ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R013-24

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

AUTHORITY: §§ 1, 2 and 4-6, NRS 639.070, 639.0727 and 639.074; § 3, NRS 639.070, 639.0727, 639.074 and 639.170.

A REGULATION relating to pharmacy; establishing the procedure for a registered nurse who is engaged in the performance of any public health program approved by the State Board of Pharmacy to obtain a certificate of registration to dispense dangerous drugs; establishing certain duties and limitations of such a registered nurse; prescribing the fees for the issuance and renewal of a certificate authorizing such a registered nurse to dispense dangerous drugs for human consumption; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes a registered nurse to dispense dangerous drugs when the nurse is engaged in the performance of any public health program approved by the State Board of Pharmacy. (NRS 454.215) Existing law authorizes the Board to adopt regulations as may be necessary to ensure that proper and adequate safeguards, including dispensing procedures, are followed to protect a registered nurse who participates in a public health program approved by the Board. (NRS 639.074)

Existing regulations require a practitioner who wishes to dispense controlled substances or dangerous drugs to apply to the Board on an application provided by the Board for a certificate of registration to dispense controlled substances or dangerous drugs. (NAC 639.742) **Section 1** of this regulation similarly requires a registered nurse who participates in a public health program approved by the Board and who wishes to dispense dangerous drugs to apply to the Board on an application provided by the Board for a certificate of registration. **Section 1** also sets forth certain limitations applicable to a registered nurse who is issued such a certificate of registration. **Section 3** of this regulation establishes the fees for the issuance or renewal of such a certificate, which are equal to the fees for the issuance or renewal of a certificate for other types of dispensing practitioners.

Existing regulations require a dispensing practitioner to: (1) counsel patients under certain circumstances; and (2) maintain certain records. (NAC 639.707, 639.708, 639.745)

Section 2 of this regulation includes registered nurses who have been issued a certificate pursuant to section 1 within the definition of "dispensing practitioner," thereby making those requirements applicable to such a registered nurse.

Sections 4 and 5 of this regulation make conforming changes to ensure that certain provisions of existing regulations are not in conflict with the provisions of **section 1**.

Section 6 of this regulation makes a conforming change relating to the discipline of a dispensing practitioner for a violation of the provisions of **section 1**.

- **Section 1.** Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:
- 1. A registered nurse who wishes to dispense dangerous drugs for human consumption pursuant to subsection 4 of NRS 454.215 must apply to the Board on an application provided by the Board for a certificate of registration to dispense dangerous drugs for human consumption. A certificate of registration issued pursuant to this section:
- (a) Entitles the registered nurse to dispense dangerous drugs for human consumption only when he or she is engaged in the performance of any public health program approved by the Board.
- (b) Must be renewed at the same time and in the same manner as certificates of registration by other practitioners.
- (c) Is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.
- 2. The operator of a public health program through which a registered nurse wishes to dispense dangerous drugs for human consumption pursuant to subsection 4 of NRS 454.215 must also submit an application to the Board on a form provided by the Board. The application must include, without limitation, a protocol for accomplishing the objective set forth in subsection 2 of NRS 454.00973. The Board will approve the protocol if:
 - (a) The applicant submits evidence that the protocol:
- (1) Has been developed or approved by the Division of Public and Behavioral Health of the Department of Health and Human Services; or

- (2) Has previously been approved by the Board; or
- (b) The Board determines that the protocol is designed to accomplish the objective set forth in subsection 2 of NRS 454.00973.
- 3. A registered nurse who is issued a certificate of registration pursuant to this section shall:
- (a) Ensure that all drugs are dispensed only to the patient personally at a facility or vehicle of the public health program;
- (b) Comply with all applicable requirements that apply to practitioners who are registered pursuant to NAC 639.742, including, without limitation, requirements concerning labeling, recordkeeping or counseling; and
- (c) Dispense drugs only in accordance with the protocol approved pursuant to subsection 2.
- 4. A registered nurse who is issued a certificate of registration pursuant to this section shall not:
 - (a) Prescribe a dangerous drug;
 - (b) Prescribe or dispense a controlled substance;
 - (c) Compound a drug product;
- (d) Employ or use the services of a dispensing technician or supervise a dispensing technician in training; or
 - (e) Operate a remote site.
- 5. As used in this section, "public health program" has the meaning ascribed to it in NRS 454.00973.
 - **Sec. 2.** NAC 639.010 is hereby amended to read as follows:

