JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

Posted: June 18, 2024

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of
Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will hold a Public Hearing at 9:00 a.m. on Thursday, July 18, 2024.

Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Element Reno Experience District
2030 Element Ln
Reno, NV 89502

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to Chapter 639 and/or 453 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

A. **Amendment to Nevada Administrative Code (NAC) 639:** The proposed amendment removes various provisions relating to compounding which are in conflict with current United States Pharmacopeia compounding standards.

   (LCB File No. R053-24)

1. The need for and the purpose of the proposed regulation or amendment.

The purpose for this regulation to align state law to federal requirements relating to compounding. Additionally, to allow flavoring of prescription medications in certain circumstances.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no economic impact from this regulation amendment on the regulated entities or on the public. The regulation amendment will have a beneficial effect on the regulated entities and on the public by making prescription compounding safer.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effects on regulated entities and on the public will be beneficial by making prescription compounding safer.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation amendment.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments, in written form, to the Board at teambc@pharmacy.nv.gov or to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521. Written submissions must be received by the Board on or before July 18, 2024. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

Members of the public who are disabled and require special accommodations or assistance at the meeting are requested to notify the Nevada State Board of Pharmacy in writing at 985 Damonte Ranch Pkwy., #206, Reno, Nevada 89521, or by calling (775) 850-1440. Please notify us at least one (1) week prior to the scheduled meeting date to allow time to secure any necessary equipment or provisions prior to the meeting.

This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request.

Pursuant to NRS 233B.064(1), upon adoption of any regulation, the Board, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at:

www.notice.nv.gov
www.bop.nv.gov
www.leg.state.nv.us.

Nevada State Board of Pharmacy
Reno, Nevada

Nevada State Board of Pharmacy
Las Vegas, Nevada

Nevada State Library
100 N. Stewart St.
Carson City, NV 89701

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R053-24

May 13, 2024

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

AUTHORITY: §§ 1-5, 7-19 and 21-29, NRS 639.070; § 6, NRS 639.070, 639.0725 and 639.23288; § 20, NRS 639.070 and 639.2807.

A REGULATION relating to pharmacy; defining the term "dispensing practitioner" for the purposes of compounding and dispensing drug products; providing that persons who are engaged in the compounding of drug products must comply with certain requirements; authorizing a pharmacist, pharmaceutical technician or dispensing practitioner to add flavoring to an oral drug product or mix ready-to-use products without complying with compounding standards under certain circumstances; revising the list of publications governing compounding standards adopted by reference; revising requirements governing the competency and proficiency of certain pharmaceutical staff engaged in the practice of compounding drug products; revising provisions relating to the labeling of nonsterile compounded drug products; eliminating the procedure governing the breach of the seal of a single-dose container; eliminating the description of an immediate-use sterile compounded drug product; revising provisions authorizing a dispensing practitioner to compound drug products; authorizing a dispensing practitioner to prepare and sell compounded drugs without a license as a manufacturer to compound drugs under certain circumstances; revising provisions relating to the preparation and sale of compounded drug products to ensure consistency with federal law; repealing various regulations that are in conflict with current compounding standards; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations regulating the practice of pharmacy. (NRS 639.070) Existing regulations establish specific standards for the compounding and dispensing of nonsterile and sterile drug products. (NAC 639.6703-639.67079) **Section 29** of this regulation repeals provisions that are in conflict with current compounding standards.

Existing regulations authorize a dispensing practitioner to compound drug products under certain circumstances. (NAC 639.742) **Section 2** of this regulation defines the term "dispensing practitioner" for such purposes. **Section 3** of this regulation requires a pharmacist, pharmaceutical technician or dispensing practitioner who is engaged in the compounding of drug products to comply with certain compounding standards. **Section 21** of this regulation requires a

pharmacy to ensure that persons who are engaged in the practice of compounding drug products comply with such compounding standards.

Sections 4 and 5 of this regulation authorize a pharmacist, pharmaceutical technician or dispensing practitioner to deviate from current compounding standards when he or she adds flavoring to an oral drug product or mixes ready-to-use products. **Sections 4 and 5** also require such persons to comply with certain requirements when adding flavoring to an oral drug product or mixing ready-to-use products.

Existing regulations provide that: (1) a licensed pharmacy may practice as an Internet pharmacy only if the pharmacy is certified by the Board; (2) to be certified by the Board, a pharmacy must apply to the Board for certification; and (3) the Board will grant an application for certification if, in relevant part, the pharmacy is certified by the Verified Internet Pharmacy Practice Sites program of the National Association of the Boards of Pharmacy. (NAC 639.426) **Section 6** of this regulation provides instead that the Board will grant an application for certification if the pharmacy is certified by the Digital Pharmacy Accreditation program of the National Association of Boards of Pharmacy.

Existing regulations adopt by reference certain standards and publications that, in general, govern compounding. (NAC 639.670) **Section 20** of this regulation revises the standards and publications adopted by reference to include the most recent versions of such standards and publications and eliminates those that are no longer applicable. **Sections 16-18** of this regulation remove a reference to an obsolete federal standard.

Existing regulations establish certain requirements concerning the labeling of nonsterile compounded drug products. (NAC 639.6703) **Section 22** of this regulation eliminates provisions concerning the labeling of nonsterile drug products that conflict with current compounding standards.

Existing regulations require each pharmacist and pharmaceutical technician who compounds sterile compounded drug products to: (1) pass a media fill test under certain circumstances; and (2) provide a sample for a gloved-fingertip sampling. (NAC 639.67053) **Section 23** of this regulation eliminates such requirements and requires a pharmacy to instead ensure that each pharmacist and pharmaceutical technician comply with the compounding standards established by certain publications adopted by reference in **section 20**.

When compounding a drug product, existing regulations require pharmaceutical staff to follow certain procedures when they breach the seal of a single-dose or multi-dose container. (NAC 639.67057) **Section 24** of this regulation eliminates the requirements for the procedure relating to the breach of a single-dose container, thereby requiring a procedure only for a breach involving a multi-dose container.

Existing regulations describe when a sterile compounded drug product is deemed an immediate-use sterile compounded drug product. (NAC 639.67073) **Section 25** of this regulation eliminates this description.

Existing regulations authorize a pharmacy or pharmacist, under certain circumstances, to prepare and sell compounded drugs without obtaining a license as a manufacturer to compound drugs. (NAC 639.757) **Section 27** of this regulation similarly authorizes a dispensing practitioner to also compound drugs without obtaining a license as a manufacturer to compound drugs under the same circumstances. **Section 27** also revises provisions relating to the substances used to compound drugs to ensure consistency with federal law.

Existing regulations define certain terms relating to the compounding of sterile drug products. (NAC 639.6613, 639.6619, 639.6633, 639.6637, 639.6639, 639.6647, 639.6649, 639.6655) **Section 29** repeals such definitions that conflict with current compounding standards.

Sections 6-11, 13-15, **19, 23 and 28** of this regulation make conforming changes to existing regulations to reflect the renumbering of paragraphs in **section 20**.

Sections 12, 19 and 26 of this regulation make conforming changes to indicate the proper placement of **sections 2-5** in the Nevada Administrative Code.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 5, inclusive, of this regulation.

