ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R096-08

Effective October 25, 2008

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

AUTHORITY: §§1-29, NRS 441A.120 and 449.037.

A REGULATION relating to ambulatory surgical centers; requiring ambulatory surgical centers to establish a program for the prevention and control of infections and communicable diseases; requiring the governing body of an ambulatory surgical center to adopt guidelines for the program; revising certain provisions relating to the administration of medication; revising certain provisions governing medications used at ambulatory surgical centers; revising the requirements for blood transfusions; and providing other matters properly relating thereto.

Section 1. Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 19, inclusive, of this regulation.

Sec. 2. ***"Biohazardous waste" means all biological waste or biologically contaminated waste that may cause harm to humans, animals or plants.***

Sec. 3. ***"Biologic indicator test" means a test used in every ethylene oxide cycle and in every sterilization load of implantable medical items to demonstrate through the destruction of highly resistant bacterial spores whether all parameters, including, without limitation, time, temperature, sterilant and humidity, were met to effectively sterilize the medical items.***

Sec. 4. ***"Cleaning" means the physical removal of organic material or soil from objects by using water, with or without detergents, that is designed to remove, rather than kill, microorganisms.***

Sec. 5. ***"High-level disinfection" means a type of disinfection which destroys all microorganisms with the exception of high levels of bacterial spores. Such disinfection may be accomplished through the use of processes that include, without limitation, boiling items in water, steaming items in water and soaking items in chemical disinfectants.***

Sec. 6. ***"Implantable device" means a medical device that is implanted in the human body, including, without limitation, a pacemaker, defibrillator, heart valve, hearing device or joint replacement.***

Sec. 7. ***"Invasive procedure" means a medical procedure involving entry into the human body by puncture or incision or by insertion of an instrument.***

Sec. 8. ***"Low-level disinfection" means a type of disinfection which eliminates most bacteria, some viruses and some fungi, but which may not kill resistant microorganisms. Such disinfection may be accomplished through the use of processes that include, without limitation, soaking items in chemical disinfectants.***

Sec. 9. ***"Multidose vial" means a vial, including, without limitation, a sealed sterile vial, which may be accessed by insertion of a needle and which, according to the manufacturer's instructions, contains:***

1. More than one dose of a medication; and

2. May be used for one or more patients.

Sec. 10. ***"Reprocess" means the process of subjecting a single-use medical device that has been previously used on a patient to additional cleaning, disinfection or sterilization, manufacturing steps, including, without limitation, repackaging and relabeling, and testing of the technical and functional safety of the device to make the device ready for safe use on another patient.***

Sec. 11. ***"Single-dose vial" means a vial, including, without limitation, a sealed sterile vial, which may be accessed by insertion of a needle and which, according to the manufacturer's instructions:***

1. Contains only one dose of a medication; and

2. May be used for only one patient.

Sec. 12. ***"Sterilization" means a process using medical equipment, including, without limitation, a dry heat sterilizer or an autoclave, to destroy all forms of microbial life.***

Sec. 13. ***1. The governing body shall adopt guidelines which must be used by the ambulatory surgical center in establishing the program for the prevention and control of infections and communicable diseases required pursuant to section 14 of this regulation.***

2. The guidelines adopted pursuant to subsection 1 may include, without limitation, guidelines, statements or recommendations issued or published by other agencies or organizations, and must:

(a) Be based on evidence, theoretical rationale or scientific data; and

(b) Include well-designed experimental, clinical or epidemiological studies which document the processes used in the development of the studies and grade the strength of the evidence relied on in the studies.

3. The governing body shall ensure that a copy of the guidelines adopted pursuant to subsection 1 is available at the ambulatory surgical center and accessible to the staff of the ambulatory surgical center and the public.

