ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R116-08

Effective September 18, 2008

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

AUTHORITY: §§1-7, NRS 639.070 and 639.071.

A REGULATION relating to pharmacy; revising provisions governing the duties of a pharmacist employed by or contracted with a surgical center for ambulatory patients; revising the requirements of certain reports by a pharmacist employed by or contracted with a surgical center for ambulatory patients; revising certain requirements for policies and procedures which must be established by a pharmacist employed by or contracted with a surgical center for ambulatory patients; 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 6, inclusive, of this regulation.

Sec. 2. ***As used in NAC 639.4992 and 639.4996 and sections 2 to 6, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3, 4 and 5 of this regulation have the meanings ascribed to them in those sections.***

Sec. 3. ***"Compounding" has the meaning ascribed to it in NRS 639.0053.***

Sec. 4. ***"Drug" has the meaning ascribed to it in NRS 639.007.***

Sec. 5. ***"Investigational drug" has the meaning ascribed to it in NAC 639.455.***

Sec. 6. ***A pharmacist employed by or contracted with a surgical center for ambulatory patients pursuant to NAC 639.4996 shall:***

1. Visit the surgical center at least once each month to:

(a) Evaluate the effectiveness of the policies and procedures established pursuant to NAC 639.4996; and

(b) Confirm that the surgical center is complying with those policies and procedures, the provisions of this section and NAC 639.4996;

2. Maintain documentation of each visit that the pharmacist makes pursuant to subsection 1;

3. Conduct an audit at least once each month using a sufficient number of records of the surgical center, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:

(a) The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;

(b) Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;

(c) The records demonstrate:

(1) That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and

(2) That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;

(d) The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;

(e) The employees of the surgical center properly maintain accurate records relating to drugs and investigational drugs; and

(f) The employees of the surgical center properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and

4. Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:

(a) The surgical center is violating a state or federal law which affects the care and safety of a patient;

(b) There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the surgical center and the amount of the controlled substance that should be in the possession of the surgical center according to the records of the surgical center, including, without limitation:

(1) Purchase orders and invoices for the controlled substance;

(2) Records which indicate the removal of the controlled substance from the storage area;

(3) Patient records;

(4) Records which indicate the return of the controlled substance to the manufacturer;

(5) Records which indicate that the controlled substance was destroyed; and

(6) Any other record for the controlled substance;

(c) The surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;

(d) The surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or

(e) The surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the surgical center.

Sec. 7. NAC 639.4996 is hereby amended to read as follows:

639.4996 1. A surgical center for ambulatory patients shall employ or enter into a contract with a pharmacist to establish policies and procedures which ~~[are]~~ ***:***

(a) Are consistent with the policies and procedures developed pursuant to NAC 639.477 ***;*** ~~[for:~~

~~(a) The storage and dispensing of drugs to patients in the surgical center for ambulatory patients, including, without limitation, drugs that the patients take away from the surgical center for ambulatory patients; and]~~

(b) ~~[The proper disposition or destruction of expired or contaminated drugs stored and dispensed at the surgical center for ambulatory patients.]~~ ***Require the maintenance of records in accordance with the provisions of NAC 639.485 and 639.486;***

(c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;

(d) Require maintenance of a perpetual inventory of all controlled substances;

(e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;

(f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;

(g) Ensure that the surgical center dispenses drugs and investigational drugs in accordance with applicable state and federal laws; and

(h) Ensure that all compounding is:

(1) Performed by a registered pharmacist in accordance with the provisions of this chapter and chapter 639 of NRS; or

(2) If performed by an employee of the surgical center, other than a registered pharmacist, performed:

(I) In accordance with the provisions of this chapter and chapter 639 of NRS;

(II) In a location designated for compounding that is clean and disinfected before each act of compounding; and

(III) By a person who has completed training for the type of compounding that will be performed.

2. The policies and procedures established pursuant to subsection 1 must be maintained, ~~[periodically]~~ reviewed ***at least annually,*** and dated upon adoption and amendment.

3. The pharmacist employed ***by or contracted with a surgical center for ambulatory patients*** pursuant to subsection 1 ~~[shall:~~

~~(a) Visit the surgical center for ambulatory patients at least once each quarter to evaluate the effectiveness of the policies and procedures established and to confirm that the surgical center for ambulatory patients is maintaining documentation of each transaction involving drugs;~~

~~(b) Maintain documentation of each visit that he makes pursuant to paragraph (a);~~

~~(c) Periodically audit the records of the surgical center for ambulatory patients that involve the dispensing of controlled substances to ensure that the surgical center for ambulatory patients is in compliance with all applicable state and federal laws; and~~

~~(d) Submit a report to the Board not later than 30 days after determining that the policies and procedures established pursuant to subsection 1 are ineffective, that the surgical center for ambulatory patients is not maintaining documentation of each transaction involving drugs or that the surgical center for ambulatory patients is not in compliance with any applicable state or federal law, explaining the basis for his determination.~~**]** ***may establish the policies and procedures required pursuant to that subsection with the assistance of a practitioner or an employee or contractor of the surgical center.***

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R116-08

The State Board of Pharmacy adopted regulations assigned LCB File No. R116-08 which pertain to chapter 639 of the Nevada Administrative Code.

INFORMATIONAL STATEMENT

1. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

There was no public response expressed relative to this proposed regulation.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was __1___.
The number of persons who testified at the hearing was ___1__.
The number of agency submitted statements was __0___.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

There was no response from affected businesses relative to this proposed regulation.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted with minor changes.

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

This regulation should have no economic impact on affected businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation will have no immediate or long-term economic effects on business or the public.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

Enforcement of the regulation will be performed during annual inspections of all pharmacies. There will be no additional cost incurred by the board.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

8. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

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

9. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

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