LCB File No. R096-08

PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

SURGICAL CENTERS FOR AMBULATORY PATIENTS

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

NOTE: The following sections are the only sections being revised or modified:

Chapter 449 of NAC is hereby amended by adding thereto a new section to read as follows:

Section 1. ***Program for control of infections.***

1. ***An ambulatory surgery center must establish and maintain an infection control program designed to prevent the development and transmission of disease and infection. The program must be appropriate for the service provided and developed according to the standard of practice approved by the governing body. A copy of the standard of practice must be available at the center.***
2. ***The program must be developed based on the following:***
   - ***(a) All surgical services provided***
   - ***(b) The patient case mix***
   - ***(c) The patient case load***
   - ***(d) The patients at risk for infections and communicable diseases***
   - ***(e) The staff's level of education and training***
   - ***(f) The level of nursing support***
   - ***(g) The types of invasive procedures performed and where they are performed***
   - ***(h) Specific instruments and equipment used***
   - ***(i) The facility design***

(j) The causes, risks, and pattern of infections that arise in the setting

3. The program must address work practices to prevent exposure to bloodborne and other potentially infectious pathogens, including but is not limited to, the following:

(a) Hand hygiene including the appropriate time and procedure for handwashing or the use of a hand sanitizer.

(b) Safe injection practices to prevent the contamination of injection equipment and medication, including but not limited to:

(1) A new sterile needle and syringe must be used for each patient

(2) A needle and a syringe must not be used more than once on any patient

(3) A needle and a syringe must not be used more than once to access a medication vial

(c) Handling of sharp instruments

(d) Disposal of sharp instruments

(e) Multi-dose vials with the provision that aseptic technique must be used when accessing the vial including:

(1) The cap of the vial must always be cleaned with an alcohol-based wipe prior to access

(2) The vial must always be accessed with a new sterile needle and syringe

(3) A needle must never be left inserted in the vial cap for multiple uses

(4) The vial must be dated and initialed upon first access and discarded when it has expired

(5) Each injection must be prepared in a clean designated area where blood or body fluids contamination is unlikely

(f) Single-dose vials with the following provisions:

(1) The cap of the vial must always be cleaned with an alcohol-based wipe prior to access

(2) The vial must always be accessed with a new sterile needle and syringe

(3) The vial must never be used for more than one patient

(4) Any medication or solution left in the vial must be discarded after each use

(5) Any medication or solution left in the vial must never be combined for use on other patients

(6) A needle must never be left inserted in the vial cap for multiple uses

(g) Infusion of intravenous medications with the following provision:

(1) Intravenous tubing and fluid bags or bottles must never be used for more than one patient

(h) Reprocessing of equipment, instrument, and devices, including:

(1) Sterilization of items that enter sterile tissue or the vascular system

(2) High-level disinfection of items that come in contact with intact mucous membranes

(3) Low-level disinfection of items that touch intact skin only

(4) Disposable equipment including the following provisions. The items:

(I) Should be properly disposed after each use

(II) Can be reprocessed only by a Federal Drug Administration (FDA) approved third party reprocessor

(III) Must never be reprocessed at the center

(i) Medical waste and specimen handling and disposal

(j) A method for tracking and documenting infections related to procedures performed at the center, reporting the infections as required by federal, state, and local laws, and identifying and addressing transmission trends

(k) Policy and procedure for caring for patients who arrive with a communicable disease or a patient who is found to have a communicable disease while undergoing treatment.

(l) Screening of all employees and independent contractors for communicable diseases in accordance with NAC 441A.375

(m) The proper cleaning and disinfection of all patient-care areas

(n) The proper procedures for maintaining a clean and sanitary environment

4. The center must designate an employee or contract with an individual with specialized training in infection control to oversee and manage all infection prevention and control efforts. The designated individual must ensure that the program:

(a) Complies with current federal, state, and local laws

(b) Is consistent with the standard of practice approved by the governing body and used to develop the program and a copy of the standard is available at the center

(c) Is reviewed with all employees and independent contractors within the first 10 days of employment, every 12 months thereafter, or more often as needed to ensure the infection control policies and procedures are understood and followed

5. All employees and independent contractors must receive training and be evaluated on the program within the first 10 days of employment and every 12 months thereafter,

or more often as if needed to ensure the infection control policies and procedures are understood and followed.

NAC 449.980 is hereby amended to read as follows:

Sec 2. Responsibilities of governing body. The governing body ~~[shall]~~ ***must*** ensure that:

1. Each patient of the center is under the care of a physician.

2. Each patient admitted to the center receives a ~~[presurgical evaluation]~~ ***history and physical*** conducted by a physician within the 7 days immediately preceding the date of his surgery.

3. A physician is on the premises of the ambulatory surgical center and immediately available at all times when there are patients in the operating rooms or the recovery room of the center. As used in this subsection, "immediately available" means the physician is sufficiently free from other duties to be able to respond rapidly to an emergency.