Sec. 14. ***1. Each ambulatory surgical center shall establish and maintain a program for the prevention and control of infections and communicable diseases.***

2. In addition to complying with the provisions of sections 13 to 19, inclusive, of this regulation, a program for the prevention and control of infections and communicable diseases must be:

(a) Appropriate for the services provided at the ambulatory surgical center;

(b) Based on the guidelines adopted by the governing body pursuant to section 13 of this regulation; and

(c) Developed in a manner that takes into consideration:

(1) All the surgical and other medical services provided at the ambulatory surgical center;

(2) The types of patients typically treated at the ambulatory surgical center, including, without limitation, those whose age or medical condition makes them vulnerable to infections and communicable diseases;

(3) The types of injuries or illnesses typically treated at the ambulatory surgical center;

(4) The number of patients typically treated at the ambulatory surgical center;

(5) The level of education and training of the staff of the ambulatory surgical center;

(6) The number of nurses available at the ambulatory surgical center, the qualifications of such nurses and the amount of support required of the nurses by the physicians at the ambulatory surgical center;

(7) The types of invasive procedures performed at the ambulatory surgical center;

(8) The locations within the ambulatory surgical center where invasive procedures are performed;

(9) The specific medical instruments and equipment used at the ambulatory surgical center;

(10) The physical design of the ambulatory surgical center; and

(11) The causes, risks and patterns of infections and transmission of communicable diseases that arise in the setting of each medical procedure performed at the ambulatory surgical center.

Sec. 15. *Each program for the prevention and control of infections and communicable diseases must include policies and procedures to prevent exposure to blood-borne and other potentially infectious pathogens, including, without limitation, policies and procedures relating to:*

1. Hand hygiene, including provisions regarding the time and procedure for handwashing with soap and water or use of an alcohol-based hand rub.

2. The proper use of medical gloves. Those policies and procedures must, at a minimum, provide that each person who works at the ambulatory surgical center must wear medical gloves when the person:

(a) Anticipates coming in contact with blood or bodily fluids;

(b) Handles contaminated instruments, items and equipment;

(c) Handles biohazardous waste;

(d) Handles linens potentially contaminated with biohazardous waste; and

(e) Performs housekeeping activities or cleans contaminated surfaces.

3. Safe injection practices to prevent the contamination of equipment used for injections and medication. Those policies and procedures must provide that a new sterile needle and new sterile syringe must be used for each patient and may not be used for more than one patient.

4. The proper handling of sharp instruments and the disposal of sharp instruments. Those policies and procedures must be consistent with the standards developed by the

Occupational Safety and Health Administration for the handling and disposal of such instruments.

5. Techniques for accessing a vial of medication. Those policies and procedures must comply with the requirements set forth in section 16 of this regulation.

6. The infusion of intravenous medications. Those policies and procedures must provide that intravenous tubing and fluid bags or bottles must not be used for more than one patient.

7. The proper sterilization and disinfection of all medical equipment, instruments and devices. Those policies and procedures must, at a minimum, require an ambulatory surgical center to:

(a) Sterilize or ascertain the sterility of items that enter sterile tissue or the vascular system, including, without limitation, surgical instruments, endoscopes, endoscopic accessories, catheters, needles and probes used for ultrasounds;

(b) Perform high-level disinfection of reusable items that come in contact with nonintact skin or mucus membranes, including, without limitation, respiratory therapy equipment, anesthesia equipment, bronchoscopes and gastrointestinal endoscopes; and

(c) Perform low-level disinfection of reusable items that come in contact with only intact skin, including, without limitation, tourniquets, blood pressure cuffs, linens, stands that are used to hold medical instruments and other furnishings.

8. The proper handling of equipment, instruments and devices. Those policies and procedures must, at a minimum, require an ambulatory surgical center to:

(a) Sterilize and disinfect reusable items as described in subsection 6;

(b) Properly dispose of single-use equipment, instruments and devices after use, if the ambulatory surgical center has decided not to have the equipment, instruments or devices reprocessed;

(c) Ensure that:

(1) All equipment, instruments and devices that may be reprocessed are reprocessed only by a third-party processor approved by the United States Food and Drug Administration; and

(2) No equipment, instruments or devices that may be reprocessed are reprocessed at the ambulatory surgical center.

