LCB File No. R049-99

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, 450B and 652. **The hearing is scheduled to begin at 9:00 a.m. on Friday, September 10, 1999, at the Grant Sawyer Building, Room 4410, 555 E. Washington Avenue, Las Vegas, Nevada.**

THIS HEARING IS TO MAKE TEMPORARY REGULATIONS PERMANENT.

RESIDENTIAL FACILITIES FOR GROUPS

In September of 1997 the Temporary Regulations for Residential Facilities for Groups were presented to the Board of Health as a Legislative Counsel Bureau file, for permanent adoption. Between the changes bureau staff proposed to the temporary regulations (after using them for almost one year) and changes that LCB made to the temporary regulations (during their preparation for permanent adoption) some language mistakes occurred and became evident during the past year. In addition the BOH has requested that we modify language at NAC 449.226.4 concerning call systems in large facilities in order to eliminate the need for variances to this particular requirement. The bureau decided it would wait until the regulations were codified by LCB before attempting to change any language.

We have established new language and modifications to existing language in the following areas: NAC 449.0168, NAC 449.193, NAC 449.200, NAC 449.209, NAC 449.226, NAC 449.229, NAC 449.2704, NAC 449.2742, NAC 449.2744, NAC 449.2746, NAC 449.2749, NAC 449.275, NAC 449.2756, and NAC 449.2764

The changes are not substantial and are designed to clarify issues rather than create more requirements.

The changes present no anticipated effect to the public.

There is no anticipated additional cost to the agency for enforcement of the proposed regulation changes.

The regulations proposed for change will not effect changes to other governmental agencies and do not overlap/duplicate other regulations.

The regulations proposed for change do not overlap/duplicate federal regulations.

The regulations do not have a counterpart in the code of federal regulations.

The regulations will add two new fees to the fee schedule at NAC 449.0168.1, 1) one for addition or change of facility type endorsements on a license and 2) one for change to the category on a license.

RESIDENTIAL FACILITIES FOR GROUPS - FEES

In September of 1997, the Temporary Regulations for Residential Facilities for Groups were presented to the Board of Health as a Legislative Counsel Bureau file, for permanent adoption. Between the changes bureau staff proposed to the temporary regulations (after using them for almost 1 year) and changes that LCB made to the temporary regulations (during their preparation for permanent adoption) it was identified that some language modification was required in the general provisions section of NAC Chapter 449. The Bureau decided it would wait until the regulations were codified by LCB before attempting to change any language.

In July the bureau received a copy of the codified regulations. The bureau subsequently drafted proposed changes to the regulations and will present these changes before the December BOH meeting.

We have established new language and modifications to existing language in the following areas:

NAC 449.0168

The changes are designed to establish standards for processing applications to change license endorsements, whereas currently there is no authority nor mechanism for the bureau to receive applications for the changes discussed. If the language is modified as presented the industry will benefit from the ability to apply for changes through the formal application process, rather than the current informal process.

The changes present no anticipated effect to the public. There is no anticipated additional cost to the agency for enforcement of the proposed regulation changes.

The regulations proposed for change will not effect changes to other governmental agencies and do not overlap/duplicate other regulations.

The regulations proposed for change do not overlap/duplicate federal regulations.

The regulations do not have a counterpart in the code of federal regulations.

The regulations will add two new fees to the fee schedule at NAC 449.0168.1, 1) a fee for addition or change of facility type endorsements on a license and 2) a fee for change to the category indicated on a license.

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.

POINT OF CARE TESTING

Proposed changes to Chapter 652 Medical Laboratories are necessary to allow healthcare professionals to perform waived and moderate complexity testing at the bedside in medical facilities licensed pursuant to Chapter 449.

Point of Care testing is defined and point of care device is described with limitations of use. Qualifications and activities of the point of care analyst are identified and certification fees are established. Continuing education requirements apply to the point of care analyst.

