July 2024 Board Meeting Handouts

5D. Nerissa Aguas

23A. Workshop – Written Public Comment

23B. Workshop – LCB File No. 053-24I

14A. Vitti Labs, LLC

5D

Nevada State Board of Pharmacy

Supplement for Mis-fill Cases

Case Number: 23-456-PH-N

Date of request: 12/20/2023

Date of mis-fill: 11/7/2023

Investigator: Monica S. Segedy

Name of pharmacist completing form: RPh Nerissa Aguas

License number of pharmacist completing form: #14977

Please provide the following information for the day in which the error occurred:

Personnel:

Total Pharmacist hours: 9 hrs

Total Technician hours: 25 hrs

Total Clerk hours: 0

Total Hours open: 9

Prescriptions:

Number of new prescriptions filled: 177

Number of refill prescriptions filled: 87

Number of vaccinations administered: 15

Counseling:

Was counseling provided to patient on mis-filled prescription: Yes, staff Pharmacist Sheila Tapay provided the counseling when she returned the prescription on Nov. 10, 2023 and verified that patient did not took any of the wrong medications.

Exhibit 1

Case#23-456.CVS#8806.021

Other Information you feel is important:

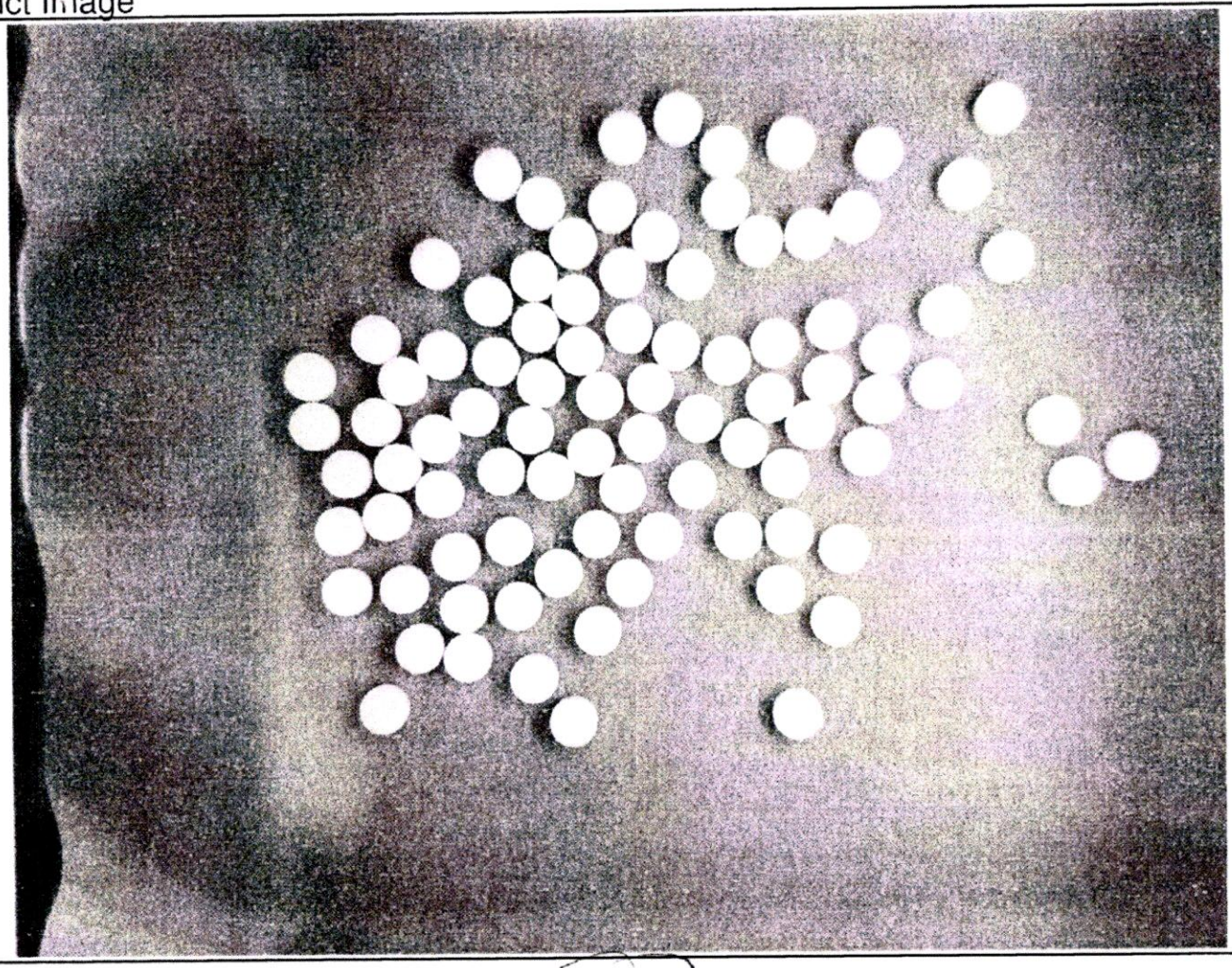
I would like to elaborate the new virtual verification process of CVS Pharmacy so that you will better understood how it was done. First, The pharmacist must verify the data entries of a prescriptions are correct, whether it is transmitted electronically , verbally, written or faxed . Then, the prescription will moved to production where the PT will print, pull the drug, scan the QR/Bar Code, then count the no. of pills needed, take a photo of the pills before it is place in the vial and labeled then bagged to be put away on the waiting bins ready for pick-up. This are all done by the PT and the PRH are not required to see the physical finished prescription. By using this new Air-Support Virtual Verification Process, any Pharmacist of CVS (on site or other stores) will be able to verify the prescription before any customer can pick it up. That being said, there will be no prescriptions going to be released to the customer/patient until a Pharmacist verified the prescription.

This new verification Process gives the Pharmacist more time to spend on customer/patient care/counselling. Other pharmacist can also verify the prescriptions at the other pharmacy that was logging behind just by using this Air-support Virtual Verification."

Request ID: 1720925
Rx Number: **1150305**

Request Submitted Date: **01/02/2024**
Store Number: **8806**

Product Image



210

CVS pharmacy
Reno, NV 89503 cvs.com

TEL: 775-747-6658
RX: 1150305
QTY: 90
REFILL: 2 by 7/30/24

PRSCBR: C. Pinkston
DATE FILLED: 11/6/23
DISCARD AFTER: 11/5/24
RPH: None Aguas
MFR: ASCEND LABORATO
TECH: ST/

This is a WHITE, ROUND-shaped TABLET imprinted with 210 on the front.

[redacted]
AMLODIPINE BESYLATE 5 MG TAB

MORNING 1 TABLET
MIDDAY
EVENING
BEDTIME

PHARMACY ADVICE

[redacted]
Brentwood, CA

AMLODIPINE BESYLATE 5 MG TAB
Common brand(s): Norvasc

Take 1 tablet by mouth every day for 90 days

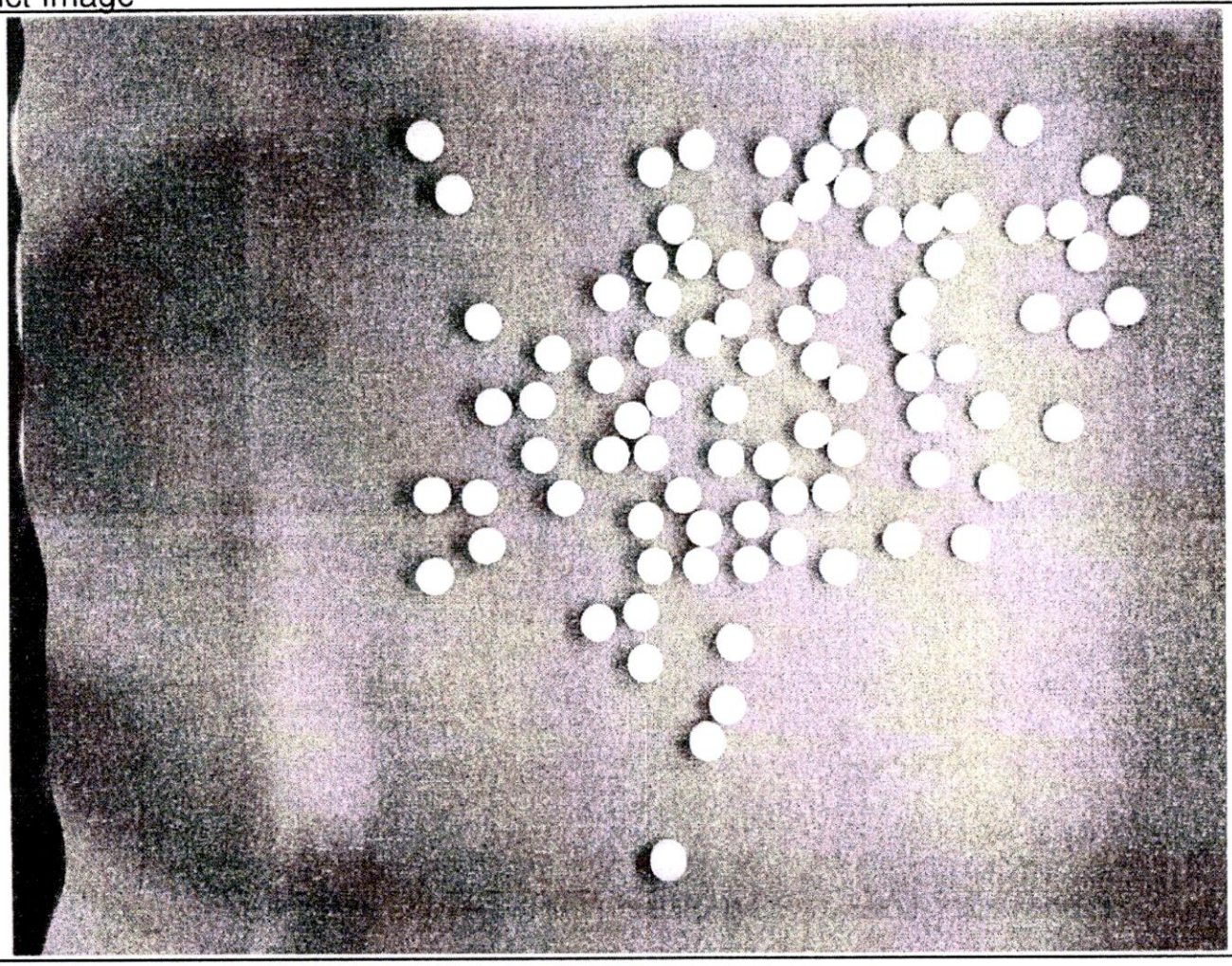
Important Information
CAUTION: DO NOT USE WITH ALCOHOL OR NONPRESCRIBED DRUGS WITHOUT CONSULTING THE PRESCRIBING PRACTITIONER.
- This medication may cause dizziness.
- Drug may impair ability to operate a vehicle, vessel or machine. Use care.

Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

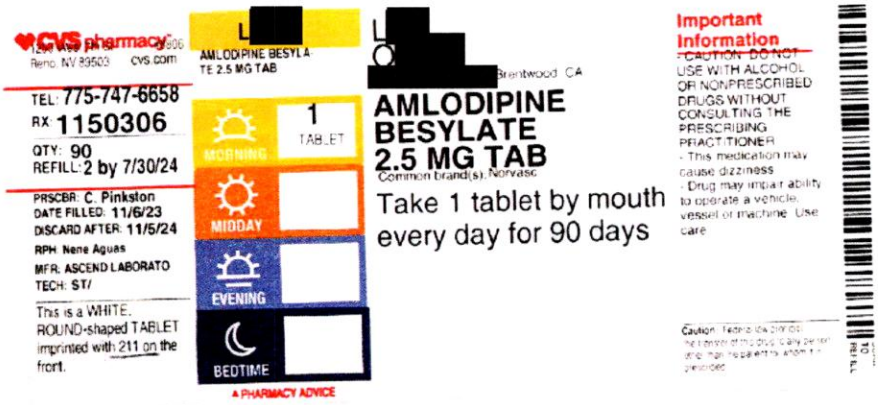
Case#23-456.CVS#8806.023

Request ID: **1720927**
Request Submitted Date: **01/02/2024**
Rx Number: **1150306**
Store Number: **8806**

Product Image



211



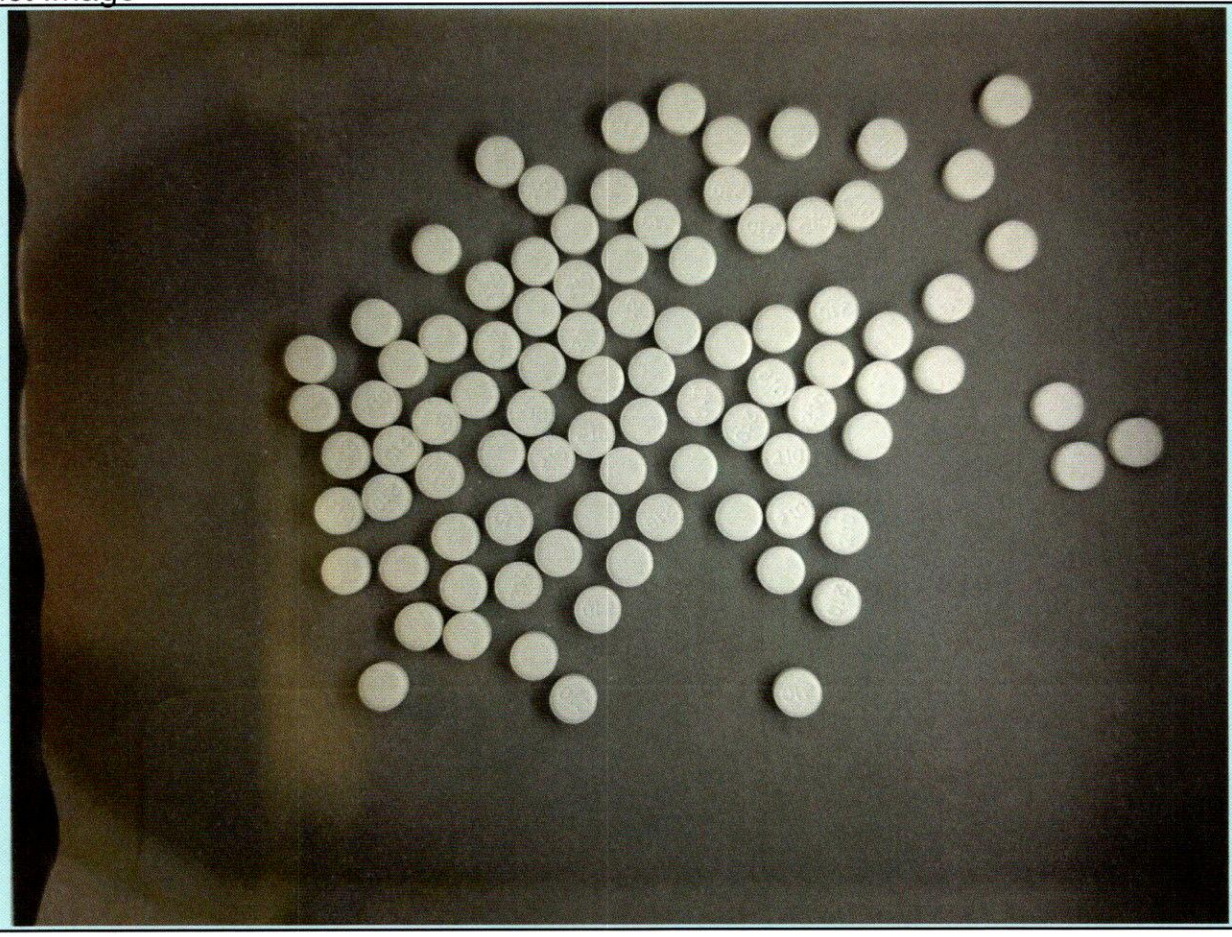
Case#23-456.CVS#8806.024

Exhibit 2

Request ID: **2047269**
Rx Number: **1150305**

Request Submitted Date: **04/04/2024**
Store Number: **8806**

Product Image



Request ID: **2047269**
Rx Number: **1150305**

Request Submitted Date: **04/04/2024**
Store Number: **8806**

Product Information			
Patient Information			
Patient Name	L[redacted]O[redacted]	Patient DOB	[redacted]
Product Information			
Rx#	1150305	Fill Date	03:20 AM 11/06/2023 EST
Fill#	1	Pill/Package Count	90.0
NDC	67877019810	Image captured by	Giovanni Bartice
Disp Qty	90.0	Date/Time captured	02:07 PM 11/07/2023 EST
Drug	AMLODIPINE BESYLATE 5 MG TAB	Origin	Accuracy Scan
		Image Recaptured	N
		Is this Partial Fill?	N
Total Images	1	This prescription is not physically verified	

Exhibit 3

Request ID: **2047271**
Rx Number: **1150306**

Request Submitted Date: **04/04/2024**
Store Number: **8806**

Product Information

Patient Information			
Patient Name	L[redacted]O[redacted]	Patient DOB	[redacted]
Product Information			
Rx#	1150306	Fill Date	03:20 AM 11/06/2023 EST
Fill#	1	Pill/Package Count	90.0
NDC	67877019710	Image captured by	Giovanni Bartice
Disp Qty	90.0	Date/Time captured	02:08 PM 11/07/2023 EST
Drug	AMLODIPINE BESYLATE 2.5 MG TAB	Origin	Accuracy Scan
		Image Recaptured	N
		Is this Partial Fill?	N
Total Images	1	This prescription is not physically verified	

Request ID: **2047271**
Rx Number: **1150306**

Request Submitted Date: **04/04/2024**
Store Number: **8806**

Product Image

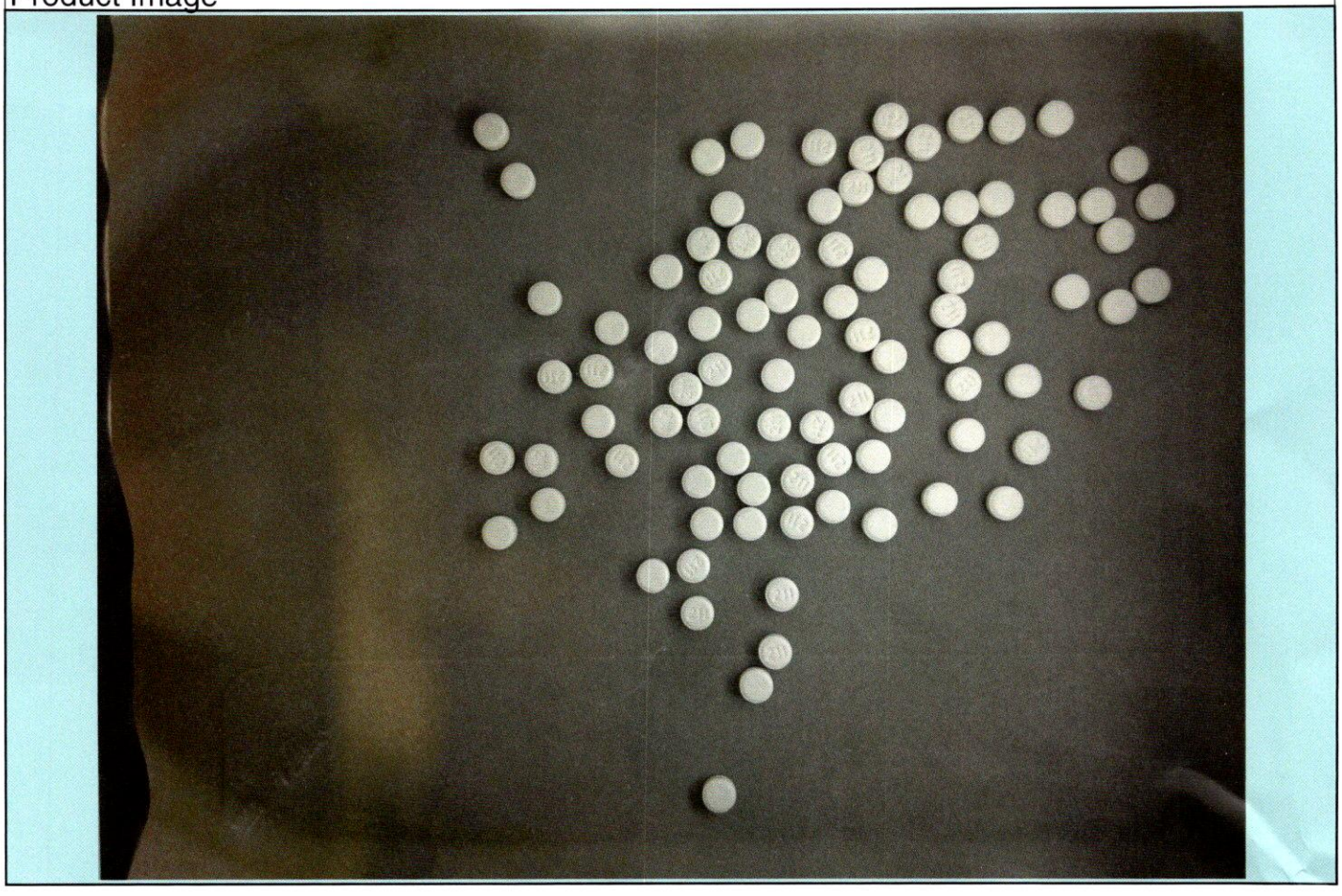
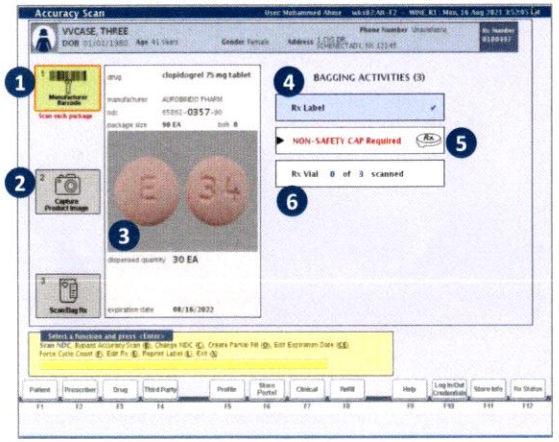