9. The proper handling and disposal of medical waste and specimens.

10. The proper cleaning and disinfection of all areas in which patient care is provided.

11. The proper maintenance of a clean and sanitary environment.

12. The identification and reporting of the development and transmission of infections and communicable diseases. Those policies and procedures must include the method by which the ambulatory surgical center must:

(a) Track and document the development and transmission of infections and communicable diseases which are related to the medical procedures performed at the ambulatory surgical center;

(b) Report the development and transmission of infections and communicable diseases as required by federal, state and local laws; and

(c) Identify and address trends in such developments and transmissions of infections and communicable diseases.

13. The care of patients with a communicable disease, including, without limitation, patients who are known to have a communicable disease at the time of arrival at the ambulatory surgical center and patients who are found to have a communicable disease during the course of treatment at the ambulatory surgical center.

14. The screening for communicable diseases as described in NAC 441A.375 of all employees and of all persons under contract with the ambulatory surgical center who work at the center and have exposure to patients at the center.

Sec. 16. *1. Each program for the prevention and control of infections and communicable diseases must include policies and procedures for single-dose vials which provide that a single-dose vial may be accessed only by using an aseptic technique. The policies and procedures must provide that:*

(a) Each injection of a medication from a single-dose vial must be prepared in a clean, designated area where contamination by blood or bodily fluid is unlikely to occur;

(b) The medication in a single-dose vial must not be used for more than one patient;

(c) A single-dose vial, including any remaining medication in the vial after its use, must be discarded; and

(d) Any remaining medication in a single-use vial after its use must not be combined with any other medication or otherwise used for any other patients.

2. Each program for the prevention and control of infections and communicable diseases must include policies and procedures for multidose vials which provide that a multidose vial may be accessed only by using an aseptic technique. The policies and procedures must provide that:

(a) The cap of a multidose vial must be cleaned with an alcohol-based wipe before the vial is accessed;

(b) A new sterile needle and new sterile syringe must be used each time to access a multidose vial;

(c) Upon first access of a multidose vial, the person who accessed the vial shall date and initial the vial;

(d) Each injection of a medication from a multidose vial must be prepared in a clean, designated area where contamination by blood or bodily fluid is unlikely to occur;

(e) A needle must not be left inserted in the cap of a multidose vial after its use; and

(f) A multidose vial must be discarded when the medication in the vial has expired or 28 days after the vial was initially accessed.

Sec. 17. *1. All surgical instruments, items or equipment used in the care of patients at an ambulatory surgical center must be sterilized or disinfected according to the program for the prevention and control of infections and communicable diseases adopted by the ambulatory surgical center pursuant to section 14 of this regulation.*

2. If such instruments, items and equipment are sterilized or disinfected by equipment or cleaning agents at the ambulatory surgical center:

(a) Before an employee or independent contractor may be assigned the responsibility for sterilizing or disinfecting any instrument, item or equipment, the employee or independent contractor must receive training concerning the instructions of the manufacturer of the device or sterilizer for:

(1) Sterilizing and disinfecting the instrument, item or equipment;

(2) The use and maintenance of the sterilizer or disinfecting equipment; and

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

(b) An employee or independent contractor assigned the responsibility for sterilizing or disinfecting the instrument, item or equipment shall:

(1) Receive annual training concerning the manufacturer's instructions described in paragraph (a); and

(2) Receive training on any new equipment or procedures if there is any change in the equipment or procedures used to sterilize or disinfect an instrument, item or equipment.

(c) The ambulatory surgical center shall ensure that documentation of all training completed pursuant to this subsection is kept in the file of the employee or independent contractor.

3. The manufacturer's instructions for operating any sterilizer or performing any disinfection procedure must be located or posted near the equipment used for sterilization or disinfection.

