LCB File No. R035-06

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

COMPOUNDING REGULATIONS

Section 1. NAC 639.670 shall be amended as follows:

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]~~ ***{current version}***. 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]~~ ***{current amount}***.

2. National Sanitation Foundation Standard No. 49, as it exists on ~~[June 1, 1986]~~ ***{current version}***, 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]~~ ***{current amount}***.

Section 2. NAC 639.674 shall be amended as follows:

1. ~~[A]~~ ***Except as otherwise provided in these regulations, a*** pharmacy engaged in the practice of compounding and dispensing of ~~[parenteral solutions]~~ ***sterile compounded drugs*** 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.]~~ ***maintain its facility and shall perform compounding operations in accordance with USP 797.***

2. Except as otherwise provided in these regulations, a pharmacy engaged in the practice of compounding and dispensing of non-sterile compounded drugs shall maintain its facility and shall perform compounding operations in accordance with USP 795.

Section 3. NAC 639.678 shall be amended as follows:

In any pharmacy preparing parenteral cytotoxic agents, all compounding must be conducted within a certified vertical laminar airflow hood. The hood must be certified ***every six months*** in accordance with National Sanitation Foundation Standard No. 49 or the manufacturer's specifications. Records of certification must be retained for at least 2 years.

Section 4. NAC 639.680 shall be amended as follows:

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

(a) The name and ***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.

Section 5. NAC 639.682 shall be amended as follows:

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.

Section 6. NAC 639.683 shall be amended as follows:

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 the patient's agent*** received that controlled substance is included with the records maintained at the pharmacy.

Section 7. NAC 639.684 shall be amended as follows:

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]~~ ***sterile and non-sterile compounded drugs*** and that the ~~[parenteral solutions]~~ ***sterile compounded drugs*** produced are sterile ***using such methods as are set out in USP 797***. ***The managing pharmacist shall assure that the verification of the sterility of the pharmacy and the technique of its employees is done***

at least as frequently as is set out in USP 797. 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]~~ ***compounded drugs***.

(b) ~~[Periodic]~~ ~~[Daily]~~ ***D***ocumentation of the temperatures of the room and refrigerator in which compounded ~~[parenteral solutions]~~ ***drugs*** are stored ***for every day in 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 compounded ~~[parenteral solutions]~~ ***drugs***.

Section 8. NAC 639.688 shall be amended as follows:

Any pharmacy engaged in the practice of compounding and dispensing parenteral solutions shall have written policies and procedures ***to assure the pharmacy's compliance with USP 795 and USP 797 and this regulation, including*** ~~[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.

Section 9. NAC 639.757 shall be amended as follows:

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 practitioner 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 drugs are only prepared upon a prescription or chart order;

~~[(c)]~~ ***(d)*** 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***~~[.]~~ ***;***

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

(3) Appear on a list of drug substances that may be used in pharmacy compounding made pursuant to the federal Food, Drug, and Cosmetic Act § 503(A)(b)(1); or

(4) Do not have a monograph in the United States Pharmacopoeia – National Formulary and are:

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

(ii) Prepared to a grade of at least:

(a) An analytical reagent certified by the American Chemical Society;

(b) Food Chemicals Codex grade;

(c) Approved by the Reagent Chemicals Committee of the American Chemical Society;

(d) Approved for use in high pressure liquid chromatography;

(e) Spectroscopic grade; or

(f) Primary standard grade for use in standard solutions for analytical purposes; and

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

~~[2.]~~ ***3.*** 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.]~~ ***4.*** 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***: (1) A*** ~~[a]~~ practitioner who will be administering the drug to a patient~~[,]~~ ***; or***

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

Section 10. NAC chapter 639 shall be amended to add the following new language:

1. "Active Ingredient" means ingredients added to a compounded product, which provides the therapeutic effect desired from the compounded product. This does not include inert ingredients.

