

Document No. 5264
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394

61-91. Standards for Licensing Ambulatory Surgical Facilities.

Synopsis:

Pursuant to S.C. Code Sections 44-7-250 and 44-7-260(A)(4), the Department establishes and enforces the minimum standards for the licensure, maintenance, and operation of ambulatory surgical facilities to ensure the safe and appropriate treatment of persons served in this state. In accordance with 2023 Act No. 20 (S.164), the Department proposes amending R.61-91 to promulgate regulations concerning the provision of uncompensated indigent/charity care required pursuant to S.C. Code Section 44-7-266(B) and -(C), including related definitions, licensure requirements, reporting requirements, and enforcement. Additionally, the Department proposes amending the regulation to address the required quality of care, services, and treatment provided by facilities and to prescribe the manner and method of fee payments. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the August 25, 2023, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

Section	Type of Change	Purpose
101	Reorganization	Recodification of definitions due to additions of new definition.
101.B, 101.J, 101.M, 101.N, 101.W, 101.X, 101.Z, 101.AA, 101.MM, 101.NN, 101.HHH, 101.III, 101.JJJ	Addition	Added definitions for clarity.
103.G	Addition	Added requirement to make payment of fees before the Department's issuance of a license.
103.H	Revision	Revised for clarification.
103.N.1 and 103.N.2	Addition	Language added in accordance with ACT 20.
202.F and 202.G	Addition	Inspection and Construction fees added for clarification.
401.A and 402.B	Revision	Revised to clarify requirements for policies and procedures, the time period for reviewing policies and procedures, and their accessibility to staff.
503	Addition	The governing body section added to address quality of care, services and treatment provided by facilities.

Section	Type of Change	Purpose
504, 505, 506, 507, 508, and 509	Reorganization	Recodification of section due to addition of section 503.
601.B	Revision	Revised to add some of the NQF Serious Reportable Events as reportable incidents.
801.D	Addition	Added a new section for transfer agreements including an exception for when a facility is unable to secure such an agreement.
804.B	Addition	Added to be consistent with federal regulation and to address quality of care.
807.A and -B	Revision	Revised to add provisions regarding the offering of cardiovascular care services.
808 and 809	Reorganization	Recodified due to the addition of 807.
804.C	Reorganization	Recodified due to the addition of 804.B.
901.A	Deletion	Deletion of incorrect reference to SC Code.
1201.A	Addition	Added emergency equipment requirements.
1201.B	Deletion	Deleted subsection.
1504.E	Addition	Added requirement concerning collection, transportation, and storage of contaminated equipment.
1601.C	Addition	Added requirements concerning governing body involvement with the quality improvement program to be consistent with federal regulations and to address quality of care.
2006.E	Revision	Revised the minimum toilet fixture requirement.

Instructions:

Print the regulation as shown below. All other items remain unchanged.

~~Indicates Matter Stricken~~

Indicates New Matter

Text:

61-91. Standards for Licensing Ambulatory Surgical Facilities.

Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394

SECTION 100

DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS

101. Definitions.

For the purpose of these standards, the following definitions shall apply:

A. Administrator. The individual designated by the facility licensee to have the authority and responsibility to manage the facility.

B. Adjusted Gross Revenue. Total Gross Revenue minus Medicaid and Medicare contractual adjustments only and bad debt.

BC. Administering Medication. The direct application of a single dose or multi-dose of medication to the body of a patient by injection, ingestion, or any other means.

CD. Advance Directive. A written statement such as a living will, a durable power of attorney for health care, or a do-not-resuscitate order relating to the provision of health care when the individual is incapacitated. The exercise by a patient of self-determination that encompasses making choices regarding life-sustaining treatment (including resuscitative services).

DE. Advanced Practice Registered Nurse. An individual who has official recognition as such by the S.C. State Board of Nursing.

EF. Ambulatory Surgical Facility. A facility organized and administered for the purpose of performing surgical procedures and/or endoscopy for which patients are scheduled to arrive, receive surgery, and be discharged on the same day.

1. The owner or operator shall make the facility available to other providers who comprise an organized professional staff, *i.e.*, an open medical staff (see Section 101.BB).

2. This definition does not apply to any facility used as an office or clinic for the private practice of licensed healthcare professionals (see Section 101.JJ).

FG. Anesthesiologist's Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

GH. Anesthesiologist. A physician who has completed a residency in anesthesiology.

HI. Anesthetic Agent. Any drug or combination of drugs administered parenterally or inhaled with the purpose of creating conscious or deep sedation.

J. Bad Debt. The amount a party has an obligation to pay, but that is considered uncollectible. Bad debt represents the portion of a patient's account not expected to be collected from the patient or other responsible party (the patient's portion). The patient's portion of a bill should not be categorized as bad debt for medically indigent patients. Bad debt must be differentiated from charity services. Patient charges

otherwise eligible for classification as charity care should only be treated as bad debt if all conditions of your facility's charity care criteria are not met.

IK. Certified Nursing Assistant. A person whose duties are assigned by a licensed nurse and who has successfully completed a state-approved training program or course with a curriculum prescribed by the South Carolina Department of Health and Human Services, holds a certificate of training from that program or course and is listed on the South Carolina Registry of Certified Nurse Aides.

JL. Certified Registered Nurse Anesthetist. A registered nurse who is authorized to practice as a certified registered nurse anesthetist by the S. C. State Board of Nursing.

M. Charity Care. Any unpaid charges for services to patients as defined in S.C. Code Ann. Section 44-6-5(5). Only the portion of a patient's account that meets the facility's charity care criteria is recognized as charity.

N. Contractual Adjustments. Any charges that are not paid by third-party payers and cannot be billed to the patient pursuant to contractual agreements. Contractual adjustments for Medicare, Medicaid and other payers should be captured separately.

KO. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act and the S.C. Controlled Substances Act.

LP. Consultation. A visit by Department representatives who will provide information to the licensee in order to facilitate compliance with these regulations.

MQ. Dentist. An individual currently licensed by the S.C. Board of Dentistry to practice dentistry.

NR. Department. The S.C. Department of Health and Environmental Control (DHEC).