4. The ambulatory surgical center shall ensure that each employee or independent contractor follows the manufacturer's instructions concerning:

(a) The instruments, items or equipment that may be sterilized or disinfected;

(b) The procedures for cleaning an instrument, item or equipment before the instrument, item or equipment is sterilized or undergoes high-level disinfection;

(c) The procedures for sterilizing or disinfecting an instrument, item or equipment;

(d) The operation and maintenance of the sterilizer or the equipment used for high-level disinfection;

(e) The frequency and type of biologic indicator testing of the sterilizer;

(f) The recommended agents for sterilizing and disinfecting the instrument, item or equipment; and

(g) The frequency of testing of any solution for disinfecting to ensure maintenance of the minimum level of effectiveness, but not less often than daily testing.

5. The effectiveness of the sterilization procedures must be checked by performing a biologic indicator test:

(a) At least weekly, or more frequently if recommended by the manufacturer; and

(b) While sterilizing all implantable devices.

6. Sterilization records and logs of the results of the biologic indicator test must be maintained by the ambulatory surgical center for at least 1 year after the test is performed to ensure that the recommended testing and maintenance of the equipment is performed and the manufacturer's instructions regarding proper sterilization techniques are followed. Each ambulatory surgical center shall establish a method to track and recall instruments, items or equipment previously sterilized or disinfected if there is a failure of the biologic indicator test.

7. To aid in environmental control, each ambulatory surgical center shall provide a physical barrier between the decontamination and sterilization areas of the ambulatory surgical center.

Sec. 18. *1. Each ambulatory surgical center shall designate an employee or enter into a contract with a person to oversee and manage all aspects of the program for the prevention and control of infections and communicable diseases.*

2. The person described in subsection 1:

(a) Shall have completed specialized training in the prevention and control of the development and transmission of infections and communicable diseases; and

(b) Shall ensure that the program for the prevention and control of infections and communicable diseases for the ambulatory surgical center:

(1) Complies with all applicable federal, state and local laws;

(2) Is consistent with the guidelines adopted by the governing body pursuant to section 13 of this regulation; and

(3) Is reviewed with all employees of the ambulatory surgical center and all persons under contract with the ambulatory surgical center who work at the center and have exposure to patients at the center within the first 10 days of employment and every 12 months thereafter, or more often if required pursuant to subsection 2 of section 19 of this regulation.

Sec. 19. ***1. Each employee of an ambulatory surgical center and each person under contract with an ambulatory surgical center who works at the center and has exposure to patients at the center shall receive training and be evaluated by supervising staff on his knowledge and skills concerning the program for the prevention and control of infections and communicable diseases within the first 10 days of employment and at least every 12 months thereafter.***

2. An employee or person under contract with the ambulatory surgical center may be required to receive the training and evaluation described in subsection 1 more often than every 12 months if his supervisor determines that such training and evaluations are necessary to ensure that he understands and will follow the policies and procedures of the program for the prevention and control of infections and communicable diseases.

Sec. 20. NAC 449.971 is hereby amended to read as follows:

449.971 As used in NAC 449.971 to 449.996, inclusive, ***and sections 2 to 19, inclusive, of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC

449.9715 to 449.9743, inclusive, ***and sections 2 to 12, inclusive, of this regulation*** have the meanings ascribed to them in those sections.

Sec. 21. NAC 449.9785 is hereby amended to read as follows:

449.9785 During the term of his license, the licensee shall continuously maintain the ambulatory surgical center in conformance with the provisions of NAC 449.971 to 449.996, inclusive ~~[.]~~ ***, and sections 2 to 19, inclusive, of this regulation.*** Any violation of these provisions may result in the suspension or revocation of the license.

Sec. 22. NAC 449.980 is hereby amended to read as follows:

449.980 The governing body shall 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 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]~~ ***:***

(a) The qualifications of all persons under contract with the center ~~[.]~~ ***; and***

(b) Whether such persons who work at the center and have exposure to patients have been screened for communicable diseases as described in NAC 441A.375.

7. ***The center establishes and maintains a program for the prevention and control of infections and communicable diseases as required pursuant to section 14 of this regulation.***

8. The center adopts, enforces and ***at least*** annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, ***and sections 2 to 19, inclusive, of this regulation,*** 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)]~~ Include procedures for the periodic review and amendment, as deemed appropriate, of the scope of the procedures performed at the center.