Anticipated benefits to both laboratories regulated by NAC 652 and the public (the patients) will be an overall cost reduction as a result of decreased length of stay due to rapid return of results to the physician. These benefits are both immediate and long term. There are no adverse effects anticipated.

The increased cost to the agency will be funded by establishing a certification fee issued for point of care testing analyst.

NAC 652 and CLIA regulations (42 CFR Part 493 of the Code of Federal Regulations) have established requirements for the performance of laboratory testing, however, with the recent

availability of small portable hand-held analyzers, bedside testing by healthcare professionals other than traditional laboratory technical staff required changes to existing regulations.

HOSPITALS

The proposed amendments are needed to update the current regulations originally adopted in 1969 relating to the licensing of hospitals. The amendments also update the construction standards relating to hospitals.

The proposed regulations affect all services/departments in acute hospitals. Current standards of care for those departments were addressed in the regulations.

The proposed regulations will have little if any effect on the acute hospitals because they were developed by utilizing current standards of care that are defined by the Medicare/Medicaid reimbursement participation standards. 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 hospitals 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 hospitals. 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 439B.410, NRS 652.217, NRS 632, 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 hospitals licensed by BLC.

The proposed regulations parallel the federal Medicare/Medicaid reimbursement participatory regulations governing acute hospitals (42 Code of Federal Regulations (CFR) Part 482, Subpart A, B, C, and D) 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 hospitals in certain areas: regulations for tuberculosis screening in employees, certain patient care areas, patient rights, and construction standards.

SKILLED NURSING REGULATIONS

The proposed amendments are needed to update the current regulations originally adopted in 1969 relating to the licensing of skilled nursing facilities. The amendments also update the construction standards relating to skilled nursing facilities.

The proposed amendments will incorporate resident rights, resident behavior and facility practices, quality of life, resident assessment, and quality of care requirements not included in the current regulations. Additionally, general requirements such as physician, nursing and dietary services will be addressed, as well as construction and design requirements.

The adoption of the proposed amendments should not create an economic or operational impact on licensed facilities because the proposed regulations parallel federal regulations the facilities have been following since 1990.

The proposed amendments are considered to provide a beneficial impact for the public by providing licensing standards for the care, safety and quality of life for nursing home residents consistent with current standards of practice.

The adoption of the proposed amendments should have no economic impact on the Bureau of Licensure and Certification because the proposed regulations parallel federal regulations that the agency has surveyed under contract with the Health Care Financing Administration.

These regulations do not duplicate the regulations of other state or local government entities. The regulations parallel federal regulations of the Health Care Financing Administration 42 C.F.R. 483.1 through 483.75, inclusive.

The proposed amendments include several sections that are more stringent than the federal regulations: Requirements for design and construction of skilled nursing facilities that are not addressed in federal regulation; requirements for TB testing of personnel.

The proposed amendments do not change existing fees or impose any new fees.

CONSTRUCTION STANDARDS

The proposed amendments are needed to update the current regulations originally adopted in 1969 relating to the construction standards of skilled nursing facilities and hospitals.

The proposed regulations affect all services/departments in acute hospitals.

The proposed regulations will have little effect on existing structures. All new construction and remodeling projects will be required to comply with the guidelines. The guidelines are used nationwide and will be beneficial to facilities in that architects or other design professionals are currently using the same guidelines in other states.

The proposed regulations will be beneficial to the general public by providing a nationally recognized standard for constructing a health care facility in a safe fashion.

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 hospitals. The current fee for initial and annual renewal of licenses will cover the cost to BLC.

The proposed regulations state that there are satisfactory assurances that the facility meets all applicable Federal, State and local laws and complies with all applicable life safety, environmental health, building and fire codes and zoning ordinances. If there are any differences between the State and local codes, the more restrictive standards apply. This is necessary to inform the facility that they are required to meet other codes or laws to pass the building inspection and zoning or certificate of occupancy requirements.

