

LCB File No. T011-98

TEMPORARY REGULATION OF THE STATE BOARD OF HEALTH

NOTICE OF PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the State Health Division will hold public hearing and act on amendments to Nevada Administrative Code (NAC) 445A, 449, and 652. **The hearing is scheduled to begin at 9:00 a.m. on Friday, December 11, 1998, at the Washoe County District Health Department, Ninth and Wells Street, Reno, Nevada.**

SURGICAL CENTERS FOR AMBULATORY PATIENTS

The proposed amendments are needed to update the current regulations originally adopted in 1988 relating to the licensing of surgical centers for ambulatory patients. The amendments also update the construction standards relating to ambulatory surgical centers.

The proposed regulations affect all services/departments in ambulatory surgical centers.

The proposed regulations will have a beneficial effect, recognized by the ambulatory surgical centers industry, on the ambulatory surgical centers because they were developed by utilizing current standards of care that are defined by the Medicare/Medicaid reimbursement participation standard. All currently licensed hospitals meet these standards at this time because all the hospitals participate in the Medicare/Medicaid reimbursement program.

The proposed regulations will have a beneficial effect on the public/consumer by assuring the public, through the state licensure process, that ambulatory surgical centers are meeting current standards of care.

There will be no change in cost to the facilities or to the Bureau of Licensure and Certification (BLC) for the change in the regulations for the licensing of ambulatory surgical centers. The current fee for initial and annual renewal of licenses will cover the cost to BLC.

The proposed regulations state that the facility must be in compliance with Nevada Revised Statutes (NRS) 449.700-449.730, NRS 453, NRS 652.217, and Nevada Administrative Code (NAC) 441 A and NAC 459. The duplication was necessary to assure certain statutes that affect the health and safety of residents and visitors to Nevada are being implemented by ambulatory surgical centers licensed by BLC.

The proposed regulations parallel the federal Medicare/Medicaid reimbursement participatory regulations governing ambulatory surgical centers (42 Code of Federal Regulations (CFR) Part 416, subpart A, B, and C) in certain sections and 42 CFR 489.24, Clinical Laboratory Improvement Amendment of 1988, Public Health Service Act (42 USC 274) and Life Safety Code, Standard 101.

The regulations are more stringent than the Federal regulations governing ambulatory surgical centers in certain areas: regulations for tuberculosis screening in employees, patient rights, and construction standards.

The regulations do not establish new fees or increase an existing fee.

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SURGICAL CENTERS FOR AMBULATORY PATIENTS

EXPLANATION – Underlined material is new; material in brackets [] is to be deleted

General Provisions

449.971 Definitions. As used in NAC 449.971 to 449.9975, inclusive, unless the context otherwise requires, the words and terms defined in NAC 449.9715 to 449.974, inclusive, have the meanings ascribed to them in those sections.

449.9715 “Allied health profession” defined. “Allied health profession” has the meaning ascribed to it by NRS 450.005.

449.972 “Ambulatory surgical center” defined. “Ambulatory surgical center” has the meaning ascribed to “surgical center for ambulatory patients” by NRS 449.019. “Surgical center for ambulatory patients means a facility with limited medical services available for diagnosis or treatment of patients by surgery where the patients recovery in the opinion of the surgeon will not require care as a patient in the facility for more than 24 hours”.

449.9725 “Division” defined. “Division” means the health division of the department of human resources.

449.973 “Governing body” defined. “Governing body” means the person or persons designated by the licensee as responsible for the total operation of the ambulatory surgical center.

449.9735 “Licensee” defined. “Licensee” means the person or public agency that is licensed by the division in accordance with the provisions of NRS 449.001 to 449.240, inclusive, and NAC 449.971 to 449.9975, inclusive.

449.974 “Patient” defined. “Patient” means a natural person who is undergoing diagnostic procedures or treatment by surgery in the ambulatory surgical center.

Administrator. A person who is a physician, registered nurse, or has a baccalaureate or postgraduate degree in administration or a health-related field; or has one year of administrative experience in a health care setting.

Autologous blood units. Units of blood or blood products derived from the recipient.

Available. On the premises and sufficiently free from other duties to enable the individual to respond rapidly to emergency situations.

Certified registered nurse anesthetist (CRNA). A currently licensed registered nurse who has current certification from the Council of Certification – Recertification of the American Association of Nurse Anesthetist and who is currently registered with the Board of Nurse Examiners as an advanced nurse practitioner.

Doctor of Podiatric Medicine. A person licensed in accordance with NRS 635.

Health Care practitioners. Individuals currently licensed under the laws of this state who may provide services in an ASC, including doctors of medicine, doctors of osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, registered nurses and licensed vocational nurses.

Physician. A person who is currently licensed under the laws of this state to practice medicine and who holds a doctor of medicine or a doctor of osteopathy degree.

Person. Any individual, firm, partnership, corporation, or association.

Registered nurse. A person who is currently licensed under the laws of this state as a registered nurse.

Surgery. Means the treatment of human beings by a physician, by the use of 1 or more of the following procedures:

1. Cutting into any part of the body by surgical scalpel, eletro-cautery, or other means for diagnosis or removal or repair of diseased or damaged tissue, organs, tumors or foreign bodies.
2. Reduction of fractures or dislocation of a bone, joint or bony structure.
3. Repair of malformations of body defects resulting from injury, birth defects or other causes that require cutting and manipulation or suture.
4. Instrumentation of the uterine cavity including the procedure commonly known as dilation and curettage for diagnostic or therapeutic purposes.
5. Any instrumentation of or injection of any substance into the uterine cavity of a woman for the purpose of terminating a pregnancy.
6. Human sterilization procedures.
7. Endoscopic procedures.
8. Laposcopic procedures.