4. An annual operating budget and a plan for capital expenditures are established.

5. The center is adequately staffed and equipped.

6. There is documentation in the files of the center of the qualifications of ***and compliance with NAC 441A.375 for*** all persons under contract with the center.

7. The center adopts, enforces and annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, including an organizational chart. These policies and procedures must:

(a) Be approved annually by the governing body.

(b) Provide that a surgical procedure may be performed on a patient only with the consent of the patient or his legal representative, except in an emergency.

~~[(c) Include procedures for the isolation or immediate transfer of a patient with a communicable disease.]~~

~~[(d)]~~ ***(c)*** Include procedures for the periodic review and amendment, as deemed appropriate, of the scope of the procedures performed at the center.

8. The center establishes and maintains an infection control program designed to prevent the development and transmission of disease and infection appropriate for the services provided in accordance with a standard of practice approved by the governing body.

NAC 449.9895 is hereby amended to read as follows:

Sec. 3. Sterilization

1. All surgical instruments, ***implantable devices,*** sutures and drains used in the care of patients must be ~~[sterile]~~ ***sterilized according to a standard of practice approved by the governing body. A copy of the standard of practice must be available at the center.***

2. ~~[If these materials are sterilized on the premises, the process of sterilization must be supervised by a person who has received specialized training in the operation of that process, including training in methods of testing to verify the efficiency of the process.]~~ ***If these instruments, devices, or other items are sterilized or disinfected at the center, the following requirements must be met:***

(a) Prior to being assigned the responsibility for sterilizing or disinfecting any instrument or item, and annually thereafter, an employee must receive training on the manufacturer's instructions for:

(1) Sterilizing and disinfecting the instrument or item

(2) The use and maintenance of the sterilizer

(3) The agents used to sterilize and disinfect the instrument or item.

(b) Documentation of the training must be kept in the employee's file.

(c) If the equipment and/or procedures used to sterilize or disinfect an instrument or item change, the employee must be trained on the new equipment and/or procedures.

3. The manufacturer's ~~[Instructions]~~ ***instructions for operating any*** ~~[autoclave or]~~ ***sterilizer or performing any disinfection procedure must be located or posted near the equipment*** ~~[, and this equipment must be maintained in a safe operating condition]~~***.***

4. The manufacturer's instructions must be followed regarding:

(a) Which instruments or items can be sterilized or disinfected

(b) How the instrument or item is to be sterilized or disinfected

(c) Operation and maintenance of the sterilizer or the equipment used for high-level disinfection

(d) The frequency and type of microbiological monitoring of the sterilizer

(e) The recommended agents for sterilizing and disinfecting instruments or items

(f) Testing of any disinfection solution to ensure maintenance of the minimum level of effectiveness, but not less often than daily

5. The ~~[efficiency]~~ ***effectiveness*** of the ~~[method of]~~ sterilization ***procedures*** ~~[used]~~ must be checked ~~[not less frequently than]~~ ***at least*** ~~[once each month]~~ ***weekly or more frequently if recommended by the manufacturer and while sterilizing all implantable devices*** by ~~[bacteriological tests]~~ ***performing a biologic indicator test.*** ~~[Records of the results of these tests must be maintained by the center for at least 1 year.]~~

6. Sterilization records and logs of the results of the bacteriological tests must be maintained by the center for at least 1 year to ensure that recommended testing and maintenance of the equipment is being performed and the manufacturer's instructions regarding proper sterilization techniques are being followed.

7. To aid in environmental control, there must be a physical separation between the decontamination and sterilization areas.

NAC 449.990 is hereby amended to read as follows:

Sec. 4. Medication and treatment.

1. Any medication or treatment may be given only upon the written or ~~[oral]~~ ***verbal*** order of a person lawfully authorized to prescribe that medication or treatment. This order must be authenticated by the prescriber and the person administering the medication. An ~~[oral]~~ ***verbal*** order must be recorded and authenticated within 24 hours after it is ~~[made]~~ ***given***.

2. Medications prepared by one nurse may not be administered by another nurse.

3. At the time the medication is administered, the patient must be identified and the medication must be identified as being ordered for that patient and recorded in the medical record of the patient.

~~[4. Records must be maintained for any substance listed as a schedule II controlled substance pursuant to chapter 453 of NRS. Any such record must indicate the name of the patient, the name of the prescriber, the name of the controlled substance, the strength and dose administered, and the balance of the controlled substance remaining. A count must be made of all such controlled substances at the change of each nursing shift by a nurse from each shift. The count must be authenticated by both nurses.]~~

4. ~~[5. Transfusions of blood or i]~~***I***ntravenous medications may be administered only by persons who have been specially trained and are authorized for that duty. ~~[An ambulatory surgical center shall adopt policies and procedures for the administration of blood.]~~

5. ~~[6]~~ Any suspected adverse reaction to a ~~[transfusion or]~~ medication must be reported by members of the nursing staff to the physician attending the patient. The nursing staff ~~[shall note]~~

must document the reaction in the medical record of the patient. ~~[Any suspected reaction to a transfusion must also be reported to the service that furnished the blood.]~~

6. All medications must be prepared and administered in a safe and effective manner in accordance with accepted standards of practice and in accordance with the manufacturer's instructions.