The proposed regulations reference the National Fire Protection Association (NFPA) as the basic codes of reference, in particular, the Life Safety Code NFPA 101, and the NFPA 99. These particular references and several others are included in "The Guidelines for Design and Construction of Hospitals and Health Care Facilities" on pages 3, 4 and 5.

The proposed regulations are more stringent than the federal regulations at 42 CFR 482.41 Condition of Participation – Physical Environment. This is necessary because the federal regulations do not address design and construction of facilities.

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

CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES

The Administrative Code Chapter 445A pertaining to Certification of Environmental Laboratories analyzing drinking water in accordance with the Federal Safe Drinking Water Act as presently constituted has some defects that require resolution. The United States Environmental Protection Agency along with stakeholders throughout the nation has developed a consensus standard called the National Environmental Laboratory Accreditation Conference (NELAC) standard. The Bureau of Licensure and Certification has participated in the development of this standard. A program for laboratories to certify according to this nationally accepted standard has been put forth. It is called the National Environmental Laboratory Accreditation Program (NELAP). States may adopt the standard and they may participate in NELAP if they so choose.

Participation in NELAP necessitates subscribing to the NELAC standard which is organized in four distinct tiers, namely: 1.) Legal Identity and Mission; 2.) Testing Capability; 3.) Regulatory Program; 4.) Test Methods.

Each of these "tiers" are addressed in the current NAC but are not organized efficiently and items referenced therein create areas of confusion due to conflicting instructions or protocols. At one juncture the authority to revoke or downgrade certification based upon information obtained from site surveys was denied the Bureau because not all of the pertinent chapters of the referenced standard were included.

Some of the material included in the current NAC, though important, does not apply to laboratory certification. It should be separated from the certification portion of the code.

It is proposed that a completely new version of Chapter 445A pertaining to Environmental Laboratory Certification be adopted in accordance with a template provided by NELAC. This code follows the organizational pattern established by the NELAC standard and includes changes that are required for NELAP participation. Standards that are unique to Nevada will be retained. Since this version is new, the section identification numbers will not coincide with or relate to those of the current code. It is proposed to eliminate the current code and replace it with the new wording. Section numbers can be changed to fit into the surrounding code.

Anticipated effects on the environmental laboratory business are beneficial and immediate. Adoption of this revision will affect environmentally sensitive businesses in the following ways:

1. EPA involvement with the Performance Testing program has been changed. The NAC will reflect these changes.
2. Nevada will be able to participate in the NELAP program if it elects to do so.
3. Ambiguous language will be replaced so consistency in agency action will be assured.
4. Laboratories electing to participate in NELAP accreditation may do so with Nevada as their sponsoring authority.
5. NELAP accredited laboratories will have automatic reciprocity among all NELAP participation states. (So far twenty states have applied for NELAP participation and several more have committed.) *Nevada laboratory certification officers recommend that Nevada participate*.
6. NELAP participating laboratories will be held to a common standard.
7. NELAP participating laboratories will be able to participate in Federal contracts.
8. NELAP participating laboratories will not suffer a competitive disadvantage relative to participants.
9. NELAP participating laboratories will be assured a level playing field nationally.
10 NELAP participating laboratories will produce data of known, consistent and comparable quality.
11. Laboratories not electing NELAP accreditation will not be required to do so, but will be held to the NELAC standard in so far as it is appropriate.
12. Agencies and businesses requiring analyses of regulated parameters will be assured that data meet a rigorous nationally accepted standard.

Anticipated effects on the public are beneficial and long-term. The changes will assist in maintaining quality laboratory analytical capacity to ensure that measurements that affect the public health will be trustworthy.

The estimated cost to the agency for enforcement of the proposed regulation will not be any different than for the current regulation. In the event Nevada elects to have Bureau of Licensure and Certification Laboratory Certification Officers trained to become NELAP assessors, the cost will be limited to the training expense. The training is required every four years.

The regulations do not overlap or duplicate any federal regulations.
The regulations will maintain the existing fee structure.

DEFIBRILLATION - 450B.900-.936 (This regulation does not apply to EMS providers under the authority of Clark County Health District.)