The ambulatory surgery center must be a distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

Although the ambulatory surgery center need not be in a separate building from a physician's office or clinic, it must be separated physically by (at least) one-hour rated construction.

The ambulatory surgery center and other entity cannot mix functions and operations in a common space during concurrent or overlapping hours of operation with the exception of the lobby.

The operating rooms and recovery areas must be used exclusively for surgical procedures.

Ambulatory surgery center staffing and record keeping must be separate and exclusive (for example, a nurse cannot provide coverage in the ambulatory surgery center and in an adjacent clinic at the same time).

449.9745 Compliance with requirements by accreditation. The operator of an ambulatory surgical center will be deemed by the division to have complied with the requirements for licensing in NAC 449.971 to 449.9975, inclusive if:

1. The center is currently accredited by the Joint Commission on Accreditation of Health Care Organizations, the Accreditation Association for Ambulatory Health Care or, if only plastic surgery is performed at the center, the American Association for Accreditation of Ambulatory Plastic Surgery Facilities;
2. The operator provides the division with evidence of the accreditation; and
3. The standards for accreditation applied by the accrediting organization are at least as stringent as the requirements of NAC 449.971 to 449.9975, inclusive.

449.9755 Investigation of applicant and inspection of center. After it receives a properly completed and notarized application, accompanied by the appropriate fee, the division shall conduct an investigation of the applicant and inspect the proposed center.

449.978 Effect of expiration of license. If a license authorizing an ambulatory surgical center expires, patients must not occupy the center.

449.9785 Conformance with regulations required. 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 449.9975, inclusive. Any violation of these provisions may result in the suspension or revocation of the license.

Administration

449.979 Governing body required. Except as otherwise provided by NAC 449.9835, each ambulatory surgical center must have a governing body, chaired by a principal in the organization of the licensee, with legal authority for the operation of the center.

449.9795 Duties of governing body. The governing body shall:

1. Adopt a set of rules which include provisions concerning:
 - (a) The criteria by which the members and officers of the governing body are selected, their terms of office and their duties;
 - (b) The frequency of its meetings; and
 - (c) The annual revision and approval of the rules by the governing body.
2. Arrange for minutes of its meeting to be taken to record the business conducted. These minutes must be available to all members.

449.980 Responsibilities of governing body. 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 **[physical examination]** pre-surgical evaluation within the preceding 7 days from a physician;

3. A physician is on [duty] the premises of the ambulatory surgery center and immediately available at all times when there are patients in the [center] operating rooms or the recovery room of the center;
4. An annual operating budget and a plan for capital expenditures are established;
5. The center is adequately staffed and equipped to conduct the services provided at the center.
6. There is documentation in the files of the center of the qualifications s of all persons [consultants] under contract with the center; and
7. [Each department or service at] The governing body shall ensure that the center adopts, enforces and annually reviews written policies and procedures, including an organization chart. These must be approved annually by the governing body.
8. A provision allowing a surgical procedure only with the consent of the patient or his legal representative, except in an emergency.

449.9805 Establishment of policy for authentication. The governing body shall establish a policy for authentication that:

1. Authorizes the use of rubber stamps and prohibits the use of any stamp by any person other than the person whose signature the stamp represents;
2. Approves a method for identifying the person making an entry in any record or chart regardless of the form of the patient's medical record.
3. Requires that the professional title of the person making such an entry and the date of that entry is included with the entry.

449.981 Appointment and responsibilities of administrator.

1. The governing body shall appoint a qualified administrator for the center. **[The governing body shall use as its criteria for the selection the actual experience of the administrator in management or graduate work in the administration of health care.]**

2. Qualifications: The administrator and his designee shall be 21 years or older and shall be experienced in administration and supervision of personnel and shall be knowledgeable about the practice of medicine to interpret and be conversant in surgery protocols

3. The administrator shall be the direct representative of the Governing Body in the management of the facility and shall be responsible to the Governing Body for the performance of his duties

[2.] 4. The administrator is responsible for:

(a) the daily operation of the center;

(b) Serving, along with any committee appointed for the purpose, as a liaison between the governing body, the medical staff and all the departments of the center;

(c) Reporting the pertinent activities concerning the center to the governing body at regular intervals;

(d) Appointing a person responsible for the center in his absence; and .

[(e) Planning for the services provided by the center and the operation of the center.]

5. Duties and responsibilities:

(a) The administrator's responsibilities shall be written in a job description and shall be available for review by the division.

(b) Responsibilities shall include:

1. To ensure the facility is in compliance with all applicable federal, state and local laws and facility policies and procedures;

2. Develop, evaluate, update, and implement facility policies and procedures annually;
3. Maintain an adequate number of qualified and competent staff to meet the needs of patients;
4. Develop clear and complete job descriptions for each position;
5. Review all incident and accident reports, take appropriate action, and maintain evidence of resolution.
6. Secure through contractual agreement the necessary services not provided directly by the facility;
7. Establish a system for continuous quality assurance to include mechanisms for reporting to the governing body and acting on their recommendation.

449.9815 Maintenance. The administrator shall ensure that the person in charge of maintenance at the center;

1. Has a written program of maintenance of all of the equipment used at the center.
2. Has written service contracts with vendors to inspect and repair equipment as needed, and maintain written records of all inspections.
3. Keeps the temperature in the center at a comfortable level.