OS. Direct Care Staff Member. An individual who provides care, treatment, surgery, and/or services, or performs procedures for a patient.

PT. Endoscopy. Visual inspection of any cavity of the body by means of an endoscope.

QU. Existing Facility. A facility that was in operation and/or one that began the construction or renovation of a building, for the purpose of operating the facility, prior to the promulgation of this regulation. The licensing standards governing new facilities apply if and when an existing facility is not continuously operated and licensed under this regulation.

RV. Facility. An ambulatory surgical facility licensed by the Department.

W. Gross Indigent and Charity Care Patient Charges. The total uncompensated charges for patients who qualify as indigent or charity under the relevant definitions.

X. Gross Patient Revenue. Includes charges generated by all patients at full-established rates before provisions for contractual and other adjustments are applied. Include any revenue forgone for provision of care for indigent/charity patients at full-established rates.

SY. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, physician assistant, or advanced practice registered nurse, or by a registered nurse, pursuant to standing orders approved by a physician, as evidenced by the physician's signature in accordance with facility policy.

Z. Indigent and Charity Care Write-Offs. Unpaid charges for indigent and charity care cases should be related only to the provision of ambulatory surgical facility services that are licensed and regulated by the Department. Unpaid charges from other lines of business should not be included.

AA. Indigent Care. Any unpaid charges for services to medically indigent patients as defined in S.C. Code Ann. Section 44-6-5(5). Unpaid charges for patients who were eligible for Medicare, Medicaid, Third Party, or patients provided other free care are not included in Indigent Care.

FBB. Inspection. A visit by Department representative(s) for the purpose of determining compliance with this regulation.

UCC. Investigation. A visit by Department representative(s) to a licensed or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to this regulation.

VDD. Initial License. A license granted to a new facility.

WEE. Legally Authorized Healthcare Provider. An individual authorized by law and currently licensed in S.C. to provide specific medical care, treatment, procedures, surgery, and/or services to patients. Examples of individuals who may be authorized by law to provide the aforementioned care, treatment, procedures, surgery, and/or services may include, but are not limited to, advanced practice registered nurses, and physician assistants.

XFF. Legend Drug.

1. A drug required by federal law to be labeled with any of the following statements prior to being dispensed or delivered:

- a. "Caution: Federal law prohibits dispensing without prescription";
- b. "Rx only."

2. A drug required by federal or state law to be dispensed pursuant to a prescription drug order or restricted to use by practitioners only;

3. Any drug products designated by the S.C. Board of Pharmacy to be a public health threat; or

4. Any prescribed compounded prescription within the meaning of the Pharmacy Act.

YGG. License. A certificate issued by the Department to an Ambulatory Surgical Facility to provide care, treatment, procedures, surgery, and/or services.

ZHH. Licensed Nurse. An individual currently licensed by the S.C. State Board of Nursing as a registered nurse or licensed practical nurse.

AAII. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care, treatment, procedures, surgery, and/or services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

BBJJ. New Facility. All buildings or portions of buildings, new and existing, that are:

1. Being licensed for the first time;
2. Providing a different service that requires a change in the type of license;
3. Being licensed after the previous licensee's license has been revoked, suspended, or after the previous licensee has voluntarily surrendered the license and the facility has not continuously operated.

~~CC~~KK. Open Medical Staff. Members of the medical staff, which includes physicians, dentists, or podiatrists, of an ambulatory surgical facility, that have individually submitted application to the facility, and subsequently been approved to perform surgery/procedures in accordance with criteria established by the facility for approving qualified applicants.

~~DD~~LL. Operating Room. A room in which surgery is performed.

MM. Other Free Care. Other uncompensated care provided as a result of employee discounts, administrative adjustments, courtesy discounts, small bill write-offs, or other similar write-offs not based on a patient's inability to pay. Should not include amounts properly classified as "contractual adjustments."

NN. Other Revenue. Other revenues or gains are derived from services other than providing services to patients. This may include revenues shared with the facility from another organizational entity.

~~EE~~OO. Nonlegend Medication. A medication that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws of this State and the Federal government.

~~FF~~PP. Pharmacist. An individual currently registered as such by the S.C. Board of Pharmacy.

~~GG~~QQ. Physical Examination. An examination of a patient by a physician or physician assistant that addresses those issues identified in Section 802 of this regulation.

~~HH~~RR. Physician. An individual currently licensed as such by the S.C. Board of Medical Examiners.

~~HSS~~. Physician Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

~~JTT~~. Podiatrist. An individual currently licensed as such by the S.C. Board of Podiatry Examiners.

~~KK~~UU. Private Practice. An individually-licensed physician or group of licensed physicians who practice together at a certain location/address in a legally-constituted professional corporation, association, or partnership; patient encounters in the office or clinic are for the purpose of diagnosis and treatment, and not limited primarily to the performance of surgery and related care, treatment, procedures, and/or services.

~~LL~~VV. Procedure Room. A room where procedures not requiring general anesthesia can be safely performed.

~~MM~~WW. Quality Improvement Program. The process used by a facility to examine its methods and practices of providing care, treatment, procedures, surgery, and/or services, identify the ways to improve its performance, and take actions that result in higher quality of care, treatment, procedures, surgery, and/or services for the facility's patients.

~~NN~~XX. Recovery Area. An area used for the recovery of patients.

ΘΘYY. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a 36-month period. The time-period determinant of repeat violation status is not interrupted by ownership changes.

ΠΠZZ. Responsible Party. A person who is authorized by law to make decisions on behalf of a patient, including, but not limited to, a court-appointed guardian or conservator, or person with a health care power of attorney or other durable power of attorney.

QQAAA. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.

RRBBB. Same Day. A period of time not to exceed twenty-four (24) hours after admission.

SSCCC. Staff Member. An adult who is a compensated employee of the facility on either a full or part-time basis.

ΤΤDDD. Surgery. Treatment of conditions by operative means involving incision, whether with a scalpel or a laser, followed by removal or repair of an organ or other tissue.

UUEEE. Surgical Suite. An area that includes one or more operating rooms and a recovery area.