Sec. 2. ***"Dispensing practitioner" means 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.***

Sec. 3. ***A pharmacist, pharmaceutical technician or dispensing practitioner who is engaged in the compounding of drug products in this State shall:***

1. Comply with the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 5, inclusive, of this regulation, concerning the drug products he or she compounds and the compounded drug products he or she dispenses;

2. Except as otherwise provided in sections 4 and 5 of this regulation, comply with the compounding standards established in the publications and standards adopted by reference in subsection 1 of NAC 639.670; and

3. Comply with all the requirements of 21 U.S.C. § 353a, as applicable.

Sec. 4. ***1. A pharmacist, pharmaceutical technician or dispensing practitioner may add flavoring to an oral drug product at the request of a patient or a legal guardian of the patient, as applicable. A pharmacist, pharmaceutical technician or dispensing practitioner who adds flavoring to an oral drug product pursuant to this subsection shall:***

(a) Make a record contemporaneous with the completion of the mixture, including, without limitation, the ingredients of the oral drug product;

(b) Ensure that the flavor additive does not compromise the stability, safety or efficacy of the dispensed oral drug product; and

(c) Assign the applicable beyond-use date to the oral drug product pursuant to chapter 795 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (b) of subsection 1 of NAC 639.670.

2. Except as otherwise provided in paragraph (c) of subsection 1, a pharmacist, pharmaceutical technician or dispensing practitioner is not required to comply with the compounding standards established in the publications and standards adopted by reference in subsection 1 of NAC 639.670 when he or she adds flavoring to an oral drug product pursuant to subsection 1 of this section.

Sec. 5. *1. A pharmacist, pharmaceutical technician or dispensing practitioner may mix components of commercially manufactured, ready-to-use products approved by the United States Food and Drug Administration. A pharmacist, pharmaceutical technician or dispensing practitioner who mixes components of commercially manufactured ready-to-use products pursuant to this subsection shall:*

(a) Make a record contemporaneous with the completion of the mixture, including, without limitation, the ingredients of the ready-to-use product;

(b) Follow all mixing instructions approved by the United States Food and Drug Administration; and

(c) Assign the applicable beyond-use date to the ready-to-use product pursuant to chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (b) of subsection 1 of NAC 639.670.

2. Except as otherwise provided in paragraph (c) of subsection 1, a pharmacist, pharmaceutical technician or dispensing practitioner is not required to comply with the compounding standards established in the publications and standards adopted by reference in subsection 1 of NAC 639.670 when he or she mixes ready-to-use products pursuant to subsection 1 of this section.

Sec. 6. NAC 639.426 is hereby amended to read as follows:

639.426 1. A licensed pharmacy may practice as an Internet pharmacy only if the pharmacy is certified by the Board pursuant to this section. To be certified by the Board pursuant to this section, a pharmacy must apply to the Board for certification on an application provided by the Board.

2. The Board will grant an application for certification as an Internet pharmacy pursuant to this section if:

(a) The pharmacy is certified by the ~~[Verified Internet Pharmacy Practice Sites]~~ ***Digital Pharmacy Accreditation*** program of the National Association of Boards of Pharmacy; or

(b) The Board determines that the pharmacy satisfies the requirements of subsection 3.

3. The Board will grant an application for certification pursuant to paragraph (b) of subsection 2 if the Board determines that the pharmacy:

(a) Is licensed to practice pharmacy in each state in which the pharmacy will practice pharmacy;

(b) Maintains and enforces policies and procedures which ensure that:

(1) The pharmacy is able to establish the authenticity of a prescription which the pharmacy receives;

(2) The pharmacy will not fill any prescription which has been previously filled by another pharmacy, and if the pharmacy fills any prescription, that prescription will not also be filled by another pharmacy;

(3) The identity of the patient and the prescribing practitioner is verified to be authentic;

(4) A prescription is filled in compliance with all applicable federal and state laws;

(5) A patient or the caregiver of the patient may make a complaint to the pharmacy regarding the prescription of the patient, and if such a complaint is made, the complaint will be investigated thoroughly, the results of the investigation will be communicated to the patient or caregiver and, if the investigation reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action will be taken by the pharmacy;

(6) The pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device; and

(7) The pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices;

(c) Obtains and maintains patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes;

(d) Provides review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides;

(e) Maintains controls of its computer system, information concerning patients and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents;

(f) Complies with applicable federal and state laws regarding:

(1) The dispensing of prescription drugs;

(2) Recordkeeping related to the patients served by the pharmacy, the purchase of prescription drugs, and the sale and dispensing of prescription drugs; and

(3) The sale of over-the-counter products, including, without limitation, any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs;

(g) Ships prescriptions to a patient using a secure and traceable means; and

(h) Ships prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670.

Sec. 7. NAC 639.472 is hereby amended to read as follows:

639.472 A pharmacy must maintain a reference library that includes the following:

1. A current copy of:

(a) All state statutes and regulations relating to the practice of pharmacy and to the sale of drugs and controlled substances; and

(b) The ~~[Federal]~~ ***federal*** Controlled Substances Act ~~[(Title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242)]~~ ***, 21 U.S.C. §§ 801 et seq.,*** and the regulations adopted pursuant thereto or

an official publication describing the requirements of that act and the regulations adopted pursuant thereto.

2. The American Hospital Formulary Service, with current supplements, or Facts and Comparisons, with current supplements.

3. At least one current text in one of the following subjects:

(a) Theoretical and practical pharmacy.

(b) Pharmacology.

(c) Therapeutics.

4. A current text relating to each of the following:

(a) Compatibility information, if parenteral admixture is performed by the pharmacy;

(b) Information concerning the interaction of drugs; and

(c) Information concerning antidotes.

5. Current copies of one of the following:

(a) *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670;

(b) *United States Pharmacopeia - Drug* ~~[Information;]~~ ***Classification;*** or

(c) *Remington's Pharmaceutical Sciences*.

6. A current copy of the ***United States*** Food and Drug ~~[Administration]~~ ***Administration's*** *Approved Drug Products* ~~[.]~~ ***with Therapeutic Equivalence Evaluation.***

Sec. 8. NAC 639.5834 is hereby amended to read as follows:

639.5834 The immediate outer shield of the container of a radiopharmaceutical to be dispensed must be labeled with:

1. The name and address of the pharmacy.

2. The name of the prescriber.

3. The date of dispensation.

4. The serial number assigned to the order for the radiopharmaceutical.

5. The standard radiation symbol.

6. The words "CAUTION RADIOACTIVE MATERIAL."

7. The name of the procedure.

8. The radionuclide and chemical form.

9. The amount of radioactivity and the date and time of the calibration.

10. If the radiopharmaceutical is a liquid, the volume.

11. If the radiopharmaceutical is a solid, the number of items or weight.

12. If the radiopharmaceutical is a gas, the number of ampules or vials.

13. The molybdenum 99 content in accordance with the limitations prescribed in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670.

14. The name of the patient or the words "Physician's Use Only" in the absence of a patient's name.

15. If the prescription is for a radiopharmaceutical for therapeutic use or use in a blood product, the patient's name must appear on the label. The requirements of this subsection are met if the name of the patient is readily retrievable from the prescriber upon demand.

Sec. 9. NAC 639.598 is hereby amended to read as follows:

639.598 1. Each wholesaler shall store prescription drugs held in the facility in the manner prescribed in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670.

2. If there are no specific requirements concerning the temperature at which a prescription drug must be stored, the drug must be stored at a controlled room temperature as defined in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670.

3. Each wholesaler shall provide the appropriate manual, electromechanical or electrical equipment to record the temperature and humidity of the area where the prescription drugs are stored.

Sec. 10. NAC 639.601 is hereby amended to read as follows:

639.601 1. A prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated must be separated from other prescription drugs until it is destroyed or returned to the supplier.

2. A prescription drug whose immediate or sealed outer or secondary container has been opened or used must be identified as such and separated from other prescription drugs until it is destroyed or returned to the supplier.