Exhibit 4

Enhancements to Virtual Verification to be implemented in Nevada

Production



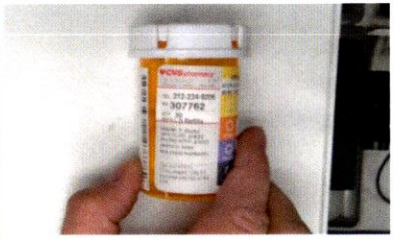
1. Manufacturer 2D barcodes incorporated to capture lot # and validate expiration date systemically
   a. System checks ensure no expired product is dispensed, and labels and updated appropriately if product is short dated
2. When multiple packages are dispensed, 2D barcodes require each package to be scanned
3. Stock images incorporated for comparison to pills being counted and dispensed
4. Bagging scans require technician to associate patient label with affixed product label
5. Non-safety cap indicator is now a system stop that requires intervention vs. looking at patient label
6. Specific label versions created so that each label printed requires it to be scanned separately

Imaging Standards*

First Image - Pills

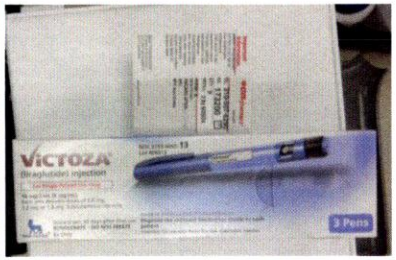
Loose Pills
Image of all tablets and capsules dispensed in prescription

Second Image - Pills



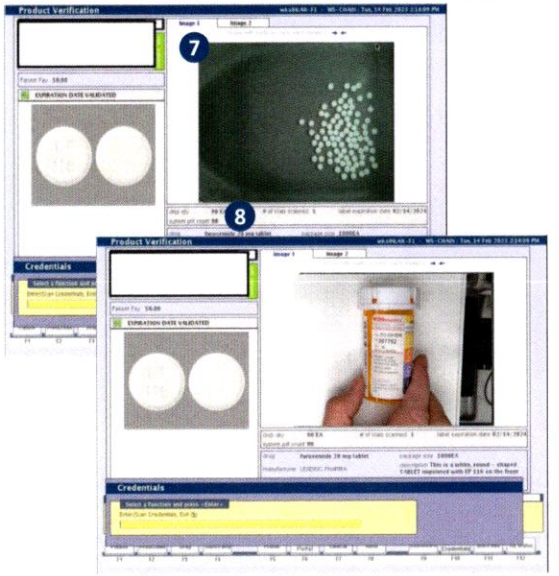
Labeled vial/product*
additional image of the labeled vial or product showing Rx #

Second Image - UoU



* Second image of labeled product is not chain standard and would be a modification for NV that would be implemented.

Product Verification



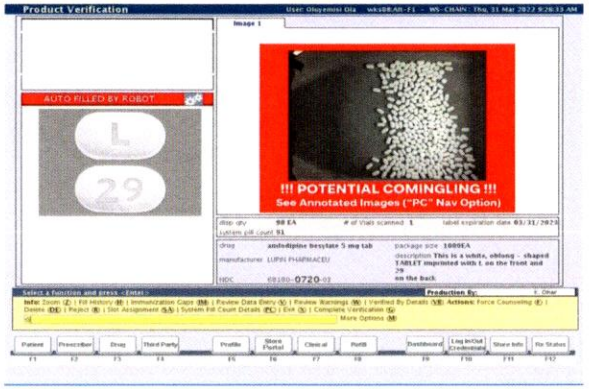
7. Virtual verified images *systemically* ensure that pharmacists must view every image taken
8. Pharmacists know how many vial labels were scanned, and can associate each scan with a separate product image

CVSHealth.

New enhancements include AI Support for pill counting, detecting comingling & more

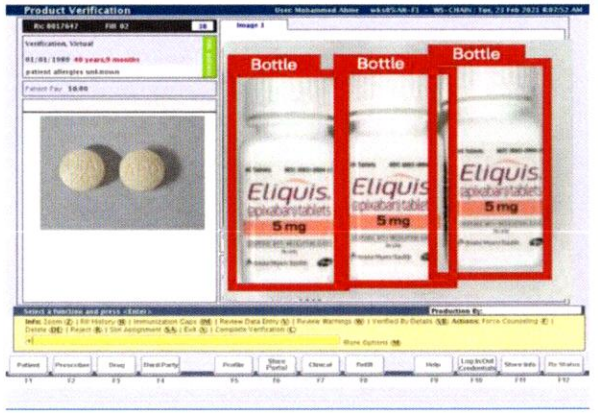
1 Pill Counting

2 Comingling Alerts



Coming Soon

3 Product Alerts



Coming Soon

CVSHealth.

Memorandum of Attorney's Fees and Costs

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8806,** **Pharmacy License No. PH00640, and** **NERISSA AGUAS, RPH,** **Certificate of Registration No. 14977,** **Respondents.**	**CASE NOS. 23-456-PH-N** **23-456-RPH-N** **MEMORANDUM OF ATTORNEY'S FEES AND COSTS RECOVERABLE PURSUANT TO NRS 622.400**

TIMESHEET FOR BRETT KANDT –

DATE	TIME
2/9/2024	3.50

Confer with staff and review investigative case file; research and draft Notice of Intended Action and Accusation.

2/13/2024	1.50

Confer with staff, research and revise Notice of Intended Action and Accusation.

3/18/2024	0.50

Confer with staff, research and revise Notice of Intended Action and Accusation.

3/18/2024	1.00

Confer with staff and finalize and file Notice of Intended Action and Accusation.

3/20/2024	0.75

Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action, continuance and proposed resolution; draft confirmation of continuance.

3/21/2024	0.50

Confer with staff and respondent Aguas regarding pending action.

3/25/2024	1.50

Confer with staff and respondent Aguas regarding pending action and proposed resolution.

Exhibit 5

4/4/2024 0.50

Confer with staff and respondent Aguas regarding pending action.

4/5/2024 2.75

Confer with counsel for respondent Aguas regarding pending action, continuance, discovery and proposed resolution; review Answer and Notice of Defense and Request for Discovery; draft confirmation of continuance.

4/8/2024 1.25

Confer with counsel for respondent Aguas regarding pending action and prepare discovery response.

4/10/2024 1.50

Confer with counsel for respondent Aguas regarding pending action and provide discovery response.

4/11/2024 0.50

Confer with counsel for respondent Aguas regarding pending action and provide discovery response.

4/26/2024 1.50

Confer with counsel for respondent Aguas regarding pending action. Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action, discovery and proposed resolution.

5/8/2024 1.25

Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action and prepare discovery response.

5/9/2024 1.50

Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action and provide discovery response.

5/20/2024 0.25

Confer with client and R. Morris regarding pending action and hearing date for respondent CVS Pharmacy #8806 .

5/21/2024 0.25

Confer with client and R. Morris regarding pending action and hearing date for respondent CVS Pharmacy #8806 .

5/29/2024 0.25

Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action and stipulations on evidence for hearing.

6/5/2024 0.50

Confer with counsel for respondent Aguas regarding pending action and issuance of subpoena for respondent.

6/21/2024 0.50

Confer with counsel for respondent Aguas regarding pending action.

6/25/2024 2.25

Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action and stipulations on evidence for hearing; confer with staff and counsel for respondent Aguas regarding pending action; prepare and issue subpoena for respondent.

6/27/2024 0.25

Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action and stipulations on evidence for hearing.

6/28/2024 0.25

Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action and stipulations on evidence for hearing.

7/1/2024 1.50

Confer with counsel for respondent Aguas regarding pending action. Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action and stipulations on evidence for hearing.

7/2/2024 0.25

Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action and stipulations on evidence for hearing.

7/3/2024 1.25

Confer with counsel for respondent CVS Pharmacy #8806 regarding pending action and stipulations on evidence for hearing; review Answer and Notice of Defense.

7/5/2024 0.50

Confer with staff regarding issuance of subpoena for PT Bartice.

7/82024 0.50

Confer with staff regarding service of subpoena for PT Bartice.

7/11/2024 3.50

Confer with counsel for respondent Aguas regarding pending action. Confer with staff and counsel for respondent CVS Pharmacy #8806 regarding pending action and stipulations on evidence and witnesses for hearing; prepare memorandum of attorney's fees and costs and prepare for hearing.

7/15/2024 2.75

Prepare for hearing; confer with staff, counsel for respondents and witnesses; finalize proposed exhibits and documentation of fees and costs.

7/17/2024 1.00

Hearing in Case 23-456-PH-N.

