ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R180-22

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

AUTHORITY: §§ 1-5 and 7-11, NRS 639.070 and 639.0727; § 6, NRS 639.070.

A REGULATION relating to pharmacy; authorizing a reproductive healthcare center to obtain a license to distribute certain drugs using an automated drug dispensing system; prescribing requirements governing the use of such a system; requiring a dispensing practitioner to provide certain information to a patient to whom a drug is dispensed and maintain certain records; 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 requires the Board to adopt regulations setting forth the powers and duties of a dispensing practitioner. (NRS 639.0727) Existing regulations define the term "dispensing practitioner" to mean a practitioner to whom the Board has issued a certificate of registration to dispense controlled substances or dangerous drugs. (NAC 639.010) Lastly, existing regulations: (1) authorize a pharmacy to operate an automated drug dispensing system if the pharmacy has obtained a license for the system from the Board; and (2) establish the requirements governing the operation of an automated drug dispensing system. (NAC 639.718)

Section 1 of this regulation: (1) authorizes a reproductive healthcare center to obtain a license to use an automated drug dispensing system to dispense prescription drugs related to reproductive health care; and (2) establishes requirements that a reproductive healthcare center must follow when using such an automated drug dispensing system, which are similar to those that currently apply to a pharmacy. **Section 1** requires an automated drug dispensing system to track: (1) who uses the system; (2) what drugs are in the system; (3) the temperature of the system; and (4) other information to ensure that the drugs in the system are safely stored and only dispensed to a person authorized to receive the dispensed drug. **Sections 2 and 6** of this regulation make conforming changes to ensure that certain terms used in **section 1** are defined in the same manner throughout chapter 639 of NAC. **Sections 5, 7 and 8** of this regulation make conforming changes to ensure that certain provisions of existing regulations are not read to conflict with the provisions of **section 1**.

Existing regulations: (1) require a pharmacist to provide certain information to a patient concerning a drug being dispensed to the patient by the pharmacist; (2) require a pharmacist to consider the therapeutic appropriateness of dispensing the drug to the patient; (3) prescribe requirements concerning the documentation of counseling of a patient by a pharmacist; and (4)

prescribe procedures for the maintenance of such records by a pharmacy. (NAC 639.707, 639.708) **Sections 3 and 4** of this regulation expand applicability of these requirements to also apply to a dispensing practitioner. **Sections 9 and 10** of this regulation make conforming changes to reflect the expanded applicability of a requirement concerning a determination of the therapeutic appropriateness of a prescription.

Section 11 of this regulation provides that an automated drug dispensing system licensed to a reproductive healthcare center is not a computerized system to fill prescriptions, and is thus not subject to requirements governing such a computerized system. (NAC 639.940)

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

1. Except as otherwise provided in this section, one or more 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 obtains a license from the Board for the automated drug dispensing system pursuant to subsection 2.

2. The Board will provide an application for a license for an automated drug dispensing system to a reproductive healthcare center 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 reproductive healthcare center; 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) Except as otherwise provided in subsection 8, the system must contain only dangerous drugs, excluding compound drug products, for treatment in reproductive health care:

(1) Approved for use in the system by a dispensing practitioner; and

(2) For which the prescription has been processed, verified and completed in the same manner as a prescription for drugs that are delivered manually by a dispensing practitioner pursuant to NAC 639.742 and 639.745, except that the requirements of paragraph (e) of subsection 3 of NAC 639.742 do not apply.

(b) 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 dispensing practitioner practicing at the reproductive healthcare center.

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

(3) Be owned or leased by the reproductive healthcare center that obtained the license for the system and operated under the supervision and control of that reproductive healthcare center.

(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 reproductive healthcare center 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 have previously indicated to the dispensing practitioner who prescribed the drug 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 reproductive healthcare center is open, that the patient may discuss questions and concerns regarding the prescription drug with the dispensing practitioner in person, if available, or through user-based access technology described in subparagraph (13).

(II) 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 the user-based access technology described in subparagraph (13).

(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 or obtain access to the system without authorization. The system must be monitored by real-time audio-visual technology or audio-visual recording technology.

(13) 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 dispensing practitioner who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.