These amendments are to repeal the existing regulations concerning defibrillation, add defibrillation to the authorized practices of emergency medical technicians, and add the definitions currently listed in sections .900 thru .914 to the “General Provisions” section of 450B.

This section of NAC 450B was placed in regulation because the use of automatic and semi-automatic defibrillation was introduced as a pilot program for emergency medical technicians and has since become a normal part of the emergency medical technician’s scope of practice.

The National Highway Traffic Safety Administration of the United States Department of Transportation has adopted in the EMT Basic program training for the use of automatic and

semi-automatic defibrillators. This eliminates the need for further training and certification in defibrillation for the EMT, as currently required in NAC 450B.918-.936.

This section of NAC 450B has generated unnecessary costs and training time for EMS services and personnel.

There are no anticipated effects on the business which NAC 450B regulates.

There are no anticipated effects on the public.

There are no anticipated additional costs to the Health Division for enforcement of the proposed regulation.

There are no existing regulations of other state or local governmental agencies which the proposed amendments to the regulations overlap or duplicate.

DO NOT RESUSCITATE - 450B.955
These amendments are to implement a fee for issuance of a Do Not Resuscitate Identification bracelet. This fee would cover the cost of the bracelet, including engraving and shipping the bracelet to the patient.

There are no anticipated effects on the business which NAC 450B regulates.

There are no anticipated effects on the public.

Estimated cost to the Health Division for enforcement of the proposed regulation:

Expenditure of $1,575.00 for purchasing an initial inventory of bracelets. This expenditure will be recouped in full through a fee to be determined by the health authority.

The amendment establishes a fee determined by the health authority not to exceed the actual cost of obtaining the medallion from a manufacturer, including the cost of engraving, shipping and handling.

There are no existing regulations of other state or local governmental agencies which the proposed amendments to the regulations overlap or duplicate.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8-1/2" x 11" pages must submit the material to the Board's Secretary by August 26, 1999.

Secretary, State Board of Health
Nevada State Health Division
Capitol Complex
505 E. King Street, Room 201
Carson City, NV 89701-4797

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

Members of the public who are disabled and require special accommodations or assistance at the meeting are required to notify Yvonne Sylva, Secretary, Board of Health, in writing at the Nevada State Health Division, 505 E. King Street, Room 201, Carson City, NV 89701, or by calling (702) 687-4740.

A copy of this notice and the proposed regulation amendments are on file for inspection at the following locations during normal business hours:

Bureau of Licensure and Certification, 1550 E. College Pkwy, Suite 158, Carson City, Nevada (702) 687-4475).

Bureau of Licensure and Certification, 4220 S. Maryland Parkway, Suite 810, Las Vegas, Nevada (702) 486-6515.

Bureau of Licensure and Certification, 1755 E. Plumb Lane, Suite 241, Reno, Nevada (702) 688-2888

Emergency Medical Services, 850 Elm Street, Elko, Nevada (702) 753-1154.

Emergency Medical Services, 100 Frankie, Tonopah, Nevada (702) 482-3722.

Copies may be obtained in person, by mail, or by calling (702) 687-4475. Copies are also available for review at all physical locations of program offices (see above) or the following main public libraries in each county:

- Carson City Library, 900 North Roop St.
  Carson City, NV 89701
- Churchill County Library, 533 S. Main St.
  Fallon, NV 89406
- Clark County Library, 4020 Maryland Parkway,
  Las Vegas, NV 89119
- Douglas County Library, 1625 Library Lane, (PO Box 337)
  Minden, NV 89423
- Elko County Library, 720 Court St.
  Elko, NV 89801
- Goldfield Public Library (Esmeralda Co.), Corner of Crook and Ramsey, (PO Box 430)
  Goldfield, NV 89013
- Eureka Branch Library, 10190 Monroe St.,
  Eureka, NV 89316
- Humboldt County Library, 85 East 5th St.,
  Winnemucca, NV 89445
- Battle Mountain Branch Library (Lander Co.), 6255 Broad St.,