TOTAL 49.25 hours x $86.50/hour = $4,260.12

Timesheet for Jessette Phaynarikone –

CVS Pharmacy #8806 - CASE NO. 23-456-PH-N

DATE	TIME
5/9/2024	0.50
Prepared Discovery Request	
6/13/2024	0.25
Sent 21-day notice for mailing	

TOTAL MAILING COST	**$9.33**
TOTAL TIME	**.75 hours x $24.50/hour = $18.37**
OVERALL TOTAL	**$27.70**

Timesheet for Monica S. Segedy

Case 23-456

DATE	TIME	ACTIVITY
11/28/2023	1.0 Hours	Interview of Complainant/Review of Photos
11/29 to 12/11/2023	2.0 Hours	Request/Review of CVS Records
12/11/2023	2.0 Hours	Additional Requests and Records of CVS
12/20/2023	1.0 Hours	Interview/Statement of Narissa Aguas
1/30/2024	2.0 Hours	Site visit/Meeting with RPh Aguas at CVS
1/30/2024	2.0 Hours	Report Writing/Documentation of Evidence

Total Hours: 10.0 Hours @ $50 per Hour = $500.00

23A

NEVADA SOCIETY OF ADDICTION MEDICINE

2950 E Flamingo Rd, Suite E
Las Vegas, Nevada 89121

June 12, 2024

Helen K. Park, PharmD
President, Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, #206
Reno, Nevada 89521

Re: Proposed Regulation Change

Dear Dr. Park:

It has come to our attention at the Nevada Chapter of the American Society of Addiction Medicine (NVSAM,) that the Nevada State Board of Pharmacy may soon be considering a more permissible approach to identification for the purposes of picking up medications for patients.

This has been a common topic of interest among our membership, as we have seen first hand patients relapse after detoxification simply because they lacked adequate means to identify themselves when picking up their medications. This is particularly true for those who are post incarceration and unhoused individuals. They are, by far, the most vulnerable to relapse and yet they have the highest hurdles to traverse in order to obtain their medications. Many of them are able to obtain Clarity cards, but these cards are unfortunately not accepted as adequate forms of identification.

It is our contention that lowering the identification bar, specifically for filling medications used for medication assisted treatment, will be a very positive harm reduction step and may greatly facilitate adequate treatment. Currently, it is estimated that only 10-15% of patients with substance use disorders receive treatment. Hopefully, with steps like this, we will improve those numbers substantially.

Please feel free to reach out to us if you need any input regarding how proposed regulation changes may impact the daily treatment of our shared patients. As always, we look forward to collaborating with our pharmacist colleagues!

Sincerely,

Maureen Strohm, MD, DFASAM
President, Nevada Society of Addiction Medicine

José M. Partida Corona, MD, FASAM
Member, NVSAM Board of Directors

23B

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

LCB FILE NO. R053-24I

The following document is the initial draft regulation proposed by the agency submitted on 03/12/2024

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop – March 7, 2024

EXPLANATION – Matter in *italics* is new; matter in brackets [~~omitted material~~] is material to be omitted. and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS 639.0727

A REGULATION relating to pharmacy; The proposed amendment removes various provisions relating to compounding which are in conflict with current United States Pharmacopeia compounding standard.

CHAPTER 639 - PHARMACISTS AND PHARMACY

General Provisions

639.440 Definitions.
639.441 "Administer" defined.
639.442 "Chart order" defined.
639.445 "Compound" and "compounding" defined.
639.446 "Consultant pharmacist" defined.
639.4465 "Correctional institution" defined.
639.447 "Deliver" and "delivery" defined.
639.448 "Device" defined.
639.449 "Direct copy" defined.
639.450 "Dispense" defined.
639.451 "Distribute" defined.
639.452 "Floor stock" defined.
639.453 "Formulary" defined.
639.455 "Investigational drug" defined.
639.456 "IV admixture" defined.
639.457 "Medical facility" defined.
639.4575 "Pharmacy" defined.
639.458 "Prescription" defined.
639.459 "Unit dose" defined.
639.460 "Unit of use" defined.
639.461 Licensing.
639.462 Biennial registration.
639.463 Change of ownership.

Standards of Operation

639.464 Scope of services in hospital or correctional institution.
639.4645 Maintenance of registration certificates required.
639.465 Managing pharmacist.
639.466 Consultant pharmacist.
639.467 Staff pharmacists.
639.468 Establishment of policies, procedures and systems.
639.4685 Handling of medications in correctional institutions without pharmacies.
639.469 Standards for premises.
639.470 Security of premises.
639.472 Maintenance of reference library.
639.473 Procurement and storage of drugs.
639.474 Development and use of formulary.
639.475 Preparation and labeling of admixtures.
639.476 Prepackaging of drugs.
639.477 Policies and procedures for distribution of drugs.
639.478 Limitations on distribution of drugs.
639.479 Withdrawal of drugs when full-time pharmacist is absent.
639.480 Withdrawal of drugs when part-time or consultant pharmacist is absent.
639.481 Withdrawal of drugs when facility uses floor stock and pharmacy is closed.

Records

Maintenance and availability of records.
Statutes applicable to maintenance of records.
Contents and maintenance of chart orders.
Maintenance of records for controlled substances.
Maintenance of records of controlled substances administered from floor stock.
Maintenance of additional records.
Maintenance of records for distribution of controlled substances to another pharmacy or practitioner.
Separation of certain records.

639.6939 Adoption by reference of code of ethics and code of professional conduct; revision of codes after adoption.
639.694 Employment of administrator required; duties; notice to Board of cessation of employment; sharing of common administrator at shared facility.
639.6941 Unprofessional conduct; responsibility of owner for acts of others.

Licensing and Fees

639.6942 Application for license; license required for each location; notification of change in information; license nontransferable; expiration.
639.6943 Board will not issue license to certain practicing health professionals.
639.6944 Licensing of applicants located outside of State.
639.6945 Waiver of license fee.

Medical Products Providers

639.6946 Duties of providers; repair and maintenance of medical products; hours of operation; restriction on location; procedure for consumer complaints.
639.6947 Change in controlling interest.
639.6948 Compliance with provisions by person or business who is not medical products provider.
639.6949 Provision of medical products to consumer with or without bona fide order or prescription; tracking requirements.
639.695 Maintenance of records.
639.6951 Communications and advisement of options and use of medical products; written record.
639.6952 Communications concerning use of medical products provided by written or oral order or prescription; written record.
639.6953 Assistive equipment.
639.69533 Customized orthotic or prosthetic devices: Approval by Board required.
639.69535 Customized orthotic or prosthetic devices: Accessibility of services and confidentiality.
639.69537 Customized orthotic or prosthetic devices: Practitioner's order required.
639.6954 Medical gases and associated equipment or respiratory equipment.
639.69543 Insulin pumps.
639.69545 Pressurized stockings.
639.6955 Life-sustaining equipment.
639.6956 Parenteral and enteral services and equipment.

Medical Products Wholesalers

639.6957 Duties of wholesalers; repair and maintenance of medical products; hours of operation; consumer complaints.
639.69573 Wholesaler who employs person to sell or market device or appliance: Annual submission of certain information to Board; review and contents of marketing code of conduct.
639.69575 Submission of certain information regarding sales and marketing staff: Submission of form after initial submittal; method of submission.
639.69577 Submission of certain information regarding sales and marketing staff: Incomplete, improperly completed or noncompliant submittal; correction of deficiencies.

Disciplinary Action

639.6958 Summary suspension of license.

TRADE PRACTICES

639.700 Performance of certain acts by pharmacists and pharmaceutical interns only.
639.701 Acts not required to be performed by pharmaceutical professionals.
639.702 Responsibility for acts and omissions of personnel who are not pharmacists.
639.704 Check of license or certification required before employment by pharmacy or wholesaler.
639.706 Marking of prescriptions with serial numbers; maintenance of files of prescriptions.
639.707 Counseling of patients: Duties of pharmacist, intern pharmacist or dispensing practitioner; exception; documentation.
639.708 Counseling of patients: Duties of pharmacy or dispensing practitioner.
639.709 Persons to whom pharmacy may furnish certain restricted products.
639.7102 Use of computer system for issuance and transmission of prescription.
639.7105 Electronic transmission of prescription.

639.711 Transmission of prescription by facsimile machine.
639.712 Transcribing prescription transmitted by oral order.
639.7125 Use of fulfillment pharmacy by dispensing pharmacy.
639.713 Transfer of information between pharmacies: Conditions; prohibitions.
639.714 Transfer of information between pharmacies: Procedure.
639.7145 Transfer of information between pharmacies: Requirements for transfer by facsimile machine.
639.715 Automated drug dispensing system or other mechanical device: Restrictions on use.
639.718 Automated drug dispensing system used by pharmacy: Licensure required for system; use to dispense prescription drugs to patients.
639.719 Automated drug dispensing system used by reproductive healthcare center: Licensure required for system; use to dispense prescription drugs to patients.
639.720 Mechanical device other than automated drug dispensing system: Licensure and use to furnish drugs and medicines for administration to registered patients in medical facility and to patients receiving treatment in emergency room of hospital.
639.725 Use of mechanical counting device for dispensing medication to be taken orally.
639.730 Inspection of damaged pharmaceuticals.
639.740 Container for dispensing prescribed medicine.
639.742 Dispensing of controlled substances or dangerous drugs for human consumption: Application by practitioner for certificate of registration at each site; application by facility required under certain circumstances; duties of dispensing practitioner, facility and federally-qualified health center vehicle relating to drugs; authority of dispensing practitioner and technician.
639.7421 Dispensing of controlled substances: Registered practitioner practicing in hospital or independent center for emergency medical care exempt from requirement to obtain certificate of registration to dispense at site.
639.7422 Dispensing of dangerous drugs: Application by dispensing practitioner to transport and dispense to patients of federally-qualified health center from federally-qualified health center vehicle; duties of dispensing practitioner; approval of vehicle not transferable.
639.7423 Dispensing of controlled substances or dangerous drugs not for human consumption: Application by veterinarian for certificate of registration; duties of veterinarian and veterinary facility; maintenance of records; exemption from certain regulations.
639.7424 Dispensing technician in training: Application and fee for registration; grounds for denial of application; issuance and expiration of registration; participation in training.
639.7425 Dispensing technician: Application and fee for certificate of registration; grounds for denial of application; issuance and expiration of certificate of registration; in-service training required for renewal of registration.
639.743 Restrictions on access to drugs by dispensing technician in training or dispensing technician; dispensing practitioner responsible for performance of functions by dispensing technician.
639.7435 Dispensing technician and dispensing technician in training: Registration transferable; notice of change of location of practice or supervisor.
639.744 Dispensing practitioner: Employment of multiple dispensing technicians.
639.7445 Dispensing practitioner: Disciplinary action for violation of NAC 639.742 to 639.7445, inclusive.
639.745 Duties of certain practitioners concerning dispensing of controlled substances and dangerous drugs; maintenance of records.
639.746 Registration of oncology group practice or group of practitioners practicing at reproductive healthcare center to maintain single inventory of dangerous drugs; issuance and renewal of certificate of registration; authority and duties of registrant.
639.748 Identification of person who picks up controlled substance.
639.750 Dispensing of medication at certain locations when services of local retail pharmacy not available.
639.751 Requirements concerning signatures or initials to be placed on prescription.
639.752 Restrictions on filling or dispensing certain prescriptions.
639.753 Declination of pharmacist to fill prescription.
639.754 Refilling prescriptions: Restrictions; authorization by patient without specific request for particular refill.
639.755 Sale of preparations for treatment of asthma.
639.756 Retail community pharmacy: Required notice of availability of prescription readers; directions or advice on

