PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R035-06

April 14, 2006

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

AUTHORITY: §§1-12, 16-19 and 28, NRS 639.070; §§13, 20-27, 30, NRS 639.070 and 639.2807; §14, NRS 639.0725 and 639.23288; §15, NRS 639.071 and 639.072; §29, NRS 639.070 and 639.267.

A REGULATION relating to pharmacy; establishing requirements for pharmacies, pharmacists and pharmaceutical technicians concerning the compounding and dispensing of drug products; revising certain provisions relating to the compounding and dispensing of parenteral solutions; revising certain provisions concerning certain standards and publications adopted by reference; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 13, inclusive, of this regulation.

Sec. 2. ***"Active ingredient" means an ingredient added to a composite product which provides the therapeutic effect desired from the composite product. The term does not include an inert ingredient.***

Sec. 3. ***"Chart order" has the meaning ascribed to it in NAC 639.442.***

Sec. 4. ***"Component" means an ingredient that is used in the compounding of a drug product, including, without limitation, an ingredient that does not appear on the labeling of the drug product.***

Sec. 5. ***1. Except as otherwise provided in subsection 2, "compound" or "compounding" means:***

(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 of the drug product that have been approved by the Food and Drug Administration.

Sec. 6. *"Nonsterile compounded drug" means a prescription drug the preparation and dispensing of which require compounding but which is not required to be sterile by either the provisions of chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation, or the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 12, inclusive, of this regulation.*

Sec. 7. *"Sterile compounded drug" means a prescription drug 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 (b) of subsection 1 of section 13 of this regulation, or the*

provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 12, inclusive, of this regulation.

Sec. 8. *1. Each pharmacist who engages in the practice of compounding drug products shall:*

(a) Inspect and either approve or reject 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, and sections 2 to 12, inclusive, of this regulation concerning the compounding of each drug product, and may review any records maintained by the pharmacy that employs the pharmacist concerning the compounding of a drug product to ensure that an error has not occurred in the process of compounding the drug product.

2. Each pharmacy that engages in the practice of compounding and dispensing drug products shall ensure that each pharmacist and pharmaceutical technician who engages in the practice of compounding drug products is competent and proficient in compounding drug products and receives sufficient training to maintain that competency and proficiency. A pharmacy engaged in the practice of compounding and dispensing drug products shall periodically evaluate the competency and proficiency of each pharmacist and pharmaceutical technician who engages in the practice of compounding drug products. The pharmacy shall document each evaluation in writing and maintain such documentation for at least 2 years after the date the documentation was made as required by section 11 of this regulation.

Sec. 9. ***1. Each pharmacy that engages in the practice of compounding drug products shall establish and maintain written policies and procedures for compounding drug products to ensure that each finished drug product has the identity, strength, quality and purity that the drug product is purported or represented to have. Such policies and procedures must include, without limitation:***

(a) Policies and procedures for recording information concerning:

(1) The components used in the compounding of each drug product;

(2) The amount of each component used in the compounding of each drug product;

(3) The order of each step in the process of compounding each drug product; and

(4) The equipment used to compound each drug product; and

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

(1) Any variation in the weight of the capsules of the same drug product;

(2) The adequacy of mixing to ensure uniformity and homogeneity of each drug product; and

(3) If applicable, the clarity, completeness and pH of a drug product.

2. Each managing pharmacist of a pharmacy that engages in the practice of compounding drug products shall ensure that:

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

(b) If a component is transferred from its original container to a new container, the new 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 container.

Sec. 10. *1. Each pharmacist who engages in the practice of compounding drug products shall label each nonsterile compounded drug, including, without limitation, any amount of the nonsterile compounded drug that is in excess of the amount required by the prescription or chart order and any nonsterile compounded drug that is compounded in bulk quantities. The label must include, without limitation:*

(a) The formula used in the process of compounding the nonsterile compounded drug;

(b) The control number assigned to the nonsterile compounded drug; and

(c) The expiration date of the effectiveness of the nonsterile compounded drug which is based on the professional judgment of the pharmacist, appropriate testing or published data and which complies with the provisions of subsection 6 of NRS 639.2801.