Battle Mountain, NV 89820

- Lincoln County Library, 63 Maine St., (PO Box 330)
  Pioche, NV 89043
- Lyon County Library, 20 Nevin Way,
  Yerington, NV 89447
- Mineral County Library, 125 A St., (PO Box 1390)
  Hawthorne, NV 89415
- Pershing County Library, 125 Central, (PO Box 781)
  Lovelock, NV 89419
- Storey County Library, 95 South R St., (PO Box 14)
  Virginia City, NV 89440
- Tonopah Public Library (Nye Co.), 171 Central, (PO Box 449)
  Tonopah, NV 89049
- Washoe County Library, 301 South Center St., (PO Box 2151)
  Reno, NV 89505
- White Pine County Library, 950 Campton St.,
  Ely, NV 89301

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

To be published in the Las Vegas Review-Journal, Reno Gazette-Journal and Elko Daily Free Press on or before August 11, 1999.
Richard J. Panelli, Chief
July 27, 1999

PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

SURGICAL CENTERS FOR AMBULATORY PATIENTS

EXPLANATION – ***Italicized*** material is new; material in brackets ~~[]~~ is to be deleted

Note: All sections in this document were adopted by Nevada State Board of Health on December 11, 1998. Section 32, NAC 449.9945 was further revised and adopted by the Nevada State Board of Health on February 12, 1999.

Section 1 Chapter 449 of NAC is hereby amended by adding thereto the provisions set fourth as sections 2 to 8, inclusive, of this regulation.

Sec. 2 ***The ambulatory surgical center must be a distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.***

Although the 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 firewall rated construction.

The ambulatory surgical center cannot mix functions and operations with any other entity 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 surgical center staffing and record keeping must be separate and exclusive.

Sec. 3 ***Quality Assurance in a Licensed Ambulatory Surgical 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 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 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, and 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 surgical 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 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;

(e) Control of infection;

(f) Pharmaceutical Services; and

(g) Studies of patient satisfaction.

Sec. 4 *Patient Rights. The center must ensure that:*

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 center.

Sec. 5 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 medical staff based upon the size and complexity of the ambulatory surgical center.

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);

(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 center must have 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]~~ ***center 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 center.

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 medical staff of the center to include the initial application, reapplication, verification, privileges granted, and other pertinent information as required by the center.

9. Credentialing, recredentialing, and the privilege granting process and decisions must be approved by the governing body

10. Clinical privileges are to be granted for a specified period of time

Sec. 6 *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 American Institute of Architecture 9.5F2

3. The center 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. Centers will be considered to be in compliance if:

(a) The center is licensed on February 1, 1999, the use of the physical space does not change, and the existing construction does not have any deficiencies which are likely to cause serious injury, serious harm or impairment to public health and welfare. If there are deficiencies that are likely to cause serious injury, serious harm, or impairment to public health and welfare, the center must take corrective action before the center can continue to operate.

(b) The center 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 in compliance with Chapter 449 Construction standards that were in effect prior to December 11, 1998. The center must be built in accordance with those standards and not have deficiencies which are likely to cause serious injury, serious harm or impairment to public health and welfare.

5. The Bureau of Licensure and Certification may review building plans for new construction or 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 a survey is conducted at the site. The plan review does not constitute pre-licensing approval but is advisory only.

7. Determination of suitability for this state of revision of publication adopted by reference. If any publication adopted by reference pursuant to NAC 449.971 to Extended Recovery Unit, inclusive, is revised, the state board of health will review the revision to determine its suitability for this state. If the board determines that the revision is not suitable for this state, it will hold a public hearing to review its determination and give notice of that hearing within 6 months after the date of the publication of the revision. If, after the hearing, the board does not revise its determination, the board will give notice that the revision is not suitable for this state within 30 days after the hearing. If the board does not give such notice, the revision becomes part of the publication adopted by reference pursuant to NAC 449.971 to Extended Recovery Unit, inclusive.

