

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

**LCB FILE NO. R180-22I**

**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, NRS 639.070; § 2, NRS 639.0727

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

1. *Except as otherwise provided in this section, one or more registered dispensing practitioners practicing at a reproductive healthcare center may use an automated drug dispensing system and maintain a shared inventory in the automated drug dispensing system to dispense a prescription drug to a patient if the reproductive healthcare center obtained a license from the Board for the automated drug dispensing system.*
2. *The Board will provide to a reproductive healthcare center an application for a license for an automated drug dispensing system upon request. The Board will issue a license for an automated drug dispensing system if the application for a license is approved and the requisite fee is paid. A license must be:*
  - a. *Issued for each automated drug dispensing system at a designated location; and*
  - b. *Posted on the system so that the license is visible to the public.*
3. *The automated drug dispensing system must conform to all the following provisions:*
  - a. *The system must contain only dangerous drugs, excluding compounded drug products, for treatment in reproductive health care:*
    - i. *Approved for use in the system by a registered dispensing practitioner;*
    - ii. *For which counseling is not required pursuant to NAC 639.707 unless the system uses user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate, in real time, with the registered dispensing practitioner who prescribed the drug who has access to any*

*patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708 or unless the dispensing practitioner is available at the site when dispensing of the drug occurs for counseling the patient in compliance with NAC 639.707 and 639.708; and*

*iii. For which the prescription has been processed, verified, and completed in the same manner as prescriptions for drugs that are delivered manually by a dispensing practitioner pursuant to NAC 639.742, except for section 3(e), and NAC 639.745.*

*b. The system must not contain:*

*i. Controlled substances included in schedules II, III, IV and V.*

*c. The system must:*

*i. Control and track access to the system for stocking, cleaning, maintenance, or any other purpose so that access to the system can be obtained only by a registered dispensing practitioner practicing at the reproductive healthcare center.*

*ii. Be secure from unauthorized access to and removal of prescription drugs.*

*iii. Be owned or leased by the reproductive healthcare center who obtained the license for the automated drug dispensing system and operated under the supervision and control of that reproductive healthcare center.*

*iv. Monitor the temperature of the system or be able to have a device installed to monitor the temperature of the system, including, without limitation, an alarm that records when the temperature of the system reaches a level outside the range compatible with the proper storage of a prescription drug and a method to notify the reproductive healthcare center of the temperature change.*

*v. Create and maintain a complete, accurate and readily retrievable record of all transactions. The record must include, without limitation:*

*1. The name, strength, quantify and form of dosage of each prescription drug stocked, inventoried, removed or dispensed from the system;*

2. *Each day and time the system is accessed;*
  3. *An inventory of the prescription drugs stored in the system; and*
  4. *The identify of each person who accesses the system.*
- vi. *Restrict access to a patient who indicated to the dispensing practitioner who prescribed the drug that the patient desires that his or her prescription drugs be dispensed by the system.*
- vii. *Provide a method to identify the patient and dispense a prescription drug only to the patient or to an authorized agent of the patient.*
- viii. *Dispense one, any combination or all the prescription drugs available to a patient at the option of the patient at the time that the patient removes the prescription drugs from the system.*
- ix. *Record the date and time that the patient removes the prescription drugs from the system.*
- x. *Inform a patient:*
1. *If the patient is using the system at the time that the reproductive healthcare center is open, that the patient may discuss questions and concerns regarding the prescription with the dispensing practitioner in person if available or through user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate, in real time, with the dispensing practitioner who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.*
  2. *If the patient is using the system at the time that the reproductive healthcare center is closed that the patient may discuss questions and concerns regarding the prescription drug through user-based access technology that includes, without limitation, an audio-visual function that*

*allows the patient to communicate, in real time, with the dispensing practitioner who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.*

*3. That the patient may choose not to purchase the prescription drug from the system at any time before the system dispenses the prescription drug.*

*xi. Dispense all prescription drugs in containers labeled in conformance with NRS 639.2801.*

*xii. Be installed at the reproductive healthcare center in such a place and manner that a person is unable to remove the system from its location or obtain access to the device without authorization. The system must be monitored by real-time audio-visual recording technology.*

*xiii. Be approved for use by the Board upon determination that the system:*

*1. Dispenses prescription drugs accurately; and*

*2. Otherwise satisfies the provisions of this section.*

*4. A registered dispensing practitioner that dispenses prescription drugs by an automated drug dispensing system pursuant to this section shall maintain a written policy that sets forth:*

*a. The duties of all persons who are authorized to access the system; and*

*b. The procedure for:*

*i. Maintaining the security of the prescription drugs stored in the system during the maintenance and repair of the system;*

*ii. The preparation of an inventory of the prescription drugs stored in the system; and*

*iii. Stocking the system with prescription drugs.*

*5. A registered dispensing practitioner practicing at the reproductive healthcare center that dispenses prescription drugs through an automated drug dispensing system pursuant to this section shall comply with all applicable federal and state recordkeeping requirements and shall maintain those records in a readily retrievable manner separate from other medical records.*

6. *Prescription drugs stored in an automated drug dispensing system pursuant to this section shall be deemed part of the inventory of the dispensing practitioner and the responsibility of the dispensing practitioner that use the automated drug dispensing system at the reproductive healthcare center that was issued the license for the system.*
7. *The Board may prohibit the reproductive healthcare center from using a system to furnish a prescription drug to a patient if the Board determines that the system or that one or more dispensing practitioners' use of the system does not comply with this section.*
8. *The provisions of this section do not prohibit the use of a system to furnish a drug or device that is approved by the Food and Drug Administration for sale over the counter without a prescription if the reproductive healthcare center using the system is otherwise authorized to use the system pursuant to this section.*
9. *As used in this section:*
  - a. *“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.*