2. "Compounding" means and includes the preparation, mixing, or assembling of a drug or device in which at least one component is a prescription drug, and the packaging and labeling incident thereto for sale or dispensing, upon the receipt of a prescription or chart order. Compounding does not include mixing or reconstituting of non-sterile products performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

3. "Component" means any ingredient used in the compounding of a drug product, including those ingredients that may not appear in the labeling of such product.

4. "Non-sterile compounded drug" means any prescription drug the preparation and dispensing of which requires compounding but which is not required to be sterile by these regulations and USP 797.

5. "Sterile compounded drug" means any prescription drug the preparation and dispensing of which requires compounding and which is required to be sterile by these regulations and USP 797.

6. "USP 797" means "USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations" as are in effect on November 1, 2004 in USP 24—NF 19, published by and available from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852.

7. "USP 795" means "USP General Chapter <795> Pharmaceutical Compounding – Non-Sterile Preparations" as are in effect on November 1, 2004 in USP 24—NF 19, published by and available from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852.

8. When portions of USP 797and USP 795 are incorporated by specific reference in these regulations, language that is advisory or precatory in the USP 797 and USP 795 is deemed to be mandatory for purposes of these regulations except where the language allows for the professional judgment of a pharmacist.

Section 11. NAC ch. 639 shall be amended to add the following new language.

1. The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

2. All pharmacists and pharmaceutical technicians who engage in drug compounding shall be competent and proficient in compounding and shall maintain that proficiency through current awareness and training. Competency and proficiency in the art of compounding for all pharmacists shall be evaluated, documented, and maintained in the files of the pharmacy.

Section 12. NAC ch. 639 shall be amended to add the following new language.

1. There shall be recorded procedures for compounded products to include components, amounts, order of procedure and equipment to insure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess.

2. Components for compounding shall be accurately weighed, measured, or subdivided as appropriate. If a component is transferred from the original container to a new container, the new container shall be labeled with the date of transfer and information sufficient to trace the contents of the new container to the original container.

3. Written control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability

in the final drug product. Such control procedures shall include, but are not limited to, the following:

(a) Capsule weight variation;

(b) Adequacy of mixing to insure uniformity and homogeneity; and

(c) Where applicable, clarity, completeness, or pH of solutions.

Section 13. NAC ch. 639 shall be amended to add the following new language.

The pharmacist shall label a non-sterile compounded drug, including any excess or bulk non-sterile compounded drug, to reference it to the formula used and the assigned control number and beyond-use date based on the pharmacist's professional judgment, appropriate testing or published data. The drug shall be stored appropriately.

Section 14. NAC ch. 639 shall be amended to add the following new language.

1. Records required to be maintained in compliance with this chapter shall be retained for a minimum period of two years from the date of last activity and be available for inspection by the Board.

2. For each non-sterile drug product compounded in excess or bulk quantities, a logbook shall be prepared containing the following information:

(a) Name of the product;

(b) List of ingredients and quantities used, including manufacturer or supplier if not the manufacturer, lot number and expiration dates;

(c) Lot number assigned by pharmacist;

(d) Beyond use date assigned as described in Section 8 of these regulations;

(e) Date of preparation;

(f) Initials of compounding pharmacist/pharmacy technician;

(g) Initials of supervising pharmacist if prepared by a pharmacy technician; and

(h) Quantity prepared.

TEXT OF EXISTING REGULATIONS THAT WERE NOT CHANGED

BUT WHICH STILL APPLY TO COMPOUNDING PRACTICES

NAC 639.661 Definitions. As used in NAC 639.661 to 639.690, inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.663, 639.665 and 639.667 have the meanings ascribed to them in those sections.

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

NAC 639.663 "Cytotoxic" defined. "Cytotoxic" means having the capability of killing living cells.

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

NAC 639.665 "Medical facility" defined. "Medical facility" has the meaning ascribed to it in NRS 449.0151.

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

NAC 639.667 "Nursing personnel" defined. "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 639.672 Reference materials required to be located in or immediately available to pharmacy. 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 639.686 Written policies and procedures for disposal of infectious materials and materials containing cytotoxic residues. (NRS 639.2807**)** 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)

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