ADOPTED REGULATION OF

THE STATE BOARD OF HEALTH

LCB File No. R181-09

Effective October 4, 2013

(Note: Various provisions have been removed from this regulation for separate consideration; see LCB File Nos. R203-09 and R170-12.)

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

AUTHORITY: §§1-21, NRS 449.0302.

A REGULATION relating to medical and other related facilities; revising provisions relating to the policies of ambulatory surgical centers; revising provisions governing the provision of certain services and care at ambulatory surgical centers; 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, 3 and 4 of this regulation.

Sec. 2. ***An ambulatory surgical center shall establish a program for the review of surgical procedures and patient outcomes, including, without limitation, a review of the program for the control and prevention of infections and the rates of infections occurring at the center. The program must require the review to be conducted by a person who does not have a financial interest in the ambulatory surgical center.***

Sec. 3. ***If services and care are provided at an ambulatory surgical center by persons who are under contract with the center or who are otherwise not employees of the center, the governing body shall establish policies for the provision of services and care by those persons, including, without limitation, policies relating to the supervision of such persons and the***

coordination of services and care. The policies must ensure that services and care are provided at the ambulatory surgical center in a safe and effective manner.

Sec. 4. *An ambulatory surgical center shall keep a complete and current register of all surgeries performed in an operating room at the center. The register must include, without limitation, for each patient who underwent surgery in an operating room:*

1. The name of the patient;

2. The identification number of the patient;

3. The date of the surgery;

4. The name of the surgeon who performed the surgery and each person who was present for the surgery;

5. The total time for performing the surgery;

6. The type of anesthesia provided to the patient;

7. The name of the person administering the anesthesia;

8. The type of surgery that was performed; and

9. The preoperative and postoperative diagnoses of the patient.

Sec. 5. NAC 449.9743 is hereby amended to read as follows:

449.9743 "Surgery" means the treatment of a human being by ~~[a physician using one or more of the following procedures:~~

~~1. Cutting into any part of the body using a scalpel, electrocautery or any other means for diagnosis or the removal or repair of diseased or damaged tissue, organs, tumors or foreign bodies.~~

~~2. The reduction of a fracture or the dislocation of a bone, joint or bony structure.~~

~~3. The repair of a malformation of the body resulting from an injury, a birth defect or another cause, that requires cutting and manipulation or a suture.~~

~~4. An instrumentation of the uterine cavity of a woman for diagnostic or therapeutic purposes, including the procedure commonly known as dilation and curettage.~~

~~5. Any instrumentation of, or injection of a substance into, the uterine cavity of a woman to terminate a pregnancy.~~

~~6. Any procedure to sterilize a human being.~~

~~7. An endoscopic procedure.~~

~~8. A laproscopic procedure.]~~ ***operative methods.***

Sec. 6. NAC 449.9755 is hereby amended to read as follows:

449.9755 After it receives a properly completed application, proof of the identity of the applicant that is acceptable to the Division and the appropriate fee, the Division shall conduct an investigation of the applicant and inspect the ***facility of the*** proposed ***ambulatory surgical*** center.

Sec. 7. 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]~~ ***:***

(a) Physical examination, which must include a medical history of the patient, within the 30 days immediately preceding the date of the patient's surgery; and

(b) Presurgical evaluation conducted by a physician ***on the day of the patient's surgery or*** within the 7 days immediately preceding the date of the patient's 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:

(a) The qualifications of all persons ***employed by or*** under contract with the center; and

(b) Whether such persons who work at ***or are under contract with*** 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 NAC 449.98452.

8. The center adopts, enforces and at least annually reviews written policies and procedures required by NAC 449.971 to ~~[449.996,]~~ ***449.997,*** inclusive, ***and sections 2, 3 and 4 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 the patient's legal representative, except in an emergency.

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

Sec. 8. NAC 449.9812 is hereby amended to read as follows:

449.9812 1. The administrator of an ambulatory surgical center shall establish a program for quality assurance for the center.

2. The program for quality assurance must include, without limitation:

(a) Periodic reviews of the clinical responsibilities and authority of the members of the staff.

(b) Periodic evaluations of members of the staff that are conducted by their peers.

(c) Procedures for the supervision of the professional and technical activities of the members of the staff.