COMPOUNDING AND DISPENSING DRUG PRODUCTS

General Provisions

NAC 639.661 Definitions. (NRS 639.070, 639.2807) As used in NAC 639.661 to 639.690, inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.6611 to 639.6677, inclusive, have the meanings ascribed to them in those sections.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94; A by R035-06, 9-18-2008)

NAC 639.6611 "Active ingredient" defined. (NRS 639.070) "Active ingredient" means an ingredient added to a compounded drug product which provides the therapeutic effect desired from the compounded drug product. The term does not include an inert ingredient.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6615 "Barrier isolator cabinet" defined. (NRS 639.070) "Barrier isolator cabinet" means a device the

interior of which creates an ISO Class 5 environment and provides an impermeable barrier to outside air at all times while it is being used for compounding purposes. The term includes, without limitation, compounding aseptic isolators and compounding aseptic containment isolators.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6617 "Beyond-use date" defined. (NRS 639.070) "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) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6621 "Chart order" defined. (NRS 639.070) "Chart order" has the meaning ascribed to it in NAC 639.442.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6623 "Component" defined. (NRS 639.070) "Component" means an ingredient that is used to compound a drug product, including, without limitation, an ingredient that does not appear on the labeling of the compounded drug product.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6625 "Compound" and "compounding" defined. (NRS 639.070)

1. Except as otherwise provided in subsection 2, "compound" and "compounding" mean:

(a) The preparation, mixing or assembling of a drug product of which at least one component is a prescription drug; and

(b) The packaging and labeling incident to the preparation, mixing or assembling of a drug product for the purpose of selling or dispensing the drug product pursuant to a prescription or chart order.

2. The terms "compound" and "compounding" do not include the mixing or reconstituting of a nonsterile drug product that is performed in accordance with:

(a) The directions contained in the labeling of the drug product that have been approved by the Food and Drug Administration and provided by the manufacturer of the drug product; or

(b) Any other directions provided by the manufacturer of the drug product that are consistent with the labeling ofthe drug product that have been approved by the Food and Drug Administration.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6627 "Compounding aseptic containment isolator" defined. (NRS 639.070) "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) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6629 "Compounding aseptic isolator" defined. (NRS 639.070) "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) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.663 "Cytotoxic" defined. (NRS 639.070, 639.2807) "Cytotoxic" means having the capability of killing living cells.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

NAC 639.6631 "Drug product" defined. (NRS 639.070) "Drug product" means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the Food and Drug Administration.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6635 "Hazardous drug" defined. (NRS 639.070) "Hazardous drug" means:

1. A compounded drug product in which one or more of the components of the compounded drug product produce one or more of the following characteristics in humans or animals:
   (a) Carcinogenicity;
   (b) Teratogenicity or other developmental toxicity;
   (c) Reproductive toxicity;
   (d) Organ toxicity at low doses; or
   (e) Genotoxicity; or
2. A compounded drug product in which the structure and toxicity profiles of the compounded drug product mimic an existing drug product which has components that produce one or more of the characteristics set forth in subsection 1.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~**NAC 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.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6641 "ISO Class 5" defined. (NRS 639.070) "ISO Class 5" means the classification of an atmospheric environment that is made by 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6643 "ISO Class 7" defined. (NRS 639.070) "ISO Class 7" means the classification of an atmospheric environment that is made by 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6645 "ISO Class 8" defined. (NRS 639.070) "ISO Class 8" means the classification of an atmospheric environment that is made by 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~**NAC 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.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.665 "Medical facility" defined. (NRS 639.070, 639.2807) "Medical facility" has the meaning ascribed to it in NRS 449.0151.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

~~**NAC 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.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.6665 "Nonsterile compounded drug product" defined. (NRS 639.070) "Nonsterile compounded drug product" means a drug product the preparation and dispensing of which require compounding and which is not required to be sterile as described in NAC 639.6677.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.667 "Nursing personnel" defined. (NRS 639.070, 639.2807) "Nursing personnel" means an employee of:

1. A medical facility who is licensed pursuant to chapter 632 of NRS;
2. A nursing pool as defined in NRS 449.0153; or
3. An agency to provide nursing in the home as defined in NRS 449.0015.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

NAC 639.6673 "Parenteral nutrition" defined. (NRS 639.070) "Parenteral nutrition" means nutrients provided intravenously.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6677 "Sterile compounded drug product" defined. (NRS 639.070) "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) of subsection 1 of NAC 639.670, or the provisions of NAC 639.661 to 639.690, inclusive.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.670 Adoption of certain publications by reference; revision of publication after adoption. (NRS 639.070, 639.2807)

1. The Board hereby adopts by reference the following, all licensees must adhere to these standards when compounding:

~~(a) Federal Standard 209E, "Airborne Particulate Cleanliness Classes in 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.~~ Clean room standards set by International Organization for Standardization (ISO), 1214 Verbier, Geneva, Switzerland.

~~(c)~~ *(a)United States Pharmacopeia - National Formulary*, 20~~08~~23 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/**, ~~for the price of $755~~.

~~(d)~~ (b)The *Food Chemicals Codex*, ~~6~~ 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/**, ~~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)~~ (c)Appendix A of *Publication No. ~~2004-165~~2016-161*, "Alert: 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~~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.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94; R035-06, 9-18-2008)

Standards for Compounding and Dispensing Generally

NAC 639.6701 Inspection of materials and equipment; recordkeeping. (NRS 639.070)

1. A pharmacy or pharmacist engaged in the practice of compounding drug products shall:

(a) Inspect and either approve or reject, without limitation, each component, container, closure, label and other material used in the process of compounding each drug product;

(b) Ensure the proper use, cleanliness and maintenance of any equipment used in the process of compounding each drug product; and

(c) Prepare the records required to be prepared pursuant to NAC 639.661 to 639.690, inclusive, concerning the compounding of each drug product to ensure that an error has not occurred in the process of compounding each drug product.

2. A pharmacy or pharmacist engaged in the practice of compounding drug products may not allow any food or drink to be stored or consumed in or at an area or room in the pharmacy that is designated for compounding.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67013 Competency and proficiency of certain pharmaceutical personnel. (NRS 639.070)

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, 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) 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67015 Establishment of policies and procedures. (NRS 639.070)

1. A pharmacy engaged in the practice of compounding drug products shall establish and maintain written policies and procedures for compounding drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have. Such policies and procedures must include, without limitation:

(a) Policies and procedures for:

(1) The processes used by the pharmacy to compound drug products;

(2) The equipment used by the pharmacy to compound drug products;

(3) Ensuring that the actual weights and measures of each component are within plus or minus 5 percent of the theoretical weights and measures required for the drug products compounded by the pharmacy;

(4) Tracking, recalling and destroying the drug products compounded by the pharmacy, which must include a

requirement that the pharmacy ensure that all drug products which could have been compounded with a particular component be located, recalled and destroyed; and

(5) Identifying the drug products or components of drug products that will be considered hazardous drugs.

(b) Control procedures for monitoring each final compounded drug product and validating the compounding processes that may be responsible for causing variability in the final compounded drug product.

(c) Control procedures to ensure that:

(1) Each component is accurately weighed, measured or subdivided, as appropriate;

(2) Any variation in the actual yield of a drug product compounded by the pharmacy is within plus or minus 10 percent of the theoretical yield of the compounded drug product; and

(3) If a component is transferred from its original storage container to a new storage container, the new storage container is labeled with the date of the transfer and information that is sufficient to trace the contents of the new container to the original storage container.

2. A member of the staff of the Board may require a pharmacy engaged in the practice of compounding drug products to provide a sample of a drug product that is being compounded at the time of the request and any records related to that compounded drug product for purposes of testing the compounded drug product for compliance with the provisions of NAC 639.661 to 639.690, inclusive. The Board will share the costs of testing such a sample equally with the pharmacy.

3. If a sample tested pursuant to subsection 2 does not comply with the provisions of NAC 639.661 to 639.690, inclusive, the Board will notify the pharmacy of the failure to comply and the pharmacy must:

(a) Provide to the Board a written plan for remediating or addressing the noncompliance; and

(b) If requested by a member of the staff of the Board, provide an additional sample of the compounded drug product for testing. The costs of a test conducted pursuant to this paragraph must be paid solely by the pharmacy.

4. If the sample provided to the Board pursuant to paragraph (b) of subsection 3 does not comply with the provisions of NAC 639.661 to 639.690, inclusive, the Board will take such action as it deems necessary to correct the noncompliance or to prevent further noncompliance, including, without limitation:

(a) Suspending the license of the pharmacy pursuant to NRS 639.210;

(b) Suspending the ability of the pharmacy to compound certain drug products; and

(c) Requiring the pharmacy to perform any other remedial or protective measures the Board deems necessary to correct the noncompliance or to prevent further noncompliance.

NAC 639.67017 Use of automated compounding devices. (NRS 639.070)

1. A pharmacy may use an automated compounding device to:

(a) Assist with the compounding of a drug product; or

(b) Produce a final compounded drug product.

2. If a pharmacy uses an automated compounding device as described in subsection 1, the pharmacy shall establish and maintain written policies and procedures, in addition to the policies and procedures established and maintained pursuant to NAC 639.67015, that address:

(a) The qualifications that a pharmacist or a pharmaceutical technician must have to use the automated compounding device;

(b) The routine maintenance and cleaning required to be performed on the automated compounding device which, at a minimum, satisfies the requirements for maintenance and cleaning established by the manufacturer of the automated compounding device; and

(c) The testing required to be performed on the automated compounding device to ensure that the automated compounding device is measuring and dispensing the components of the compounded drug product and manufacturing the final compounded drug product within tolerances of not more than plus or minus 5 percent.

3. If a pharmacy uses an automated compounding device to assist with the compounding of a drug product for parenteral nutrition, the pharmacy shall establish safe maximum limits for each additive that may be used in compounding such a drug product. The pharmacy shall ensure that:

(a) The automated compounding device will cease compounding the drug product for parenteral nutrition if a maximum limit for an additive will be exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order; or

(b) If an automated compounding device cannot be programmed to cease the compounding process as described in paragraph (a):

(1) The automated compounding device is equipped with an audible alarm or some other mechanism that will alert the pharmacist if a maximum limit for an additive has been exceeded; and

(2) The pharmacy has written policies and procedures to prevent the continuation of the compounding process once a maximum limit for an additive has been exceeded until a pharmacist, after consultation with the prescribing

practitioner, makes changes to or validates the correctness of the prescription or chart order.