3. If a prescription drug is returned to a wholesaler by a purchaser or purchasing wholesaler under conditions which cast doubt on the prescription drug's safety, identity, strength, quality or purity, the wholesaler shall destroy the prescription drug or return it to the supplier unless, after conducting an examination, testing or other investigation, the wholesaler determines that the prescription drug complies with the appropriate standards of safety, identity, strength, quality and purity as prescribed in the package insert as approved by the Food and Drug Administration or in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670. The wholesaler shall keep a readily

retrievable record of any examination, testing or other investigation conducted and make any records available for inspection by the Board.

4. Unless the reason a prescription drug must be destroyed or returned to the supplier is related to the expiration date of the prescription drug, a wholesaler that is required to destroy a prescription drug or return it to the supplier pursuant to subsection 3 shall maintain a readily retrievable record that includes:

(a) The name of the prescription drug;

(b) The lot number and expiration date of the prescription drug;

(c) The quantity of the prescription drug;

(d) The name and address of the business that returned the prescription drug to the wholesaler;

(e) Whether the wholesaler will:

(1) Return the prescription drug to the supplier; or

(2) Destroy the prescription drug; and

(f) The reason for the action taken by the wholesaler.

Sec. 11. NAC 639.639 is hereby amended to read as follows:

639.639 1. Each authorized warehouse shall store prescription drugs held in the facility in the manner prescribed in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670.

2. If there are no specific requirements concerning the temperature at which a prescription drug must be stored, the drug must be stored at a controlled room temperature as defined in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670.

3. Each authorized warehouse shall provide the appropriate manual, electromechanical or electrical equipment to record the temperature and humidity of the area where the prescription drugs are stored.

Sec. 12. NAC 639.661 is hereby amended to read as follows:

639.661 As used in NAC 639.661 to 639.690, inclusive, ***and sections 2 to 5, inclusive, of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 639.6611 to 639.6677, inclusive, ***and section 2 of this regulation*** have the meanings ascribed to them in those sections.

Sec. 13. NAC 639.6617 is hereby amended to read as follows:

639.6617 "Beyond-use date" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670.

Sec. 14. NAC 639.6627 is hereby amended to read as follows:

639.6627 "Compounding aseptic containment isolator" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670.

Sec. 15. NAC 639.6629 is hereby amended to read as follows:

639.6629 "Compounding aseptic isolator" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670.

Sec. 16. NAC 639.6641 is hereby amended to read as follows:

639.6641 "ISO Class 5" means the classification of an atmospheric environment that is made by ***ISO 14644 - Cleanrooms and Associated Controlled Environments Package of*** the

International Organization for Standardization , ~~[based on an adaptation of Federal Standard 209E,]~~ as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:

1. Less than 3,520 particles that are 0.5 micron or larger in diameter per cubic meter of air; or

2. Less than 100 particles that are 0.5 micron or larger in diameter per cubic foot of air.

Sec. 17. NAC 639.6643 is hereby amended to read as follows:

639.6643 "ISO Class 7" means the classification of an atmospheric environment that is made by ***ISO 14644 - Cleanrooms and Associated Controlled Environments Package of*** the International Organization for Standardization , ~~[based on an adaptation of Federal Standard 209E,]~~ as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:

1. Less than 352,000 particles that are 0.5 micron or larger in diameter per cubic meter of air; or

2. Less than 10,000 particles that are 0.5 micron or larger in diameter per cubic foot of air.

Sec. 18. NAC 639.6645 is hereby amended to read as follows:

639.6645 "ISO Class 8" means the classification of an atmospheric environment that is made by ***ISO 14644 - Cleanrooms and Associated Controlled Environments Package of*** the International Organization for Standardization , ~~[based on an adaptation of Federal Standard 209E,]~~ as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:

1. Less than 3,520,000 particles that are 0.5 micron or larger in diameter per cubic meter of air; or

2. Less than 100,000 particles that are 0.5 micron or larger in diameter per cubic foot of air.

Sec. 19. NAC 639.6677 is hereby amended to read as follows:

639.6677 "Sterile compounded drug product" means a drug product the preparation and dispensing of which require compounding and which is required to be sterile by either the provisions of chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670, or the provisions of NAC 639.661 to 639.690, inclusive ***,*** ~~[.]~~ ***and sections 2 to 5, inclusive, of this regulation.***

Sec. 20. NAC 639.670 is hereby amended to read as follows:

639.670 1. The Board hereby adopts by reference the following:

(a) ~~[Federal Standard 209E, "Airborne Particulate Cleanliness Classes in]~~ ***"ISO 14644 -*** Cleanrooms and ~~[Clean Zones," as revised on September 11, 1992, by the Institute of Environmental Sciences. A copy of this publication may be obtained free of charge at the Internet address http://www.set3.com/papers/209e.pdf.~~

~~(b) NSF International Standard 49, "Class II (Laminar Flow) Biosafety Cabinetry," NSF/ANSI 49-2007, 2007 edition. A copy of this standard may be obtained from Techstreet, 3916 Ranchero Drive, Ann Arbor, Michigan 48108, or at the Internet address http://www.techstreet.com/, for the price of $160.~~

~~(c)]~~ ***Associated Controlled Environments Package of the International Organization for Standardization." A copy of the standard may be obtained from the American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, New York 10036, by telephone at (212) 642-4900 or at the Internet address https://webstore.ansi.org, at a price of $178.40 for members and $223.00 for non-members..***

(b) *United States Pharmacopeia - National Formulary*, ~~[2008]~~ ***2023*** edition, published by the United States Pharmacopeial Convention. A copy of this publication may be obtained from the United States Pharmacopeial Convention ~~[, Customer Service Department, 12601 Twinbrook Parkway, Rockville, Maryland 20852, or]~~ at the Internet address ~~[http://www.usp.org/products/,]~~ ***https://store.usp.org through an online subscription,*** for the price of ~~[$755.~~

~~(d)]~~ ***$800.***

(c) The *Food Chemicals Codex*, ~~[6th]~~ ***13th*** edition, published by the United States Pharmacopeial Convention. A copy of this publication may be obtained from the United States Pharmacopeial Convention ~~[, Customer Service Department, 12601 Twinbrook Parkway, Rockville, Maryland 20852, or]~~ at the Internet address ~~[http://www.usp.org/products/,]~~ ***http://store.usp.org through an online subscription,*** for the price of ~~[$495.~~

~~(e) Reagent Chemicals: Specifications and Procedures, 10th edition, published by the American Chemical Society. A copy of this publication may be obtained from the Oxford University Press, 2001 Evans Road, Cary, North Carolina 27513, or at the Internet address http://www.oup-usa.org, for the price of $274.50.~~

~~(f)]~~ ***$375.***

(d) Appendix A of *Publication No.* ~~[2004-165, "Alert:]~~ ***2016-161, "*** Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings," published by the National Institute for Occupational Safety and Health. A copy of this publication may be obtained free of charge by telephone at (800) 232-4636 or at the Internet address ~~[http://www.cdc.gov/niosh/docs/2004-165/.]~~ ***http://www.cdc.gov/niosh/docs/2016-161/.***

2. The Board will periodically review the standards and publications adopted by reference pursuant to ~~[paragraphs (b) to (f), inclusive, of]~~ subsection 1 and determine within 120 days after

the review whether any change made to those standards or publications is appropriate for application in this State. If the Board does not disapprove a change to an adopted standard or publication within 120 days after the review, the change is deemed to be approved by the Board.