Sec. 7 *Extended Recovery. A Center may offer extended recovery as long as the total time the patient is in the center does not exceed 23 hours and 59 minutes and if it meets the following requirements:*

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

2. 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.

3. 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 in the ERU at all times.

4. 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.

5. Adequate supervision of the ERU must be the responsibility of one or more qualified physicians who are approved by the governing body upon the recommendation of medical personnel:

6. At least one physician must be present or immediately available by telephone any time patients are present in the ERU; and

7. A patient must be admitted or discharged to the ERU only upon the order of a physician who is responsible for the medical care of that patient.

8. The ERU must have policies and procedures that include but are not limited to:

(a) Clinical criteria for determining eligibility for admission;

(b) Clinical criteria for determining eligibility for discharge;

(c) Arrangements for emergency services; and

(d) Arrangements for transfer to other health care services as needed.

9. Food service must be provided to meet the needs of patients:

(a) Food must be purchased, stored, prepared, and served in compliance with local health department requirements; Special dietary requirements for patient care must be met; and

(b) If food is prepared by the center, the center must:

(1) Comply with the standards prescribed in Chapter 446 of the Nevada Administrative Code; and

(2) Obtain the necessary permits from the Bureau of Health Protection Services of the division.

10. ERU care and services are reviewed as part of the center's quality assurance program.

Sec. 8 ***If laboratory services are provided by contractual agreement, the contracted lab must be certified in accordance with the Clinical Laboratory Improvement Amendment.***

Sec. 9 NAC 449.972 is hereby amended to read as follows:

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".**

Sec. 10 NAC 449.974 is hereby amended to read as follows:

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 patient.

Certified registered nurse anesthetist (CRNA). A CRNA holds active certification issued by the Nevada State Board of Nursing under NRS Chapter 632.

Doctor of Podiatric Medicine. A person licensed in accordance with NRS 449.635.

Health Care practitioners. Individuals currently licensed under the laws of this state who may provide services in an Ambulatory Surgical Center, 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, electro-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. Laproscopic procedures.

Sec. 11 NAC 449.980 is hereby amended to read as follows:

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 surgical center*** and immediately available at all times when there are patients in the~~[center]~~ ***operating rooms or the recovery room of the center. For the purpose of this section, the terms "immediately available" means on the premises and sufficiently free from other duties to enable the individual to respond rapidly to emergency situations.***

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 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.

Sec. 12 NAC 449.981 is hereby amended to read as follows:

449.981 Appointment and responsibilities of administrator.

1. The governing body must 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 must be 21 years or older and must be experienced in administration and supervision of personnel and must 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 center 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 must be written in a job description and must be available for review by the division.

(b) Responsibilities shall include:

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

2. Develop, evaluate, update, and implement center 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 center;

7. Establish a system for continuous quality assurance to include mechanisms for reporting to the governing body and acting on their recommendation.

8. Provisions have been made for the isolation or immediate transfer of patients with communicable disease.

Sec. 13 NAC 449.9815 is hereby amended to read as follows:

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.

Sec. 14 NAC 449.982 is hereby amended to read as follows:

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:

~~[Areas for the isolation of patients with communicable diseases;]~~

(a) The sanitary disposal of pathological and infectious waste;

(b) Methods for handling contaminated linen ***or linen substitutes***; and

(c) 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.***

Sec. 15 NAC 449.9825 is hereby amended to read as follows:

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 National Fire Protection Association 99 Standard for Healthcare Facilities 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.]~~

Sec. 16 NAC 449.983 is hereby amended to read as follows:

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 surgical center must be equipped with an approved automatic sprinkler system.

Sec. 17 NAC 449.9835 is hereby amended to read as follows:

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 group of physicians]~~ operating an ambulatory surgical center for the purpose of performing surgery only upon his ~~[or their]~~ own patients.