4. A reproductive healthcare center 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 dispensing practitioner practicing at a 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 and the responsibility of each dispensing practitioner that uses the automated drug dispensing system at the reproductive healthcare center that holds the license for the system. Prescription drugs dispensed from the system shall

be deemed to have been dispensed by that dispensing practitioner or those dispensing practitioners, as applicable.

7. The Board may prohibit a reproductive healthcare center from using an automated drug dispensing system to furnish a prescription drug to a patient if the Board determines that the system, or 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 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 reproductive healthcare center using the system is otherwise authorized to use the system pursuant to this section.

9. As used in this section, "reproductive healthcare center" means a health care facility that is:

(a) Owned and operated by a nonprofit corporation or a public health center, as defined in subsection 8 of NRS 449.260; and

(b) Principally engaged in providing family planning services and reproductive health care, including, without limitation, the testing, diagnosis and treatment of, or providing of medication to prevent sexually transmitted infections or other infections of the urogenital system.

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.

~~[2.]~~ ***3.*** "Controlled substances" has the meaning ascribed to it in NRS 0.031.

~~[3.]~~ ***4.*** "Dangerous drug" has the meaning ascribed to it in NRS 454.201.

~~[4.]~~ ***5.*** "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.]~~ ***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.

~~[6.]~~ ***7.*** "Executive Secretary" means the Executive Secretary employed by the Board pursuant to NRS 639.040.

~~[7.]~~ ***8.*** "Federally-qualified health center" has the meaning ascribed to it in 42 U.S.C. § 1396d(l)(2)(B).

~~[8.]~~ ***9.*** "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.]~~ ***10.*** "Licensed veterinarian" has the meaning ascribed to it in NRS 638.007.

~~[10.]~~ ***11.*** "Oncology group practice" means two or more dispensing practitioners who practice oncology in a group practice.

~~[11.]~~ ***12.*** "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.

~~[12.]~~ ***13.*** "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.

~~[13.]~~ ***14.*** "Practitioner" has the meaning ascribed to it in NRS 639.0125.

~~[14.]~~ ***15.*** "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.

~~[15.]~~ ***16.*** "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.]~~ ***17.*** "Surgical center for ambulatory patients" has the meaning ascribed to it in NRS 449.019.

18. "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 639.707 is hereby amended to read as follows:

639.707 1. Except as otherwise provided in this section, a pharmacist ***,*** ~~[or]~~ an intern pharmacist under the supervision of a pharmacist ***or a dispensing practitioner*** shall verbally provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient that:

(a) Has not been previously dispensed to the patient from that pharmacy ~~[,]~~ ***or dispensing practitioner, as applicable;*** or

(b) Has been previously dispensed to the patient from that pharmacy ~~[,]~~ ***or dispensing practitioner, as applicable,*** including, without limitation, a prescription drug or a device that is being refilled, if, in the professional judgment of the pharmacist ***,*** ~~[or]~~ intern pharmacist ~~[:]~~ ***or dispensing practitioner:***

(1) The information would further or improve the drug therapy of the patient; or

(2) A reasonable concern relating to the safety or efficacy of the drug therapy of the patient was raised by the review of the patient's record that the pharmacist ***,*** ~~[or]~~ intern pharmacist ***or dispensing practitioner*** conducted pursuant to subsection 4.

2. The information provided by the pharmacist ***,*** ~~[or]~~ intern pharmacist ***or dispensing practitioner*** pursuant to subsection 1 may include, without limitation:

(a) The name and a description of the drug;

(b) The form of dosage, dose, route of administration and duration of drug therapy;

(c) The intended use of the drug or device and expected responses from that use;

(d) Any special directions and precautions for the preparation, administration and use of the drug or device by the patient;

(e) Any common severe side effects, interactions and contraindications that may occur, recommendations to avoid these side effects, interactions or contraindications, and the action required if they occur;

(f) Techniques for the patient or the person caring for the patient to monitor the drug therapy;

(g) Proper storage of the drug or device;

(h) Information about refilling the prescription;

(i) Actions to be taken in the event of a missed dose;

(j) Any relevant information contained in the record of medication of the patient; and

(k) Any other information which, in the professional judgment of the pharmacist ***,*** ~~[or]~~ intern pharmacist ~~[,]~~ ***or dispensing practitioner,*** is necessary to ensure the safe and effective use of the drug or device by the patient.