Sec. 21. NAC 639.67013 is hereby amended to read as follows:

639.67013 1. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall ensure that each pharmacist and pharmaceutical technician engaged in the practice of compounding drug products:

(a) Is competent and proficient in compounding the drug products that the pharmacist or pharmaceutical technician will be authorized and expected to compound;

(b) Complies with the provisions of NAC 639.661 to 639.690, inclusive, ***and sections 2 to 5, inclusive, of this regulation*** concerning the drug products which the pharmacist or pharmaceutical technician compounds and the compounded drug products which the pharmacist or pharmaceutical technician dispenses at the pharmacy; ~~[and]~~

(c) ***Except as otherwise provided in sections 4 and 5 of this regulation, complies with the compounding standards established in the publications and standards adopted by reference in subsection 1 of NAC 639.670; and***

(d) Receives, on an ongoing basis, sufficient training to maintain that competency and proficiency.

2. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall evaluate the competency and proficiency of a pharmacist and pharmaceutical technician:

(a) If the pharmacist or pharmaceutical technician is newly hired or is newly assigned to compound drug products, before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound drug products; and

(b) If the pharmacist or pharmaceutical technician will be assigned to compound drug products that involve a higher level of risk than the drug products which the pharmacist or pharmaceutical technician had previously been trained to compound, before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound those drug products.

Sec. 22. NAC 639.6703 is hereby amended to read as follows:

639.6703 1. Each pharmacist engaged in the practice of compounding nonsterile compounded drug products shall label each nonsterile compounded drug product, including, without limitation, any amount of the nonsterile compounded drug product that is in excess of the amount required by the prescription or chart order and any nonsterile compounded drug product that is compounded in bulk quantities. The label must include, without limitation:

(a) The name of the final compounded drug product or the name of each active ingredient present in the nonsterile compounded drug product and, as appropriate, the concentration of each active ingredient in the final compounded drug product;

(b) The internal control number assigned to the compounded drug product by the pharmacist; and

(c) The beyond-use date of the compounded drug product.

2. ~~[Except as otherwise provided in subsection 3 or in the published data or data of the manufacturer, or as otherwise determined to be earlier in the judgment of the pharmacist, the latest beyond-use date of a nonsterile compounded drug product is:~~

~~(a) For nonaqueous liquids and solid formations, not later than the expiration date of the active ingredient present in the nonsterile compounded drug product with the earliest expiration date or 6 months after the date on which the nonsterile compounded drug product was compounded, whichever is earlier;~~

~~(b) For compounds which contain nonsterile water, not later than 14 days after the date on which the nonsterile compounded drug product was compounded; and~~

~~(c) For compounds other than those listed in paragraph (a) or (b), not later than the intended duration of the therapy or 30 days after the date on which the nonsterile compounded drug product was compounded, whichever is earlier.~~

~~3. Except as otherwise provided in subsection 7 of NRS 639.2801, a pharmacy may use a beyond-use date that is later than the dates described in subsection 2 if the pharmacy can prove by appropriate testing or published data that the nonsterile compounded drug product is safe and effective using the extended beyond-use date.~~

~~4.]~~ Each pharmacist engaged in the practice of compounding nonsterile compounded drug products shall ensure that each nonsterile compounded drug product, including, without limitation, any amount of the nonsterile compounded drug product that is in excess of the amount required by the prescription or chart order, and any nonsterile compounded drug product that is compounded in bulk quantities is stored in the pharmacy in a manner that:

(a) Maintains the efficacy of the nonsterile compounded drug product; and

(b) Ensures that the nonsterile compounded drug product remains free from contamination.

Sec. 23. NAC 639.67053 is hereby amended to read as follows:

639.67053 ~~[1. Except as otherwise provided in subsections 4 and 5, a]~~ *A* pharmacy engaged in the practice of compounding and dispensing sterile compounded drug products shall

require each pharmacist and pharmaceutical technician who compounds sterile compounded drug products to ~~[pass a media fill test which must be conducted in the manner]~~ ***comply with the compounding standards*** provided by chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670 **.** ~~[,~~ ~~and which must be commensurate to the highest level of risk of compounding sterile compounded drug products that the pharmacist or pharmaceutical technician will be authorized by the pharmacy to perform:~~

~~(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a sterile compounded drug product that will be administered or dispensed to a patient;~~

~~(b) At least once each year thereafter if the pharmacy authorizes the pharmacist or pharmaceutical technician to compound low-risk sterile compounded drug products or medium-risk sterile compounded drug products; and~~

~~(c) At least twice each year thereafter if the pharmacy authorizes the pharmacist or pharmaceutical technician to compound high-risk sterile compounded drug products.~~

~~2. A pharmacy engaged in the practice of compounding and dispensing sterile compounded drug products shall ensure the competency and proficiency of each pharmacist and pharmaceutical technician at the highest level of risk of compounding sterile compounded drug products the pharmacist or pharmaceutical technician is authorized by the pharmacy to perform by:~~

~~(a) Requiring the pharmacist or pharmaceutical technician to provide a sample for a gloved fingertip sampling which must be conducted in the manner provided by chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670;~~

(b) Testing a sample taken from a surface cleaned by the pharmacist or pharmaceutical technician to determine sterility;

(c) Ensuring the pharmacist or pharmaceutical technician receives, on an ongoing basis, sufficient training to maintain that competency and proficiency through attending in-house training programs or continuing education courses;

(d) Observing the pharmacist or pharmaceutical technician as he or she compounds sterile compounded drug products; or

(e) Correcting any error and initiating remedial measures for a pharmacist or pharmaceutical technician to take after an error has been noted with a sterile compounded drug product that was made or verified by the pharmacist or pharmaceutical technician.

3. A pharmacy shall make and maintain records concerning all the actions listed in subsection 2 which the pharmacy takes to ensure the competency and proficiency of each pharmacist and pharmaceutical technician who is authorized by the pharmacy to compound sterile compounded drug products.

4. A sterile compounded drug product that is compounded by a pharmacist or pharmaceutical technician who has not passed the media fill test required by paragraph (a) of subsection 1 may be dispensed and administered to a patient if:

(a) The managing pharmacist of the pharmacy determines that it is appropriate to dispense and administer the sterile compounded drug product; and

(b) The entire compounding process was personally witnessed by a pharmacist or pharmaceutical technician who passed the media fill test.

~~5. A pharmacy is not required to make a pharmacist or pharmaceutical technician pass a media fill test pursuant to paragraph (a) of subsection 1 if the pharmacist or pharmaceutical technician provides evidence of passing a media fill test:~~

~~(a) Within the immediately preceding 9 months if the pharmacist or pharmaceutical technician will compound low-risk sterile compounded drug products and medium-risk sterile compounded products; or~~

~~(b) Within the immediately preceding 5 months if the pharmacist or pharmaceutical technician will compound high-risk sterile compounded drug products.]~~

Sec. 24. NAC 639.67057 is hereby amended to read as follows:

639.67057 1. ~~[If, in the course of compounding a drug product, the seal of a single-dose container, including, without limitation, a bag, bottle, syringe or vial of a sterile drug product, is breached, the time and date of the breach must be marked upon the container and the contents of the container may be used:~~

~~(a) Within 1 hour after the breach of the seal if:~~

~~(1) The breach occurred in an environment with an air quality that is worse than ISO Class 5; and~~

~~(2) The container is subsequently stored in an environment with an air quality that is worse than ISO Class 7;~~

~~(b) Within 6 hours after the breach of the seal if:~~

~~(1) The breach of the seal occurred and the contents of the container were used in an environment with an air quality that satisfies or exceeds ISO Class 5; and~~

~~(2) The container is subsequently stored in an environment with an air quality that satisfies or exceeds ISO Class 7; or~~

~~(c) Within 24 hours after the breach of the seal if the breach occurred in an environment with an air quality that satisfies or exceeds ISO Class 5 and the container remains in an environment with an air quality that satisfies or exceeds ISO Class 5.~~

~~2.]~~ If, in the course of compounding a drug product, the seal of a multi-dose container is breached:

(a) The container must be stored according to the requirements of the manufacturer; and

(b) The contents of the container may be used within 28 days after the breach of the seal occurred.

