

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

LCB File No. R179-22

August 24, 2022

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

AUTHORITY: § 1, NRS 639.070 and 639.2655.

A REGULATION relating to pharmacy; authorizing the operation of an automated drug dispensing system at sites of certain governmental agencies; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations: (1) relating to the practice of pharmacy as necessary for the protection of the public; and (2) governing the dispensing, recordkeeping, storage and handling of drugs. (NRS 639.070) Existing law further authorizes the use of computerized mechanical equipment to perform work that a pharmacist is required to perform by law in accordance with the regulations adopted by the Board. (NRS 639.2655)

Existing regulations establish the requirements for a pharmacy to obtain a license to operate an automated drug dispensing system. Such requirements include limitations on the location at which an automated drug dispensing system may operate. (NAC 639.718) This regulation authorizes an automated drug dispensing system to be located at a site operated by the Division of Public and Behavioral Health of the Department of Health and Human Services or a local health department if the system is operated by a pharmacy owned by the Division or local health department, as applicable.

Section 1. NAC 639.718 is hereby amended to read as follows:

639.718 1. Except as otherwise provided in this section, a pharmacy may use an automated drug dispensing system to dispense a prescription drug to a patient if the pharmacy obtains a license from the Board for the automated drug dispensing system pursuant to subsection 2.

2. The Board will provide to a pharmacy 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 Board determines that the system dispenses prescription drugs accurately and otherwise meets the requirements of this section and the fee prescribed by NAC 639.220 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 of the following provisions:

(a) The system must contain only prescription drugs:

- (1) Approved for use in the system by a registered pharmacist employed by the pharmacy;

and

(2) For which the prescriptions have been processed, verified and completed in the same manner as prescriptions for drugs that are delivered manually by the pharmacy, including the provision of printed medication guides and any other information required pursuant to NAC 639.707.

(b) The system must not contain:

- (1) Controlled substances included in schedule II; or

(2) Controlled substances included in schedules III, IV and V, unless authorized by the Drug Enforcement Administration of the United States Department of Justice to dispense such substances.

(c) The system must:

(1) Control and track access to the system for stocking, cleaning, maintenance or any other purpose to ensure that access to the system can be obtained only by a registered pharmacist,

pharmaceutical technician, or intern pharmacist employed by the pharmacy using user-based access technology.

(2) Be secure from unauthorized access to and removal of prescription drugs.

(3) Be owned or leased by the pharmacy that holds the license for the system and operated under the supervision and control of that pharmacy.

(4) Monitor the temperature of the system or be able to have a device installed to monitor the temperature of the system. Such monitoring must include, 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 pharmacy of the temperature change.

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

(I) The name, strength, quantity and form of dosage of each prescription drug stocked, inventoried, removed or dispensed from the system;

(II) Each day and time the system is accessed;

(III) An inventory of the prescription drugs stored in the system; and

(IV) The identity of each person who accesses the system.

(6) Authorize access only to patients who previously have indicated to the pharmacy their desire to have their prescription drugs dispensed by the system.

(7) Provide a method to identify the patient and dispense a prescription drug only to the patient or to an authorized agent of the patient.

(8) Dispense one, any combination or all of 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.

(9) Record the date and time that the patient removes the prescription drugs from the system.

(10) Inform a patient:

(I) If the patient is using the system at the time that the pharmacy is open, that the patient may discuss questions and concerns regarding the prescription drug with a pharmacist at the pharmacy or through the user-based access technology described in subparagraph (14).

(II) If the patient is using the system at the time that the pharmacy is closed, that the patient may discuss questions and concerns regarding the prescription drug through the user-based access technology described in subparagraph (14).

(III) That the patient may choose not to purchase the prescription drug from the system at any time before the system dispenses the prescription drug.

(11) Dispense all prescription drugs in containers labeled in conformance with NRS 639.2801.

(12) Be installed in such a place and manner that a person is unable to remove the system from its location and any attempts to obtain access to the system without authorization are visible to the pharmacist of the pharmacy, either through the system being in view of the pharmacist or by real-time audio-visual communication technology or audio-visual recording technology.

(13) Be located in a:

(I) Pharmacy;

(II) Medical facility, as defined in NRS 449.0151, other than a mobile unit; ~~for~~

(III) Practice site of one or more practitioners of medicine  ; or

(IV) Site operated by the Division of Public and Behavioral Health of the Department of Health and Human Services or a district, county or city health department. The system may only be located at such a site if the pharmacy that operates the system is owned by the same governmental agency that operates the site.

(14) Be equipped with user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate, in real time, with a registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.

4. A pharmacy 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 procedures for:

(1) Maintaining the security of the prescription drugs stored in the system during the maintenance and repair of the system;

(2) The preparation of an inventory of the prescription drugs stored in the system; and

(3) Stocking the system with prescription drugs.

5. A pharmacy 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 pharmacy records.

6. Prescription drugs stored in an automated drug dispensing system pursuant to this section shall be deemed part of the inventory and the responsibility of the pharmacy that holds the

license for the system. Prescription drugs dispensed from the system shall be deemed to have been dispensed by that pharmacy.

7. The Board may prohibit a pharmacy from using an automated drug dispensing system to furnish a prescription drug to a patient if the Board determines that the system or the pharmacy's use of the system does not comply with this section.

8. The provisions of this section do not prohibit the use of an automated drug dispensing 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 pharmacy using the system is otherwise authorized to use the system pursuant to this section.

9. As used in this section:

(a) "Automated drug dispensing system" means a system that performs operations, other than compounding or administration, related to the storage and dispensing of drugs.

(b) "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.