3. The pharmacist or intern pharmacist shall provide the information required pursuant to subsections 1 and 2 in written form to the patient if a drug or device will be distributed to the patient outside the confines of the pharmacy by mail or any other delivery service. A pharmacist or intern pharmacist is not required to provide written information pursuant to this subsection if the drug or device is being delivered to a patient who is in a licensed medical facility where other licensed health care professionals are authorized to administer drugs.

4. The pharmacist ***,*** ~~[or]~~ intern pharmacist ***or dispensing practitioner*** shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness and, in making that determination, may consider, without limitation:

(a) Overutilization of the drug and drug abuse;

(b) Underutilization of the drug;

(c) Therapeutic duplications, contraindications and any warning labels or other information included with the drug;

(d) Interactions between the drug and any:

(1) Other drugs which the patient is taking or has recently taken;

(2) Diseases which the patient has, including any stages of that disease; and

(3) Allergies that the patient may have; and

(e) Incorrect dosage or duration of treatment.

5. A pharmacist ***,*** ~~[or]~~ intern pharmacist ***or dispensing practitioner*** is not required to counsel a patient pursuant to this section if the patient or a person caring for the patient refuses to accept the counseling.

6. Except as otherwise provided in subsection 7, the pharmacist ***,*** ~~[or]~~ intern pharmacist ***or dispensing practitioner*** shall, at the time that counseling is provided or refused:

(a) Initial a written document that is maintained at the pharmacy ***or at the primary place of business of the dispensing practitioner*** to record whether counseling was provided to or refused by a patient or the person caring for the patient; or

(b) Enter, pursuant to NAC 639.751, initials onto a record in a computerized system used by the pharmacy ***or dispensing practitioner, as applicable,*** for recording information concerning prescriptions to indicate whether counseling was provided to or refused by a patient or the person caring for the patient.

7. The pharmacist ***,*** ~~[or]~~ intern pharmacist ***or dispensing practitioner*** is not required to comply with the provisions of subsection 6 if the prescription drug or device dispensed to the patient is being refilled.

Sec. 4. NAC 639.708 is hereby amended to read as follows:

639.708 To facilitate counseling regarding a prescription, a pharmacy ***or dispensing practitioner*** shall:

1. Maintain a record of medication for each patient to whom a prescription has been dispensed by that pharmacy ~~[.]~~ ***or dispensing practitioner, as applicable.*** The record must:

(a) Be retrievable for use by the pharmacist ~~[;]~~ ***or dispensing practitioner;***

(b) Be maintained for at least 2 years after the most recent entry;

(c) List all prescriptions dispensed to the patient at that pharmacy ~~[;]~~ ***or by the dispensing practitioner;*** and

(d) Include all data required to be placed on the prescription.

2. Make a reasonable effort to obtain and retain in the record of medication the:

(a) Telephone number or numbers, if any, of the patient;

(b) Gender of the patient;

(c) Age or date of birth of the patient;

(d) History of the patient, including allergies, reactions to particular drugs and any medications or medical devices used by the patient; and

(e) Any comments relevant to the drug therapy of the patient, including any other information which is specific to the patient or drug.

3. Ensure that a pharmacist ***or dispensing practitioner who has access to the medical records of the patient*** is available by telephone during business hours and, ~~[if the]~~ ***for a***

pharmacy ***that*** routinely delivers prescriptions outside of the trade area covered by local telephone service, provide a toll-free telephone number.

4. Include with each prescription container ***of a pharmacy that is*** delivered or distributed by a public carrier:

(a) The local, and if applicable toll-free, telephone numbers of the pharmacy;

(b) The hours during which the patient may contact the pharmacy by telephone; and

(c) A written notice in substantially the following form:

> Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available between the hours of ..... and ..... to answer your questions.

5. Maintain the confidentiality of each patient's records, including prescriptions, pursuant to NRS ***449A.112 or*** 639.238 ~~[.]~~ ***, as applicable.*** A pharmacist ***or dispensing practitioner*** shall not divulge the contents of a patient's records, except as authorized by NRS 639.238 ~~[.]~~ ***or any other applicable provision of law.***

6. Make available to a practitioner, upon request, all information relating to a prescription that is provided to a patient of that practitioner by the pharmacist ***,*** ~~[or]~~ an intern pharmacist ~~[.]~~ ***or a dispensing practitioner.***

7. Ensure that counseling is conducted in a confidential manner to prevent disclosure of information to any person other than the patient or the person caring for the patient.