~~[3.]~~ ***2.*** Any drug product that is not used within the ~~[periods]~~ ***period*** set forth in subsection 1 ~~[or 2]~~ may not be used and must be destroyed.

~~[4.]~~ ***3.*** If the seal of a single-use ampule is breached or the entire seal has been removed from a multi-use vial and the contents are not used at the time of the breach, the contents may not be used and must be destroyed.

Sec. 25. NAC 639.67073 is hereby amended to read as follows:

639.67073 1. ~~[A sterile compounded drug product is an immediate-use sterile compounded drug product if:~~

~~(a) The compounded drug product is intended only for the purpose of emergency care or immediate care of a patient;~~

~~(b) The compounding of the drug product occurs in an environment other than an ISO Class 5 environment and the compounding process consists of simple aseptic measuring and transfer manipulations performed with not more than six sterile nonhazardous commercial drug products and diagnostic radiopharmaceutical drug products, excluding infusion solutions or diluents;~~

~~(c) The preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour unless a period longer than 1 hour is required for the reconstitution of the compounded drug product;~~

~~(d) During compounding and before the administration of the compounded drug product, no part of the drug product or critical surfaces and ingredients of the drug product is directly exposed to contact contamination, including, without limitation, human touch, cosmetic flakes or particulates, blood or other bodily substances of a person or nonsterile inanimate sources; and~~

~~(e) Except as otherwise provided in paragraph (c), the administration of the compounded drug product begins not later than 1 hour after the start of the preparation of the compounded drug product and the compounded drug product is fully administered as soon as practicable but not longer than 24 hours after the administration of the compounded drug product began or the compounded drug product is disposed of promptly and safely.~~

~~2.~~ If an immediate-use sterile compounded drug product is not immediately administered by direct injection into a patient by the person who compounded it, the compounded drug product must bear a label which includes, without limitation:

(a) The name and, if the patient has an identification number, the identification number of the patient;

(b) The name and amount of each ingredient of the compounded drug product;

(c) The initials of the person who compounded the compounded drug product; and

(d) The exact date and time of expiration of the compounded drug product.

~~3.~~ ***2.*** An immediate-use sterile compounded drug product must not be stored for later use.

Sec. 26. NAC 639.742 is hereby amended to read as follows:

639.742 1. Except as otherwise provided in NAC 639.7421 and 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 639.7421, 639.7422 and 639.7423, 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, 639.719 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, 639.719, 639.7423 and 639.7424, 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, ***and sections 2 to 5, inclusive, of this regulation*** 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 NAC 639.746, the dispensing practitioners of an oncology group practice or a group of practitioners practicing at a reproductive healthcare center registered pursuant to NAC 639.746 are jointly responsible for ensuring that the requirements of subsection 3 are met.

Sec. 27. NAC 639.757 is hereby amended to read as follows:

639.757 1. A pharmacy **,** ~~[or]~~ pharmacist ***or dispensing practitioner*** is not required to obtain a license as a manufacturer to compound drugs if:

(a) The compounded drugs are prepared in a quantity that is:

(1) Necessary to fill a prescription or chart order; or

(2) Reasonably necessary to fill future prescriptions or chart orders based upon the previous history of practitioners and patients who regularly use the pharmacy ~~[,]~~ ***or dispensing practitioner;***

(b) The compounded drugs are not sold or otherwise provided by the pharmacy **,** ~~[or]~~ pharmacist ***or dispensing practitioner*** to any person other than the ultimate user of the drugs ~~[,]~~ ***or*** the agent of the ultimate user of the drugs ~~[or a practitioner who will be administering the drugs to a patient;]~~ ***; and***

(c) The compounded drugs are dispensed pursuant to a prescription or chart order **.** ~~[;~~

(d) Except as otherwise provided in paragraph (e) and subsection 2, the active ingredients used to compound the drugs:

(1) Have a monograph in and meet or exceed the standards of the United States Pharmacopoeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670;

(2) Have been components of drugs approved by the Food and Drug Administration; or

(3) Are authorized to be used in pharmacy compounding pursuant to 21 U.S.C. § 353a(b)(1) or the regulations adopted pursuant thereto; and

(e) Except as otherwise provided in subsection 2, for an active ingredient used to compound the drugs that does not have a monograph in the United States Pharmacopoeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, the active ingredient is:

(1) Prepared by a manufacturer or distributed by a distributor registered with the Food and Drug Administration;

(2) Accompanied by a certificate of analysis provided by the manufacturer or distributor of the ingredient; and

(3) Prepared to a grade that, at a minimum, satisfies the requirements set forth in:

(I) The Food Chemicals Codex, as adopted by reference in paragraph (d) of subsection 1 of NAC 639.670; or

(II) Reagent Chemicals: Specifications and Procedures, as adopted by reference in paragraph (e) of subsection 1 of NAC 639.670, if the active ingredient is a certified analytical reagent, is for use in high pressure liquid chromatography, is for use in spectrophotometric applications or is a primary standard grade for use in standard solutions for analytical purposes.]

2. In compounding a drug product, a pharmacy ***,*** ~~[or]~~ pharmacist ~~[may use an active ingredient that does not satisfy the requirements of paragraphs (d) and (e) of subsection 1 if the pharmacy or pharmacist establishes the purity and safety of the ingredient by reasonable means, satisfactory to the Board, which include, without limitation, analysis of the lot in which the ingredient was packaged, the reputation of the manufacturer of the ingredient and the reliability of the source of the ingredient. A pharmacy shall make and maintain a record of the means that the pharmacy relied upon in determining that an ingredient was pure and safe pursuant to this subsection.]~~ ***or dispensing practitioner shall use bulk drug substances in compliance with 21 U.S.C. § 353a, as applicable.***

3. Except as otherwise provided in this subsection, a pharmacy ***,*** ~~[or]~~ pharmacist ***or dispensing practitioner*** shall not compound a drug that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective. A pharmacy ***,*** ~~[or]~~ pharmacist ***or dispensing practitioner*** may compound a drug for veterinary use that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective for use in humans if the drug remains available for veterinary use.

~~[4. A pharmacy shall not sell or otherwise provide a compounded drug to a retail pharmacy or a practitioner, except that a pharmacy may sell or otherwise provide a compounded drug to:~~

~~(a) A practitioner who will be administering the drug to a patient; or~~

~~(b) A practitioner or another pharmacy if the compounded drug is:~~

~~(1) A highly concentrated drug product that is not commercially available; or~~

~~(2) Needed to fill a particular prescription or chart order in the possession of the receiving pharmacy at the time the receiving pharmacy orders the compounded drug from the compounding pharmacy.~~

~~5. The quantity of a compounded drug that is sold or otherwise provided to a practitioner or pharmacy pursuant to subsection 4 must not exceed the amount necessary for the practitioner or pharmacy to serve the present needs of the patients of the practitioner or pharmacy.]~~

Sec. 28. NAC 639.760 is hereby amended to read as follows:

639.760 1. Dangerous drugs and controlled substances may be returned to the pharmacy which dispensed them, pursuant to subsection 3 of NRS 639.267, if they are packaged in unit doses by the original manufacturer, the packages and the packaging of which conform to chapters 661 and 671 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph ~~[(c)]~~ ***(b)*** of subsection 1 of NAC 639.670.