Sec. 23. NAC 449.9835 is hereby amended to read as follows:

449.9835 1. If a licensee is a physician operator, the ambulatory surgical center operated by the licensee is not required to have a governing body or an administrator. In such a case, in the absence of a governing body or an administrator, the physician operator is responsible for complying with all the provisions of NAC 449.971 to 449.996, inclusive ~~[.]~~ ***, and sections 2 to 19, inclusive, of this regulation.***

2. As used in this section, "physician operator" means a physician, a podiatric physician licensed pursuant to chapter 635 of NRS or a dentist licensed pursuant to chapter 631 of NRS

who is operating an ambulatory surgical center for the purpose of performing surgery only upon his patients.

Sec. 24. NAC 449.990 is hereby amended to read as follows:

449.990 1. Any medication or treatment may be given only upon the written or oral 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 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.~~

~~5. Transfusions of blood or intravenous]~~ ***Intravenous*** medications ***or fluids*** 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.~~

~~6.]~~ ***5.*** 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]~~

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 the program for the prevention and control of infections and communicable diseases adopted pursuant to section 14 of this regulation and in accordance with the manufacturer's instructions.

Sec. 25. NAC 449.9905 is hereby amended to read as follows:

449.9905 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 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. Records of all transactions must be in writing and maintained so the receipt and disposition of any drug may be readily traced.

3. Drugs 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. 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 and controlled substances. ~~[Substances listed as schedule II controlled substances pursuant to]~~ ***Controlled substances as described in*** 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.]~~ ***All drugs must be logged into and checked out of stock only by a licensed health care professional.***

6. The ambulatory surgical center shall obtain a license to operate a pharmacy pursuant to chapter 639 of NRS.

Sec. 26. NAC 449.9925 is hereby amended to read as follows:

449.9925 1. If the ambulatory surgical center provides its own service for blood transfusions through its ~~[clinical laboratory:]~~ ***medical laboratory as defined in NRS 652.060:***

(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 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 ~~[.]~~ ***; and***

(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 derivatives of blood used in the ambulatory surgical center must be administered only by a physician or a registered nurse.

4. The ambulatory surgical center shall establish policies and procedures for the administration of blood and derivatives of blood that are in accordance with the program for the prevention and control of infections and communicable diseases adopted pursuant to section 14 of this regulation.

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

Sec. 27. NAC 449.9895 is hereby repealed.

Sec. 28. Notwithstanding the provisions of sections 18 and 19 of this regulation, a person who, on October 25, 2008:

1. Is employed by an ambulatory surgical center as defined in NAC 449.972; or

2. Is under contract with an ambulatory surgical center as defined in NAC 449.972, works at the ambulatory surgical center and has exposure to patients at the ambulatory surgical center,

➥ is not required to satisfy the initial training requirements set forth in those sections until December 24, 2008.

Sec. 29. This regulation becomes effective on October 25, 2008.

TEXT OF REPEALED SECTION

449.9895 Sterilization. (NRS 449.037)

1. All surgical instruments, sutures and drains used in the care of patients must be sterile.

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.

3. Instructions for operating any autoclave or sterilizer must be posted near the equipment, and this equipment must be maintained in a safe operating condition.

4. The efficiency of the method of sterilization used must be checked not less frequently than once each month by bacteriological tests. Records of the results of these tests must be maintained by the center for at least 1 year.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R096-08

The State Board of Health adopted regulations assigned as LCB File No. R096-08 which pertains to chapter 449 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.

A Small Business Impact Questionnaire was mailed to all licensed Surgical Centers for Ambulatory Patients on April 21, 2008. Attachment A is the Small Business Impact Statement Letter and Questionnaire. Attachment B is a copy of the Small Business Impact Summary.