(d) ~~[Periodic evaluations that are conducted to determine whether the clinical and administrative policies of the center are cost-effective. The evaluations required by this paragraph must not be limited to the cost-effectiveness of the administrative policies of the center.~~

~~(e)]~~ Procedures for identifying and correcting any problems or concerns that provide an opportunity for all members of the staff who are health care practitioners to participate in the program for quality assurance.

~~[(f)]~~ ***(e)*** Techniques for self-assessment that are required to be used by the members of the staff and provide for an examination of the manner in which care has been, is and will be provided and the quality of the care provided.

~~[(g)]~~ ***(f)*** Procedures for identifying and addressing any problems or concerns related to the care provided to patients using the medical records of the center and any other sources of data that may be useful to identify previously unrecognized concerns, and for assessing the frequency, severity and sources of suspected problems and concerns. The procedures must include, without limitation, procedures for assessing:

(1) The clinical performances of members of the staff who are health care practitioners;

(2) The standards used for the maintenance of medical records;

(3) The procedures used to control the quality of radiological, pathological, laboratory and pharmaceutical services provided by the center;

(4) The procedures used to control the quality of other professional and technical services provided by the center;

(5) The care and services provided by the extended recovery unit, if such a unit is operated by the center;

(6) The procedures used to control infection; and

(7) The satisfaction of patients who have been treated at the center.

~~[(h)]~~ ***(g)*** The maintenance of a record of all fires and deaths that have occurred at the center and the transfer of all patients from the center to a hospital.

~~[(i)]~~ ***(h)*** Procedures for assessing any actions taken to correct identified problems or concerns and for determining whether the actions taken have achieved or sustained the desired result and, if not, why not.

3. The members of the professional and administrative staffs of the center shall:

(a) Understand, support and participate in the program for quality assurance; and

(b) Participate in the resolution of any problems and concerns identified pursuant to the procedures required by subsection 2.

4. The members of the staff who are health care practitioners shall participate in the development and application of the criteria used to evaluate the care provided at the center and the evaluation of any problems and concerns identified pursuant to the procedures required by subsection 2.

5. Activities conducted pursuant to the program for quality assurance must be reported to the appropriate members of the staff and to the governing body. The administrator of the center shall establish procedures for carrying out any recommendations of the governing body.

6. As used in this section, "health care practitioner" means a person who is licensed or certified to provide health care services in this State, including, without limitation, a physician, dentist, podiatrist, and registered or licensed practical nurse.

Sec. 9. NAC 449.9813 is hereby amended to read as follows:

449.9813 1. The governing body shall establish a committee for quality assurance.

2. The committee must be composed of members of the staff who represent the various clinical and medical services provided by the center.

3. The committee shall ~~[carry]~~ ***:***

(a) Meet at least once each quarter and maintain minutes of its meetings.

(b) Develop and make available a plan of action for carrying out the program for quality assurance established pursuant to NAC 449.9812.

(c) Carry out the program for quality assurance established pursuant to NAC 449.9812.

Sec. 10. NAC 449.9855 is hereby amended to read as follows:

449.9855 1. An ambulatory surgical center shall have written policies for the personnel employed at the center. These policies must be provided to each employee in the form of a manual and must include provisions concerning hours of work, grievances in connection with termination, vacation, sick leave and leaves of absence.

2. Each employee of the center must:

(a) Have a skin test for tuberculosis in accordance with NAC 441A.375. A record of each test must be maintained at the center.

(b) Within 10 days after the date of his or her employment, and periodically thereafter, be instructed in the control of infections, the prevention of fires, the safety of the patients, preparation in case of disaster, and the policies and procedures of the center.

3. A current and accurate personnel record for each employee of the center must be maintained at the center. The record must include, without limitation:

(a) A job description that:

(1) Includes the duties and responsibilities of, and the qualifications required for, the position held by the employee; and

(2) Is signed by the employee;

(b) Evidence that the employee ~~[has obtained]~~ ***:***

(1) Holds in good standing any license, certificate or registration ~~[,]~~ ***required for the position held by the employee;*** and ~~[possesses]~~

(2) Possesses the experience and qualifications ~~[,]~~ required for the position held by the employee;

(c) An annual evaluation of the employee that is signed by the employee and his or her supervisor; ~~[and]~~

(d) Such health records as are required by chapter 441A of NAC ~~[.]~~ ***; and***

(e) A statement signed by the employee indicating that the employee has read and understands the provisions of NAC 449.971 to 449.997, inclusive, and sections 2, 3 and 4 of this regulation.