2. A drug may not be returned to the issuing pharmacy unless its package contains the expiration date of the usefulness of the drug.

3. A person or agency returning the unused drugs and the pharmacy receiving the unused drugs shall maintain a current audit of the drugs which are returned and received on forms approved by the Board. Such forms will be furnished at the expense of the facility or pharmacy.

4. A prescription for a dangerous drug or controlled substance dispensed by a pharmacy that has been removed from the premises of the pharmacy may not be returned to the pharmacy pursuant to subsection 3 of NRS 639.267 for the destruction of the drug or substance, or for the return of the drug or substance to the stock of drugs of the pharmacy, if the dangerous drug or controlled substance is not packaged in a unit dose by its original manufacturer as required by subsection 1.

5. A drug dispensed by a pharmacy to a patient may be returned to the pharmacy to be repackaged or relabeled only if the drug will be dispensed by the pharmacy to the same patient.

6. Nothing in this section establishes any condition of reimbursement, credit or refund of a prescription purchased in a pharmacy.

Sec. 29. NAC 639.6613, 639.6619, 639.6633, 639.6637, 639.6639, 639.6647, 639.6649, 639.6655, 639.67033, 639.67037, 639.6705, 639.67051, 639.67059, 639.67061, 639.67063, 639.67065, 639.67067, 639.67069, 639.67071 and 639.67075 are hereby repealed.

TEXT OF REPEALED SECTIONS

639.6613 "Ante-area" defined. (NRS 639.070) "Ante-area" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

639.6619 "Buffer area" defined. (NRS 639.070) "Buffer area" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

639.6633 "Gloved fingertip sampling" defined. (NRS 639.070) "Gloved fingertip sampling" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

639.6637 "High-risk sterile compounded drug product" defined. (NRS 639.070) "High-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67067.

639.6639 "Immediate-use sterile compounded drug product" defined. (NRS 639.070) "Immediate-use sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67073.

639.6647 "Low-risk sterile compounded drug product" defined. (NRS 639.070) "Low-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67061.

639.6649 "Media fill test" defined. (NRS 639.070) "Media fill test" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

639.6655 "Medium-risk sterile compounded drug product" defined. (NRS 639.070) "Medium-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67065.

639.67033 Environmental standards. (NRS 639.070) A pharmacy engaged in the practice of compounding nonsterile compounded drug products shall:

1. Designate a specific area of the pharmacy in which nonsterile compounded drug products will be compounded;

2. Ensure that the area described in subsection 1 has adequate space in which to place, in an orderly manner, the equipment and materials that will be used in the compounding process;

3. Ensure that the area described in subsection 1 is cleaned using an antiseptic cleaning method before and after any compounding occurs in the area to prevent cross-contamination

between the previously compounded drug products and any subsequently compounded drug products;

4. Ensure that any equipment used to compound a nonsterile compounded drug product is cleaned after the compounding of that drug product is completed to prevent cross-contamination from occurring when the equipment is used in the compounding process of any subsequently compounded drug products;

5. If the pharmacy compounds both nonsterile compounded drug products and sterile compounded drug products, ensure that none of the equipment which is used to compound nonsterile compounded drug products is used to compound sterile compounded drug products unless the equipment is cleaned and sanitized before the compounding of sterile compounded drug products begins; and

6. Ensure that any employee of the pharmacy who compounds nonsterile compounded drug products washes his or her hands with soap and water or with an antimicrobial agent before and after compounding nonsterile compounded drug products.

639.67037 Safety procedures for storage, handling, compounding and disposal; training required. (NRS 639.070)

1. A pharmacy engaged in the practice of compounding nonsterile hazardous drugs shall:

(a) Store the components of the hazardous drugs separately from all the other inventory at the pharmacy and in such a manner and location as to minimize the contamination of other drugs in and employees of the pharmacy;

(b) Handle the components of the hazardous drugs with caution by using appropriate gloves while distributing, receiving, stocking, inventorying, and preparing for administering and disposing of the components of a hazardous drug or a final compounded drug product;

(c) Ensure that an employee of the pharmacy involved with compounding hazardous drugs wears personal protective equipment, including, without limitation, gowns, face masks, eye protection, double gloves or chemotherapy gloves;

(d) Dispose of all waste relating to compounding hazardous drugs in a manner that complies with any applicable state, federal and local laws and regulations; and

(e) Ensure that any employees of the pharmacy who are known to the pharmacy to be at special risk with regard to the properties of the hazardous drugs are limited from exposure to those drugs.

2. A pharmacy engaged in the practice of compounding nonsterile hazardous drugs and dispensing compounded nonsterile hazardous drugs shall require each pharmacist and pharmaceutical technician who compounds nonsterile hazardous drugs to be trained in the storage, handling, compounding, safety procedures and disposal of such compounded drugs:

(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a nonsterile hazardous drug that will be administered or dispensed to a patient; and

(b) At least once each year thereafter.

3. The training required pursuant to subsection 2 must, at a minimum, include information concerning:

(a) Safe manipulation practices that minimize exposure to the hazardous drug and protect employees of the pharmacy from any overt exposure to the hazardous drug;

(b) Procedures for containment, cleaning and disposal with regard to breaks and spills; and

(c) Treatment of employees of the pharmacy with regard to exposure by contact and inhalation.

4. The pharmacy shall make and keep a record of any training given pursuant to subsection 2.

639.6705 Environmental standards. (NRS 639.070)

1. Except as otherwise provided in NAC 639.67059, a pharmacy engaged in the practice of compounding sterile compounded drug products shall provide an ISO Class 5 environment.

2. If a pharmacy uses a laminar airflow hood as its ISO Class 5 environment within which to compound sterile compounded drug products, the pharmacy:

(a) Shall ensure that the laminar airflow hood is located within a room with a buffer area that maintains an ISO Class 7 environment under normal conditions of use.

(b) Shall maintain an ante-area or space in close proximity to any entrance to the room containing the laminar airflow hood that maintains an ISO Class 8 environment under normal conditions of use.

(c) Shall ensure that the room that contains the laminar airflow hood maintains a constant temperature and humidity that:

(1) Ensures the safety and efficacy of the compounded drug products, components and equipment; and

(2) Provides an environment in which the employees of the pharmacy can work comfortably for the duration of the compounding that will be conducted in the room.

(d) Shall require each employee of the pharmacy who enters the buffer area containing the laminar airflow hood to:

(1) Remove all jewelry from his or her hands and arms;

(2) Perform sanitizing scrubbing; and

(3) Wear fresh protective clothing, including, without limitation, gowns, shoe covers or dedicated shoes, and hair covers, in the ante-area or space in close proximity to an entrance to the room and to remove all such items of protective clothing whenever the employee leaves the room. A gown may be used more than once within a 12-hour period if it is removed in the ante-area and is stored in the ante-area until it is used again.

(e) Shall require an employee to wear nonpowdered gloves and a face mask and beard cover, as applicable, before the employee enters the buffer area.

(f) Shall ensure, to the extent practicable, that all items located in or brought into the room containing the laminar airflow hood have nonporous, smooth, impermeable surfaces that:

(1) Can withstand being cleaned repeatedly with a disinfectant; and

(2) Do not shed particles which may become airborne in the room.

(g) Must have floors, walls and ceilings in the room containing the laminar airflow hood that are made of materials that can withstand being cleaned and disinfected repeatedly with solutions and products.

(h) Shall ensure, before any compounding can occur within the laminar airflow hood, that the laminar airflow hood is used according to the manufacturer's directions with regard to starting and using the laminar airflow hood in a manner which ensures that the interior of the laminar airflow hood creates and maintains an ISO Class 5 environment.