4. If the pharmacy uses a computerized order entry system in conjunction with the automated compounding device, the pharmacy must ensure that the computerized order entry system will cease processing the order if a maximum limit for an additive will be exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

5. A pharmacy shall make and maintain records that evidence compliance by the pharmacy with the policies and procedures required by this section.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67019 Retention of records. (NRS 639.070)

1. Except as otherwise provided in NAC 639.67055, each record required to be made pursuant to NAC 639.661 to 639.690, inclusive, must be:

(a) Maintained by the pharmacy for which the record was made for at least 2 years after the date the record was made; and

(b) Available for inspection and copying by the Board or its representative.

2. Records made and maintained by a pharmacy pursuant to NAC 639.67055 must be available for inspection and copying by the Board or its representative after the 6-month period required by NAC 639.67055 if the pharmacy maintains the records longer than the required 6-month period.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6702 Records concerning drug products compounded in excess and in bulk quantities. (NRS 639.070) For each compounded drug product that is in excess of the amount required by the prescription or chart order and each compounded drug product that is compounded in bulk quantities, the pharmacist who compounded or supervised the compounding of the compounded drug product shall prepare a record, either on paper or in the pharmacy's computer system, that includes, without limitation:

1. The name of the compounded drug product;
2. A list of the components and quantities of components used to compound the drug product, including, without limitation, the manufacturer or supplier of the components used, the lot number of the components used and the expiration dates of the components used;
3. The internal control number assigned to the compounded drug product by the pharmacist or the number of the prescription of the compounded drug product;
4. The beyond-use date of the compounded drug product;
5. The date of preparation of the compounded drug product;
6. The initials of the pharmacist or pharmaceutical technician who compounded the compounded drug product;
7. If the drug product was compounded by a pharmaceutical technician, the initials of the pharmacist who supervised the pharmaceutical technician; and
8. The quantity of the final compounded drug product.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

Standards for Compounding and Dispensing Nonsterile Products

NAC 639.6703 Labeling. (NRS 639.070)

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.~~ 2. 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~**NAC 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.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.67035 Establishment of policies and procedures. (NRS 639.070) A pharmacy engaged in the practice of compounding nonsterile compounded drug products shall, in addition to the requirements of NAC 639.67015, establish and maintain written policies and procedures for compounding nonsterile compounded drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have. Such policies and procedures must include, without limitation:

~~1.~~ Policies and procedures for:

(a) Making and maintaining records concerning the components used to compound each nonsterile compounded drug product;

(b) The amount of each component used to compound each nonsterile compounded drug product;

(c) The order of each step in the process of compounding each nonsterile compounded drug product; and

(d) Including the information listed in paragraphs (a), (b) and (c) on the original hard copy of the prescription maintained in the written records of the pharmacy or in a computer system that may be accessed to provide information:

(1) For refilling the prescription; or

(2) Requested by the staff of the Board.

~~2.~~ Control procedures for monitoring each final nonsterile compounded drug product and validating the processes for compounding that may be responsible for causing variability in the final nonsterile compounded drug product. Such control procedures must include, without limitation, procedures for evaluating:

(a) Any variation of more than plus or minus 10 percent in the weight of the capsules, tablets or any other solid form of a dosage of the same nonsterile compounded drug product;

(b) The adequacy of mixing to ensure uniformity and homogeneity of each nonsterile compounded drug product;

(c) If applicable, the clarity, completeness and pH of a nonsterile compounded drug product;
(d) If applicable, the even distribution of coloring agents; and
(e) Any variation of more than plus or minus 10 percent in the actual yield of a nonsterile compounded drug product compounded by the pharmacy as compared to the theoretical yield of the nonsterile compounded drug product.
~~3.~~ Control procedures to ensure:
(a) If the final nonsterile compounded drug product is a capsule, that the capsule is properly locked;
(b) If the final nonsterile compounded drug product is a tablet or any other solid form of dosage, that the final compounded drug product is of a uniform size and is intact;
(c) If the final nonsterile compounded drug product is a suppository, that the suppository is properly sealed;
(d) If the final nonsterile compounded drug product is an oral liquid, that, to the extent possible, the liquid is palatable to the patient;
(e) If the final nonsterile compounded drug product is a suspension, that the visible suspended particles are of uniform size and are readily dispersed upon shaking; and
(f) If the final nonsterile compounded drug product is a topical compounded drug product, that the final compounded drug product is smooth and not gritty and has a uniform viscosity unless grittiness is required for a particular therapeutic purpose.
(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~**NAC 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.
(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.XXX Flavoring a prescription.

1. A pharmacist may add flavoring to an oral solution at the request of a patient or their legal guardian.
   a. The pharmacist must make the record contemporaneous with the completion of the mixture, including but not limited to ingredients of the product, and
   b. The flavor additive shall in no way compromise the stability, safety, or efficacy of the dispensed drug, and
   c. The beyond use date of the product is assigned in accordance with USP 795 standards.

NAC 639.XXX Mixing of ready to use products.

1. A pharmacist may mix components of commercially manufactured ready to use FDA approved products.
   a. The pharmacist must make the record contemporaneous with the completion of the mixture, including but not limited to ingredients of the product, and
   b. The beyond use date of the product is assigned in accordance with USP 795 standards, and
   c. The pharmacist must follow all FDA approved mixing instructions.

Standards for Compounding and Dispensing Sterile Products

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67053 Tests for competency and proficiency of certain pharmaceutical personnel. (NRS 639.070)

1. Except as otherwise provided in subsections 4 and 5, a 1. 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 compound 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, 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 who compounds 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.~~

2. A pharmacy shall make and maintain records concerning all the actions listed in subsection 1 ~~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.

~~3. 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.~~

~~4. 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.~~

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67055 Record verifying accuracy required to be made. (NRS 639.070)

1. For all sterile compounded drug products compounded by a pharmacy, other than an institutional pharmacy, and for all sterile drug products for parenteral nutrition and sterile antineoplastic drug products compounded by an institutional pharmacy, a pharmacist shall make a record verifying the accuracy of each sterile compounded drug product that the pharmacist:

(a) Compounded;

(b) Verified the accuracy of after it was compounded by a pharmaceutical technician; or

(c) Dispensed for administration to a patient in a medical facility.

2. A pharmacist required to make a record pursuant to subsection 1 shall:

(a) Make the record contemporaneous with the completion of the compounding, verifying or dispensing of the sterile compounded drug product;

(b) Include in the record information identifying the patient for which the sterile compounded drug product was made and the date the sterile compounded drug product was compounded; and

(c) Initial the record if it is a written record or enter an initial or other identifying mark onto the record if the record is made in a computerized system.

3. A pharmacy for which a record was made pursuant to subsection 1 shall ensure that the record is maintained for at least 6 months after the date the sterile compounded drug product was compounded, verified or dispensed.

4. If a sterile compounded drug product is compounded by a pharmaceutical technician, the pharmaceutical technician shall make a record of the compounding in the same manner as a pharmacist is required to make a record pursuant to this section.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67057 Procedures following breach of seal of single-dose and multi-dose containers. (NRS 639.070)~~-~~

~~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. (1) 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 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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-volumetransfer;

(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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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 10^7 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67073 Immediate-use sterile compounding: Preparation and labeling. (NRS 639.070) 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. (1) 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. (Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 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.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67077 Sterile hazardous drugs: Safety procedures for storage, handling, compounding and disposal. (NRS 639.070)

1. A pharmacy engaged in the practice of compounding sterile 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 during preparation, handling and disposal of the components of the hazardous drug or final compounded drug product;

(c) Compound the hazardous drugs pursuant to the requirements set forth in NAC 639.661 to 639.690, inclusive, and applicable to the risk level of the compounded hazardous drugs;

(d) Ensure that an employee of the pharmacy involved with compounding hazardous drugs wears personal protective equipment, including, without limitation, gowns, gloves, face masks, hair covers, shoe covers or dedicated shoes, and, if the hazardous drugs contain one or more antineoplastic agents or it is recommended by the drug manufacturer, double gloves or chemotherapy gloves;

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

(f) 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 shall ensure that the process of compounding sterile hazardous drugs is performed only in an ISO Class 5 environment in either a biological safety cabinet or a compounding aseptic containment isolator if one or more of the components of the hazardous drug are:

(a) An antineoplastic drug;

(b) A radiopharmaceutical drug; or

(c) A drug whose manufacturer has recommended that the drug only be compounded in an ISO Class 5 environment in either a biological safety cabinet or a compounding aseptic containment isolator.

3. The biological safety cabinet or compounding aseptic containment isolator described in paragraph (c) of subsection 2 must be vented to outside air during the compounding process through the use of high efficiency particulate air filtration if one or more of the components of the compounded hazardous drug are antineoplastic drugs.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67079 Sterile hazardous drugs: Required training for certain pharmaceutical personnel. (NRS 639.070)

1. A pharmacy engaged in the practice of compounding sterile hazardous drugs and dispensing sterile compounded hazardous drugs shall require each pharmacist and pharmaceutical technician who compounds sterile 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 sterile hazardous drug that will be administered or dispensed to a patient; and

(b) At least once each year thereafter.

2. The training required pursuant to subsection 1 must include, at a minimum, information concerning:

(a) Safe aseptic manipulation practices;

(b) Negative pressure techniques for use with a biological safety cabinet, compounding aseptic containment isolator or compounding aseptic isolator;

(c) The correct use of a vial transfer device in a closed system;

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

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

3. The pharmacy shall make and keep a record of any training given pursuant to subsection 1.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

Standards for Compounding and Dispensing Parenteral Solutions

NAC 639.672 Reference materials required to be located in or immediately available to pharmacy. (NRS 639.070, 639.2807) Any pharmacy engaged in the practice of compounding and dispensing parenteral solutions shall have current reference materials located in or immediately available to the pharmacy. The reference materials must include information on:

1. All drugs and chemicals used in services related to parenteral therapy; and

2. The activities involved in parenteral therapy, including manufacturing, dispensing, distribution and counseling.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87)

NAC 639.680 Labeling. (NRS 639.070, 639.2807)

1. In addition to any other requirements for labeling, the label of any parenteral solution must include:

(a) The name and concentrations of all ingredients contained in the parenteral solution, including the primary solution; and

(b) Instructions for storage and handling.