Sec. 11. NAC 449.9865 is hereby amended to read as follows:

449.9865 1. The medical staff of an ambulatory surgical center is answerable to the governing body for the quality of medical care provided to patients and for the ethical and professional practices of its members.

2. The governing body, or a person or committee designated by the governing body, shall appoint the members of the medical staff and grant, deny and withdraw the privileges to be

accorded members of the medical staff as it deems appropriate. Appointments to the medical staff must be made in writing and must be documented in the records of the center.

3. Each member of the medical staff must be qualified for the position to which the member is appointed and the privileges which he or she is accorded.

4. A roster of the surgical privileges of each member of the medical staff must be kept in the files of the operating room, specifying the privileges accorded him or her.

5. ***A member of the medical staff shall not perform a surgical procedure or provide a treatment for which the member has not been granted privileges.***

6. The governing body shall establish procedures for disciplining a member of the medical staff who fails to comply with the policies and procedures of the center ~~[.]~~ ***, including, without limitation, disciplining a member of the medical staff for performing a surgery for which the member has not been granted privileges.***

Sec. 12. NAC 449.989 is hereby amended to read as follows:

449.989 The medical record of each patient must be complete, authenticated, accurate and current, and must include the following information:

1. A complete identification of the patient, including information on his or her next of kin and on the person or agency legally or financially responsible for him or her.

2. A statement concerning the admission and diagnosis of the patient.

3. The medical history of the patient.

4. Documentation that the patient has been given a ~~[presurgical]~~ ***:***

(a) Physical examination, which must include a medical history of the patient, conducted by a physician within the 30 days immediately preceding the date of the patient's surgery; and

(b) Presurgical evaluation conducted by a physician ***on the day of the patient's surgery or*** within the 7 days immediately preceding the date of the patient's surgery.

5. Evidence of any informed consent given for the care of the patient.

6. Any clinical observations of the patient, such as the notes of a physician, a nurse or any other professional person in attendance. Such an entry must be signed by the person making the entry and include the title of that person.

7. Reports of all studies ordered, including laboratory and radiological examinations.

8. Confirmation of the original diagnosis, or the diagnosis at the time of discharge.

9. A report of any ~~[operation]~~ ***surgery*** performed on the patient, prepared by the surgeon.

10. A description of the procedure followed in any administration of anesthesia to the patient.

11. A recovery report for the patient.

12. A summary of discharge, including, without limitation, the disposition of the patient and any recommendations and instructions given to the patient.

13. Documentation that a member of the nursing staff interviewed the patient within 72 hours after the patient was discharged from the center to determine the condition of the patient and whether the patient was satisfied with the services provided, and to receive any complaints or problems the patient may have.

Sec. 13. NAC 449.9902 is hereby amended to read as follows:

449.9902 1. An ambulatory surgical center must be equipped with:

(a) A cardiac defibrillator;

(b) A tracheostomy ***or cricothyroidotomy*** set; ~~[and]~~

(c) ***A mobile cart which contains the equipment and supplies specified by the medical staff pursuant to subsection 3;***

(d) If the ambulatory surgical center provides services to pediatric patients who are less than 9 years of age, the equipment and supplies specified by the medical staff pursuant to subsection 3 needed to treat a pediatric patient during an emergency;

(e) If general anesthesia is provided at the ambulatory surgical center or if the center offers to patients a triggering agent for malignant hyperthermia, a mobile cart which contains the equipment and supplies specified by the medical staff pursuant to subsection 3 needed to treat a patient with malignant hyperthermia;

(f) In addition to the mobile cart required by paragraph (e), if general anesthesia is provided at the ambulatory surgical center, the equipment and supplies specified by the medical staff pursuant to subsection 3 needed to manage a difficult airway of a patient; and

(g) Such other emergency medical equipment and supplies as are specified by the members of the medical staff ~~[.]~~ ***pursuant to subsection 3.***

2. A person trained ~~[in]~~ ***:***

(a) In the use of emergency equipment ~~[and in cardiopulmonary resuscitation]~~ ***;***

(b) In advanced cardiac life support; and

(c) If the ambulatory surgical center provides services to pediatric patients less than 9 years of age, in pediatric advanced life support,

➥ must be on the premises of the ambulatory surgical center and immediately available at all times when there is a patient in the center. As used in this subsection, "immediately available" means that the person is sufficiently free from other duties to be able to respond rapidly to an emergency.