449.982 Sanitation and housekeeping. The administrator shall ensure that the sanitation and housekeeping staff of the center:

1. Maintains a clean and sanitary environment in the center with particular regard for:
 - (a) [**Areas for the isolation of patients with communicable diseases;**] Provisions have been made for the isolation or immediate transfer of patients with communicable disease.
 - (b) The sanitary disposal of pathological and infectious waste;

- (c) Methods for handling contaminated linen or linen substitutes; and
- (d) An effective program to control pests.
- 2. Keeps the center free of offensive odors, dirt and hazards.
- 3. Has suitable equipment and supplies for the routine cleaning of all surfaces in the center and keeps the equipment in sanitary condition.
- 4. Uses methods of cleaning that minimize the spread of pathogenic organisms.
- 5. Cleans all floors in the center on a daily basis.
- 6. Maintains all toilet facilities and storage areas in a sanitary and orderly manner on a daily basis.

449.9825 Emergency electrical power. The administrator shall ensure that the center has adequate emergency electrical power in accordance with National Fire Protection Association 99. The current NFPA 99 is available from National Fire Protection Association, 11 Tracy Drive, Avon, MA 02322, 1-800-344-3555. The cost is \$35.50.

- [1. **By procuring batteries, or an electricity-producing generator with sufficient fuel, capable of providing power to all lights and electrical equipment in the center for not less than 2 hours.**
- 2. **By having the source of emergency power serviced on a regular basis and keeping records of maintenance.]**

449.983 Protection from fire and other disasters. The administrator shall ensure that the center, staff and patients are adequately protected from fire or other disasters. He shall prepare a written plan describing all actions to be taken by the staff and patients in the case of any such incident. This plan must be approved by the governing body and the local fire department and must include provisions for:

- 1. Evacuation routes and procedures that are posted in the center.

2. The assignment of personnel to specific tasks and responsibilities.
3. Instruction on the use of alarm stations and location of signals.
4. Instruction concerning methods of containing a fire.
5. Procedures for the notification of appropriate persons.
6. The location of equipment for fighting fires.
7. The conduct of fire drills not less frequently than once each quarter for each shift of employees and requirements for a dated, written report and an evaluation of each drill.
8. The maintenance of records showing that all employees have been trained in the execution of the plan at the beginning of their employment and annually thereafter.
9. A rehearsal and a review of the plan at least once each year with a separate annual rehearsal for **[bomb threats]** other disasters. A written report and evaluation of each rehearsal must be on file.
10. The ambulatory surgery center must be fully sprinklered.

449.9835 Exemption from requirements for governing body and administrator.

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 **[licensee]** physician operator is responsible for complying with all the provisions of NAC 449.971 to 449.9975, inclusive.
2. As used in this section, “physician operator” means any one physician or doctor of podiatric medicine **[or group of physicians]** operating an ambulatory surgical center for the purpose of performing surgery only upon his **[or their]** own patients.

[449.984 Appointment of committees by governing body.

1. The governing body may appoint those committees it considers necessary to manage the finances, building and maintenance of the center, and serve as liaison with the medical staff. These committees shall meet as often as necessary to perform their functions. Documentation detailing the activities of each committee must be maintained by the governing body for at least 3 years.
2. In lieu of any other committee required to be established by NAC 449.971 to 449.9975, inclusive, the governing body may establish a single committee responsible for:
 - (a) The control of infection;
 - (b) Pharmaceutical services;
 - (c) Laboratory services;
 - (d) pathology services;
 - (e) Serving as liaison with the medical staff; and
 - (f) Evaluating the quality of all services provided at the center.

Any such committee must be established by a rule adopted pursuant to NAC 449.9795. The rule establishing the committee must specify the frequency with which the committee evaluates the quality of services pursuant to this section.]

[449.9845 Committee for pharmaceutical services.

1. Unless a committee has been established pursuant to subsection 2 of NAC 449.984, a committee for pharmaceutical services must be established by the governing body. This committee shall annually review and approve the formulary and the policies for procuring, storing, distributing, prescribing, dispensing and administering any drug in the center

2. The committee must consist of a pharmacist, a physician, the chief nurse or a person permanently designated by him, the administrator or a person permanently designated by him, and any other person appointed by the administrator.
3. The committee shall meet not less frequently than once each quarter and shall keep sufficient records to document its activities, findings and recommendations.]

[449.985 Committee for control of infection.

1. Unless a committee has been established pursuant to subsection 2 of NAC 449.984, the ambulatory surgical center must have a committee established for the control of infection. This committee must be composed of one member from each of the following departments of the center:

- (a) Administration.
- (b) Housekeeping.
- (c) Laboratory.
- (d) Maintenance.
- (e) Medical.
- (f) Nursing.
- (g) Pharmacy.

2. The committee shall establish policies and procedures for preventing the spread of infections in the center and shall:

- (a) Review, at least annually:
 - (1) The procedures for handling contaminated linen;
 - (2) The procedures for the disposal of wasted, including body tissue and pathological and infectious waste;

- (3) The traffic routes of personnel and patients in the center;
 - (4) The rules for visitors of patients; and
 - (5) The sources of air pollution.
- (b) Meet, not less frequently than once each quarter, to discuss any spread of infections reported and to evaluate the efficiency of the staff in practicing aseptic techniques. The minutes of each committee meeting must be recorded and maintained for inspection by the division.]

New Section Paragraph

Quality Assurance in a Licensed Ambulatory Surgery Center.