(i) Shall ensure that:

(1) The ISO Class 5 environment is cleaned:

(I) At the beginning of each work shift;

(II) Before the compounding of each batch preparation begins;

(III) At least every 30 minutes after the compounding of a sterile compounded drug product has begun during a period of continuous compounding activity;

(IV) After there has been a spill within the ISO Class 5 environment; and

(V) Whenever it is known or suspected that surface contamination exists as a result of a breach in procedure.

(2) The counters and easily cleanable work surfaces in close proximity to the laminar airflow hood and in, or in close proximity to, the buffer area are cleaned at least once each day in which the ISO Class 5 environment is used and whenever a counter or surface may require cleaning as a result of its use throughout the working day.

(3) The floors are cleaned at least once each day in which the ISO Class 5 environment is used and whenever the floors may require cleaning as a result of its use throughout the working day.

(4) The walls, ceilings, storage, shelving and other surfaces that are not easily cleaned are cleaned at least once each month.

3. If a pharmacy uses a barrier isolator cabinet that maintains an ISO Class 5 environment at all times when it is in use as its ISO Class 5 environment within which to compound sterile compounded drug products, the pharmacy shall ensure that:

(a) The barrier isolator cabinet is placed in the pharmacy at a location where:

(1) The compounding may occur without interruption or inconvenience; and

(2) The barrier isolator cabinet will not be compromised by its proximity to air vents, doorways or other pharmacy fixtures or equipment.

(b) Before any compounding may occur within the barrier isolator cabinet, the barrier isolator cabinet is used according to the manufacturer's directions with regard to starting and using the

barrier isolator cabinet in a manner which ensures that the interior of the barrier isolator cabinet creates and maintains an ISO Class 5 environment.

(c) The barrier isolator cabinet is cleaned:

(1) At the beginning of each work shift;

(2) Before the compounding of each batch preparation begins;

(3) At least every 30 minutes after the compounding of a sterile compounded drug product has begun during a period of continuous compounding activity;

(4) After there has been a spill within the ISO Class 5 environment; and

(5) Whenever it is known or suspected that surface contamination exists as a result of a breach in procedure.

(d) The counters and easily cleanable work surfaces in close proximity to the barrier isolator cabinet are cleaned at least once each day in which the barrier isolator cabinet is used and whenever a counter or surface may require cleaning as a result of its use throughout the working day.

(e) The floors in close proximity to the barrier isolator cabinet are cleaned at least once each day in which the barrier isolator cabinet is used and whenever the floors may require cleaning as a result of its use throughout the working day.

4. A barrier isolator cabinet that cannot maintain an ISO Class 5 environment at all times when it is being used shall be deemed a laminar airflow hood for purposes of satisfying the requirements of this section.

5. As used in this section, “batch preparation” means the compounding of multiple units of sterile compounded drug products, not for immediate use, in a single process by the same person.

639.67051 Air quality testing and certification. (NRS 639.070)

1. Except as otherwise provided in NAC 639.67059, a pharmacy engaged in the practice of compounding sterile compounded drug products shall test the air in each of its controlled environments to ensure that the environments attain the air quality required by the provisions of NAC 639.661 to 639.690, inclusive, for an ISO Class 5, ISO Class 7 or ISO Class 8 environment, as applicable.

2. The air quality testing required by subsection 1 must be performed randomly with regard to:

(a) The time of day the air samples are collected;

(b) The staff who is on duty when the samples are gathered; and

(c) The locations within the pharmacy from which the samples are collected.

3. A pharmacy engaged in the practice of compounding sterile compounded drug products shall have its ISO Class 5 environment certified pursuant to subsection 4:

(a) At least twice each year; and

(b) Before compounding a sterile compounded drug product after:

(1) A substantial change or renovation is made in the room that contains the laminar airflow hood or barrier isolator cabinet;

(2) Sizeable equipment is placed in the room that contains the laminar airflow hood or barrier isolator cabinet;

(3) The laminar airflow hood or barrier isolator cabinet is moved from the location at which the laminar airflow hood or barrier isolator cabinet was most recently tested; or

(4) The laminar airflow hood or barrier isolator cabinet is repaired.

4. The certification required by subsection 3 must be completed by a person who is independent of the pharmacy requesting the certification and who is capable of certifying that the

ISO Class 5 environment can satisfy and maintain the minimum requirements set forth in NAC 639.6641 for air quality under normal conditions of use.

5. A pharmacy engaged in the practice of compounding sterile compounded drug products shall have each of its ISO Class 7 and ISO Class 8 environments tested or certified pursuant to subsection 7 for particulates:

(a) At least twice each year; and

(b) Before compounding a sterile compounded drug product after:

(1) A substantial change or renovation is made in the room that contains the laminar airflow hood or barrier isolator cabinet;

(2) Sizeable equipment is placed in the room that contains the laminar airflow hood or barrier isolator cabinet;

(3) The laminar airflow hood or barrier isolator cabinet is moved from the location at which the laminar airflow hood or barrier isolator cabinet was most recently tested; or

(4) A laminar airflow hood or barrier isolator cabinet is added to or removed from the room that contains the laminar airflow hood or barrier isolator cabinet.

6. The air quality testing required by subsection 5 must be performed randomly with regard to:

(a) The time of day the air samples are collected;

(b) The staff who are on duty when the samples are gathered; and

(c) The locations within the pharmacy from which the samples are collected.

7. The testing or certification required by subsection 5 must be completed by the pharmacy or by a person who is independent of the pharmacy requesting the certification and who is capable of testing or certifying that the ISO Class 7 or ISO Class 8 environment can satisfy and

maintain the minimum requirements set forth in NAC 639.6643 and 639.6645, respectively, for air quality under normal conditions of use.

8. If the pharmacy performs the testing or certification required by subsection 5, the testing or certification process of the pharmacy must be validated semiannually by the managing pharmacist.

9. If any of the results of the air quality testing or certification required by this section exceed the tolerances set forth in NAC 639.6641, 639.6643 and 639.6645, for the particular controlled environment, the pharmacy shall take whatever action is necessary to remediate the deficiency and retest the environment until the environment produces results within the tolerances for the particular controlled environment.

10. The pharmacy shall make and maintain records concerning the air quality testing and certification and any corrections and retesting that were conducted pursuant to this section.

639.67059 Exemptions for certain institutional pharmacies. (NRS 639.070) The Board may, upon application and for good cause shown, waive or modify any requirement set forth in NAC 639.6705 and 639.67051 for an institutional pharmacy engaged in the practice of compounding drug products if the institutional pharmacy serves an institution that:

1. Has less than 100 beds licensed for providing acute care; and

2. Is located in a county:

(a) Whose population is less than 100,000; or

(b) Whose population is 100,000 or more if the hospital is designated as a rural hospital by the Nevada Office of Rural Health within the University of Nevada School of Medicine.