3. The medical staff of the ambulatory surgical center shall annually review and prescribe the equipment and supplies which must be available pursuant to subsection 1, including, without limitation, equipment and supplies frequently used in hospitals at the sites of medical and surgical emergencies for life support protocols to potentially save the life of a patient.

Sec. 14. 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. The pharmacist]~~ ***employed by or contracted with an ambulatory surgical center pursuant to NAC 639.4996*** is responsible for all matters pertaining to the use of drugs in the ***ambulatory surgical*** center.

2. Records of all transactions must be in writing and maintained ***in accordance with the provisions of state and federal law*** 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.

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. 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. 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. 15. NAC 449.992 is hereby amended to read as follows:

449.992 1. Pathology services must be provided by a staff pathologist or by a pathologist used as a consultant by the ambulatory surgical center. The pathologist must be licensed to practice in this State.

2. All material removed from a patient during surgery must be clearly labeled and examined microscopically as required by a pathologist. In the absence of a staff pathologist, written arrangements must be made to send tissues to a pathologist outside the center.

3. A list of tissues that do not routinely require microscopic examination must be approved by a pathologist and made available to the laboratory and the members of the medical staff.

4. Reports of examinations of tissues must be ~~[authenticated]~~ ***signed, which may include an electronic signature,*** by the examining pathologist. The original report must be filed in the medical record of the patient.

Sec. 16. NAC 449.993 is hereby amended to read as follows:

449.993 1. Each ambulatory surgical center shall maintain diagnostic radiological services or have such services immediately available. Whether these services are provided directly or by contract, personnel capable of supervising the performance of the services must be available.

2. If a center provides diagnostic radiological services directly, the center must have a full-time radiologist or a radiologist who works as a part-time consultant available to supervise the department of radiology and to interpret films.

3. Only a person designated as qualified by the radiologist may operate the equipment for X-rays. ~~[Only a physician may perform a fluoroscopy.~~

~~4. A radiological technician must be on duty or available within 15 minutes after being called while the center is open.]~~

4. Only the following persons may operate a fluoroscopy machine:

(a) A physician or a podiatric physician licensed pursuant to chapter 635 of NRS;

(b) A physician assistant, advanced practice registered nurse or certified registered nurse anesthetist if that person has at least 16 hours of documented training in radiation safety;

(c) A radiologic technologist registered by the American Registry of Radiologic Technologists if the person is acting under the personal direction or written protocol of a physician and registrant of the fluoroscopy machine; and

(d) A registered nurse or operating room technician if the person is acting under the direct supervision of a physician or surgeon who is present in the room at the time the fluoroscopy machine is used and the person has documented training in radiation safety as follows:

(1) The applicable provisions of chapter 459 of NAC;

(2) Orientation to field size;

(3) Orientation to the energy used and the setting (kVp) to use on patients of varying sizes and pathology;

(4) Orientation to the concept of "as low as is reasonably achievable," as defined in NAC 459.0205;

(5) The use of protective gloves, aprons, thyroid shields and glasses;

(6) The use of particular machines and the operation of each type of machine;

(7) Orientation to the concept of source to image distance;

(8) Safety protocol for staff in the operating room and adjacent areas, including, without limitation, physicians, patients and operators;

(9) The requirements for dosimetry and postings and the certificate and output measurements necessary to allow use of the fluoroscopy machine;

(10) The appropriate use of high-level versus regular settings;

(11) The relevance of pregnancy in the use of machines that produce radiation; and

(12) An annual review of radiation safety.

5. Examinations by X-ray must be ordered by the physician ***or podiatrist*** responsible for the care of the patient, and the order must contain a concise statement of the reason for the examination. Reports of these examinations must be signed by the reporting physician. The original report must be filed in the medical records of the patient, and a copy of the report must be kept in the radiology department.