Sec. 18 NAC 449.9855 is hereby amended to read as follows:

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 center.***

~~[(b)]~~ ***3.*** Each employee shall, 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. Each employee of the ambulatory surgical center must have a current and accurate personnel record that includes:

(a) A job description 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.

(b) Evidence of current licensure, registration, specific experience and other information showing his qualifications for the position;

(c) An annual evaluation of the employee that is authenticated by the employee and his supervisor.

(d) Health records as required by NAC Chapter 441A.

Sec. 19 NAC 449.9865 is hereby amended to read as follows:

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 center must be periodically reviewed and amended as appropriate.

~~[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.]~~ ***6.*** 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.]~~

Sec. 20 NAC 449.988 is hereby amended to read as follows:

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 provision of nursing services must be in compliance with appropriate state statutes and regulations including the Nevada Nursing Practice Act NRS 632. ~~[The chief nurse is responsible for the supervision and evaluation of the nursing staff and its activities. 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.]~~

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 ~~[nurses]~~ ***technicians under the direct supervision of a registered nurse;*** ~~[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.]~~

Sec. 21 NAC 449.9885 is hereby amended to read as follows:

449.9885 Medical records: Maintenance.

1. A***n*** ~~[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.

Sec. 22 NAC 449.989 is hereby amended to read as follows:

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.***

Sec. 23 NAC 449.9895 is hereby amended to read as follows:

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.

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

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.

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

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 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.

Sec. 26 NAC 449.991 is hereby amended to read as follows:

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.~~**]**

Sec. 27 NAC 449.992 is hereby amended to read as follows:

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.~~**]**

Sec. 28 NAC 449.9925 is hereby amended to read as follows:

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***.

Sec. 29 NAC 449.972 is hereby amended to read as follows:

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.

Sec. 30 NAC 449.9935 is hereby amended to read as follows:

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 surgical 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 center.***

For the purposes of this section, the term "available" means on the premises and sufficiently free from other duties to respond rapidly to emergency situations.

Sec. 31 NAC 449.994 is hereby amended to read as follows:

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.

Sec. 32 NAC 449.9945 is hereby amended to read as follows:

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]~~ ***under*** the direction of the operating physician, a certified registered nurse anesthetist ***(CRNA) in accordance with NRS 632 and regulation promulgated thereunder***.

~~[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 credentialling and approved by the governing body.***

3. General anesthesia shall not be administered unless the physician 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 physician 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.

Sec. 33 NAC 449.9955 is hereby amended to read as follows:

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.

Sec. 34 NAC 449.984 is hereby repealed:

~~[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~~

~~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.~~**]**

Sec. 35 NAC 449.9845 is hereby repealed:

~~**[**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.~~**]**

Sec. 36 NAC 449.985 is hereby repealed:

~~***[**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.~~**]**

Sec. 37 NAC 449.986 is hereby repealed:

~~**[**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;~~

~~2. 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 his performance that is authenticated by the employee and his supervisor.~~~~]~~

Sec. 38 NAC 449.987 is hereby repealed:

~~[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.]

Sec. 39 NAC 449.9875 is hereby repealed:

[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.]

Sec. 40 NAC 449.9915 is hereby repealed:

[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 form an outside laboratory must identify the reporting laboratory, must be legible and must be included in the medical record of the patient.]

Sec. 41 NAC 449.9951 is hereby repealed:

[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.]

Sec. 42 NAC 449.9975 is hereby repealed:

[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.~~**]**

INFORMATIONAL STATEMENT PER NRS 233B.066

1. DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION OF HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Notice of public workshops held on October 16, 1998, in Las Vegas and October 19, 1998, in Reno was published in the Las Vegas Review Journal, Reno Gazette Journal, and Elko Daily Free Press on or before October 1, 1998. Notices of public workshops and proposed regulations were mailed to all county libraries in Nevada, surgical centers for ambulatory patients, and interested parties.