639.67061 Low-risk sterile compounding: Process and storage. (NRS 639.070)

1. A compounded drug product is a low-risk sterile compounded drug product if:

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is at a low risk of contamination; and

(c) One or more of the following conditions are present:

(1) The compounding process involves aseptic manipulations that are performed entirely within an environment with an air quality of at least ISO Class 5 and uses only sterile ingredients, products, components and devices;

(2) The compounding process involves only transferring, measuring and mixing manipulations and uses not more than three commercially manufactured sterile drug products or other entries of a sterile drug product into one container, including, without limitation, a bag or vial, to make the final compounded drug product;

(3) The manipulations needed to compound the drug product are limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers or other sterile drug products and containers for storage and dispensing;

(4) The final compounded drug product contains a volume of 15 milliliters or less of a radiopharmaceutical and has an expiration time of 18 hours or less per dosage unit, including, without limitation, a dosage unit of a radiopharmaceutical prepared from an eluate by using a molybdenum-99technetiym-99m generator; or

(5) The final compounded drug product contains commercially manufactured cyclotron radiopharmaceuticals which contain preservatives and which have expiration times of 72 hours or less.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a low-risk sterile compounded drug product must not exceed:

(a) Forty-eight hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Fourteen days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

639.67063 Low-risk sterile compounding: Radiopharmaceutical drug products. (NRS 639.070) If a nuclear pharmacy compounds radiopharmaceutical drug products, the nuclear pharmacy shall ensure that, in addition to satisfying the requirements of NAC 639.5828:

1. The radiopharmaceutical compounded drug products are compounded in a vertical laminar airflow hood or Class II type B2 biological safety cabinet that is located in an environment with an air quality of ISO Class 8 or higher;

2. Only shielded vials, syringes and other devices and containers specifically manufactured for use with radiopharmaceutical components are used in the compounding process;

3. Each employee of the nuclear pharmacy who will compound radiopharmaceutical drug products is trained and knowledgeable with regard to compounding, handling, cleaning and any special techniques used with radiopharmaceutical drug products; and

4. Any special equipment or device that is used to compound radiopharmaceutical products, including, without limitation, a molybdenum-99technetiym-99m generator, is used, stored and maintained according to the directions of the manufacturer of the equipment or device.

639.67065 Medium-risk sterile compounding: Process and storage. (NRS 639.070)

1. A compounded drug product is a medium-risk sterile compounded drug product if:

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is compounded using aseptic techniques pursuant to one of the conditions listed in NAC 639.67061 as a condition for a low-risk sterile compounded drug product; and

(c) One or more of the following conditions are present:

(1) Individual or small doses of sterile drug products are combined or pooled to prepare the final compounded drug product that will be administered to multiple patients or to one patient multiple times;

(2) The compounding process includes complex aseptic manipulations other than a single-volume transfer;

(3) The compounding process uses more than three commercially manufactured sterile drug products or other entries of a sterile drug product into one container, including, without limitation, a bag or vial, to make the final compounded drug product;

(4) The final compounded drug product does not contain broad-spectrum bacteriostatic substances and will be administered over a period which exceeds 24 hours; or

(5) The compounding process requires an unusually long duration, as determined by the managing pharmacist, including, without limitation, the period required to complete dissolution or homogeneous mixing.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a medium-risk sterile compounded drug product must not exceed:

(a) Thirty hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Nine days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

639.67067 High-risk sterile compounding: Process and storage. (NRS 639.070)

1. A compounded drug product is a high-risk sterile compounded drug product if:

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is contaminated with or at a high risk of becoming contaminated with infectious microorganisms; and

(c) One or more of the following conditions are present:

(1) One or more of the ingredients or devices used in the compounding process are nonsterile; or

(2) One or more of the ingredients or devices used in the compounding process were sterile but were exposed or are suspected of having been exposed for more than 1 hour to an air quality inferior to an ISO Class 5 environment.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a high-risk sterile compounded product must not exceed:

(a) Twenty-four hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Three days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

639.67069 High-risk sterile compounding: Sterilization. (NRS 639.070)

1. Except as otherwise provided in subsection 5, a pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products shall ensure that each such compounded drug product is sterilized through filtration, by using steam in an autoclave or by dry heat. Except as otherwise provided in subsection 5, a pharmacist engaged in the practice of compounding high-risk sterile compounded drug products shall choose the method of sterilization that ensures the strength, purity, quality and packaging integrity of the final compounded drug product.

2. If a pharmacy sterilizes high-risk sterile compounded drug products using the filtration method, the pharmacy shall:

(a) Use commercially available sterile filters that are:

(1) Pyrogen-free and have a nominal porosity of 0.2 micron or 0.22 micron; and

(2) Certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta on each square centimeter of upstream filter surface area under conditions similar to the conditions of sterilization of the high-risk compounded drug products;

(b) Ensure that the filters used have sufficient capacity to permit the sterilization process to be completed rapidly and without compromising the sterility of the filtration process; and

(c) Subject the filtration units to the manufacturer's recommended integrity testing, including, without limitation, the bubble point test, after the filtration of the high-risk sterile compounded drug products is completed.

3. If a pharmacy sterilizes high-risk sterile compounded drug products using steam in an autoclave, the pharmacy shall:

(a) Expose each high-risk sterile compounded drug product to steam at 121 degrees Celsius (250 degrees Fahrenheit) under a pressure of 15 pounds per square inch for the duration of the sterilization process;

(b) Before starting the sterilization process, ensure that plastic, glass and metal devices are wrapped in low particle shedding paper or fabric or sealed in envelopes that prevent microbial penetration after the sterilization of the high-risk sterile compounded drug products is completed;

(c) Ensure that the solutions that will be used to fill the vials which will be steam sterilized are passed through a filter having a porosity of not more than 1.2 microns to remove particulate matter immediately before filling those vials; and

(d) Verify the mass of the container that will be sterilized using steam in an autoclave to ensure that the container will be sterile after the period of exposure in that autoclave.

4. If a pharmacy sterilizes high-risk sterile compounded drug products using dry heat, the pharmacy shall ensure that:

(a) The heated air is filtered and evenly distributed by a blower throughout the chamber or oven used for the sterilization process; and

(b) The chamber or oven used for the sterilization process is equipped with accurate temperature controls and a timer.

5. A pharmacy may only use dry heat as a method of sterilization for a high-risk sterile compounded drug product if the final high-risk sterile compounded drug product would be damaged by moisture or is impermeable to moisture.

639.67071 High-risk sterile compounding: Testing of certain drug products. (NRS 639.070)

1. A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for injection into the vascular system or central nervous system shall test a quantity of the high-risk sterile compounded drug product for:

(a) Sterility using a membrane filtration method or an equivalent method, as determined by the Board, before any of the compounded drug product may be administered or dispensed to a patient; and

(b) Excessive bacterial endotoxins using an appropriate test, as determined by the Board, for the particular product at issue before any of the compounded drug product may be administered or dispensed to a patient.

2. A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for inhalation or ophthalmic use shall test a quantity of each such high-risk sterile compounded drug product for sterility.

3. The provisions of subsections 1 and 2 apply only to high-risk sterile compounded drug products:

(a) Compounded in groups of more than 25 identical individual single-dose packages;

(b) Compounded in multiple-dose vials for administration to multiple patients; or

(c) That will be exposed for a period of more than:

(1) Twelve hours to temperatures of at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(2) Six hours to temperatures exceeding 8 degrees Celsius (46 degrees Fahrenheit) before the compounded drug product is sterilized.

4. If any high-risk sterile compounded drug product tested pursuant to this section tests positive for antimicrobial growth or endotoxin production, the high-risk sterile compounded drug product must not be administered or dispensed to a patient.

639.67075 Immediate-use sterile compounding: Compounding standards. (NRS 639.070)

1. An immediate-use sterile compounded drug product that contains three or less commercial sterile drug products that will be stored more than 1 hour before administration is begun must comply with all compounding standards applicable to low-risk sterile compounded drug products.

2. An immediate-use sterile compounded drug product which contains more than three commercial sterile drug products or which requires complex manipulations or complex preparation must comply with all compounding standards applicable to medium-risk sterile compounded drug products.

3. An immediate-use sterile compounded drug product that contains one or more nonsterile ingredients or components must comply with all compounding standards applicable to high-risk sterile compounded drug products.