Sec. 17. NAC 449.9935 is hereby amended to read as follows:

449.9935 1. The operating and recovery rooms of an ambulatory surgical center must be used exclusively for surgical procedures.

2. Except as otherwise provided in subsection 3, surgical procedures must be conducted in a class A, B or C operating room in accordance with chapter 9 of the *Guidelines for Design and Construction of Hospital and Health Care Facilities*, adopted by reference pursuant to NAC 449.0105.

3. If an ambulatory surgical center is licensed to perform only endoscopic procedures, such procedures may be conducted in an endoscopy suite in accordance with chapter 9 of the *Guidelines for Design and Construction of Hospital and Health Care Facilities*, adopted by reference pursuant to NAC 449.0105.

4. A registered nurse experienced in surgical procedures shall supervise the operating room.

5. Only a registered nurse may function as the circulating nurse in the operating room.

6. ***Each employee of an ambulatory surgical center who provides medical services and care to a patient must be trained to carry out the medical services and care that the employee will provide.***

7. The operating room must be equipped with:

(a) A system for making emergency calls;

(b) Oxygen;

(c) Mechanical ventilatory assistance equipment, including, without limitation, a manual breathing bag and a ventilator;

(d) Cardiac monitoring equipment;

(e) Laryngoscopes and endotracheal ***and airway*** tubes ~~[;]~~ ***in sizes sufficient to meet the needs of the patients of the ambulatory surgical center;*** and

(f) Suction equipment.

~~[7.]~~ ***8. The recovery room must:***

(a) Meet nationally recognized standards of practice for postanesthesia care, as approved by the governing body, and maintain a copy of those standards at the ambulatory surgical center during all hours of operation and in a location which is accessible to the medical staff;

(b) Comply with the guidelines for postanesthesia patient classification and staffing recommendations as published in the 2010-2012 Perianesthesia Nursing Standards and Practice Recommendations, which is adopted by reference in subsection 10;

(c) Be equipped with or have easily accessible a mobile cart which contains the equipment and supplies specified by the medical staff pursuant to subsection 3 of NAC 449.9902 needed to treat a patient with malignant hyperthermia; and

(d) Be equipped with all other equipment and supplies needed to safely care for patients.

9. If the operating team consists of persons who are not physicians, such as a dentist, a podiatrist or a nurse, a physician must be on the premises and immediately available in case of an emergency. As used in this subsection, "immediately available" means the physician is sufficiently free from other duties to be able to respond rapidly to the emergency.

10. The 2010-2012 Perianesthesia Nursing Standards and Practice Recommendations, published by the American Society of PeriAnesthesia Nurses is hereby adopted by reference. A copy of the standards may be obtained at a cost of $60 for members and $130 for nonmembers from the American Society of PeriAnesthesia Nurses by mail at 90 Frontage Road, Cherry Hill, New Jersey 08034-1424, by telephone at (877) 737-9696 or at the Internet address http://www.aspan.org.

Sec. 18. NAC 449.9937 is hereby amended to read as follows:

449.9937 1. An ambulatory surgical center may operate an extended recovery unit.

2. An extended recovery unit must:

(a) Be located in an area of the center that is separate from the other operations of the center;

(b) Provide audio and visual privacy for each patient in the unit;

(c) Be supervised by at least one physician who is recommended for the position by the members of the medical staff and approved by the governing body;

(d) Have at least one physician on the premises or immediately available by telephone at all times when there is a patient in the unit;

(e) Except as otherwise provided in paragraph (f), have at least one nurse who is trained in advanced cardiac life support on duty for every two patients in the unit;

(f) Have at least two nurses who are trained in advanced cardiac life support on duty at all times when there is a patient in the unit; and

(g) Be equipped with:

(1) A system for making emergency calls;

(2) Oxygen;

(3) A cardiac defibrillator;

(4) ***Cardiac monitoring equipment;***

(5) A mobile cart which contains the equipment and supplies specified by the medical staff pursuant to subsection 3 of NAC 449.9902;

(6) A manual breathing bag;

~~[(5)]~~ ***(7)*** Suction equipment; and

~~[(6)]~~ ***(8)*** Such other emergency equipment as is needed to provide care to patients in the unit.