VVFFF. Surgical Technologist. An individual who meets one of the requirements listed in 1976 Code Section 44-7-380(B)(1)(a) – (d) to practice surgical technology in South Carolina.

WWGGG. Suspension of License. An action by the Department requiring a facility to cease operation for a period of time or to require a facility to cease admitting patients until such time as the Department rescinds that restriction.

HHH. Total Expenses. The sum of resources consumed in fulfillment of a facility’s ongoing major or central operations. Expenses may result from current expenditures, incurring obligations to make future expenditures, or consuming resources obtained from previous expenditures. Expenses related to activities shared with entities other than the ambulatory surgical facility should be allocated between the entities. The expense component not allocated to the ambulatory surgical facility should not be included in the report. Appropriate matching of revenues and expenses excluded from the report should be made. Do not include bad debt as a total expense, but as a deduction from revenue.

III. Total Gross Revenue. The total revenue for the facility from all patient revenue and from other revenues or gains derived from services other than providing services to patients.

JJJ. Total Indigent and Charity Compensation. Funds provided by all public and private sources that are earmarked as compensation to offset uncompensated charges from indigent or charity care cases.

102. References.

The following publications/standards are referenced in this regulation:

A. Departmental:

1. R.61-4, *Controlled Substances*;

2. R.61-12, *Standards for Licensing Abortion Clinics*;
3. R.61-16, *Standards for Licensing Hospitals and Institutional General Infirmaries*;
4. R.61-20, *Communicable Diseases*;
5. R.61-25, *Retail Food Establishments*;
6. R.61-58, *State Primary Drinking Water Regulations*;
7. R.61-63, *Title A, Rules and Regulations for Radioactive Materials*;
8. R.61-64, *X-Rays, (Title B)*;
9. R.61-67, *Standards for Wastewater Facility Construction*;
10. R.61-105, *Infectious Waste Management Regulations*;
11. Guidelines for Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings.

B. Non-Departmental:

1. American Association of Blood Banks;
2. American National Standards Institute (ANSI);
3. American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE);
4. Bloodborne Pathogens Standards, Occupational Safety and Health Act (OSHA) of 1970;
5. Civil Rights Act of 1964;
6. Centers for Disease Control and Prevention (CDC);
7. International Building Code (IBC);
8. National Fire Protection Association (NFPA);

103. License Requirements (II).

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise/market) as an ambulatory surgical facility in S.C. without first obtaining a license from the Department. No such party shall provide care, treatment, procedures, surgery, and/or services to patients prior to the effective date of licensure. Upon the Department's determination that such party provides care, treatment, procedures, surgery, and/or services without a Department-issued license, the party shall cease operation immediately and ensure safety, health, and well-being of the patients. Current or previous violations of the S.C. Code and/or Department regulations may jeopardize the issuance of a license or licensing of another facility or addition to an existing facility owned or operated by the violating licensee. (I)

B. Compliance. An initial license shall not be issued to a proposed facility that has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed facility is in substantial compliance with the licensing standards. In the event a licensee who already has a facility/activity licensed by the Department makes application for another facility or increase in licensed capacity, the currently licensed facility/activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or an amended license to the existing facility. A copy of the licensing standards shall be maintained at the facility and accessible to all staff members. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

C. Compliance with Structural Standards. Facilities possessing a license issued prior to January 1, 2016 are considered in compliance with Section 1703 without modification of its licensed structure.

D. Licensed Capacity. No facility that has been licensed for a set number of operating rooms or procedure rooms shall exceed that number of operating or procedure rooms or establish new care, treatment, procedures, surgery, and/or services without first obtaining authorization from the Department. (I)

E. Issuance and Terms of License.

1. A license is issued by the Department and shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, treatment, procedures, surgery, and/or services, personal safety, fire safety, or the well-being of any patient or occupant of a facility.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this State.

4. A license shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

5. Facilities owned by the same entity but not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, *e.g.*, interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property.

6. Separate licenses are not required, but may be issued, for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

7. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

8. A facility shall provide only the care, treatment, procedures, surgery, and/or services of which it is capable and equipped to provide, and has been authorized by the Department to provide pursuant to the definition in Section 101.E of this regulation.

9. Abortions shall not be performed in an ambulatory surgical facility unless it is also licensed as an abortion clinic pursuant to R.61-12.

F. Facility Name. No proposed facility shall be named nor shall any existing facility have its name changed to the same or similar name as any other facility licensed in S.C. The Department shall determine if names are similar. If the facility is part of a “chain operation” it shall then have the geographic area in which it is located as part of its name.

G. Application. Applicants for a license shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes the applicant’s oath, assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in the event his or her address is different from that of the facility, and the names of the persons in control of the facility. The Department may require additional information, including affirmative evidence of the applicant’s ability to comply with these regulations. Corporations or partnerships shall be registered with the S.C. Office of the Secretary of State. Applicants shall make payment of all outstanding fees (initial licensure fees, annual licensure fees, inspection fees, construction fees, etc.) prior to the Department’s issuance of a license.

H. Fees. The initial and annual license fee shall be \$150.00 per operating/procedure room or \$600.00, whichever is greater. ~~Such fee shall be made payable by check or money order to the Department and is not refundable. The Department may charge a fee for plan reviews, construction inspections and licensing inspections. All fees are non-refundable and shall be made payable to the Department via a secured portal or specific website.~~

I. Late Fee. Failure to submit a renewal application after the license expiration date may result in a late fee of 25% of the licensing fee amount, in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time-period specified by the Department may result in an enforcement action.

J. License Renewal. To renew a license, an applicant shall file an application with the Department and pay a license fee. If the license renewal is delayed due to enforcement action, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department or when the adjudicatory process is completed, whichever is applicable. If an application is denied, a portion of the fee shall be refunded based upon the remaining months of the licensure year.

K. Change of License.

1. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

- a. Change of ownership;
- b. Reallocation of types of operating or procedure rooms as shown on the license;
- c. Change of facility location from one geographic site to another;

d. The addition or replacement of a surgical suite or any part thereof, or the deletion of operating or procedure rooms.

2. Changes in facility name or address (as notified by the post office) shall be accomplished by application or by letter from the licensee.