2. Each pharmacist who engages in the practice of compounding drug products shall ensure that each nonsterile compounded drug, including, without limitation, any amount of the nonsterile compounded drug that is in excess of the amount required by the prescription or chart order, and any nonsterile compounded drug that is compounded in bulk quantities, is stored in an appropriate manner.

Sec. 11. *Each record required to be made pursuant to NAC 639.661 to 639.690, inclusive, and sections 2 to 12, inclusive, of this regulation must be:*

1. Maintained by the pharmacy for which the record was made for at least 2 years after the date the record was made; and

2. Available for inspection and copying by the Board or its representative.

Sec. 12. *1. For each nonsterile compounded drug that is in excess of the amount required by the prescription or chart order and each nonsterile compounded drug that is compounded in bulk quantities, the pharmacist who compounded or supervised the*

compounding of the nonsterile compounded drug must prepare a logbook that includes, without limitation:

(a) The name of the drug product;

(b) A list of the components and quantities of components used in the compounding of 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;

(c) The lot number assigned to the drug product by the pharmacist;

(d) The expiration date of the effectiveness of the drug product that is included on the label required pursuant to section 10 of this regulation;

(e) The date of preparation of the drug product;

(f) The initials of the compounding pharmacist or pharmaceutical technician;

(g) If the drug product was compounded by a pharmaceutical technician, the initials of the supervising pharmacist of the pharmaceutical technician; and

(h) The quantity of the drug product that was compounded.

2. A logbook required to be prepared pursuant to this section must be maintained for at least 2 years after the date the logbook was prepared as required by section 11 of this regulation.

Sec. 13. *1. The Board hereby adopts by reference:*

(a) National Sanitation Foundation Standard No. 49, concerning Class II (Laminar Flow) Biosafety Cabinetry, NSF/ANSI 49-04a, 2004 edition and addenda. A copy of this standard and its addenda may be obtained from Techstreet, 777 East Eisenhower Parkway, Ann Arbor, Michigan 48108, or at the Internet address http://www.techstreet.com/, for the prices of $150 and $45, respectively.

(b) United States Pharmacopeia - National Formulary, 2006 edition, published by United States Pharmacopeial Convention Inc. A copy of this publication may be obtained from the United States Pharmacopeial Convention Inc., Attention: Customer Service Department, 12601 Twinbrook Parkway, Rockville, Maryland 20852, or at the Internet address http://www.usp.org/products/, for the price of $690.

(c) The Food Chemicals Codex, fifth edition, adopted by the Committee on Food Chemicals Codex. A copy of the publication may be obtained from The National Academies Press, 500 Fifth Street, NW, Lockbox 285, Washington, D.C. 20055, for the price of $495 or at the Internet address http://www.nap.edu/contact.html, for the price of $445.50.

(d) Reagent Chemicals, tenth edition, published by the American Chemical Society. A copy of the 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.

2. Any provision in chapter 795 or 797 of the United States Pharmacopeia - National Formulary as adopted by reference in this section that is advisory or precatory shall be deemed to be mandatory for the purposes of NAC 639.661 to 639.690, inclusive, and sections 2 to 12, inclusive, of this regulation, unless the provision authorizes a pharmacist to use his professional judgment in which case the pharmacist must use his professional judgment.

3. The Board will periodically review the standards and publications adopted by reference pursuant to this section and determine within 30 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 30 days after the review, the change is deemed to be approved by the Board.

Sec. 14. NAC 639.426 is hereby amended to read as follows:

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

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

(a) The pharmacy is certified by the Verified Internet Pharmacy Practice Sites Program of the National Association of Boards of Pharmacy; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The dispensing of prescription drugs;

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

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

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

(h) Ships prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the *United States Pharmacopeia* ~~[, 25th edition, 2002, which is hereby]~~ ***- National Formulary, as*** adopted by reference ~~[. A copy of the publication may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, for the price of $589, plus $13 for shipping and handling.]~~ ***in paragraph (b) of subsection 1 of section 13 of this regulation.***

Sec. 15. NAC 639.472 is hereby amended to read as follows:

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

1. A current copy of:

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

(b) The Federal Controlled Substances Act (Title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242) and the regulations adopted pursuant thereto, or an official publication describing the requirements of that act and the regulations adopted pursuant thereto.