3. A patient must be admitted and discharged from an extended recovery unit only upon the order of the physician of record. If a patient is admitted to the unit, the time he or she remains in the unit for treatment, when added to the time he or she remains in any other area of the ambulatory surgical center for treatment, may not exceed 23 hours and 59 minutes.

4. The center shall adopt policies and procedures for the extended recovery unit that include, without limitation:

(a) Clinical criteria for determining a patient's eligibility for admission into the unit;

(b) Clinical criteria for determining a patient's eligibility for being discharged from the unit;

(c) Procedures for providing emergency services; and

(d) Procedures for transferring a patient in need of other health care services.

5. An ambulatory surgical center shall provide food to meet the needs of patients in an extended recovery unit. A patient on a special diet must be served food that conforms to the patient's prescribed diet. If the food is prepared by the center, the center shall:

(a) Comply with the applicable provisions of chapter 446 of NRS and the regulations adopted pursuant thereto; and

(b) Obtain such permits as are necessary from the ~~[Health]~~ Division ***of Public and Behavioral Health*** to prepare the food.

Sec. 19. NAC 449.994 is hereby amended to read as follows:

449.994 1. A ***physical examination, which must include a medical history of the patient, within the 30 days immediately preceding the date of the patient's surgery and a*** presurgical evaluation conducted by a physician ~~[and the pertinent past medical history of a patient]~~ ***on the day of the patient's surgery or within the 7 days immediately preceding the date of the patient's surgery*** must be recorded in the chart of the patient before surgery.

2. A properly executed form of consent to surgery ***as set forth in NRS 449.710*** must be placed in the medical record of the patient before surgery.

3. A report must be prepared ~~[immediately]~~ ***within 24 hours*** after surgery describing the ~~[technique]~~ ***techniques*** and findings of the surgery ~~[.]~~ ***and the tissues removed or altered during the surgery. If a report is dictated, a written report must be signed by the surgeon within 7 days after the surgery.***

Sec. 20. NAC 449.9945 is hereby amended to read as follows:

449.9945 1. Anesthetics must be administered in the operating room of an ambulatory surgical center by an anesthesiologist, a qualified physician, a dentist or, under the direction of

the operating physician and in accordance with the provisions of chapter 632 of NRS and the regulations adopted pursuant thereto, a certified registered nurse anesthetist.

2. Persons designated to administer anesthetics must be qualified to administer anesthetics based on their credentials and must be approved by the governing body.

3. General anesthesia must not be administered to a patient unless a physician has evaluated the patient immediately before surgery to assess and document the risks of administering the anesthesia relative to the surgical procedure to be performed. A patient who receives general anesthesia must be evaluated by a physician after the patient has recovered from the general anesthesia and before he or she is discharged from the recovery room.

4. ***A person who administers anesthetics shall continuously monitor a patient who has received anesthesia and shall not have any other responsibility while the patient is under anesthesia. A person who administers anesthetics shall not leave a patient who is under anesthesia unless relieved by a person authorized to administer anesthetics pursuant to this section who agrees to assume responsibility for the care of the patient.***

5. A record of anesthesia must be completed after surgery, and there must be a follow-up on each patient who has received anesthesia with the findings recorded by the person who administered the anesthesia.

~~[5.]~~ ***6.*** As used in this section, "certified registered nurse anesthetist" has the meaning ascribed to it in NRS 632.014.

Sec. 21. NAC 449.996 is hereby amended to read as follows:

449.996 1. ***An ambulatory surgical center shall establish written guidelines for transferring patients to a licensed general hospital using an ambulance or air ambulance for***

emergencies that require medical care which is not provided at the center. The guidelines must be approved by the governing body of the ambulatory surgical center.

2. Each ambulatory surgical center shall maintain with a licensed general hospital a written agreement concerning the transfer of patients. The agreement must provide for the security of, and the accountability for, the personal effects of the patient.

~~[2.]~~ ***3.*** If a patient is transferred, all medical and administrative information relating to the patient must be transferred with him or promptly made available to the licensed center or agency responsible for the patient's continuing care.

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

June 28, 2013

LCB File # R181-09

Information Statement per NRS 233B.066
as amended by Assembly Bill 252, 2013 Legislative Session

(a) A clear and concise explanation of the need for the adopted regulation.