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

- 1. "Automated drug dispensing system" means a system that performs operations, other than compounding or administration, related to the storage and dispensing of drugs.
 - 2. "Board" means the State Board of Pharmacy.
 - 3. "Controlled substance" has the meaning ascribed to it in NRS 0.031.
 - 4. "Dangerous drug" has the meaning ascribed to it in NRS 454.201.
- 5. "Direct supervision" means the direction given by a supervising pharmacist or dispensing practitioner who is:
- (a) On the premises of the pharmacy or telepharmacy at all times when the person he or she is supervising is working at the pharmacy or telepharmacy or at a remote site or satellite consultation site; and
- (b) Aware of the activities of that person related to the preparation and dispensing of medications, including the maintenance of appropriate records.
 - 6. "Dispensing practitioner" means:
- (a) A practitioner to whom the Board has issued a certificate of registration pursuant to NAC 639.742 to dispense controlled substances or dangerous drugs, or both, for human consumption; [or]
- (b) A licensed veterinarian to whom the Board has issued a certificate of registration pursuant to NAC 639.7423 to dispense controlled substances or dangerous drugs, or both, not for human consumption $\{\cdot,\cdot\}$; or
- (c) A registered nurse to whom the Board has issued a certificate of registration pursuant to section 1 of this regulation to dispense dangerous drugs for human consumption.

- 7. "Dispensing technician" means a person who performs technical services in a pharmacy under the direct supervision of a dispensing practitioner and is registered with the Board pursuant to NAC 639.7425.
- 8. "Dispensing technician in training" means a person who is registered with the Board pursuant to NAC 639.7424 in order to obtain the training and experience required to be a dispensing technician pursuant to subparagraph (1) of paragraph (c) of subsection 2 of NAC 639.7425.
- 9. "Executive Secretary" means the Executive Secretary employed by the Board pursuant to NRS 639.040.
- 10. "Federally-qualified health center" has the meaning ascribed to it in 42 U.S.C. § 1396d(1)(2)(B).
- 11. "Federally-qualified health center vehicle" means a vehicle that meets the requirements of paragraph (c) of subsection 1 of NAC 639.7422.
 - 12. "Licensed veterinarian" has the meaning ascribed to it in NRS 638.007.
- 13. "Oncology group practice" means two or more dispensing practitioners who practice oncology in a group practice.
- 14. "Pharmaceutical technician" means a person who performs technical services in a pharmacy under the direct supervision of a pharmacist and is registered with the Board pursuant to NAC 639.240.
- 15. "Pharmaceutical technician in training" means a person who is registered with the Board pursuant to NAC 639.242 in order to obtain the training and experience required to be a pharmaceutical technician pursuant to subparagraph (3) of paragraph (d) of subsection 2 of NAC

639.240, or who is enrolled in a program of training for pharmaceutical technicians that is approved by the Board.

- 16. "Practitioner" has the meaning ascribed to it in NRS 639.0125.
- 17. "Prescription drug" means a drug or medicine as defined in NRS 639.007 which:
- (a) May be dispensed only upon a prescription order that is issued by a practitioner; and
- (b) Is labeled with the symbol "Rx only" pursuant to federal law or regulation.
- 18. "Public or nonprofit agency" means a health center as defined in 42 U.S.C. § 254b(a) which:
 - (a) Provides health care primarily to medically underserved persons in a community;
- (b) Is receiving a grant issued pursuant to 42 U.S.C. § 254b or, although qualified to receive such a grant directly from the Federal Government, is receiving money from such a grant under a contract with the recipient of that grant; and
 - (c) Is not a medical facility as defined in NRS 449.0151.
- 19. "Reproductive healthcare center" means a health facility owned and operated by a nonprofit corporation or a public health center, as defined in subsection 8 of NRS 449.260, principally engaged in providing family planning services and reproductive healthcare, including, without limitation, the testing, diagnosis and treatment of, or providing of medication to prevent, a sexually transmitted infection or other infection of the urogenital system.
- 20. "Surgical center for ambulatory patients" has the meaning ascribed to it in NRS 449.019.
- 21. "User-based access technology" means software or hardware that restricts access to an automated drug dispensing system to authorized users by requiring two-factor authentication.

Authentication factors may include, without limitation, knowledge, hardware tokens or biometric information.

