

**PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY**

CHANGES REGARDING CONSULTANT PHARMACISTS TO AMBULATORY SURGICAL CENTERS
(ver. 5/8/08)

Section 1. NAC 639.4992 is hereby amended to read as follows:

Each surgical center for ambulatory patients shall:

1. Register with the Board and the Drug Enforcement Administration of the United States Department of Justice to dispense controlled substances;
2. Ensure that each practitioner who dispenses controlled substances in the surgical center is registered with the Board and the Drug Enforcement Administration of the United States Department of Justice; ~~and~~;
3. Require each person employed to work in ~~a pharmacy of~~ the surgical center for ambulatory patients and any person with whom the surgical center for ambulatory patients has entered into a contract to provide pharmaceutical services to possess a current state license or certificate to provide such services ~~;~~;
4. *Be inspected no less than annually by the Board or its representative; and*
5. *Ensure that the premises and all records be available for inspection and copying by the Board or its representative, or any other authorized federal, state or local law enforcement or regulatory agency.*

Section 2. NAC 639.4996 is hereby amended to read as follows:

1. A surgical center for ambulatory patients shall employ or enter into a contract with a pharmacist ~~[to establish policies and procedures which 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.] .~~ *The pharmacist for a surgical center for ambulatory patients shall:*
 - (a) *Create policies and procedures, either by himself or in conjunction with other employees or contractors at the surgical center for ambulatory patients, regarding the controlled substances and dangerous drugs used by the surgical center for ambulatory patients addressing:*
 - (1) *The purchase, storage, recordkeeping, administration, and dispensing of:*
 - (i) *Controlled substances;*
 - (ii) *Dangerous drugs;*
 - (iii) *Investigational drugs; and*
 - (iv) *Drug samples.*
 - (2) *The accurate keeping of a perpetual inventory of:*
 - (i) *All controlled substances;*

- (ii) Propofol; and
- (iii) Ephedrine.

(3) *The auditing of the patient records and records regarding the drugs purchased, stored, administered, and dispensed at the surgical center for ambulatory patient at least once monthly to assure that:*

(i) *The drugs are being administered in a safe and effective manner in accordance with accepted standards of practice and in accordance with manufacturers' directions and instructions;*

(ii) *The drugs are not being improperly diluted;*

(iii) *The drugs that are in single-use vials are not being administered to more than one patient beyond one hour from the initial breach of the vial;*

(iv) *The drugs that are in multi-use vials are not being used beyond 28 days from the initial breach of the vial;*

(v) *The records regarding the removing from stock, administration and wasting of drugs by staff of the surgical center for ambulatory patients are being made properly and accurately; and*

(vi) *The perpetual inventory is being properly monitored and maintained.*

(4) *The quarantining and destroying of drugs that have expired, are adulterated or mislabeled, or are otherwise unsafe for human use.*

(5) *That all drugs are being stored appropriately as directed by the drugs' manufacturers.*

(b) *Assure that all drugs dispensed by the surgical center for ambulatory patients are dispensed in compliance with all applicable Nevada and federal laws.*

(c) *Assure that records for schedule II controlled substances are properly made and maintained.*

(d) *Assure that all compounding:*

(1) *If it is done by a pharmacist, is done in accordance with the regulations of the Board related to compounding; or*

(2) *If it is done by personnel of the surgical center for ambulatory patients other than a pharmacist, is performed:*

(i) *In a location specifically designated for compounding that is cleaned before each act of compounding is performed; and*

(ii) *By a person trained and competent in performing the type of compounding that will be performed.*

(e) *Require that all employees and contractors engaged in the administration of drugs in the surgical center for ambulatory patients receive at least once annually a live presentation regarding aseptic technique and safe medication administration.*

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

3. The pharmacist employed pursuant to subsection 1 shall:

(a) Visit the surgical center for ambulatory patients at least once each ~~quarter~~ *month* 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~~ *compliant with these regulations*;

(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 *written* report to the Board not later than ~~[30]~~ *five business* 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 : (1) ~~[is]~~ *Is* not in compliance with any applicable state or federal law *that would potentially affect patient care or safety*, explaining the basis for his determination ~~[.]~~ ;

(2) *Has an unresolved discrepancy in the quantity of a particular controlled substance of $\pm 5\%$ or more of the quantity that should have been at the surgical center for ambulatory patients;*

(3) *Is intentionally or recklessly failing to make and maintain the records required by this regulation or the policies and procedures of the surgical center for ambulatory patients regarding the drugs purchased, stored, administered, dispensed, wasted or destroyed at the surgical center for ambulatory patients;*

(4) *Is not using a drug in accordance with accepted standards of practice or in accordance with the manufacturer's directions or instructions; or*

(5) *Is engaged in practices that endanger the health, safety, or welfare of the patients or staff of the surgical center for ambulatory patients.*