The Notice of Public Workshops held on May 16, 2008, in Carson City and on May 20, 2008, in Las Vegas, was published in the Las Vegas Review Journal and Reno Gazette Journal on or before May 1, 2008. The Notice of Public Workshops and proposed regulations were mailed to all county libraries in Nevada, Southern Nevada Health District, Washoe County District Health Department, Surgical Centers for Ambulatory Patients, and interested parties on April 21, 2008. The Small Business Impact Summary was available at both workshops.

Copies of the workshop minutes may be obtained by calling the Bureau of Licensure and Certification at (775) 687-4475.

The Notice of Public Hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal and Reno Gazette Journal on or before May 20, 2008January 16, 2008. The Notice of Public Hearing and proposed regulations were mailed to all county libraries in Nevada, Southern Nevada Health District, Washoe County District Health Department, Surgical Centers for Ambulatory Patients, and interested parties on May 16, 2008.

Summary of the public response:

<u>Comments received at the Carson City Workshop:</u>
Eric Mortensen, MD, Associated Anesthesiologists of Reno, stated two items of concern. The first was Chapter 449, Section 1, (3)(b)(2) "A needle and a syringe must not be used more than once on any patient." This requirement would be a problem for anesthesiologists because anesthesiology is the practice of titration. For example, a 5 cubic centimeter (cc) syringe of medication might be used 10 times in ½ cc increments during a case. Titration of the medication keeps the patient anesthetized versus giving too much medication and having to treat blood pressure or cardiac output problems. This would have an impact on delivery of care. Another example, ophthalmologists use prefilled syringes of healon during eye surgeries. Each syringe may cost approximately $50.00, but the syringe of medication is used multiple times for one patient. If the regulations are adopted, ophthalmologists could not continue this practice. This would significantly increase costs.

Dr. Mortensen's second item of concern in Chapter 449, Section 1 (3)(e)(5) "Each injection must be prepared in a clean designated area where blood or body fluids contamination is unlikely." He stated there is an anesthesia cart at the patient's head in the operating room which contains medications and syringes. The anesthesiologists are constantly interacting with patients during procedures and a surveyor could cite that as possible contamination and the need for the medications to be prepared in a separate clean area. If this was enforced, medication would have to be prepared in a separate area and then transported into the operating room. Administration of medication could be delayed putting the patient at risk.

Louis Ling, General Counsel, Nevada Board of Pharmacy, provided the following changes: NAC 449.9905, Section 5, delete the word "medications" throughout the section and keep the word "drugs," because the Board of Pharmacy does not have any jurisdiction over medications. Add the following new language in subsection (1): "The pharmacist shall ensure that he and the ambulatory surgical center comply with NAC 639.4992 through NAC 639.4996." Delete subsection (2)(a)(b)(c) and (d). Delete subsection (3)(a)(b)(c) and (d). Under subsection (6) delete Substances listed as schedule II. Change subsection (7), "Controlled substances" to "all drugs." Delete subsection (8). Mr. Ling stated there has always been a crossover between BLC and the Board of Pharmacy when it comes to Surgical Centers for Ambulatory Patients, because BLC regulations require the centers to have consultant pharmacists and so does the Board of Pharmacy. Mr. Ling's concern with the proposed regulations is that if the pharmacist violates the NAC 449 regulations, the Board of Pharmacy and BLC could not discipline the pharmacist, only the center. The proposed Board of Pharmacy regulations would allow the Board of Pharmacy to take disciplinary action on a pharmacist's working in ASCs. The Board of Pharmacy regulations have been reviewed by a number of consultant pharmacists and all agreed with the changes. The proposed regulation changes regarding consultant pharmacists for ASCs, pursuant to, NAC 639, would be more stringent than the proposed regulation changes that BLC is requesting in NAC 449. Mr. Ling then read the Nevada Board of Pharmacy regulations, NAC 639. The Board of Pharmacy will be holding proposed regulation workshops on June 4, 2008. Mr. Ling believes the Board of Pharmacy regulations will become effective in July 2008.

Autumn Uyechi, Clinical Director of Reno Endoscopy Center, and Barbara Williams, Clinical Director of South Meadows Endoscopy Center, stated that they are in favor of the phrasing of having industry related standards and the facilities would be held to the standards. Additional concern was if the related industry standards changed, whether that would impact the regulations.