NAC 449.9905 is hereby amended to read as follows:

Sec 5. Pharmacist required; records, storage, and administration of ~~[drugs]~~ *medications*.

1. A pharmacist must be on the staff of each ambulatory surgical center or under contract with the center. ~~[He]~~ ***The pharmacist*** is responsible for all matters pertaining to the use of ~~[drugs]~~ ***medications*** in the center. ~~[If the center employs a part-time pharmacist by contract, he shall visit the center not less frequently than once each month. These visits must be documented.]~~

2. The pharmacist must establish policies and procedures to address:

(a) The storage of medications

(b) The administration of medications to patients

(c) The proper procedure for discharging patients with ordered medications in hand

(d) The proper disposition or destruction of expired or contaminated medications

3. The pharmacist must:

(a) Visit the center at least once each month to evaluate the effectiveness of the policies and procedures established pursuant to subsection 2 and to confirm that documentation of each transaction involving medications is maintained

(b) Document each visit

(c) Periodically audit the records of the center related to the dispensing of controlled substances to ensure compliance with all applicable state and federal laws

(d) Ensure that medications are provided, prepared and administered in a safe and effective manner in accordance with accepted standards of practice and in accordance with the manufacturer's instructions.

~~[2]~~ ***4.*** Records of all transactions must be in writing and maintained so the receipt and disposition of any ~~[drug]~~ ***medication*** may be readily traced.

~~[3]~~ ***5***. ~~[Drugs]~~ ***Medications*** requiring refrigeration must be stored in a locked refrigerator or a refrigerator in a locked room. ~~[Food must not be stored in this refrigerator except for food used as a vehicle for the administration of drugs.]~~

~~[4]~~ ***6***. In the absence of a full-time pharmacist, the director of nursing must be designated in writing as responsible for the control of dangerous ~~[drugs]~~ ***medications*** and controlled substances. Substances listed as schedule II controlled substances pursuant to chapter 453 of NRS must be stored in a storage area with two locks. If a box is used, it must be securely fastened and immovable. ***The keys or combinations to the locks must be accessible only to licensed health care professionals.***

~~[5. Drugs may not be kept in stock after the expiration date on the label. Obsolete, contaminated or deteriorated drugs must be destroyed.]~~

7. Controlled substances must be logged in to and checked out of stock only by a licensed health care professional.

8. Records for any schedule II controlled substance must be maintained pursuant to chapter 453 of NRS. The record must indicate the name of the patient, the name of the prescriber, the name of the controlled substance, the dose administered, and the balance of the

substance remaining. A count must be completed of all such controlled substances at the beginning and the end of each shift by two licensed health care professionals. The count must be authenticated by two licensed health care professionals. If a discrepancy in the count cannot be corrected, the pharmacist must be notified immediately or not later than the next working day.

9. The center must obtain a license pursuant to chapter 639 of NRS.

NAC 449.9925 is hereby amended to read as follows:

Sec. 6. Procurement, storage and transfusion of blood.

1. If the ambulatory surgical center provides its own service for blood transfusions through its ~~[clinical]~~ ***medical*** laboratory ***pursuant to chapter 652.060 of NRS***:

(a) Any arrangement for the procurement, safekeeping or transfusion of blood or derivatives of blood must be under the supervision of a ~~[physician]~~ ***pathologist***.

(b) Any reaction to a transfusion of blood must be investigated.

(c) The storage equipment for blood and derivatives of blood must be protected by an alarm system which ~~[is]~~ ***must be*** tested each month ***and the temperature must be continuously monitored*** to ~~[check]~~ ***verify*** its operation.

(d) Samples of the blood of any patient receiving a transfusion and of each unit of blood used in the center must be retained in accordance with the written policy of the laboratory for at least 7 days for further testing in the event of a reaction to the transfusion.

(e) Blood and derivatives of blood that have exceeded their expiration date ~~[may]~~ must not be used ***and must be disposed of as biohazardous waste***.

2. If the ambulatory surgical center depends on an outside source for blood, there must be in force a written agreement governing the procurement of blood and derivatives of blood that is

reviewed annually by the governing body and the staff pathologist or the pathologist used as a consultant by the center.

3. Blood and blood products must be administered only by a physician or a registered nurse.

4. The center must establish policies and procedures for the administration of blood and blood products that are in accordance with acceptable standards of practice.

5. Any suspected adverse reaction to a blood transfusion must be reported by members of the nursing staff to the physician attending the patient. The nursing staff must document the reaction in the medical record of the patient. Any suspected reaction to a blood transfusion must also be reported to the service that furnished the blood.