L. An ambulatory surgical facility license shall not be required for, nor shall such a license be issued to:

1. Facilities operated by the federal government;

2. Ambulatory surgical services or procedures provided in licensed hospitals (such services remain within the purview of R.61-16);

3. Private practices (see Section 101.JJ).

M. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well-being of the patients are not compromised, and provided the standard is not specifically required by statute.

N. Indigent/Charity Care. Any Facility established or constructed after May 16, 2023, and which did not require a Certificate of Need, must provide indigent charity care as described below in Section 103.N.2 after it has been in operation for two calendar years:

1. Annual Reports: After being in operation for two calendar years, a Facility subject to Section 103.N shall submit annual reports in a form prescribed by the Department and located on the Department's website. Further, a Facility subject to Section 103.N shall submit the annual reports by a deadline set by the Department and indicated on the Department's website. The annual reports shall include, but not be limited to the following information:

a. Gross patient revenue;

b. Medicare contractual adjustments;

c. Medicaid contractual adjustments;

d. Other contractual adjustments;

e. Bad debt;

f. Indigent care gross charges;

g. Indigent care compensation;

h. Charity care gross charges;

i. Charity care compensation;

j. Other free care;

k. Other revenue; and

l. Total expenses.

2. Indigent/Charity Care requirements:

a. If the Facility provides care to Medicaid beneficiaries, it must provide uncompensated indigent/charity care to the underinsured or medically indigent in an amount equal to or greater than 2% of its adjusted gross revenue; or

b. If the Facility does not provide care to Medicaid beneficiaries, it must provide uncompensated indigent/charity care to the underinsured or medically indigent in an amount equal to or greater than 3% of its adjusted gross revenue.

c. Noncompliance with Section 103.N.2.a or -b shall result in a monetary penalty in the amount of the difference between the services which the Facility is required to provide and the amount it actually provided.

SECTION 200

ENFORCING REGULATIONS

201. General.

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

202. Inspections/Investigations.

A. An inspection shall be conducted prior to initial licensing of a facility and subsequent inspections conducted as deemed appropriate by the Department. Other regulatory-related inspections may be considered in determining the appropriateness of Department inspections, e.g., Joint Commission on Accreditation of Health Care Organizations (JCAHO), Accreditation Association for Ambulatory Health Care (AAAHC), American Osteopathic Association (AOA), American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) inspections.

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the Department.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records, and have the authority to require the facility to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. (II)

D. A facility found noncompliant with the standards of this regulation shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar);
3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the facility response, shall be made available upon written request with the redaction of the names of those individuals in the report as provided by § 44-7-310 and 315 of the S.C. Code Ann. (2002).

F. Inspection Fees. The Facility shall pay the inspection fee for initial, relocation, routine inspection, and routine follow-up. The Facility shall pay a fee for unit increase of service modification or follow-up.

<u>Initial/Relocation Inspection Fee</u>	<u>Calculated - \$350 + \$45 per operating, endoscopy, and procedure room</u>
<u>Initial/Relocation Follow-Up Fee</u>	<u>Calculated - \$200 + \$45 per operating, endoscopy, and procedure room</u>
<u>Routine Inspection Fee</u>	<u>Calculated - \$350 + \$45 per operating, endoscopy, and procedure room</u>
<u>Routine Follow-Up Fee</u>	<u>Calculated - \$350 + \$45 per operating, endoscopy, and procedure room</u>
<u>Unit Increase or Service Modification Fee</u>	<u>Calculated - \$200 + \$45 per operating, endoscopy, and procedure room</u>
<u>Unit Increase of Service Modification Follow-Up Fee</u>	<u>Calculated - \$200 + \$45 per operating, endoscopy, and procedure room</u>

G. Construction Fees. The Facility shall pay the following inspection fees during the construction phase of the project.

<u>Construction Inspection Fees</u>	
<u>Plan Inspection</u>	
<u>Total Project Cost</u>	<u>Fee</u>
<u>< \$10,001</u>	<u>\$750</u>
<u>\$10,001 - \$100,000</u>	<u>\$1,500</u>
<u>\$100,001 - \$500,00</u>	<u>\$2,000</u>
<u>> \$500,000</u>	<u>\$2,500 plus \$100 for each additional \$100,000 in project costs</u>
<u>Site Inspection</u>	<u>\$500</u>

SECTION 300

ENFORCEMENT ACTIONS

301. General.

When the Department determines that a facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice to the licensee, may impose a mandatory penalty and/or deny, suspend, and/or revoke its license.

302. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of the persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or

operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time established by the Department may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety, or well-being of persons in the facility. The citation of a Class II violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. The notations “(I)” or “(II)”, placed within sections of this regulation, indicate that those standards are considered Class I or II violations, if they are not met, respectively. Standards not so annotated are considered Class III violations.

E. In arriving at a decision to take enforcement actions, the Department shall consider the following factors: specific conditions and their impact or potential impact on health, safety, or well-being of the patients; efforts by the facility to correct cited violations; behavior of the licensee that reflects negatively on the licensee’s character, such as illegal or illicit activities; overall conditions; history of compliance; and any other pertinent factors that may be applicable to current statutes and regulations.

F. When a decision is made to impose monetary penalties, the following schedule shall be used as a guide to determine the dollar amount:

**Frequency of violation
of standard within a
36-month period:**

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	\$ 500 - 1,500	\$ 300 - 800	\$ 100 - 300
2nd	1,000 - 3,000	500 - 1,500	300 - 800
3rd	2,000 - 5,000	1,000 - 3,000	500 - 1,500
4th	5,000	2,000 - 5,000	1,000 - 3,000
5th	7,500	5,000	2,000 - 5,000
6th	10,000	7,500	5,000

G. Any enforcement action taken by the Department may be appealed in a manner pursuant to the Administrative Procedures Act, 1976 Code Section 1-23-310, et seq.