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

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

(a) Theoretical and practical pharmacy.

(b) Pharmacology.

(c) Therapeutics.

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

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

(b) Information concerning the interaction of drugs; and

(c) Information concerning antidotes.

5. Current copies of one of the following:

(a) *United States Pharmacopeia - National Formulary* ~~[;]~~ ***, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation;***

(b) *United States Pharmacopeia - Drug Information*; or

(c) *Remington's Pharmaceutical Sciences*.

6. A current copy of the Food and Drug Administration Approved Drug Products.

Sec. 16. NAC 639.5834 is hereby amended to read as follows:

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

1. The name and address of the pharmacy.

2. The name of the prescriber.

3. The date of dispensation.

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

5. The standard radiation symbol.

6. The words "CAUTION RADIOACTIVE MATERIAL."

7. The name of the procedure.

8. The radionuclide and chemical form.

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

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

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

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

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

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

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

Sec. 17. NAC 639.598 is hereby amended to read as follows:

639.598 1. Each wholesaler shall store prescription drugs held in the facility in the manner prescribed in the *United States Pharmacopeia* ~~[, 22nd edition, 1990, which is hereby adopted by reference. A copy of the publication may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, for the price of $91, plus $7 for shipping and handling.]~~ ***- National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation.***

2. If there are no specific requirements concerning the temperature at which a prescription drug must be stored, the drug must be stored at a controlled room temperature as defined in the *United States Pharmacopeia* ~~[, 22nd edition, 1990.]~~ ***- National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation.***

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

Sec. 18. NAC 639.601 is hereby amended to read as follows:

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

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

3. If a prescription drug is returned to a wholesaler by a purchaser or purchasing wholesaler under conditions which cast doubt on the prescription drug's safety, identity, strength, quality or purity, the wholesaler shall destroy the prescription drug or return it to the supplier unless, after conducting an examination, testing or other investigation, the wholesaler determines that the prescription drug complies with the appropriate standards of safety, identity, strength, quality and purity as prescribed in the package insert as approved by the Food and Drug Administration or in the *United States Pharmacopeia - National Formulary* ~~[in effect as of March 1, 2000.]~~ ***, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation.*** The wholesaler shall keep a record of any examination, testing or other investigation conducted and make any records available for inspection by the Board.

4. Unless the reason a prescription drug must be destroyed or returned to the supplier is related to the expiration date of the prescription drug, a wholesaler that is required to destroy a

prescription drug or return it to the supplier pursuant to subsection 3 shall provide to the Board a written notice that includes:

(a) The name of the prescription drug;

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

(c) The quantity of the prescription drug;

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

(e) Whether the wholesaler will:

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

(2) Destroy the prescription drug; and

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

5. Within 48 hours after receipt by the Board of a notice required pursuant to subsection 4, a member of the staff of the Board shall inspect the prescription drug at the facility of the wholesaler and may impound or remove the prescription drug. If the member of the staff of the Board does not impound or remove the prescription drug, the wholesaler may return the prescription drug to the supplier or destroy the prescription drug.

Sec. 19. NAC 639.639 is hereby amended to read as follows:

639.639 1. Each authorized warehouse shall store prescription drugs held in the facility in the manner prescribed in the *United States Pharmacopeia* ~~[, 22nd edition, 1990, which is hereby adopted by reference. A copy of the publication may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, for the price of $91, plus $7 for shipping and handling.]~~ ***- National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation.***

2. If there are no specific requirements concerning the temperature at which a prescription drug must be stored, the drug must be stored at a controlled room temperature as defined in the *United States Pharmacopeia* ~~[, 22nd edition, 1990.]~~ ***- National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation.***

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

Sec. 20. NAC 639.661 is hereby amended to read as follows:

639.661 As used in NAC 639.661 to 639.690, inclusive, ***and sections 2 to 12, inclusive, of this regulation*** unless the context otherwise requires, the words and terms defined in NAC 639.663, 639.665 and 639.667 ***and sections 2 to 7, inclusive, of this regulation*** have the meanings ascribed to them in those sections.

