirements of a general or any other special hospital.

NRS 639.2806 Parenteral solutions: Limitation on sale and dispensing. A parenteral solution which is used by a patient in his or her home or in a facility for the dependent or a medical facility, other than a hospital as defined in NRS 449.012, may only be sold or dispensed:

1. By a pharmacy licensed in this state or a practitioner;
2. If the date of expiration is on its label; and
3. If a practitioner, registered pharmacist and a registered nurse are available at all times for immediate assistance to the patient in case of any pharmaceutical problems encountered in its use.

(Added to NRS by 1985, 867; A 1995, 295)

NRS 639.2807 Parenteral solutions: Compounding, packaging and labeling; regulations.

1. Any parenteral for use in a home or a facility for the dependent or a medical facility, other than a hospital as defined in NRS 449.012, must be compounded, packaged and labeled:

(a) By a registered pharmacist in a pharmacy or a practitioner licensed in this state. The practitioner shall ensure that the parenterals are delivered to the patient and are not available for use after the date of expiration.

(b) Pursuant to regulations adopted by the Board.

2. To maintain the stability of parenteral solutions, to prevent their contamination and that of the personnel of the practitioner and to ensure the quality and continuity of care for patients, the Board shall adopt regulations, to include:

(a) The procedures for the compounding, packaging, replacement and disposal of parenteral solutions;

(b) The conditions under which those solutions must be prepared, stored and delivered;

(c) The equipment required for the preparation, sterilization and storage of those solutions and the maintenance and cleaning of that equipment;

(d) The procedures for the proper disposal of any material used in the preparation of those solutions;

(e) The procedures for maintaining records and clinical monitoring of patients;

(f) The education and training of persons employed by practitioners; and

(g) The requirements for the education of patients relating to the use of parenterals.

(Added to NRS by 1985, 867; A 1989, 1123; 1995, 295)

NAC 639.476 Prepackaging of drugs. (NRS 639.070, 639.071, 639.072)

1. A pharmacy may prepackage drugs in quantities suitable for distribution within the facility or institution. The prepackaging may be performed only by a pharmacist or a pharmaceutical technician.

2. The label of a prepackaged unit must include:

(a) The generic or trade name of the drug, its strength and the dosage form;

(b) The lot number;

(c) The expiration date of the drug; and

(d) The quantity of the drug if the unit dose does not equal the unit of use.

3. A record of a prepackaged drug must be maintained that includes:

(a) The generic or trade name of the drug, its strength and the dosage form;

(b) The pharmacy's lot number;

(c) The name of the manufacturer;

(d) The manufacturer's lot number;

(e) The manufacturer's expiration date for the drug;

(f) The quantity per package, if more than one tablet or capsule is in a unit dose package;

(g) The number of packages;

(h) The date it was packaged and the assigned expiration date; and

(i) The initials of the responsible pharmacist.

4. Stock packages, prepackaged units and control records must be inspected by the pharmacist before the drugs may be included in regular stock.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91; 11-15-93)

NAC 639.515

1. A facility for skilled nursing or a facility for intermediate care may maintain a stock of the following drugs for emergency treatment for inpatients:

Analgesic-CII
Analgesic-non CII
Anesthetics, local
Antiarrhythmics
Antibiotics
Oral

Intravenous
Anticholinergic
Antidiarrheal
Antihistamine
Antihypertensive
Antinauseants
Antipsychotic
Bronchodilators
Calcium injectable
Dextrose injection
Diazepam
Digoxin
Diuretic injectable
Epinephrine
Glucagon
Heparin
Insulin
Intravenous solutions
Magnesium sulfate
Muscle relaxant
Naloxone
Nitroglycerin tablets
Normal saline
Phenobarbital
Phenytoin
Potassium chloride
Pressor amine
Protamine
Sodium bicarbonate
Steroids
Vitamin K
Water for injection

2. The quantity of each drug stocked must not exceed 20 units of each drug at each nursing station in the facility.
3. All drugs must be stored and maintained in unit dosages, if manufactured in that form.