1. Quality assurance includes the selection of professional personnel prior to engagement for service, ongoing review of clinical responsibilities and authority, and peer review and supervision of all professional and technical activities of personnel.
2. The professional and administrative staff shall understand, support, and participate in the quality assurance program.
3. The quality assurance program shall address clinical, administrative, and cost effective issues. Exclusive concentration on administrative cost effective issues does not fulfill this requirement.
4. Quality assurance activities shall be conducted by the Quality Assurance Committee, which is composed of specific clinical disciplines within the Ambulatory surgery center (individual medical specialties, nursing, etc.) and shall be consistent with the characteristics of the overall quality assurance program and the services provided by the ambulatory surgery center.

5. Problem identification and resolution activities shall be conducted as part of an ongoing, organized quality assurance program in which all practitioners in all clinical disciplines have an opportunity to participate. A variety of self-assessment methodologies shall be used to implement the quality assurance program. Assessment techniques shall examine the structure, process, or outcome of care, and shall be assessed prospectively, concurrently, or retrospectively.
6. Quality assurance activities shall address the following:
 - (a) Important problems or concerns in the care of patients shall be identified. Although the medical record is an important data source for identifying previously unrecognized problems, any sources may be used.
 - (b) The frequency, severity, and source of suspected problems or concerns shall be assessed.
7. Health care practitioners shall participate in the development, application of the criteria used to evaluate the care they provide, and evaluation of problems or concerns identified.
8. A log shall be maintained of all fires, patient deaths, emergency and non-emergency transfers from the ambulatory surgery center to the hospital.
9. Measures shall be implemented to resolve important problems or concerns that have been identified. Health care practitioners as well as administrative staff shall participate in the resolution of the problems or concerns that are identified.
10. The problems or concerns shall be reassessed to determine objectively whether or not the measures have achieved and sustained the desired result, and if not, why not.
11. Through the ambulatory surgery center's designated mechanisms, quality assurance activities shall be reported, as appropriate to the proper personnel, and the governing body.

12. Quality assurance activities described in subsection (6) of this section shall encompass, but are not limited to:

- (a) The clinical performance of health care practitioners;
- (b) The standards for medical records;
- (c) Quality controls for the use of radiology, pathology, and medical laboratory services if provided;
- (d) Other professional and technical services provided. Studies of patient satisfaction;
- (e) Control of infection; and
- (f) Pharmaceutical Services.

Personnel

449.9855 Policies and requirements for personnel

1. The [governing body] center shall [develop] 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. In addition, [the governing body shall require that:

- (a) **A skin test for tuberculosis be conducted for each new employee. If the skin test is positive, an X-ray of the chest is required.]** each employee of the center shall have a skin test for tuberculosis in accordance with NAC 441A.375. Records of testing must be retained at the facility.

[(b)] 3. Each employee, within 10 days after the date of his 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.

4. **[449.986 Records of personnel.]** Each employee of the ambulatory surgical center must have a current and accurate personnel record that includes[:1.] A job description[, **authenticated by the employee and his supervisor,**] that lists the duties, responsibilities and general qualifications for the position. The employee must show evidence of having read the job description by signing his or her name.

[2.] 5. Evidence of current licensure, registration, specific experience and other information showing his qualifications for the position;

[3. **Documentation of a physical examination of the employee by a physician, given at the time of his employment, with a certificate from the physician stating that the employee has been found to be in good health and free from communicable disease;**

4. **Documentation that the employee has been given an orientation concerning the center, the policies and procedures of the center, and any other information required to enable him to perform his duties safely;**

5. **A record of an annual skin test or X-ray of the chest for tuberculosis and the results thereof; and]**

6. An annual evaluation of the employee that is authenticated by the employee and his supervisor.

7. Health records as required by NAC 441A.

449.9865 Medical staff: Generally.

1. The medical staff 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. Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges. Privileges granted,

must be consistent with the license to practice in the State and the experience of each clinical practitioner.

3. The governing body shall establish policies concerning disciplinary procedure for infractions of the policies and rules of the center.

[2.] 4. Appointments to the medical staff must be made in writing and must be documented in the records of the center.

5. Medical staff privileges must be periodically reappraised by the ambulatory surgical center. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

6. Disciplinary procedures for infractions of the policies and rules of the center.

[3. Standards and procedures must be established for:

- (a) the selection of members of the medical staff;
- (b) the delineation of the privileges to be accorded to members of the medical staff and members of allied health professionals;
- (c) Appealing the withdrawal or denial of any privilege; and
- (d) The reappraisal and appointment of each member.]

[4.] 7. 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 awarded him.

[5. All members of the medical staff must agree to abide by the rules of the center and NAC 449.971 to 449.9975, inclusive.]

Credentialing of Medical Staff. The governing body either directly or by delegation, makes (in a manner consistent with state law) initial appointment, reappointment, and assignment or

curtailment of clinical privileges based on professional peer evaluation. This process shall have the following characteristics:

1. The governing body has specific criteria for the credentialing and recredentialing of practitioners based upon the size and complexity of the ambulatory health care organization.
2. Provisions are made for the expeditious processing of applications for clinical privileges.
3. On an application for initial privileges, the applicant is required to provide sufficient evidence of training, experience, and current competence in performance of the procedures for which privileges are requested. The following shall be included in the information provided for evaluation of the candidate:
 - (a) education and training;
 - (b) peer evaluation;
 - (c) current state license;
 - (d) Drug Enforcement Administration (DEA certification);
 - (e) a description or list of privileges requested;
 - (f) only as may be required by federal law, information obtained from the National Practitioner Data Bank;
 - (g) other pertinent information which may include, but need not be limited to, professional liability claims history; information on licensure revocation, suspension, voluntary relinquishment, licensure probationary status, or other licensure conditions or limitations; complaints or adverse action reports filed against the applicant with a local, state, or national professional society or licensure board; refusal or cancellation of professional liability coverage; denial, suspension, limitation, termination, or non-renewal of