Sec. 21. NAC 639.674 is hereby amended to read as follows:

639.674 1. ~~[A]~~ ***Except as otherwise provided in subsection 3, a*** pharmacy engaged in the practice of compounding and dispensing of ~~[parenteral solutions shall have a designated room for the preparation of sterile products for dispensing which must:~~

~~(a) In accordance with Federal Standard 209(b), meet the standards for class 100 HEPA (high efficiency particulate air) filtered air such as having a laminar airflow hood or a clean room;~~

~~(b) Be maintained in a clean condition and have cleanable surfaces, including walls, ceilings and floors; and~~

~~(c) Be ventilated in a manner which does not interfere with the laminar airflow hood.~~

~~2. The laminar airflow hood must be certified annually, in accordance with Federal Standard 209(b). Records of certification must be retained for at least 2 years.~~

~~3. The pharmacy must be arranged so that the laminar airflow hood is located in an area which is exposed to a minimal flow of traffic and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions. Items related to the compounding of parenteral solutions which are stored in the area where parenterals are compounded must not obstruct the intake of the laminar airflow hood.~~

~~4. There must be sufficient space which is well separated from the area of the laminar airflow hood for the storage of bulk materials, equipment and waste materials.~~

~~5. A sink with hot and cold running water must be provided within the pharmacy.~~

~~6. There must be a refrigerator, freezer, or both, of sufficient capacity to store all materials requiring refrigeration.~~] ***sterile compounded drugs shall maintain its facility and ensure that compounding operations are performed in accordance with chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation.***

2. Except as otherwise provided in subsection 3, a pharmacy engaged in the practice of compounding and dispensing of nonsterile compounded drugs shall maintain its facility and ensure that compounding operations are performed in accordance with chapter 795 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation.

3. For the purposes of this section, if the provisions of chapter 795 or 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation, conflict with the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 12, inclusive, of this regulation, the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 12, inclusive, of this regulation, control.

Sec. 22. NAC 639.678 is hereby amended to read as follows:

639.678 In any pharmacy preparing parenteral cytotoxic agents, all compounding must be conducted within a certified vertical laminar airflow hood. The hood must be certified ~~[annually]~~ ***every 6 months*** in accordance with *National Sanitation Foundation Standard No. 49* ***, as adopted by reference in paragraph (a) of subsection 1 of section 13 of this regulation,*** or the manufacturer's specifications. Records of certification must be retained for at least 2 years.

Sec. 23. NAC 639.680 is hereby amended to read as follows:

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

(a) The name and ***either amounts or*** 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 his 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.

Sec. 24. NAC 639.682 is hereby amended to read as follows:

639.682 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 his 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 ***or chart orders*** 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) His history of medication, including his 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 his 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 his 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 his home, the ability of the patient to receive parenteral therapy in his home.

Sec. 25. NAC 639.683 is hereby amended to read as follows:

639.683 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 ***or an agent of the patient*** received that controlled substance is included with the records maintained at the pharmacy.

Sec. 26. NAC 639.684 is hereby amended to read as follows:

639.684 1. The managing pharmacist shall develop and maintain a program to ensure that there is a clean and sanitary environment for the preparation of sterile ~~[products]~~ ***compounded drugs and nonsterile compounded drugs*** and that the ~~[parenteral solutions produced are sterile.]~~ ***sterile compounded drugs produced satisfy the sterility requirements set forth in chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation. As part of the program developed and maintained pursuant to this section, the managing pharmacist shall ensure that the sterility of the pharmacy and the technique of the employees of the pharmacy is verified at least as frequently as required by chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation.*** Records of the activities related to this program must be established and made available to the Board.