These regulations are being modified because a thorough review of the ambulatory surgery center regulations revealed several areas requiring updating. The previous review of these regulations occurred 10 years previous to the Hepatitis-C outbreak events and a thorough review of these regulations was precipitated due to the Hepatitis-C outbreak events. The Hepatitis-C outbreak prompted emergency regulations that were later adopted as permanent and codified into NAC. Whereas these changes were developed through the regular process separate from the emergency regulations.

(b) 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 via the Notice of Public Hearing posted at Division locations, State Library and Archives, county libraries and the notice was mailed to affected stakeholders. The following is a summary of the testimony provided during the public hearing on June 28, 2013:

During the public hearing held before the State Board of Health (SBOH), staff presented LCB file #R181-09RP1 and explained the proposed errata. An opportunity was allowed for public comment and only one individual commented as follows: a representative from the State Board of Nursing (SBON) explained that the SBON had not yet had an opportunity to entertain the errata language that allows nurses to operate a fluoroscopy machine. A member of the SBOH questioned legal counsel as to whether this would necessarily affect adoption of the errata. Legal counsel for the SBOH explained the language in the errata allows qualified/trained nurses to operate fluoroscopy machines, however it does not mandate nurses to operate the machines. As such, nurses would be responsible for compliance with their scope of practice as defined by the SBON, thus no conflict is anticipated.

No one testified in opposition to the proposed regulations.

The Board of Health adopted LCB File #R181-09RP1 along with the errata as presented.

A summary of the hearing for amendment of Nevada Administrative Code (NAC) 449, “Medical and Other Related Facilities” LCB File #R181-09RP1 and errata, can be obtained by contacting the State Board of Health, through the Division of Public and Behavioral Health,

4150Technology Way, Suite 300, Carson City, Nevada 89706, phone: (775) 684-4200, fax: (775) 684-4211.

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

- 22 people attended the hearing in Las Vegas, 14 people attended the hearing in Carson City.
- Paul Shubert, Health Facilities Inspection Manager with the Division of Public and Behavioral Health presented the proposed amendments and errata. During public comment, Chris Sansom, Director of Operations for the State Board of Nursing presented information as described in (b) above. No one testified for or in opposition.
- No one provided written statements at the public hearing.

(d) For each person identified in subparagraphs (2) and (3) of item (c), the following information if provided to the agency conducting the hearing:
(1) Name;
(2) Telephone number;
(3) Business address;
(4) Business telephone number;
(5) Electronic mail address; and
(6) Name of entity or organization represented

Paul Shubert and Chris Sansom provided information as indicated in item (c) above.

(e) 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.

Small business impact questionnaires and workshop notices that included information on how to obtain a copy of the proposed regulations and errata were sent to ambulatory surgical centers, via U.S. postal service or list-serve for those facilities signed on to the Division's list-serve account. The workshop notice and draft regulations/errata were also posted on the Division's website and distributed through the Division's List Serv and posted in accordance with open meeting law. The Division provided several opportunities for impacted facilities to offer input and comments regarding the proposed regulations. The Division started discussing the effects of these regulations with ambulatory surgery centers since the initial introduction of the modified language in 2009. Meetings included discussion of better language in the proposed regulations and encouraged input via submission of small business impact questionnaires. Subsequent to these discussions, a public workshop was conducted on 11/28/09 in Las Vegas and on 11/30/09 in Carson City. During the workshops several individuals provided improved language for proposed changes. Modifications were made to reduce the impact of the regulations on small businesses. More recently, discussion regarding the regulations and solicitation for input occurred on 4/1/13 with the Nevada Ambulatory Surgery Center Association.

A second workshop was held via videoconference to both Carson City and Las Vegas on 5/2/13 allowing for additional input by impacted facilities. All comments received were taken into consideration for further revisions to the regulations and to reduce the economic impact on facilities.

Out of 65 small business impact questionnaires distributed, 1 response was received. The following is a summary of the response:

Summary of Response

(Q#1) The 1 respondent indicated the business had less than 150 employees.