Sec. 3. NAC 639.220 is hereby amended to read as follows:

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

For the examination of an applicant for registration as a pharmacist Actual cost
of the
examination
For the investigation or registration of an applicant as a registered
pharmacist\$200
For the investigation, examination or registration of an applicant as a
registered pharmacist by reciprocity
For the investigation or issuance of an original license to conduct a retail
pharmacy
For the biennial renewal of a license to conduct a retail pharmacy
For the investigation or issuance of an original license to conduct an
institutional pharmacy
For the biennial renewal of a license to conduct an institutional
pharmacy
For the investigation or issuance of an original license to conduct a
pharmacy in a correctional institution
For the biennial renewal of a license to conduct a pharmacy in a
correctional institution

For the investigation or issuance of an original license to conduct a	
pharmacy in a recovery center or ambulatory surgical center licensed	
pursuant to chapter 449 of NRS	
For the biennial renewal of a license to conduct a pharmacy in a	
recovery center or ambulatory surgical center licensed pursuant to	
chapter 449 of NRS	00
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	00
For the reinstatement of a lapsed registration (in addition to the fees for	
renewal for the period of lapse)	00
For the initial registration of a pharmaceutical technician,	
pharmaceutical technician in training, dispensing technician or	
dispensing technician in training	50
For the biennial renewal of registration of a pharmaceutical technician,	
pharmaceutical technician in training, dispensing technician or	
dispensing technician in training	50
For the investigation or registration of an intern pharmacist	40
For the biennial renewal of registration as an intern pharmacist	40
For the investigation or registration of an advanced practice registered	
nurse or a physician assistant to prescribe drugs that are not controlled	
substances	٥n

For the biennial renewal of registration of an advanced practice
registered nurse or a physician assistant to prescribe drugs that are not
controlled substances
For authorization of a physician, advanced practice registered nurse,
physician assistant, euthanasia technician, facility for treatment with
narcotics, researcher, instructional user or any other authorized
person, except a practitioner who is a medical intern or resident
physician, to prescribe or possess controlled substances
For the biennial renewal of authorization of a physician, advanced
practice registered nurse, physician assistant, euthanasia technician,
facility for treatment with narcotics, researcher, instructional user or
any other authorized person, except a practitioner who is a medical
intern or resident physician, to prescribe or possess controlled
substances
For authorization of a practitioner who is a medical intern or resident
physician to prescribe or possess controlled substances
For the biennial renewal of authorization of a practitioner who is a
medical intern or resident physician to prescribe or possess controlled
substances
For the investigation or issuance of an original license to engage in
business as an authorized warehouse or medical products provider 500
For the biennial renewal of a license to engage in business as an
authorized warehouse or medical products provider

For the investigation or issuance of an original license to a manufacturer
or wholesaler
For the biennial renewal of a license for a manufacturer or wholesaler
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
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
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
For authorization of a licensed veterinarian to dispense controlled
substances or dangerous drugs, or both, not for human consumption
For the biennial renewal of authorization of a licensed veterinarian to
dispense controlled substances or dangerous drugs, or both, not for
human consumption

For authorization of a registered nurse to dispense dangerous drugs
for human consumption while engaged in the performance of a
public health program approved by the Board
For the biennial renewal of authorization of a registered nurse to
dispense dangerous drugs for human consumption while engaged
in the performance of a public health program approved by the
Board
For the investigation or issuance of an original license for an automated
drug dispensing system
For the biennial renewal of a license for an automated drug dispensing
system
For the investigation or issuance of an original license to a pharmacy
authorizing the use of a mechanical device to furnish drugs and
medications for administration to patients at a medical facility
For the biennial renewal of a license to a pharmacy authorizing the use
of a mechanical device to furnish drugs and medications for
administration to patients at a medical facility

2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection 6 of NRS 639.170, is 50 percent of the renewal fee for each period of delinquency in addition to the renewal fee for each period of delinquency.

- 3. Any person who has been registered as a pharmacist in this State for at least 50 years is not required to pay the fee for the biennial renewal of a certificate of registration as a registered pharmacist.
- 4. The provisions of this section concerning the fee for the biennial renewal of the authorization to dispense controlled substances or dangerous drugs do not apply to an advanced practice registered nurse who is required to pay a fee pursuant to NAC 639.870.
 - 5. A practitioner employed by or serving as an independent contractor of a health center:
- (a) Which is a federally-qualified health center that provides health care primarily to medically underserved persons in a community; and
 - (b) Which is not a medical facility as defined in NRS 449.0151,
- → is not required to pay a fee to the Board for a change of address or for an additional address at which the practitioner dispenses drugs.
- 6. A practitioner who is exempt from the payment of a fee pursuant to subsection 5 shall notify the Board in writing of each change of address or additional address, or both.
- 7. In addition to any other fees paid by an applicant for a certificate, license or permit issued pursuant to chapter 639 of NRS, the Board may require that the applicant pay the actual costs of inspection incurred by the Board.
 - **Sec. 4.** NAC 639.742 is hereby amended to read as follows:
- 639.742 1. Except as otherwise provided in NAC 639.7421 and 639.7423 [,] and section 1 of this regulation, a practitioner who wishes to dispense controlled substances or dangerous drugs, or both, for human consumption must apply to the Board on an application provided by the Board for a certificate of registration to dispense controlled substances or dangerous drugs. A practitioner must submit a separate application for each site of practice, including, without

limitation, a telepharmacy, remote site or satellite consultation site, from which the practitioner wishes to dispense controlled substances or dangerous drugs, or both, for human consumption. A certificate of registration to dispense controlled substances or dangerous drugs, or both, for human consumption is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.