Diane Allen stated that she would speak with BLC's legal counsel.

Stacy Ingram, Director of St. Mary's Outpatient Surgery Center in Galena, stated that she was in agreement with Dr. Mortensen's comments related to medication administration at the patient's bedside. Ms. Ingram indicated that she did not have a problem with multi-dose vial, reusing the same needle and syringe into the patient's intravenous (IV) site. There would be no cross-contamination of syringes or patients, only additional medication being added to the drip. Ms. Ingram indicated that the ASC that she is employed with performs a high volume of ophthalmology cases. Going to single-use ophthalmology drops would be a challenge. The drops only come in three and ten cc vials. Each patient receives up to 5 - 7 drops of different

medications. For example, expenses have ranged from $300 dollars for ophthalmology costs to $3,000 dollars in one month. With the appropriate training for nursing staff, administration of that medication can be provided in a safe manner. In coordination with the Board of Pharmacy and medication manufacturers, if there was another way to devise smaller amounts of the medication, the ASCs would be more lucrative. Ms. Ingram stated that she was in support of Dr. Mortensen's sterility comments, referring to Section 1, subsection (3)(m), "The proper cleaning and disinfection of all patient-care areas," proper cleaning procedures need to be defined. Ms. Ingram agreed that between patients, one must absolutely change bottles, needles and syringes.

Mary English indicated that she is in charge of Infection Control and Compliance at the Galena Surgery Center. Ms. English shared investigative details of the laryngoscope cleaning process. The Centers for Disease Control and Prevention (CDC) stated that the same process should be implemented when disinfecting handles and blades.

There was discussion concerning the costs for sterilization practices.

Marian Panter, RN, Western Nevada Surgical Center, stated that she had worked at a couple of different eye centers in Carson City. Ms. Panter referred to Section 4, subsection 2, "Medication prepared by one nurse may not be administered by another nurse." Ms. Panter stated that this requirement would pose a problem when hanging solutions, due to these solutions have been mixed all at once and are then distributed to the surgery rooms where the RN administers the solution to the patient. This regulation would require that nurses mix a new bottle for each patient and this requirement would not be cost or time effective.

Ms. Allen asked Ms. Panter to draft and propose language she would like for that section.

Dr. Mortensen stated that pre-operative antibiotics are given within an hour before surgery. In some of the ASCs, a nurse sets up the antibiotic in an IV solution bag. The IV is not started until the surgery is about ready to begin. The circulation nurse comes in the operating room and opens the IV to start administering the medication. Dr. Mortensen said he does not like putting a patient to sleep where the antibiotic is running in at the time of the induction. He would rather have the antibiotic a couple minutes before surgery because there is not enough time after surgery to give the antibiotics before the tourniquet is applied. This regulation will necessitate having two different nurses, one who mixes the IV and sets it up for the patient, and either the anesthesiologist or a circulating nurse would normally start it. If the pre-operative nurse is not in the area when the patient goes to surgery, the regulation becomes a problem.

Ms. Allen asked Dr. Mortensen to draft and propose language he would like for that section.

Ms. Williams referred to Section 1(3)(b)(2), "A needle and syringe must not be used more than once on any patient." Ms. Williams stated that the administration of moderate sedation for a patient would not be cost or time effective, and could actually have an adverse impact on a patient if there are delays in titration of sedation for a procedure. Ms. Williams indicated that the needle and syringe is used for one patient then discarded.

Comments received at the Las Vegas Workshop:
Mary Grear, Pharmacy Consulting Services Group, referred to page 2(3)(e)(4), which indicated a vial must be dated and initialed upon first access and discarded upon expiration. Ms. Grear suggested adding the following wording at the end of the sentence: "or reach its 28th day beyond use date." On June 1, 2008, The United States Pharmacopeia will have new standards go into effect which includes any opened multi dose vial would be discarded after 28 days after the first entry. The terminology is "beyond use date" rather than expiration date.