- professional privileges at any clinic, hospital, health plan, or other institution; DEA license suspension or revocation; conviction of a criminal offense (other than minor traffic violation); currently present physical, mental health, or chemical dependency problems that would interfere with applicants' ability to provide high-quality professional services.
4. On an application for reappointment, the applicant will provide evidence of present compliance with the above requirements.
 5. The organization has established procedures necessary to obtain, with respect to applicants for privileges, information necessary for verification of the application. Such procedures may include the requirement for a signed statement releasing the organization from liability and attesting to the correctness and completeness of the submitted information.
 6. Provisions require that the applicant for privileges be required to divulge professional liability insurance information, if requested to do so by the ambulatory health care organization.
 7. Upon completion of the application, the credentials are verified according to procedures established in the bylaws, rules, and regulations.
 8. Credentials files are maintained for each member of the health care organization to include the initial application, reapplication, verification, privileges granted, and other pertinent information as required by the organization.
 9. Credentiaing, recredentiaing, and the privilege granting process and decisions are approved by the governing body
 10. Clinical privileges are granted for a specified period of time

[449.987 Medical staff: Rule for organization.]

1. The medical staff of the center must be organized under its own rules approved by the governing body.
2. These rules must include:
 - (a) A descriptive outline of the organization of the medical staff;
 - (b) A statement concerning the qualifications of the members of the staff must have to practice in the center;
 - (c) A policy regarding the requirements for meetings of the staff and the minimum number of such meetings to be attended each year by each member of the staff;]
 - (d) A provision allowing a surgical procedure only with the consent of the patient or his legal representative, except in an emergency;
 - (e) A requirement that if dental or podiatric patients are admitted to the center a physician must be in attendance who is responsible for the medical care of the patient throughout his admittance; and
 - (f) A requirement that if any member of an allied health profession provides services in the center, his entries on the medical record of a patient must be verified by his signature.]

[449.9875 Medical staff: Administration.

1. The medical staff shall:
 - (a) Establish policies concerning:
 - (1) The holding and recording of consultations.
 - (2) Disciplinary procedures for infractions of the policies and rules of the center.
 - (b) In the case of the death of a patient, document the efforts made to secure a necropsy.
2. the medical staff or, if necessary, the committees comprised of members of the staff appointed by the governing body, shall:

- (a) Act, not less frequently than once each month, on administrative matters concerning the medical staff.
 - (b) Investigate any report of a breach of ethics by any member of the staff.
 - (c) Coordinate the activities and general policies of the various departments of the staff.
 - (d) Make advisory recommendations concerning the medical staff to the governing body in accordance with existing policy.
 - (e) Establish procedures for the procurement, storage, safety, use and disposal of drugs in the center.
 - (f) In the case of a committee, serve as a liaison between the governing body and the medical staff.
 - (g) Develop policies relating to entries in medical records and the completion, filing and confidentiality of those records.
 - (h) Regularly review, analyze and evaluate the clinical work in the center, including the surgical procedures performed in the center. In this connection, the staff or the committee shall consider any agreement or disagreement about the diagnosis and the acceptability of the procedures undertaken.
 - (i) Recommend policies to the governing body concerning transfusions of blood and blood derivatives.
3. Meetings of the medical staff must be open to the administrator or his representative.
 4. There must be a chief for each department of the medical staff who is responsible for the operation of that department.]

449.988 Nursing staff.

1. Each ambulatory surgical center must have a department of nursing under the direction of a chief nurse who is a registered nurse.
2. [The chief nurse is responsible for the supervision and evaluation of the nursing staff and its activities., and he shall:
 - (a.) Establish job descriptions;
 - (b.) Provide for the orientation and training of the nursing staff;
 - (c.) Evaluate the performance of the staff; and
 - (d.) Assign nurses.
2. The provision of nursing services must be in compliance with appropriate state statutes and regulations including the Nevada nursing practice act NRS 632.
3. A sufficient number of members of the nursing staff must be on duty at all times to ensure that proper care is provided to each patient. A sufficient number of registered nurses must be on duty at all times to ensure the immediate availability of a registered nurse for the care of any patient. A person who is not a registered nurse may be assigned to care for a patient to the extent consistent with his education, experience and authorized scope of practice.
4. Surgical technicians and licensed practical nurses may be permitted to serve as scrub technicians under the direct supervision of a registered nurse; they shall not be permitted to function as circulating nurses in the operating rooms.[The governing body shall ensure the adequacy of treatment, medications and care provided by the nursing staff and shall ensure that each patient has a comfortable and clean environment that protects him from injury or accident.]

