

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

LCB File No. R087-22

August 8, 2022

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

AUTHORITY: § 1, NRS 453.221 and 639.070; § 2, NRS 639.070.

A REGULATION relating to controlled substances; authorizing a practitioner to dispense certain controlled substances without a certificate of registration to dispense controlled substances or dangerous drugs at a specific site; requiring such a practitioner to comply with certain labeling, recordkeeping and reporting requirements; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations relating to the registration and control of the dispensing of controlled substances. (NRS 453.221) Existing law requires every practitioner who dispenses a controlled substance to register with the Board. (NRS 453.226) Existing regulations further require a practitioner who dispenses controlled substances or dangerous drugs to obtain a certificate of registration for each site where he or she practices. (NAC 639.742) **Sections 1 and 2** of this regulation authorize a practitioner who is registered with the Board to dispense controlled substances and practices in a hospital or independent center for emergency medical care to dispense a controlled substance that has been federally approved for the treatment of opioid use disorder without a certificate of registration to dispense controlled substances or dangerous drugs at the specific site where he or she practices. **Section 1** requires such a practitioner to comply with: (1) certain federal regulations relating to prescribing a controlled substance; and (2) certain regulations concerning labeling, recordkeeping and reporting when a controlled substance is dispensed.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. A practitioner who is practicing in a hospital or independent center for emergency medical care may dispense a controlled substance that has been approved by the United States Food and Drug Administration for the treatment of opioid use disorder without registering

pursuant to NAC 639.742 if the practitioner is registered to dispense controlled substances pursuant to NRS 453.226.

2. A practitioner who dispenses a controlled substance that has been approved by the United States Food and Drug Administration for the treatment of opioid use disorder shall comply with:

(a) 21 C.F.R. Parts 1306 and 1307;

(b) Any requirements concerning labeling or recordkeeping that apply to practitioners who are registered pursuant to NAC 639.742; and

(c) The requirements of NAC 639.926 concerning the transmission of information to the Board.

3. A pharmacist who is employed by a hospital or independent center for emergency medical care may assist a practitioner in the dispensing of the controlled substance pursuant to this section.

4. As used in this section, “independent center for emergency medical care” has the meaning ascribed to it in NRS 449.013.

Sec. 2. NAC 639.742 is hereby amended to read as follows:

639.742 1. Except as otherwise provided in NAC 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 639.7423, section 3 of LCB File No. R004-19 *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 NRS 639.23277 and NAC 639.395, 639.648 and 639.7423, 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 and 639.7423, 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, 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.