SECTION 400

POLICIES AND PROCEDURES

401. General (II).

~~A. The Facility shall maintain and adhere to Ppolicies and procedures addressing each section of this regulation regarding care, treatment, procedures, surgery, and/or services, patient rights, and the operation of the facility shall be developed and implemented, and revised as required in order to accurately reflect actual facility operation. The policies and procedures shall follow current accepted standards of medical and surgical practice to ensure services are provided in a manner which protects the health and safety of patients. The Facility shall be in full compliance with the policies and procedures. The licensee shall establish a time period for review of all policies and procedures. These policies and procedures shall be accessible in each facility at all times, either by hard copy or electronically.~~

~~B. Policies and procedures shall describe the means by which the facility shall assure that the standards described in this regulation that the licensee has agreed to meet, as confirmed by signature on the application for licensing, will be met (see Section 1601.B). The Facility shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented. The Facility shall ensure all policies and procedures are accessible to staff at all times, either by hard copy or electronically.~~

SECTION 500

STAFF

501. General (II).

A. A facility shall be fully staffed in sufficient numbers and training as required by this Section at all times a patient is in the facility or the facility is open to accept patients, in order to:

1. Effectively meet the needs and condition of the patients, to include the demands of effective emergency on-site action that might arise;
2. Properly operate equipment in accordance with the equipment manufacturer's recommendations;
3. Adhere to current professional organizational standards;
4. Comply with all local, state, and federal laws.

B. The facility shall provide additional staff members if the Department determines that the facility staff on duty is inadequate to provide appropriate care, treatment, procedures, surgery, and/or services to the patients of a facility.

C. All staff members shall be assigned duties and responsibilities in accordance with the individual's capability that shall be in writing and be reviewed on an annual basis by the staff member and supervisor.

D. There shall be accurate current information maintained regarding all staff members of the facility, to include at least an address, phone number, and health and personal/work/training background. For those staff members who are licensed/certified, a copy of the license/certificate shall be available for review.

E. Direct care staff members of the facility shall not have a prior conviction or have pled no contest (nolo contendere) within the last 10 years for child or adult abuse, neglect, exploitation, or mistreatment, or for sexual assault or assault with a deadly weapon. Facilities may take certain considerations into account regarding criminal records when making hiring decisions, i.e., discretion may be exercised regarding convictions/nolo contendere pleas occurring more than 10 years ago and may determine that an applicant, who would otherwise be disqualified, could be hired. (I)

F. A staff member shall not have an active dependency on a psychoactive substance(s) that would impair his or her ability to perform assigned duties. (I)

502. Administrator (II).

A. The facility shall have an administrator who shall be capable of meeting the responsibilities of operating the facility to ensure that it is in compliance with these regulations, and shall demonstrate adequate knowledge of these regulations. An administrator appointed subsequent to the promulgation of this regulation shall be a registered nurse or shall have a baccalaureate or associate degree with at least three years experience in a health-related field within the past five years.

B. A staff member shall be designated, by name or position, in writing, to act in the absence of the administrator.

503. Control (I).

The Facility must have a governing body designated in writing by the licensee that assumes full responsibility for determining, implementing, and monitoring policies governing the Facility's total operations. The governing body has oversight and accountability for the quality improvement program, and ensures that Facility policies and programs are administered so as to provide quality health care in a safe environment.

503504. Medical Director (II).

A. There shall be a medical director of the facility who is a physician.

B. The administrator and medical director may be the same individual.

504505. Medical Staff (I).

A. Physicians, dentists, and podiatrists performing surgery and/or procedures shall be appropriately licensed to perform these functions as well as adequately trained in any special requirements that are necessary to perform such surgery/procedures, including being board certified or board eligible.

B. Privileges for each physician, dentist, and podiatrist performing surgery/procedures shall be in accordance with criteria that the facility has established and approved.

C. There shall be a roster of medical staff having surgery, procedures, and anesthesia privileges at the facility, specifying the privileges and limitations of each and a current listing of all types of surgery and/or procedures offered by the facility.

D. A physician shall be physically present or available within 30 minutes until all patients have departed the premises.

E. There shall be at least one physician on staff who has admitting privileges at one or more hospitals.

505506. Nursing Staff (I).

A. An adequate number of licensed nurses shall be on duty to meet the total nursing needs of patients.

B. At least one registered nurse shall be on duty whenever patients are present in the facility.

C. Nursing staff shall be assigned to duties consistent with their scope of practice as determined through their licensure and educational preparation.

506507. Advanced Cardiac Life Support (I).

A. An individual who possesses a valid Advanced Cardiac Life Support credential shall be on duty in the facility whenever patients are present in the facility.

B. An individual who possesses a valid Pediatric Advanced Life Support credential shall be on duty in the facility whenever pediatric patients are present in the facility.

507508. Inservice Training (II).

A. Training for the tasks each staff member performs shall be conducted in order to provide the care, treatment, procedures, surgery, and/or services delineated in Sections 501.A and 800.

B. The following training shall be provided to staff members by appropriate resources, e.g., licensed or registered persons, video tapes, books, *etc.*, to all staff members in context with their job duties and responsibilities, prior to patient contact and at a frequency determined by the facility, but at least annually:

1. Cause, effect, transmission, prevention, and elimination of infections, to include management and care of persons with contagious and/or communicable disease, e.g., hepatitis, tuberculosis, HIV infection;

2. OSHA standards regarding bloodborne pathogens;

3. Confidentiality of patient information and records and the protection of patient rights;

4. Emergency procedures and disaster preparedness within 24 hours of their first day on the job in the facility (see Section 1200).

5. Fire response training within 24 hours of their first day on the job in the facility (see Section 1303);

6. Aseptic techniques such as handwashing and scrubbing practices, proper gowning and masking, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of equipment and supplies.

C. All licensed nurses shall possess a valid cardio-pulmonary resuscitation (CPR) certificate within three months from the first day on the job in the facility; a staff member with a valid CPR certificate shall be on duty whenever patients are present in the facility.

D. All newly-hired staff members shall be oriented to acquaint them with the facility organization and physical plant, specific duties and responsibilities of staff members, and patients' needs.

508509. Health Status (I).

A. All staff members who have contact with patients shall have, within 12 months prior to initial patient contact, a health assessment as defined in Section 101.R.