- 2. Except as otherwise provided in NAC 639.7421, 639.7422 and 639.7423 [,] and section 1 of this regulation, if a facility from which the practitioner intends to dispense dangerous drugs or controlled substances, or both, for human consumption is not wholly owned and operated by the practitioner, the owner or owners of the facility must also submit an application to the Board on a form provided by the Board.
- 3. Except as otherwise provided in this section and NRS 639.23277 and NAC 639.395, 639.648, 639.719 and 639.7423 [,] and section 1 of this regulation, the dispensing practitioner and, if applicable, the owner or owners of the facility and any federally-qualified health center vehicle, shall ensure that:
 - (a) All drugs are ordered by the dispensing practitioner;
 - (b) All drugs are received and accounted for by the dispensing practitioner;
- (c) All drugs are stored in a secure, locked room or cabinet to which the dispensing practitioner has the only key or lock combination;
 - (d) All drugs are dispensed in accordance with NAC 639.745;
- (e) No prescription is dispensed to a patient unless the dispensing practitioner is on-site at the facility or federally-qualified health center vehicle, as applicable;
- (f) All drugs are dispensed only to the patient personally at the facility or federally-qualified health center vehicle, as applicable;

- (g) The price of each drug dispensed to a patient is separately itemized on any bill or statement provided to the patient;
- (h) All drugs are dispensed only for medically necessary purposes and according to prevailing standards of care for practitioners practicing in the specialty claimed or practiced by the dispensing practitioner; and
- (i) The certificate for each dispensing technician employed at the facility is displayed in the room or cabinet in which drugs are stored.
- 4. Except as otherwise provided in NAC 639.648, 639.719, 639.7423 and 639.7424 [,] and section 1 of this regulation, with regard to the filling and dispensing of a prescription at a facility, only the dispensing practitioner or a dispensing technician may:
 - (a) Enter the room or cabinet in which drugs are stored;
 - (b) Remove drugs from stock;
 - (c) Count, pour or reconstitute drugs;
 - (d) Place drugs into containers;
 - (e) Produce and affix appropriate labels to containers that contain or will contain drugs;
 - (f) Fill containers for later use in dispensing drugs; or
 - (g) Package or repackage drugs.
- 5. Except as otherwise provided in NAC 639.7423 [,] and section 1 of this regulation, a dispensing practitioner may compound drug products if he or she complies with the provisions of NAC 639.661 to 639.690, inclusive, as if:
 - (a) He or she were a pharmacist;
 - (b) His or her practice site was a pharmacy; and
 - (c) Any dispensing technician involved in the compounding was a pharmaceutical technician.

- 6. Except as otherwise provided in subsection 6 of NAC 639.746, the dispensing practitioners of an oncology group practice or a group of practitioners practicing at a reproductive healthcare center registered pursuant to NAC 639.746 are jointly responsible for ensuring that the requirements of subsection 3 are met.
 - **Sec. 5.** NAC 639.744 is hereby amended to read as follows:
- 639.744 [A] Except as otherwise provided in section 1 of this regulation, a dispensing practitioner may employ more than one dispensing technician at a time, except that only one of those dispensing technicians, including, without limitation, a dispensing technician staffing a remote site or satellite consultation site, may be designated and allowed to perform the functions described in subsection 4 or 5 of NAC 639.742 at one time. A dispensing practitioner shall make and maintain a document on which must be recorded for each day the name of the dispensing technician so designated and allowed to perform the functions described in subsection 4 or 5 of NAC 639.742, and maintain the record for not less than 2 years.
 - **Sec. 6.** NAC 639.7445 is hereby amended to read as follows:
- 639.7445 If a dispensing practitioner allows any person to perform any act in violation of NAC 639.742 to 639.7445, inclusive, *and section 1 of this regulation*, the dispensing practitioner is subject to discipline relating to his or her registration as a dispensing practitioner, including, without limitation, the temporary and immediate suspension of his or her registration as a dispensing practitioner until:
 - 1. The violation is remedied; or
 - 2. If an accusation has been made pursuant to NRS 639.241, the Board holds a hearing.