Summary of Comments Received (1 response was received out of 65 small business impact questionnaires distributed)			
(Q#2) Will a specific regulation have an adverse economic effect upon your business?	**(Q#3) Will the regulation(s) have any beneficial effect upon your business?**	**(Q#4) Do you anticipate any indirect adverse effects upon your business?**	**(Q#5) Do you anticipate any indirect beneficial effects upon your business?**
1 "Yes" Responses	0 "Yes" Responses	1 "Yes" Responses	0 "Yes" Responses
0 "No" Responses	1 "No" Responses	0 "No" Responses	1 "No" Responses

Comments (Q#2):
-none

Comments (Q#3):
-none

Comments (Q#4):
-It is almost impossible to find a radiologist willing to take on the additional liability of a surgery center, without the benefit of increasing their cases/income. Also it would have a negative financial impact, as they do not fulfill any true position. Having a radiologist on staff would not be a benefit, because physicians on staff already fulfill this role. I feel the State of Nevada should not be imposing changes in the area of radiology, until CMS makes its final ruling.

Comments (Q#5):
-none

The small business impact summary regarding the proposed language in LCB File #R181-09RP1 and errata, can be obtained by contacting the Division of Public and Behavioral Health, Bureau of Health Care Quality and Compliance, 727 Fairview Drive, Suite E, Carson City, NV 89701, phone: (775) 684-1030, fax: (775) 684-1073.

(f) The regulation was adopted with changes from the initial proposal. After the first set of public workshops in 2009, several changes were made to the proposed regulations in order to make improvements suggested by industry representatives. Subsequently a revised proposed draft was generated by LCB. After the second workshop was held on May 2, 2013, additional changes were proposed as indicated in the errata.

- Errata (section 7 of the proposed regulations); establishes a simple definition for surgery because, use of the term is common and therefore the definition should be generic, rather than specific to certain procedures.
- Errata (section 9 of the proposed regulations); modifies language that was adopted in R170-12P, to ensure physical exams and pre-surgical exams are conducted within 30 days and 7 days respectively, while recognizing podiatrists may conduct pre-surgical exams.
- Errata (a new section not numbered); modifies requirements for fluoroscopy. The changes will continue to require personnel performing fluoroscopy to be highly trained individuals, but allows for a wider range of individuals to perform fluoroscopy, rather than requiring all fluoroscopy to be performed by physicians.

(g) 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:

(1) Both adverse and beneficial effects; and

(2) Both immediate and long-term effects.

- Beneficial effects: There's an anticipated beneficial effect on ambulatory surgical centers in which fluoroscopy is used, as additional qualified/trained individuals will be allowed to operate the fluoroscopy machine. This will increase efficiencies for those centers and improve availability of these services, thus reducing wait times for patients to undergo treatments requiring fluoroscopy. There's anticipated beneficial effects with regard to infection prevention due to required reviews of surgical procedures and patient outcomes with regard to control of and prevention of infections and rates of infections at the center. A dollar value cannot be quantified, however, it is recognized that availability of services will benefit the communities served and reduced infections has several positive implications.
- Adverse effects: In order to comply with new requirements regarding infection tracking, the center must contract with an entity that has no financial interest in the center. Separately owned centers could enter into reciprocal agreements for such services to reduce the costs associated with these requirements, but due to competition, it is more likely facilities will contract for such services with an independent entity. Depending on the complexity of the infection control program (based on the number of distinct procedures performed and infection rates), this service may range from approximately $100 per hour to $500 per hour.
- Immediate effects: Allowing additional individuals to perform fluoroscopy will improve availability of these services and wait times will be reduced for patients to undergo treatments requiring fluoroscopy. Infection prevention reviews should result in less patient infections.

- Long term effects: The costs for independent review of the infection control program will occur at least annually in accordance with section 9 of LCB File #181-09, so at least annually centers will need to contract for these services.

(h) The estimated cost to the agency for enforcement of the proposed regulation.

The estimated cost to the agency for enforcement of the proposed regulations is $0.

(i) 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 regulatory federal agency.

Federal regulations are enforced in certified ambulatory surgery centers. These regulations are found at 42 CFR Part 416. However, overlapping with these regulations is necessary because participation in Centers for Medicare and Medicaid Services (CMS) certification/reimbursement program is voluntary. Whereas all ambulatory surgical centers must obtain a state license regardless of their desire to participate in CMS's reimbursement program and therefore state licensure regulations are necessary.

(j) 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 not more stringent than the federal regulations, however they are more detailed, especially in the requirements for infection prevention.

(k) 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.

There is no new fee or increase of an existing fee associated with the proposed regulations.