B. The health assessment shall include a tuberculin skin test as described in Sections 1505 and 1506.

C. If a staff member is working at multiple facilities operated by the same licensee, copies of records for tuberculin skin testing and the pre-employment health assessment shall be acceptable at each facility.
(II)

SECTION 600

REPORTING

601. Accidents/Incidents (II).

A. The licensee shall report a record of each accident and/or incident occurring at the facility to the Department within five (5) days of occurrence. Reports submitted to the Department shall contain only: facility name, license number, type of accident/incident, date of accident/incident occurred, number of patients directly injured or affected, patient medical record identification number, patient age and sex, number of staff directly injured or affected, number of visitors directly injured or affected, witness(es) name(s), identified cause of accident/incident, internal investigation results if cause unknown, a brief description of the accident/incident including location where occurred, and treatment of injuries. The report retained by the facility, in addition to the minimum reported to the Department, shall contain: names of patient(s), staff, and/or visitor(s), the injuries and treatment associated with each patient, staff, and/or visitor. Records of all accidents and incidents shall be retained by the facility for ten (10) years after the patient stops receiving services at the facility.

B. The licensee shall report each accident and/or incident resulting in unexpected death or serious injury to the next of kin or party responsible for each affected individual at the earliest practicable hour, not exceeding twenty-four (24) hours. The licensee shall notify the Department immediately, not to exceed twenty-four (24) hours, via telephone, email or facsimile. The licensee shall submit a report of the licensee's investigation of the accident and/or incident to the Department within five (5) days. Accidents and/or incidents requiring reporting include, but are not limited to,:

1. ~~Abuse, Neglect or Exploitation (Confirmed);~~
2. ~~Abuse, Neglect or Exploitation (Suspected);~~
3. ~~Criminal event against patient;~~
4. ~~Death;~~
5. ~~Fall resulting in fracture of bone or joint;~~
6. ~~Hospitalization as a result of accident/incident;~~
7. ~~Medication Error;~~
8. ~~Procedures on wrong person;~~
9. ~~Procedures on wrong site;~~
10. ~~Severe burn;~~
11. ~~Severe hematoma;~~

~~12. Severe laceration;~~

~~13. Attempted suicide; or~~

~~14. Anesthesia apparatus malfunction;~~ Surgical or Invasive Procedure Events

a. Surgery or other invasive procedure performed on the wrong site;

b. Surgery or other invasive procedure performed on the wrong patient;

c. Wrong surgical or other invasive procedure performed on a patient;

d. Unintended retention of a foreign object in a patient after surgery or other invasive procedure;

and

e. Intraoperative or immediately/postprocedure death.

2. Product or Device Events

a. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the Facility;

b. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended; and

c. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in the Facility.

3. Patient Protection Events

a. Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person;

b. Patient death or serious injury associated with patient elopement; and

c. Patient suicide, attempted suicide, or self-harm that results in serious injury while being cared for in the Facility.

4. Care Management Events

a. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration);

b. Patient death or serious injury associated with unsafe administration of blood products;

c. Patient death or serious injury associated with a fall while being cared for in the Facility;

d. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.

5. Environmental Events

a. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in the Facility;

b. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances;

c. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in the Facility; and

d. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in the Facility.

6. Potential Criminal Events

a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;

b. Abduction of any patient of any age;

c. Sexual abuse/assault on a patient or staff member within or on the grounds of the Facility; and

d. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the Facility.

602. Fire/Disasters (II).

A. The Department shall be notified immediately via telephone, email or facsimile regarding any fire in the facility, and followed by a complete written report, to include fire department reports, if any, to be submitted within a time-period determined by the facility, but not to exceed seventy-two (72) hours from the occurrence of the fire.

B. Any natural disaster that requires displacement of the patients or jeopardizes or potentially jeopardizes the safety of the patients, shall be reported to the Department via telephone, email or facsimile immediately, with a complete written report submitted within a time-period as determined by the facility, but not to exceed seventy-two (72) hours.

C. Where a required fire protection system is out of service, the facility shall notify the fire department and the fire code official immediately, and where required by the fire code official, the building shall either be evacuated or the facility shall provide an approved fire watch for all occupants left unprotected by the shut down until the fire protection system has been returned to service, as applicable to Division of Health Facilities Construction (DHFC) Guidelines Manual.

603. Communicable Diseases (I).

All cases of diseases that are required to be reported to the appropriate county health department shall be accomplished in accordance with R.61-20.

604. Administrator Change.

The Department shall be notified in writing by the licensee within 10 days of any change in administrator. The notice shall include at a minimum the name of the newly-appointed individual, documented qualifications as required by Section 502, and the effective date of the appointment.

605. Joint Annual Report.

Facilities shall complete and return a “Joint Annual Report” to the Department’s Planning and Certificate of Need Division within the time-period specified by that division.

606. Accounting of Controlled Substances (I).

Any facility registered with the Department’s Bureau of Drug Control and the federal Drug Enforcement Agency shall report any theft or loss of controlled substances to local law enforcement and to the Bureau of Drug Control within three working days of the discovery of the loss/theft. Any facility permitted by the S.C. Board of Pharmacy shall report the loss or theft of drugs or devices within three working days of the discovery of the loss/theft.

607. Facility Closure.

A. Prior to the permanent closure of a facility, the Department shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the facility shall notify the Department of the provisions for the maintenance of the records. On the date of closure, the current original license shall be returned to the Department.

B. In instances where a facility temporarily closes, the Department shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards to the facility prior to its reopening. If the facility is closed for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

608. Zero Census.

In instances when there have been no patients in a facility for any reason, for a period of 90 days or more, the facility shall notify the Department in writing no later than the 100th day following the date of the last procedure/surgery performed. At the time of that notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the facility prior to any new and/or re-admissions to the facility. The facility shall still apply and pay the licensing fee to keep the license active despite being at zero census or temporarily closed. If the facility has no patients for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

SECTION 700

PATIENT RECORDS

701. Content (II).

A. The facility shall initiate and maintain an organized record for each patient. The record shall contain: sufficient documented information to identify the patient; the person responsible for each patient; the description of the diagnosis and the care, treatment, procedures, surgery, and/or services provided, to include the course of action taken and results; and the response and reaction to the care, treatment, procedures, surgery, and/or services provided. All entries shall be indelibly written, authenticated by the author, and dated.