Sec. 5. NAC 639.715 is hereby amended to read as follows:

639.715 No drug, controlled substance, medicine, chemical or poison, as those terms are defined in chapters 453, 454 and 639 of NRS, may be sold or offered for sale or dispensed by means of any mechanical device except as otherwise provided in NAC 639.718 and 639.720 ~~[.]~~ ***and section 1 of this regulation.***

Sec. 6. 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 ~~[other]~~ 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; or

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

(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.]~~

Sec. 7. NAC 639.720 is hereby amended to read as follows:

639.720 1. Except as otherwise provided in this section, a mechanical device, other than an automated drug dispensing system licensed pursuant to NAC 639.718 ~~,~~ ***or section 1 of this regulation,*** may be used to furnish drugs and medicines for administration to registered patients in a medical facility if the pharmacy which supplies drugs and medicines to the medical facility has obtained a license from the Board for a mechanical device pursuant to subsection 4. A license is not required for a mechanical device that meets the requirements of this section and is located inside a hospital licensed pursuant to chapter 449 of NRS.

2. The mechanical device must conform to all the following provisions:

(a) All drugs and medicines stocked in the device must be approved for use in the device by a registered pharmacist employed by the:

(1) Medical facility in which the drug or medicine is administered; or

(2) Pharmacy that supplies the medical facility in which the drug or medicine is administered.

(b) Access to the device must be:

(1) Limited to pharmaceutical technicians, pharmaceutical technicians in training, intern pharmacists, registered pharmacists, licensed practical nurses, registered nurses or other practitioners who are:

(I) Authorized by law to prescribe or administer controlled substances, poisons, or dangerous drugs and devices; and

(II) Employed by the medical facility or pharmacy that supplies the medical facility.

(2) Monitored and controlled by the pharmacy which supplies the medical facility or the registered pharmacist who is employed by the medical facility.

(c) Each container of a drug or medicine stored in the device must be labeled in a manner which includes the information required pursuant to subsection 2 of NAC 639.476.

(d) The device must be designed in such a manner that:

(1) Each time a person obtains access to the device, the device automatically prepares a record which is readily retrievable and which includes:

(I) The name, strength, quantity and form of dosage of the drug or medicine which is stocked, inventoried or removed for administration to a patient;

(II) The day and time access to the device is obtained;

(III) If a drug or medicine is removed for administration to a patient, the name of the patient;

(IV) An inventory of the drugs and medicines stored in the device; and

(V) The name of the person who obtained access to the device.

(2) Access to the device may be obtained only by a person with the use of a code which identifies that person.

3. A pharmacy which supplies drugs and medicines to a medical facility which are furnished by a mechanical device pursuant to subsection 1 shall maintain a written policy which sets forth:

(a) The duties of all persons who are authorized to obtain access to the device; and

(b) The procedure for:

(1) Maintaining the security of the drugs and medicines stored in the device during the maintenance and repair of the device;

(2) The preparation of an inventory of the drugs and medicines stored in the device; and

(3) Stocking the device with drugs and medicines.

4. The Board will issue a license for a mechanical device if the Board determines that the mechanical device meets the requirements of this section and the fee required by NAC 639.220 is paid. A license authorizes the use of the mechanical device at the medical facility at which the mechanical device is located.

5. Each medical facility that uses a mechanical device pursuant to subsection 1 must make and maintain a record of any waste of a controlled substance in the manner provided in NAC 639.486. The record of any waste of a controlled substance may be prepared:

(a) By the mechanical device if the mechanical device is capable of making and maintaining such a record and documenting the record of the waste being witnessed by another person as provided in paragraph (g) of subsection 1 of NAC 639.486; or

(b) As a written record.

6. A mechanical device may be used to furnish drugs and medicines for administration to a patient receiving treatment in the emergency room of a hospital. The device must conform to all the following provisions:

(a) All drugs and medicines stocked in the device must be approved for use in the device by a registered pharmacist employed by or contracted with the:

(1) Hospital in which the drug or medicine is furnished; or

(2) Pharmacy that supplies the hospital in which the drug or medicine is furnished.