Medical Records, Services and Facilities

449.9885 Medical records: Maintenance.

1. An [full-time] employee shall oversee the completion, filing and retention of each medical record.
2. Records must be maintained for each patient admitted for care in the center in accordance with accepted professional principles.
3. Only authorized personnel may have access to medical records. Information contained in a medical record must not be released without the written consent of the patient or his guardian except:
 - (a) As required by law;
 - (b) Under a contract involving a third-party payor; or
 - (c) As otherwise provided by the agreement on admission.
4. A medical record may be microfilmed if the record can be legibly reproduced.
5. A licensee who ceases operations shall notify the division of the arrangements made for access to and the safe preservation of medical records.
6. Medical records must not be removed from the center except upon the issuance of an order by a court of competent jurisdiction.
7. The records of each patient discharged from the center must be completed within 30 days after the date of his discharge.
8. An index of medical records must be maintained. the medical records of each patient must be indexed, within 6 months after discharge, according to the surgery performed and the physician attending the patient.
9. Each record must be protected against loss, destruction or unauthorized use.

449.989 Medical records: Contents. 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 next of kin and on the person or agency legally or financially responsible for him.
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 [complete physical examination upon admission] pre surgical evaluation by a physician within the preceding seven days prior to 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. Each entry in the medical record of a patient must be verified by signature and title.
7. Reports of all [prescribed tests and examination] studies ordered to include laboratory and radiology examinations .
8. Confirmation of the original diagnosis, or the diagnosis at the time of discharge.
9. A report of any operation 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 prepared in accordance with established policy and any provisions made for continuing care of follow-up of the patient after discharge.]
- 12 A discharge summary to include disposition, recommendations, and instructions given to the patient.
- [13. If the patient has died and these documents are available, a death certificate and necropsy report.]

13. Documentation that the nursing staff of the center conducted a follow-up interview with the patient within 72 hours after discharge to determine patient condition, patient satisfaction, and complaints or problems.

449.9895 Sterilization.

1. All [dressings, bandages,] surgical instruments, sutures, and drains [and solutions] 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 1 year.

449.990 Medication and treatment.

1. Any medication or treatment may be given only upon the written or oral order of 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.
2. [Any medication for a patient must be prepared, administered and recorded as soon as possible after administration by a registered nurse. Medications must be prepared shortly before use.] Medications prepared by one nurse may not be administered by another.

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 medications may be administered only by those who have been specially trained and are authorized for that duty. Policies and Procedures for the accurate and safe administration of blood must be developed and implemented.

[6. Medications brought by a patient to the ambulatory surgical center may not be used unless:

- (a) The proper orders for medication have been entered by the prescriber in the medical record of the patient;
- (b) The container for the medication has been clearly and properly labeled; and
- (c) The contents of the container have been examined and positively identified by the prescriber or a pharmacist retained by the center.

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

449.9905 Pharmacist required; storage of drugs.

1. A pharmacist must be on the staff of each ambulatory surgical center or under contract with the center. He 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 [in the pharmacy or room for drugs] must be in writing and maintained so the receipt and disposition of any drug may be readily traced.
3. Pharmaceutical Services are provided in accordance with ethical and professional practice and applicable federal and state laws. [All prescriptive drugs and devices used in the center must be stored in well-illuminated compartments, drawers, cabinets, rooms or emergency carts that are locked except for carts containing drugs and devices located in areas in which a member of the staff is always present and where there is constant surveillance. The physical setting and the arrangements for personnel for these areas must have prior approval from the division. Poisons and medications for external use must be stored separately from medications for internal use. Poisons must be stored as if they were drugs.]
4. [Prescription] 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.
- [5. Only the pharmacist, the nurse in charge of a change of shift and the nurse in charge of medications may be provided with keys to the room for medications, the room where the drugs are stored or the cart containing drugs.
6. Medications may not be transferred from one storage container to another after having been dispensed from the pharmacy or drug room. Each container must be legibly marked with a

securely attached label. Containers with illegible, incomplete, makeshift, damaged, worn, soiled, or missing labels must be returned to the dispensing pharmacy for relabeling or disposal.

7.] 5. 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 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.

[8. Prescriptions may be released to a patient upon his discharge or transfer if the release is ordered in writing by a physician on the medical record of the patient.

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

449.991 Clinical laboratory: Generally.

1. [Services provided by a clinical laboratory must be adequate to meet the needs of patients]

Laboratory services must be provided to meet the needs of the patient and must be available to each center at all times.

2. If the ambulatory surgical center has its own laboratory[:

(a)]It must be a licensed clinical laboratory under the provisions of chapter 652 of NRS.[, with the necessary space, facilities and equipment to provide the laboratory services necessary for a routine examination.

(b) A laboratory technologist must be on duty or available within 15 minutes after being called when the center is open.

- (c) The laboratory must be able to chemistry, microbiology, hematology, serology and clinical microscopy examinations and examinations for blood transfusions.
 - (d) The laboratory may not perform procedures and tests that are outside the scope of the training of its personnel.
 - (e) Equipment in the laboratory must be in good working order and properly calibrated.
3. Each laboratory shall provide the results of tests within a reasonable time to the person who ordered them. Any report of the results of a test must be authenticated by the person designated as responsible for the preparation of the test. The original report must be filed in the medical record of the patient, and a copy must be kept in the laboratory for not less than 1 year.
 4. Each laboratory shall establish a system whereby the person who performed each test may be identified.]

[449.9915 Clinical laboratory: Laboratory outside of center.

1. Laboratory services that are beyond the capacity of a laboratory at the ambulatory surgical center must be provided by an outside laboratory.
2. Any report from an outside laboratory must identify the reporting laboratory, must be legible and must be included in the medical record of the patient.]
3. If laboratory services are provided by contractual agreement, the contracted lab must be certified in accordance with the Clinical Laboratory Improvement Amendment.

449.992 Pathological services.

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:
 - (a) Must be currently licensed in this state. [

(b) Shall participate in meetings of the medical staff and department.