B. Specific entries/documentation shall include at a minimum:

1. Consultations by physicians or other legally authorized healthcare providers;
2. Physical examination report, including pertinent medical history;
3. Orders and recommendations for all care, treatment, procedures, surgery, and/or services from physicians or other legally authorized healthcare providers, completed prior to, or at the time of patient arrival at the facility, and subsequently, as warranted;
4. Care, treatment, procedures, surgery, and/or services provided;
5. Record of administration of each dose of medication;
6. Medications administered and procedures followed if an error is made;
7. Special procedures and preventive measures performed, *e.g.*, isolation for symptoms of tuberculosis;
8. Notes of observation during recovery, to include vital signs pre- and post-operative;
9. Discharge summary, including condition at discharge or transfer, instructions for self-care and instructions for obtaining postoperative emergency care;
10. Special information, *e.g.*, allergies, *etc.* Documentation regarding organ donation shall be included in the record at the patient's request;
11. Signed informed consent;
12. If applicable, anesthesia records of pertinent preoperative and postoperative reports including pre-anesthesia evaluation, type of anesthesia, technique and dosage used, and post-anesthesia follow-up note;
13. Operative report (dictated or written into the record after surgery/procedure) to include at least:
 - a. Description of findings;
 - b. Techniques utilized to perform procedure/surgery;
 - c. Specimens removed, if applicable;
 - d. Primary surgeon and assistants.

14. Reports of all laboratory, radiological, and diagnostic procedures along with tests performed and the results appropriately authenticated.

C. Except as required by law, patient records may contain written and interpretative findings and reports of diagnostic studies, tests, and procedures, *e.g.*, interpretations of imaging technology and video tapes without the medium itself.

702. Authentication.

A. Each document generated by a user shall be separately authenticated.

B. Written signatures or initials and electronic signatures or computer-generated signature codes are acceptable as authentication.

C. In order for a facility to employ electronic signatures or computer-generated signature codes for authentication purposes, staff shall be identified who are authorized to authenticate patient records utilizing electronic or computer-generated signatures.

1. At a minimum, the facility shall provide authentication safeguards to ensure confidentiality, including, but not limited to, the following:

a. Each user shall be assigned a unique identifier that is generated through a confidential code;

b. The facility shall certify in writing that each identifier is kept strictly confidential. This certification shall include a user's commitment to terminate his or her use of an assigned identifier if it is found that the identifier has been misused, meaning that the user has allowed another person(s) to use his or her personally-assigned identifier, or that the identifier has otherwise been inappropriately utilized;

c. The user shall certify in writing that he or she is the only person with access to the identifier and the only person authorized to use the signature code.

2. The authentication system shall include a verification process to insure that the content of authenticated entries is accurate. The verification process shall include, at a minimum, the following provisions:

a. Blanks, gaps, obvious contradictory statements, or other documentation that require the attention of the authorized user shall be considered authenticated until reviewed and corrected by the user and a revised report issued;

b. Opportunity shall be provided for the user to verify that the document is accurate and that the signature has been properly recorded.

3. A user may terminate authorization for use of electronic or computer-generated signature upon written notice to the individual responsible for the maintenance of patient records.

D. The use of rubber stamp signature is acceptable under the following conditions:

1. The individual whose signature the rubber stamp represents shall be the only individual who has possession of and utilizes the stamp;

2. The individual places in the administrative offices of the facility a signed statement indicating that he or she is the only individual who has possession of and shall utilize the stamp;

3. Rubber stamp signatures are not permitted on orders for medications listed as “controlled substances” pursuant to R.61-4.

703. Record Maintenance.

A. The licensee shall provide accommodations, space, supplies, and equipment adequate for the protection, security, and storage of patient records.

B. When a patient is transferred to an emergency facility, a transfer summary to include, at a minimum, the diagnosis and medication administration record, shall accompany the patient to the receiving facility at the time of transfer or forwarded immediately after the transfer. Documentation of the information forwarded shall be maintained in the facility’s patient record. (I)

C. The patient record is confidential. Records containing protected or confidential health information shall be made available only to individuals granted access to that information, in accordance with state and federal laws. The facility shall have a written policy designating the persons allowed to access confidential patient information. (II)

D. Records generated by organizations or individuals contracted by the facility for care, treatment, procedures, surgery, and/or services shall be maintained by the facility that has admitted the patient. Appropriate information shall be provided to assure continuity of care.

E. The facility shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by facility staff, as needed, and for regulatory compliance inspections.

F. Upon discharge of a patient, the record shall be completed within 60 days and filed in an inactive/closed file maintained by the licensee. Prior to the closing of a facility for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations and other applicable law. The licensee shall notify the Department, in writing, describing these arrangements and the location of the records.

G. Records of patients shall be maintained for at least six years following the discharge of the patient. Other documents required by the regulation, *e.g.*, fire drills, shall be retained at least 12 months or until the next Department inspection, whichever is longer.

H. Patient records are the property of the facility; the original record shall not be removed without court order. (II)

SECTION 800

CARE/TREATMENT/PROCEDURES/SURGERY/SERVICES

801. General (I).

A. Care, treatment, procedures, surgery, and/or services shall be provided, given, or performed effectively and safely in accordance with orders from physicians or other legally authorized healthcare providers, and precautions shall be taken for patients with special conditions, *e.g.*, pacemakers, pregnancy,

Alzheimer's disease, etc., and/or for those who may be susceptible to deleterious effects as a result of the treatment.

B. The facility shall comply with all current federal, state, and local laws and regulations related to patient care, treatment, procedures, surgery, and/or services, and protection.

C. When a facility engages a source other than the facility to provide services normally provided by the facility, *e.g.*, staffing, training, food service, maintenance, housekeeping, there shall be a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and a statement that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to patient care, treatment, procedures, surgery, and/or services, confidentiality, and rights. (II)

D. The Facility shall have a written transfer agreement with one (1) or more hospitals that provides reasonable assurance that transfer of patients will be made between the hospital and the facility. The transfer agreement shall be dated and signed by authorized officials who are a party to the agreement. The agreement shall be updated following a change of Administrator; the agreement shall be updated following changes in licensee or at any other time as deemed advisable to maintain or further improve continuity of care.