Dr. Larry Matheis, Executive Director of the Nevada State Medical Association, expressed the Association's support for the Health Division revising the regulations for ASCs. The Nevada State Medical Association is working with HonoReform, the National Hepatitis Patient Advocacy Group, and the CDC to develop an educational and outreach campaign for patients, physician practices, and eventually all provider practices in the state. Some of the proposed revisions to BLC's ASC regulations will be used for training. Dr. Matheis then stated that the regulations are still "murky" when addressing vials and the intent of the various dosages. The terms used are single-dose vials, single-use vials, multi-dose vials, and multi-use vials. There is a lot of confusion among some health care professionals about what can be completed safely. It is the view of the Nevada State Medical Association to never reuse a needle or syringe. Dr. Matheis stated that he believes, there are some circumstances when proper hygienic and sterile techniques are in place, trained medical professionals can reuse multi-use vials. Mr. Matheis suggested that BLC be flexible with these restrictions on the safe use of prepackaged vials of drugs. Dr. Matheis offered to assist BLC, as appropriate.

There was discussion on screening of employees and independent contractors for communicable diseases pursuant to, NAC 441A.375.

There was discussion on hand washing techniques.

2. The number of persons who:
   (a) Attended the hearing;
   (b) Testified at each hearing;
   (c) Submitted to the agency written statements.

(a) Approximately 58 people attended the BOH meeting (the hearing).

(b) Larry Matheis, Executive Director of the Nevada State Medical Association, commended the Bureau of Licensure and Certification and supported the regulations.

(c) The following submitted written statements, which were included in the Board's packets:

Autumn Uyechi, RN BSN Clinical Director GI Consultants, Ltd Reno North, Reno Endoscopy Center, LLP

Barbara Williams, RN BSN Clinical Director GI Consultants, Reno South, South Meadows Endoscopy Center LLC

Jonathan Zucker, MD, President, Nevada State Society of Anesthesiologists

Eric J. Mortensen, MD

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.

Comment was solicited from affected or potentially affected businesses by mailing appropriate facilities and all interested parties the proposed regulations, a small business impact questionnaire, a copy of the small business impact summary, and the notices for the workshops and Board of Health hearings. Copies of the workshop minutes and Board of Health hearing minutes may be obtained by calling the Bureau of Licensure and Certification at (775) 687-4475.

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 statement should also explain the reasons for making any changes to the regulation as proposed.

No changes were made to the proposed regulation. The state agency received comments about potential conflict with local municipalities however, the state agency's investigation revealed these concerns to not be valid. No other comments were received indicating that changes should be made.

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; and
   (b) Both immediate and long term effects.

   (a) The regulatory change will have no adverse effects on the regulated businesses. The regulatory change will be beneficial on businesses as these additional regulations will provide specific requirements to ambulatory surgery centers to follow to ensure the safe delivery of medications and to establish effective programs of infection control.

   The regulatory change will have no adverse effects on the public. The regulatory change will be beneficial to the public by protecting patient safety.

   (b) The regulatory change will have an immediate and long term effects on businesses, both would be for the Surgical Centers for Ambulatory Patients to implement systems for establishing and maintaining medications in a safe manner to patients.

   The regulatory change will have an immediate and long term effect on the public by protecting patient safety.

6. The estimated cost to the agency for enforcement of the proposed regulation,

There will be no cost to the state agency for enforcement of the regulation.

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, name the regulating federal agency.

These regulations do not overlap nor duplicate other regulations.

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 proposed regulations are more stringent than the federal regulations for the same activity because more specific state regulations were needed to protect the public.

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.

The regulation doesn't propose a new fee or increase and existing fee.

10. If the proposed regulation is likely to impose a direct and significant economic burden upon a small business or directly restrict the formulation, operation or expansion of a small business. What methods did the agency use in determining the impact of the regulation on a small business?

A small business impact questionnaire was sent to all licensed Surgical Centers for Ambulatory Patients. A copy of the small business impact summary can be obtained by calling (775) 687-4475.