2. The program must include the following:

(a) The procedures for cleaning and sanitization of the area used for preparing ~~[parenteral solutions.~~

~~(b) Periodic documentation~~] ***sterile compounded drugs and nonsterile compounded drugs.***

(b) Documentation of the temperatures of the room and refrigerator in which ***sterile*** compounded ~~[parenteral solutions]~~ ***drugs and nonsterile compounded drugs*** are stored ~~[.]~~ ***for each day on which the pharmacy operates.***

(c) The steps to be taken in the event of a recall of a drug.

(d) A written ~~[justification of]~~ ***policy used to establish*** the dates of expiration for ***sterile*** compounded ~~[parenteral solutions.]~~ ***drugs and nonsterile compounded drugs.***

Sec. 27. NAC 639.688 is hereby amended to read as follows:

639.688 ~~[Any]~~ ***In addition to the requirements of section 9 of this regulation, any*** pharmacy engaged in the practice of compounding and dispensing parenteral solutions shall have written policies and procedures ~~[relating to:]~~ ***to ensure that the pharmacy complies with the requirements of chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation, and NAC 639.661 to 639.690, inclusive, and sections 2 to 12, inclusive, of this regulation, including, without limitation, 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 parenteral therapy 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.

Sec. 28. NAC 639.757 is hereby amended to read as follows:

639.757 1. A pharmacy or pharmacist 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;

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

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

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

(1) Have a monograph in and meet or exceed the standards of the *United States Pharmacopoeia - National Formulary* ~~[. If a component of the compounded drug]~~ ***, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation;***

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

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

(e) For an active ingredient used to compound the drugs that does not have a monograph in the *United States Pharmacopoeia - National Formulary*, ~~[the component may still be used if the component is in a list of approved substances developed by the Secretary of Health and Human Services.]~~ ***as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation, the active ingredient is:***

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

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

(I) <u>The Food Chemicals Codex</u>, as adopted by reference in paragraph (c) of subsection 1 of section 13 of this regulation; or

(II) Reagent Chemicals, as adopted by reference in paragraph (d) of subsection 1 of section 13 of this regulation, 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; and

(3) Accompanied by a certificate of analysis provided by the manufacturer of the ingredient.

2. 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.

3. A pharmacy ~~[or pharmacist]~~ shall not sell or otherwise provide a compounded drug to:

(a) ~~[Another]~~ ***A retail*** pharmacy; or

(b) A practitioner, except that a pharmacy ~~[or pharmacist]~~ may sell or otherwise provide a compounded drug to ~~[a]~~ ***:***

(1) A practitioner who will be administering the drug to a patient ~~[.]~~ ***; or***

(2) A practitioner or another pharmacy if the compounded drug is a high-dose product that is not commercially available and the compounded drug is intended to be used in the treatment of a patient who is deemed by the practitioner of the patient to be in the final stages of a terminal illness.

Sec. 29. NAC 639.760 is hereby amended to read as follows:

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

~~force on March 1, 2000. This publication is hereby incorporated by reference. This publication may be obtained from:~~

~~United States Pharmacopeial Convention, Inc.~~

~~Customer Service Department~~

~~12601 Twinbrook Parkway~~

~~Rockville, Maryland 20852,~~

~~for the price of $549, plus $9 for shipping.]~~ ***, as adopted by reference in paragraph (b) of subsection 1 of section 13 of this regulation.***

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

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

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

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

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

Sec. 30. NAC 639.670 is hereby repealed.

TEXT OF REPEALED SECTION

639.670 Adoption of materials by reference. (NRS 639.070, 639.2807) The Board hereby adopts by reference the following:

1. Federal Standard 209(b), "Clean Room and Work Station Requirements" of the Federal Supply Service, General Services Administration, as it exists on June 1, 1986. A copy of this publication is available from the General Services Administration, Specifications Section, Room 6039, 7th and D Streets, S.W., Washington, D.C. 20407, for the price of $1.40.

2. National Sanitation Foundation Standard No. 49, as it exists on June 1, 1986, concerning Class II (Laminar Flow) biohazard cabinetry and hoods. A copy of this standard is available from the National Sanitation Foundation, P.O. Box 1468, Ann Arbor, Michigan 48106, for the price of $2.