2. The label of a parenteral solution which is used by a patient in the patient's home, in a facility for the dependent or in a medical facility which does not furnish the parenteral solution from a pharmacy located in that medical facility must include the telephone number of the pharmacy that furnished the parenteral solution.

3. Any cytotoxic agent must bear a special label which states:
(a) "Chemotherapy - Dispose of Properly;" or
(b) "Biohazard - Dispose of Properly."
4. As used in this section, "biohazard" means a biological agent that may be hazardous to persons or the environment.
(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94)

NAC 639.682 Record for each patient. (NRS 639.070, 639.2807)
1. A pharmacy engaged in the practice of compounding and dispensing parenteral solutions shall have on the premises or readily accessible:
(a) A record for each patient being treated with parenteral therapy;
(b) A summary of the most recent hospitalization of the patient or the patient's medical history; and
(c) Any notes taken by the pharmacist concerning the progress of the patient which document any contact with the patient or the practitioner concerning the parenteral therapy.
2. In addition to any other requirements for keeping records, the following records must be maintained in the pharmacy:
(a) Records concerning any prescriptions and medical supplies furnished to the patient.
(b) Information relevant to the patient's parenteral therapy, including, but not limited to:
(1) The patient's name, age, height, weight, sex and address and the telephone number of the location where the patient is receiving parenteral therapy;
(2) The diagnosis of the patient; and
(3) The patient's history of medication, including his or her current regimen concerning diet and medication and any allergies to drugs or food.
(c) Data of a laboratory relevant to the parenteral therapy.
(d) If the patient is using a parenteral solution in the patient's home, in a facility for the dependent or in a medical facility which does not furnish the parenteral solution from a pharmacy located in that medical facility, records indicating that the care of the patient is coordinated by the pharmacy, practitioner and nursing personnel before the administration of the parenteral solution, including:
(1) Documentation of all orders for medication, laboratory tests or other treatment related to the medication of the patient.
(2) Documentation of all orders given by a practitioner which were communicated to nursing personnel by a pharmacist.
(3) Documentation that a total assessment of the patient has been performed.
(4) Documentation that a plan for the parenteral therapy of the patient has been developed by the pharmacy. The plan must include:
(I) The identification of any problem related to a drug that is administered to the patient; and
(II) Any suggested solution for that problem and the monitoring of the results of the therapy.
3. As used in this section, "total assessment" means an evaluation of the circumstances of the administration of parenteral therapy to a patient in the patient's home, in a facility for the dependent or in a medical facility which does not furnish the parenteral solution from a pharmacy located within that medical facility that includes a review of:
(a) The state of the disease of the patient;
(b) The regimen of medication of the patient;
(c) The medical history of the patient;
(d) Any therapies other than parenteral therapy administered to the patient; and
(e) If the patient is using the parenteral solution in the patient's home, the ability of the patient to receive parenteral therapy in his or her home.
(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94)

NAC 639.683 Delivery, storage and recordation of delivery. (NRS 639.070, 639.2807) A managing pharmacist shall ensure that:
1. A sterile parenteral solution is furnished to a patient in a container which is capable of maintaining the appropriate temperature for the storage of the sterile parenteral solution;
2. A patient is advised of the appropriate conditions for the storage and disposal of the sterile parenteral solution; and
3. The delivery of a controlled substance listed in schedule II, as set forth in NAC 453.520, is documented and a receipt which indicates that the patient received that controlled substance is included with the records maintained at the pharmacy.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

NAC 639.686 Written policies and procedures for disposal of infectious materials and materials containing cytotoxic residues. (NRS 639.070, 639.2807) In addition to the requirements of NAC 639.67015 and 639.67017, any pharmacy providing parenteral solutions shall have written policies and procedures for the disposal of infectious materials and materials containing cytotoxic residues. The procedures must contain methods for the cleanup of spills and must be in conformance with the regulations of the local health authority. The pharmacy shall ensure the return of infectious materials and materials containing cytotoxic residues to the pharmacy or shall inform the provider of care of the procedures for the proper destruction of such materials.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A by R035-06, 9-18-2008)

NAC 639.688 Written policies and procedures regarding provision of services related to parenteral therapy. (NRS 639.070, 639.2807) In addition to the requirements of NAC 639.67015 and 639.67017, any pharmacy, other than an institutional pharmacy, engaged in the practice ofcompounding and dispensing parenteral solutions shall have written policies and procedures relating to:

1. The qualifications and training of employees of the pharmacy to compound and dispense parenteral solutions.
2. A determination of the necessity for administering the medication a patient requires in a parenteral form.
3. The compounding and control of the quality of parenteral solutions.
4. The distribution and delivery of parenteral solutions.
5. The clinical monitoring of parenteral therapy.
6. The availability of a practitioner, pharmacist and nursing personnel during the administration of parenteral therapy to a patient.
7. The availability of products and equipment which are necessary during the administration of parenteraltherapy to a patient.
8. The communication of orders among the practitioner, pharmacist and nursing personnel for a patient who requires parenteral therapy.
9. The coordination of the care of a patient who requires parenteral therapy by the pharmacist, practitioner and nursing personnel, including documentation of participation in any conference relating to the care of that patient.
10. The education of a patient relating to:

(a) The self-administration of a parenteral solution;
(b) The proper maintenance and storage of a parenteral solution; and
(c) The operation of devices used to administer parenteral solutions.

11. The cleaning and maintenance of equipment used to administer a parenteral solution furnished to a patient by the pharmacy.
12. The provision of services relating to parenteral therapy furnished by the pharmacy in an emergency.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94; R035-06, 9-18-2008)

NAC 639.690 Pharmacist: Consultation with patient; proper training in safe handling, compounding and therapy related to parenteral solutions. (NRS 639.070, 639.2807)

1. Any pharmacy furnishing parenteral solutions shall ensure that a pharmacist is available 24 hours a day for consultation with the patient and the patient's primary provider of care concerning the proper use of any parenterals and related supplies furnished by the pharmacy.
2. The managing pharmacist shall ensure that all pharmacists engaging in compounding parenteral solutions have the proper training in the safe handling, compounding and therapy related to parenteral solutions, including cytotoxic agents.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94)

OUTSOURCING FACILITIES

NAC 639.691 Definitions. (NRS 639.070, 639.100) As used in NAC 639.691 to 639.6916, inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.6911, 639.6912 and 639.6913 have the meanings ascribed to them in those sections.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6911 "Compounding" defined. (NRS 639.070, 639.100) "Compounding" includes, without limitation, the

combining, admixing, mixing, pooling, reconstituting or other altering of a drug or bulk drug substance, as defined in 21 C.F.R. § 207.3, to create a drug.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6912 "Outsourcing facility" defined. (NRS 639.070, 639.100) "Outsourcing facility" means a facility at one geographic location or address that:

1. Is engaged in the compounding of sterile drugs; and
2. Has registered with the Secretary of Health and Human Services as an outsourcing facility pursuant to 21 U.S.C. § 353b.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6913 "Sterile drug" defined. (NRS 639.070, 639.100) "Sterile drug" means a drug that is:

1. Intended for parenteral administration;
2. An ophthalmic or oral inhalation drug in aqueous format; or
3. Required to be sterile pursuant to the provisions of federal law or the provisions of NAC 639.661 to 639.690, inclusive.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6915 Duties of facility. (NRS 639.070, 639.100) An outsourcing facility that is engaged in the compounding of sterile drugs in this State or for shipment into this State shall:

1. Obtain a license from the Board as a manufacturer in accordance with NRS 639.100 and 639.233 by submitting an application on a form prescribed by the Board;
2. Comply with the provisions of NAC 639.609 to 639.619, inclusive; and
3. Comply with all the requirements of 21 U.S.C. § 353b.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015; A by R025-21, 4-11-2022)

NAC 639.6916 When licensure as pharmacy required. (NRS 639.070, 639.100)

1. Except as otherwise provided in subsection 2, an outsourcing facility is not required to be licensed as a pharmacy.
2. An outsourcing facility may dispense dangerous drugs or controlled substances for identified individual patients pursuant to a prescription only if the outsourcing facility is licensed by the Board as a pharmacy in accordance with NRS 639.230 or 639.2328, as applicable.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.757 Preparation and sale of compounded drugs by registrants ~~pharmacy or pharmacist~~: License as manufacturer not required under certain circumstances; unsafe or ineffective drug; restrictions on sale. (NRS 639.070)

1. A ~~pharmacy or pharmacist~~ pharmacy, pharmacist, or 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~~ registrant to any person other than the ultimate user of the drugs, the agent of the ultimate user of the drugs and; ~~or a practitioner who will be administering the drugs to a patient~~;

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

(d) 2. A pharmacy, pharmacist or practitioner may only compound drugs products using substances that: ~~Except as otherwise provided in paragraph (e) and subsection 2, the active ingredients used to compound the drugs:~~

(a) Comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph if one exists, and the USP chapter on pharmacy compounding;

(b) Are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or

(c) Appear on FDA's list of bulk drug substances that can be used in compounding (the 503A) if such a

monograph does not exist and the substance is not a component of an FDA-approved drug product.

3. An outsourcing facility is not required to obtain a license as a manufacturer to compound drugs if,

(a) Compounding drug products that appear on FDA's drug shortage list at the time of compounding, distribution, and dispensing; or

(b) Compounding drug products that appear on FDA's list of bulk drug substances for which there is a clinical need (the 503B bulks list).

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

~~(d) 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.~~

~~4. 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.~~

5. 4. Except as otherwise provided in this subsection, a pharmacy or pharmacist 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 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.

~~6. 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.~~

~~7. 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.~~

(Added to NAC by Bd. of Pharmacy by R032-02, eff. 5-31-2002; A by R035-06, 9-18-2008)

14A

WARNING LETTER

Vitti Labs, LLC

MARCS-CMS 627699 – JULY 28, 2022

Delivery Method:

VIA UNITED PARCEL SERVICE

Product:

Biologics

Recipient:

Miriam McKinney

President and Co-Owner

Vitti Labs, LLC

834 W. Kansas St., Suite C
Liberty, MO 64068
United States

Issuing Office:

Office of Biological Products Operations – Division 2

United States

WARNING LETTER

July 28, 2022

Warning Letter #OBPO 22-627699

Philipp R. Vitti
Chief Science Officer and Co-Owner

Christopher Bartalos, DO
Medical Director and Co-Owner

Dear Mr. Vitti, Dr. Bartalos, and Ms. McKinney:

During an inspection of your firm, Vitti Labs, LLC (Vitti Labs), located at 834 W. Kansas St., Suite C, Liberty, MO 64068, conducted between December 6, 2021, and December 20, 2021, the United States Food and Drug Administration (FDA) documented your manufacture of products derived from human umbilical cord, EV-

PURE+, WJ-PURE+, and VITTI-PURE, or human amniotic membrane, NS-PURE, and EV-OPTI DROPS (collectively, "your products") for allogeneic use[1]. You have distributed your products to third-party distributors, some under private label, and directly to health care professionals and medical facilities for use in patients[2]. Your products are intended for injection, ophthalmic administration, and/or topical application and purport to be sterile.