(c) Is responsible for the qualifications and in-services training of his staff.]

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 the [medical staff] pathologist and made available to the laboratory and the medical staff.
4. Reports of examinations of tissues must be authenticated by the examining pathologist. The original report must be filed in the medical record of the patient.[and a copy kept in the laboratory. An index of a diagnosis of tissues must be maintained in the laboratory.]

449.9925 Procurement, storage and transfusion of blood.

1. If the ambulatory surgical center provides its own service for blood transfusions through its clinical laboratory:
 - (a) Any arrangement for the procurement, safekeeping or transfusion of blood or derivatives of blood must be under the supervision of a physician.
 - (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 tested each month to check its operation.
 - (d) Samples of the blood of any patient receiving a transfusion and of each unit of blood used in the center must be retained in accordance with the written policy of the laboratory for at least 7 days for further testing in the event of a reaction to the transfusion.
 - (e) Blood and derivatives of blood that have exceeded their expiration date may not be used.

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 **[technologist in charge of the laboratory]** Governing Body and the staff or contract pathologist.

449.993 Diagnostic radiological services.

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 the center maintains diagnostic radiological services, the **[Each]** 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. **[If the radiologist is a part-time consultant, in his absence a physician who has been qualified by the medical staff and approved by the governing body may supervise the department and interpret films.]**
3. Only a person designated as qualified by the radiologist **[or by a committee of the medical staff]** 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.
5. Examinations by X-ray must be ordered by the physician 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 **[authenticated]** 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.

449.9935 Operating room.

1. A registered nurse experienced in surgical procedures shall supervise the operating room. [A physician qualified to assist in major surgery must be present and scrubbed for any surgical procedure that may require his skills or qualifications.
2. A first assistant may be a registered nurse or technician if he is not otherwise required to be a physician and is designated by the medical staff as having sufficient training to assist properly and adequately in the procedure.
3. Any surgical technician or licensed practical nurse may serve as a scrub assistant under the direct supervision of a registered nurse, but] 2. Only a registered nurse may function as the circulating nurse in the operating room.[
4.] 3. The operating [suite must be equipped with a cardiac monitor, apparatus to assist the respiratory function, a defibrillator, an aspirator, sets for a thoracotomy and tracheotomy and any other equipment reasonably necessary for the surgeries performed in the center.]room must be equipped with an emergency call system, oxygen, mechanical ventilatory assistance equipment including airways, manual breathing bag and ventilator, cardiac monitoring equipment, laryngoscopes and endotracheal tubes and suction equipment. [
5.] 4. The ambulatory surgery center must be equipped with a cardiac defibrillator, a tracheostomy set, and emergency medical equipment and supplies specified by the medical staff.

[The rules and policies relating to the operating room must be available and, where appropriate posted. A registry concerning the personnel assigned to the operating room must be kept current.]

[6.] 5 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. Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ambulatory surgery center.

449.994 Records required before surgery; report of surgery.

1. A [**complete history and physical examination**] presurgical evaluation by a physician and pertinent past medical history must be recorded in the chart of each patient before surgery.

[**If the complete history and physical examination have been transcribed but not yet recorded in the chart, a statement to that effect and an admission note by the physician must be included in the chart.**]

2. A properly executed form of consent to surgery must be placed in the medical record of the patient before surgery. A report must be prepared immediately after surgery describing the technique and findings of the surgery.

449.9945 Administration and record of anesthesia.

[**1. If the ambulatory surgical center has a department of anesthesia, the department is responsible for the administration of anesthetics and the maintenance of strict safety controls. If there is no department of anesthesia in the center, then the department of surgery must be responsible.**]

[2.] 1. Anesthetics must be administered in the operating room by an anesthesiologist, a qualified physician, a dentist or, at the direction of the operating physician, [and] a certified registered nurse anesthetist (CRNA).

[3. **The medical staff shall designate those**

2. Designations of persons qualified to administer anesthetics [and shall specify what each person is qualified to do.] shall be based upon credentialing and approved by the governing body.

3. General anesthesia shall not be administered unless the anesthesiologist has evaluated the patient immediately prior to surgery to assess and document the risk of anesthesia relative to the surgical procedure to be performed.

4. Patients who have received general anesthesia shall be evaluated by the anesthesiologist after recovery from the anesthesia and prior to discharge from the recovery room.

[4.] 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.

[**449.9951 Report of change in condition of patient. Any significant change in the physical, mental or emotional condition of a patient must be reported immediately to:**

1. His physician; and
2. Next of kin or other person legally responsible for him.]

449.9955 Informing patient of rights, services and cost.

1. Each patient admitted to the ambulatory surgical center must be informed of his rights as a patient in accordance with Nevada Revised Statutes (NRS) 449.700. He must be informed,

at the time of his admission, of the services available and the estimated cost of those services.

2. If a patient is unable to understand his rights, they must be explained to his guardian, next of kin or the agency financially responsible for his care.

NEW SECTION PARAGRAPH

Patient Rights

1. Patients are treated with respect, consideration, and dignity.
2. Patients are provided appropriate privacy.
3. Patient disclosures and records are treated with confidentiality, and except when required by law, patients are given the opportunity to approve or refuse their release.
4. Patients are given the opportunity to participate in decisions involving their health care, except when such participation is contraindicated for medical reasons.
5. Information is available to patients and staff concerning:
 - a. patient rights;
 - b. patient conduct and responsibilities;
 - c. services available at the center;
 - d. provisions for after hours and emergency care;
 - e. fees for services;
 - f. payment policies;
 - g. patient's right to refuse to participate in experimental research; and
 - h. methods for expressing grievances and suggestions to the organization.