Notice of public hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal, Reno Gazette Journal, and Elko Daily Free Press on or before November 11, 1998. Notices of public hearing and proposed regulations were mailed to all county libraries in Nevada, surgical centers for ambulatory patients, and interested parties on November 5, 1998.

Notice of public workshops held on January 25, 1999, in Reno was published in the Las Vegas Review Journal, Reno Gazette Journal, and Elko Daily Free Press on or before January 11, 1999. Notice of public workshops and proposed regulations were mailed to all county libraries in Nevada, hospitals, surgical centers for ambulatory patients, and interested parties.

Notice of public hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal, Reno Gazette Journal, and Elko Daily Free Press on or before January 13, 1999. Notice of public hearing and proposed regulations were mailed to all county libraries in Nevada, hospitals, surgical centers for ambulatory patients, and interested parties on November 5, 1998.

Notice of public workshops held on September 7, 1999, in Las Vegas was published in the Las Vegas Review Journal, Reno Gazette Journal, and Elko Daily Free Press on or before August 23, 1999. Notices of public workshops and proposed regulations were mailed to all county libraries in Nevada, surgical centers for ambulatory patients, and interested parties.

Notice of public hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal, Reno Gazette Journal, and Elko Daily Free Press on or before August 11, 1999. Notices of public hearing and proposed regulations were mailed to all county libraries in Nevada, surgical centers for ambulatory patients, and interested parties on July 30, 1999.

In addition, copies of the proposed regulations were available during normal office hours at:

Bureau of Licensure and Certification - Carson City
Bureau of Licensure and Certification - Las Vegas
Bureau of Licensure and Certification - Reno
Nevada State Library
Emergency Medical Services - Elko
Emergency Medical Services - Tonopah

For public response copies of the minutes of the Board of Health meetings may be obtained by calling the Health Division at 684-4200.

2. THE NUMBER OF PERSONS WHO:

(A) ATTENDED THE HEARING;

Approximately 85 people attended the December 11, 1998, Board of Health hearing.
Approximately 102 people attended the February 12, 1999, Board of Health hearing.
Approximately 37 people attended the September 10, 1999, Board of Health hearing.

(B) TESTIFIED AT EACH HEARING; AND

Thirteen people testified at the December 11, 1998, Board of Health hearing.
Twelve people testified at the February 12, 1999, Board of Health hearing.
Three people testified at the September 10, 1999, Board of Health hearing.

(C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

Two people submitted written statements at the December 11, 1998, Board of Health hearing.
No written statements were submitted at the February 12, 1999, Board of Health hearing.
No written statements were submitted at the September 10, 1999, Board of Health hearing.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY

Comment was solicited from affected or potentially affected businesses by mailing surgical centers for ambulatory patients, hospitals, and all interested parties the proposed regulations and notice for the workshops and Board of Health hearing. Copies the workshop minutes and Board of Health hearing minutes may be obtained by calling the Bureau of Licensure and Certification at (775) 687-4475.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

None

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:
(A) BOTH ADVERSE AND BENEFICIAL EFFECTS; AND
(B) BOTH IMMEDIATE AND LONG TERM EFFECTS.

December 11, 1998: 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.

February 12, 1999: The proposed change will not affect the way ambulatory surgical centers conduct business since the requirement has been present in both state and federal regulations since their inception.

There will be no anticipated adverse effect on the public.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There will be no additional cost to the Bureau of Licensure and Certification for enforcement of the proposed regulation.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, NAME THE REGULATING FEDERAL AGENCY.

December 11, 1998: The proposed regulations state that the facility must be in compliance with Nevada Administrative Statutes (NRS) 449.700 – 449.730, NRS 439B.410, NRS 652.217, NRS 632, 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 license 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, C, and D.) 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.

February 12, 1999: This regulation overlaps the federal Medicare regulation at 42CFR 416.42(b) Administration of Anesthesia.

8. IF THE REGULATION INCLUDES PROVISION WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISION.

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.

9. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

There are no additional or increased fees associated with the passage of these regulations.