(b) Access to the device for the purposes of stocking, inventory and monitoring must be limited to pharmaceutical technicians, pharmaceutical technicians in training, intern pharmacists or registered pharmacists employed by the hospital or the pharmacy that supplies the hospital.

(c) The device must be designed in such a manner that:

(1) Each time a person obtains access to the device, the device automatically prepares a record which is readily retrievable and which includes:

(I) The name, strength, quantity and form of dosage of the drug or medicine which is stocked, inventoried or removed for administration to a patient;

(II) The day and time access to the device is obtained;

(III) If a drug or medicine is removed for administration to a patient, the name of the patient;

(IV) An inventory of the drugs and medicines stored in the device; and

(V) The name of the person who obtained access to the device.

(2) Access to the device may be obtained only by a person with the use of a unique code which identifies that person.

(d) The device must be located in such a place and manner that a person is unable to remove it from the hospital, and that attempts to obtain access to the device without authorization are visible to employees of the hospital.

7. As used in this section, "medical facility" has the meaning ascribed to it in NRS 449.0151.

Sec. 8. 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, 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 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 care 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 ~~[,]~~ ***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, 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 section 1 of LCB File No. R007-21, the dispensing practitioners of an oncology group practice registered pursuant to section 1 of LCB File No. R007-21 are jointly responsible for ensuring that the requirements prescribed by subsection 3 are met.

Sec. 9. NAC 639.910 is hereby amended to read as follows:

639.910 1. Any computerized system used by a pharmacy for recording information concerning prescriptions must be designed in such a manner that it provides:

(a) A readily retrievable printed record of the information relating to a prescription or a patient which the pharmacy is required to maintain pursuant to state or federal law, including, without limitation, information relating to the original prescription or the refill or modification of that prescription;

(b) The original prescription number;

(c) The prescribing practitioner's name, address and the registration number issued to him or her by the Drug Enforcement Administration if the prescribing practitioner is registered with that agency;

(d) The full name and address of the patient;

(e) The date on which the original prescription was filled, if it is different from the date prescribed;

(f) The name, strength, form, dosage, quantity and directions for use of the drug prescribed;

(g) The name or common abbreviation of the manufacturer, packer or distributor or the National Drug Code number of the drug dispensed to the patient;

(h) The total number of refills authorized by the prescriber;

(i) The date and quantity of each refill of a drug dispensed to a patient;

(j) The total number of refills of a drug dispensed to a patient;

(k) The quantity dispensed, if that is different from the quantity prescribed;

(l) At the time a prescription is filled or refilled, an automatic notice of the information the pharmacist ***,*** ~~[or]~~ intern pharmacist ***or dispensing practitioner*** considered pursuant to subsection 4 of NAC 639.707; and

(m) A procedure that may be conducted at least once each day to ensure that the information which is recorded in the system is not lost or destroyed.

2. The managing pharmacist of a pharmacy that uses a computerized system for recording information concerning prescriptions shall ensure that a procedure is conducted upon the computerized system that ensures that the information which is recorded in the system is not lost or destroyed.

3. As used in this section, "National Drug Code number" means the number assigned to a drug by the Food and Drug Administration.

Sec. 10. NAC 639.938 is hereby amended to read as follows:

639.938 If the computerized system is not functioning, the pharmacy must have an auxiliary procedure to document the dispensing of an original or refilled prescription. The auxiliary procedure must ensure that:

1. The information concerning a prescription which is filled or refilled during the period the system is not functioning is retained and entered into the system as soon as it is functioning again.

2. The information that is required for:

(a) The pharmacist ***,*** ~~[or]~~ intern pharmacist ***or dispensing practitioner*** who dispenses the drug to the patient to comply with the provisions of NAC 639.707; and

(b) The pharmacy to comply with the provisions of NAC 639.708,

↪ is readily available.

Sec. 11. NAC 639.940 is hereby amended to read as follows:

639.940 As used in NAC 639.940 to 639.943, inclusive, "computerized system to fill prescriptions" means an automated device operated by a computer which is used to prepare and package specified dosage units of drugs for dispensing to patients or ultimate users. The term does not include an automated drug dispensing system, a mechanical device or mechanical counting device governed by NAC 639.718, 639.720 or 639.725 ~~[.]~~ ***or section 1 of this regulation.***