Information and records gathered prior to, during and/or after the inspection, including information on your website www.vittilabs.com, reflect that your products are intended for clinical use in humans to treat a variety of diseases or conditions. Therefore, your products are drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 321(g)] and biological products as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 U.S.C. 262(i)].

Your products are also human cells, tissues, or cellular or tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d) and are subject to regulation under 21 CFR Part 1271, issued under the authority of section 361 of the PHS Act [42 U.S.C. 264]. HCT/Ps that do not meet all the criteria in 21 CFR 1271.10(a), and when no exception in 21 CFR 1271.15 applies, are not regulated solely under section 361 of the PHS Act [42 U.S.C. 264] and the regulations in 21 CFR Part 1271. Such products are regulated as drugs, devices, and/or biological products under the FD&C Act and/or the PHS Act, and are subject to additional regulation, including appropriate premarket review.

Vitti Labs does not qualify for any exception in 21 CFR 1271.15, and your products fail to meet all the criteria in 21 CFR 1271.10(a). Therefore, your products are not regulated solely under section 361 of the PHS Act [42 U.S.C. 264] and the regulations in 21 CFR Part 1271.

Specifically, your umbilical cord derived products, EV-PURE+, WJ-PURE+, and VITTI-PURE, fail to meet the criterion in 21 CFR 1271.10(a)(2) that the HCT/Ps be "intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent." These products are not intended to perform the same basic function or functions of umbilical cord in the recipient as in the donor, such as serving as a conduit. Rather, using these products to treat orthopedic diseases or conditions, for example, is not homologous use as defined in 21 CFR 1271.3(c).

In addition, your products fail to meet other criteria set forth in 21 CFR 1271.10(a). Your products fail to meet the minimal manipulation criterion set forth in 21 CFR 1271.10(a)(1) and defined for structural tissue in 21 CFR 1271.3(f)(1), because your processing alters the original relevant characteristics of the umbilical cord or amniotic membrane related to their utility for reconstruction, repair, or replacement.

Please be advised that to lawfully market a drug that is a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]. Such licenses are issued only after showing that the product is safe, pure, and potent. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug application (IND) in effect as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312]. None of your products are the subject of an approved biologics license application (BLA), nor is there an IND in effect for your products. Based on this information, your actions have violated the FD&C Act and the PHS Act.

Additionally, during the inspection, FDA investigators documented evidence of significant deviations from current good manufacturing practice (CGMP) requirements, including deviations from section 501(a)(2)(B) of the FD&C Act and 21 CFR Parts 210 and 211.

- At the close of the inspection, the FDA investigators issued a Form FDA 483 to you listing inspectional observations, which described significant CGMP deviations applicable to your products. FDA identified additional significant deviations upon further review of the information collected during the December 2021 inspection, as discussed below. The CGMP deviations, involving tens of thousands of vials of products manufactured and distributed between July 2020 and December 2021, include, but are not limited to, the following:

1. Failure to establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, including procedures for validation of all aseptic and sterilization processes [21 CFR 211.113(b)].
For example:

a. The aseptic processes used to manufacture your products have not been validated (e.g., by performing media fill simulations) since your firm's manufacturing operations began in July 2020. These products purport to be sterile and are expected to be sterile.

b. The **(b)(4)** sterilization process used for equipment that comes into direct contact with your products has not been adequately validated. For example, you have not defined the optimal parameters and conditions, including the load configuration, for sterilizing equipment such as the **(b)(4)** used to process your products.

c. You did not establish and follow appropriate written procedures for environmental monitoring. For example:

i. Your action limit for microbiological monitoring of surfaces within the critical area was observed to be greater than **(b)(4)** colony forming units (CFUs) per "plate & floor" for Biological Safety Cabinets, greater than **(b)(4)** CFUs per plate for personnel sterile gloves, and greater than **(b)(4)** CFUs per plate in the supporting cleanroom. Such high numbers of microorganisms could contribute to product contamination and pose a potentially significant safety concern.

ii. Your action limit for non-viable particulates in the supporting cleanroom is greater than or equal to **(b)(4)** µm particles per m^3. Your allowance of such high particulate numbers could contribute to product contamination and pose a potentially significant safety concern.

iii. You have not established alert and action limits for samples collected using settle plates during each processing run.

iv. You do not require microbiological monitoring of operators' arm coverings used in the critical area for manually processing your products.

v. You do not perform non-viable particulate monitoring, active viable air sampling, or sampling of critical surfaces for microorganisms in association with each production batch.

vi. During the inspection, our investigators documented that personnel don gowning, including sterile sleeves and sterile gloves, in an area that is not environmentally monitored prior to performing aseptic processing in the critical area. This practice increases the risk of introduction of contaminants.

2. Failure to have ceilings of smooth, hard surfaces that are easily cleanable in an aseptic processing area [21 CFR 211.42(c)(10)(i)]. Specifically, during the inspection, our investigators observed unused pieces of equipment, remnants of a surgical suite operated by a previous tenant of your facility,

suspended from the ceiling of your cleanroom such that the ceiling and attached, unused equipment is not easily cleanable.

3. Failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity [21 CFR 211.160(b)]. For example, you have not established scientifically sound and appropriate specifications and test procedures to assure that your products conform to appropriate standards of identity, strength, quality, and purity.

4. Failure to establish and follow written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess [21 CFR 211.100(a)-(b)]. Specifically:

a. You have not adequately validated the manufacturing processes for your products with respect to identity, strength, quality, and purity. Your validation did not include amniotic membrane processing[3]. Additionally, your validation for umbilical cord processing only included sterility testing and endotoxin testing as measurements of product attributes.

b. At the time of the FDA inspection, your written procedures for processing your umbilical cord derived products did not reflect your actual practice. The procedures in effect at the start of the inspection indicate that **(b)(4)** should be removed from the umbilical cord tissue for further processing into your finished products. In contrast, you indicated that your firm's practice has been to use the entire umbilical cord tissue except for **(b)(4)**.

5. Failure to withhold from use each lot of components, drug product containers, and closures until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit [21 CFR 211.84(a)]. For example, you failed to appropriately test or examine before release for use **(b)(4)** used in the manufacture of your products and the vials that contain the final product.

6. Failure to establish and follow a written testing program designed to assess the stability characteristics of drug products and to use the results of such stability testing to determine appropriate storage conditions and expiration dates [21 CFR 211.166(a)]. Specifically, your firm has assigned a two-year expiration date to your products without adequate data regarding the stability characteristics of the products. For example, the shelf-life study performed, completed September 27, 2021, only included sterility and endotoxin testing as part of the stability protocol.

FDA received your written response, dated January 10, 2022, to the inspectional observations on the Form FDA-483 issued at the conclusion of the inspection, and we have reviewed its contents. The corrective actions described in your response are not adequate to address the above-noted violations. We note that certain of your planned corrective actions cannot be evaluated because of a lack of supporting documentation. Additionally, your response does not address your firm's continued manufacture and distribution of your products under the violative conditions outlined above or your plans for the disposition of the product inventory you may still have at your facility. We note your products carry a two-year shelf life.

While you assert that your products should be regulated solely under section 361 of the PHS Act, as explained above, the available evidence shows that your products do not meet all the criteria in 21 CFR 1271.10(a) for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR Part 1271. Your response also

- does not adequately address your failure to have an IND in effect to study your products addressed in this letter or your lack of an approved BLA to lawfully market your products. As noted above, to lawfully market a drug that is a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]. Such licenses are issued only after showing that the product is safe, pure, and potent. While in the development stage, such a product may be distributed for clinical use in humans only if the sponsor has an IND in effect for that product, as specified by FDA regulations, that covers such clinical use [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312].

Neither this letter nor the observations noted on the Form FDA 483, which were discussed with you at the conclusion of the inspection, are intended to be an all-inclusive list of deficiencies that may be associated with your products. It is your responsibility to ensure full compliance with the FD&C Act, PHS Act, and all applicable regulations.

This letter notifies you of our findings and provides you an opportunity to address them. Failure to adequately address these matters may lead to regulatory action without further notice. Such actions include seizure and/or injunction.

For further information about IND requirements, please contact the Center for Biologics Evaluation and Research (CBER), Division of Regulatory Project Management, Office of Tissues and Advanced Therapies, at (240) 402-8190, or OTATRPMS@fda.hhs.gov. Please include a copy of this letter with your initial submission to CBER.

We request that you respond in writing within fifteen (15) working days from your receipt of this letter, outlining the specific steps you have taken or plan to take to address any violations and prevent their recurrence. Include any documentation necessary to show that the matters have been addressed. If you do not believe your products are in violation of the FD&C Act, PHS Act, or applicable regulations, include your reasoning and any supporting information for our consideration. If you cannot address these matters completely within fifteen (15) working days, please explain the reason for your delay and the time frame for completion.

Your response should be sent to the following address: Amy Graf, Compliance Officer, U.S. Food and Drug Administration, Office of Biological Products Operations – Division 2, 300 River Place Dr. – Suite 5900, Detroit, MI 48207 or emailed to Amy.Graf@fda.hhs.gov. If you have any questions, please contact Ms. Graf at (313) 393-2034 or via e-mail.

Sincerely,
/S/

Karlton T. Watson
Program Division Director
Office of Biological Products Operations – Division 2

cc:**(b)(4)**

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1 This letter does not address Vitti's EV-PURE and WJ-PURE products, which are excluded from any reference to "your products" in this letter.

2 Your umbilical cord derived products are manufactured for private label distributors using the same manufacturing process used for EV-PURE+, WJ-PURE+, and VITTI-PURE. The same instructions for use are provided. EVPURE+ is privately labeled as **(b)(4)**. WJ-PURE+ is privately labeled as **(b)(4)**, **(b)(4)**, and **(b)(4)**. VITTI-PURE is privately labeled as **(b)(4)**, **(b)(4)**, and **(b)(4)**.

3 Your documentation of "Amniotic Membrane Processing Validation" only included **(b)(4)** batches. According to information you provided during the inspection, **(b)(4)** is an umbilical cord derived product.