449.996 Transfer of patients.

1. 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. 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 his continuing care.

449.9965 Prohibited locations for construction of center. A new ambulatory surgical center must not be constructed over any underground liquid butane, propane or transmission line for gas, or over any underground high pressure lines, under high voltage electrical lines or near hazardous or hazard-producing plants.

449.997 Conversion of hazardous building into center prohibited. No building may be converted for use as an ambulatory surgical center if, because of its location, physical condition, state of repair or arrangement of facilities, the building would be hazardous to the health and safety of patients.

449.9975 Construction of facilities.

1. [The entrance of and the administrative and public areas in an ambulatory surgical center must comply with NAC 449.848.
2. If a radiology suite is provided, it must comply with NAC 449.931.
3. The pharmacy suite must comply with NAC 449.924.
4. The presurgery examination room must contain cabinets for the storage of medication, a work counter, illuminators for X-ray film, facilities for washing hands, cubicle curtains and a storage area for patients' clothing and possessions. The room must have 80 square feet for each preparation area.

5. The surgical suite must comply with NAC 449.884, except for the requirement that an operating room must have a clear area of at least 360 square feet exclusive of fixed and movable equipment.
6. Laundry facilities, if provided, must comply with NAC 449.905.]

Newly constructed and existing Ambulatory Surgical Centers must be designed and maintained to comply with the current National Fire Protection Association, Life Safety Code, Standard 101. A copy of the code may be obtained from the national Fire Protection Association, 11 Tracy Drive, Avon, Massachusetts 02322, for the price of \$44.50, plus \$4.84 for shipping and handling.

2. Newly constructed and existing Ambulatory Surgical Centers must be designed and maintained to comply with the current edition of “The Guidelines for Design and Construction of Hospital and Healthcare Facilities.” A copy of the guidelines may be obtained from AIA Rizzoli Bookstore, 1735 New York Ave., NW, Washington, D.C. 20006, for the price of \$60.00 plus \$6.00 for shipping. The telephone number is (202) 626-7541. These guidelines must be used when planning for sizing, arranging, and equipping of space that is being altered or newly constructed, with the following exception:
 - a. Renovation Section 1.2 of the introduction to the guidelines.
 - b. Refurbishing (only making changes in paint, floor, window and/or wall coverings).
 - c. Dedicated Laser rooms must meet the requirements of AIA 9.5F2
3. The facility must meet all applicable federal, state and local laws and must comply with all applicable life _____ safety, environment, health, building and fire codes, and zoning ordinances. If there are any differences between the state and local codes, the more restrictive standards apply.

4. Facilities will be considered to be in compliance if:
 - (a) The facility is licensed on January 1, 1999, the use of the physical space does not change, and the existing construction does not have any condition of deficiencies which are hazardous or detrimental to the public health and welfare; or
 - (b) The facility has submitted architectural plans to the Bureau of Licensure and Certification by February 1, 1999, and begun construction by August 1, 1999. The plans must be determined by the Bureau of Licensure and Certification to be I compliance with Chapter 449 Construction standards that were in effect prior to
 - (c) October 9, 1998. The facility must be built in accordance with those standards and not have any condition of deficiencies which are hazardous or detrimental to the public health and welfare, the facility must make changes before the facility can continue to operate.
5. The Bureau of Licensure and Certification may review building plans for new construction of remodeling. A complete copy of the plans, drawn to scale, may be brought to the Bureau for a plan review pursuant to the provisions of NRS 449.050 and NAC 449.0165.
6. Approval for licensing will not be given by the Bureau until all construction has been completed and survey is conducted at the site. The plan review does not constitute pre-licensing approval but is advisory only.

Extended Recovery. A Center may offer extended recovery within the ASC as long as the total time the patient is in the ASC does not exceed 23 hours and 59 minutes and if it meets the following requirements:

- A. The extended recovery unit (ERU) must be in a separate defined area and must provide audio and visual privacy for the patient.

- B. The ERU must be staffed by at least two (2) Advanced Cardiac Life Support (ACLS) trained nurses at all times when patients are present in the ERU.
- C. The ratio of ACLS trained nurses to patients in the ERU must be no more than two patients per nurse with a minimum of two ACLS trained nurses at all times.
- D. The ERU must be equipped with a defibrillator, airways, manual breathing bag, oxygen, and suction and other emergency medication and equipment as needed. There must be an emergency call system.
- E. Adequate supervision of the ERU is the responsibility of one or more qualified physicians who are approved by the governing body upon the recommendation of medical personnel:
1. At least one physician is present or immediately available by telephone any time patients are present in the ERU; and
 2. A patient is admitted or discharged to the ERU only upon the order of a physician who is responsible for the medical care of that patient.
- F. The ERU has policies and procedures that include but are not limited to:
1. Clinical criteria for determining eligibility for admission;
 2. Clinical criteria for determining eligibility for discharge;
 3. Arrangements for emergency services; and
 4. Arrangements for transfer to other health care services as needed.
- G. Food service is provided to meet the needs of patients:

1. Food is purchased, stored, prepared, and served in compliance with local health department requirements; Special dietary requirements for patient care are met; and
2. If food is prepared by the center, the center must:
 - a) Comply with the standards prescribed in Chapter 446 of the Nevada Administrative Code; and
 - b) Obtain the necessary permits from the Bureau of Health Protection Services of the division
H. ERU care and services are reviewed as part of the organization's quality assurance program.