PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

LCB FILE NO. R181-22I

The following document is the initial draft regulation proposed by the agency submitted on 08/03/2022

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop July 14, 2022

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: §§1-3, NRS 639.070.

A REGULATION relating to pharmacy; establishing the requirements for a group of practitioners practicing at a reproductive healthcare center to obtain a certificate of registration from the State Board of Pharmacy to maintain a single inventory of certain dangerous drugs received at a site of practice; prescribing the procedure for renewing such a certificate; prescribing certain powers and duties of the dispensing practitioners; and providing other matters properly relating thereto.

Section 1. **Section 1 of LCB File No. R007-21AP** is hereby amended to read as follows:

1. An oncology group practice or a group of practitioners practicing at a reproductive healthcare center that wishes to maintain a single inventory of dangerous drugs, excluding compounded drug products, received at a site of practice in lieu of maintaining separate inventories for each dispensing practitioner of the oncology group practice or group of practitioners practicing at a reproductive healthcare center must apply to the Board on an application provided by the Board for a certificate of registration and submit the fee prescribed in NAC 639.220 for authorization of a practitioner, other than a licensed veterinarian, to dispense dangerous drugs. An oncology group practice or a group of practitioners practicing at a reproductive healthcare center must submit a separate application and fee for each site of practice at which the oncology group practice or group of practitioners practicing at a reproductive healthcare center wishes to maintain a single inventory of dangerous drugs, excluding compounded drug products.

2. Upon receipt of a fee and approval of an application, the Board will issue a certificate of registration to an oncology group practice or a group of practitioners practicing at a reproductive healthcare center.

3. To renew a certificate of registration, an oncology group practice or a group of practitioners practicing at a reproductive healthcare center must submit to the Board another completed application and the fee prescribed in NAC 639.220 for biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense dangerous drugs.

4. A certificate of registration issued pursuant to this section:

(a) Entitles the oncology group practice or a group of practitioners practicing at a reproductive healthcare center to maintain a single inventory of dangerous drugs, excluding compounded drug products, at the site of practice for which the oncology group practice or group of practitioners practicing at a reproductive healthcare center received certification.

(b) Is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.

5. An oncology group practice or a group of practitioners practicing at a reproductive healthcare center registered pursuant to this section shall provide written notice to the Board of the addition to or removal of a dispensing practitioner from the oncology group practice or group of practitioners practicing at a reproductive healthcare center not later than 15 days after the addition or removal, as applicable.

6. A dispensing practitioner of an oncology group practice or a group of practitioners practicing at a reproductive healthcare center registered pursuant to this section:

(a) May dispense any dangerous drug accounted for in the single inventory of the oncology group practice or group of practitioners practicing at a reproductive healthcare center.

(b) Shall ensure that he or she complies with the requirements prescribed by NAC 639.745, including, without limitation, maintaining separate records of each dangerous drug dispensed by him or her.

7. As used in this section:

(a) "Compounded" has the meaning ascribed to "compound" and "compounding" in NAC 639.6625.

(b) "Drug product" has the meaning ascribed to it in NAC 639.6631.

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. "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. "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.

6. "Executive Secretary" means the Executive Secretary employed by the Board pursuant to NRS 639.040.

7. "Federally-qualified health center" has the meaning ascribed to it in 42 U.S.C. § 1396d(l)(2)(B).

8. "Federally-qualified health center vehicle" means a vehicle that meets the requirements of paragraph (c) of subsection 1 of section 3 of LCB File No.R004-19.

9. “Licensed veterinarian” has the meaning ascribed to it in NRS 638.007.

10. ***“Oncology group practice” means two or more dispensing practitioners who practice oncology in a group practice.***

11. “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.

[11.] ***12.*** “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 (c) 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.

[12.] ***13.*** “Practitioner” has the meaning ascribed to it in NRS 639.0125.

[13.] ***14.*** “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.

[14.] ***15.*** “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.

16. “Reproductive healthcare center” means a health facility owned and operated by a non-profit corporation, or a public health center as defined in NRS 449.260(8), principally engaged in providing family planning services and reproductive healthcare, including the testing, diagnosis, treatment of, or medication to prevent a sexually transmitted infection or

other infection of the urogenital system.

17. "Surgical center for ambulatory patients" has the meaning ascribed to it in NRS 449.019.

Sec. 3. NAC 639.742 is hereby amended to read as follows:

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

3. 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.

4. Except as otherwise provided in this section and 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.

5. 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.

6. 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.

7. Except as otherwise provided in subsection 6 of section 1 of this regulation, the dispensing practitioners of an oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** registered pursuant to section 1 of this regulation are jointly responsible for ensuring that the requirements prescribed by subsection 3 are met.