Exception: A facility which has attempted, but has been unable to secure such an agreement shall maintain documentation of its efforts, and shall provide the local hospitals written notice of its hours of operation and patient population.

802. Physical Examination (I).

A. A preoperative history and physical examination, pertaining to the procedure to be performed, shall be completed by a physician or legally authorized healthcare provider no earlier than 14 days prior to surgery/procedure, or 30 days prior to surgery/procedure with the condition that, on the day of surgery/procedure, the physician or legally authorized healthcare provider documents no notable changes in the original history and physical examination. If notable changes are discovered at that time, a history and physical examination shall be completed. A discharge summary from a health care facility that includes a history and physical examination may be acceptable as the preoperative history and physical examination, provided the summary is within the time requirements of this section, and is reviewed by the physician or legally authorized healthcare provider performing the surgery/procedure.

B. If a patient or potential patient has a communicable disease, a physician or other legally authorized healthcare provider shall insure that the facility has the capability to provide adequate care and prevent the spread of the disease, and that the staff members are adequately trained and qualified to manage the patient, or transfer the patient to an appropriate facility, if necessary.

803. Surgical Services.

If surgical services are provided, a current listing of all types of surgical services offered by the facility shall be available.

804. Anesthesia Services (I).

A. Anesthesia shall be administered only by:

1. An anesthesiologist;

2. A physician, other than an anesthesiologist, or dentist, or podiatrist who is qualified to administer anesthesia pursuant to the S.C. Code of Laws;

3. A certified registered nurse anesthetist; or

4. An anesthesiologist's assistant.

B. Immediately before surgery:

1. A physician must examine the patient to evaluate the risk of the procedure to be performed; and

2. A physician, certified registered nurse anesthetist, or anesthesiologist's assistant must examine the patient to evaluate the risk of anesthesia.

BC. After the administration of a general anesthetic, a patient shall be attended by a physician until the patient may be safely placed under post-operative/procedure supervision by the nursing staff who shall then attend the patient until he or she has regained full consciousness, or until the effects of the anesthetic have sufficiently subsided for the patient to be able to summon aid when needed.

805. Laboratory Services (II).

A. Each facility shall provide or make arrangements for obtaining laboratory services required in connection with the surgery/procedure to be performed.

B. Should the facility conduct tests that involve human specimens by utilizing any laboratory equipment such as finger-stick glucose, hemoglobin, monitoring devices, *etc.*, for the purpose of providing information for the diagnosis, prevention, or treatment of disease or impairment, or assessment of health, the facility shall obtain a Certificate of Waiver from the Clinical Laboratories Improvement Amendments (CLIA) Program through the Department's CLIA Program.

C. Laboratory supplies shall not be expired.

D. A pathologist shall examine all surgical specimens except for those types of specimens that the medical staff has determined and documented do not require examination.

806. Radiology Services (II).

A. Each facility shall have the capability of providing or obtaining diagnostic radiology services in connection with the surgery/procedure to be performed.

B. Those facilities where radiological equipment and materials are used shall be in compliance with R.61-63 and R.61-64.

807. Cardiovascular Care Services.

A. Prior to establishing or offering invasive cardiac procedures, including cardiac catheterization services, a facility must have applied for and be in the process of obtaining accreditation for such services from the American College of Cardiologists, Accreditation for Cardiovascular Excellence, or other nationally recognized accrediting organization approved by the Department with standards at least equal to those of the Accreditation for Cardiovascular Excellence or American College of Cardiologists. To continue providing such services, a facility must obtain such accreditation within two years from application unless

otherwise approved by the Department. Facilities must maintain documentation evidencing their application for accreditation and accreditation for such services. If a facility is denied accreditation or has its accreditation revoked, the facility must immediately notify the Department in writing, cease offering such services, and cannot resume offering such services until the facility is accredited or re-accredited.

B. Facilities that offer cardiac catheterization services shall have written protocols ensuring immediate, efficient, and safe transfer of patients to the nearest hospital with onsite cardiac surgery in the case of an emergency.

808. Adverse Conditions (I).

Patients in whom any adverse condition exists or in whom a complication is known or suspected to have occurred during or after the performance of the operative procedure shall remain in the facility until the condition/complication is eliminated, as determined by the physician, and the patient is stabilized. Patients requiring care for periods in excess of those set forth in Section 101.RR shall be transferred to a hospital.

808809. Patient Instruction (I).

Written instructions shall be issued to all patients upon discharge and shall include, at a minimum, the following:

- A. Signs and symptoms of possible complications;
- B. Telephone number of the facility or the attending physician or other knowledgeable professional staff member from the facility should any complication occur or question arise;
- C. An emergency telephone number should any complication occur. It shall be the responsibility of the attending physician to arrange for needed care;
- D. Limitations regarding activities, foods, *etc.*;
- E. Date for follow-up or return visit, if applicable.

SECTION 900

RIGHTS AND ASSURANCES

901. General (II).

A. The facility shall comply with all current federal, state, and local laws and regulations concerning patient care, treatment, procedures, surgery, and/or services, patient rights and protections, and privacy and disclosure requirements, *e.g.*, § 44-81-10, *et seq.*, S.C. Code Ann. (2002).

B. The facility shall comply with all relevant federal, state, and local laws and regulations concerning discrimination, *e.g.*, Title VII, Section 601 of the Civil Rights Act of 1964, and insure that there is no discrimination with regard to source of payment in the recruitment, location of patient, acceptance or provision of services to patients or potential patients, provided that payment offered is not less than the cost of providing services.

C. The facility shall develop and post in a conspicuous place in a public area of the facility a grievance/complaint procedure to be exercised on behalf of the patients that includes the address and phone number of the Department and a provision prohibiting retaliation should the grievance right be exercised.

D. Care, treatment, procedures, surgery, and/or services provided by the facility, and the charges for such, shall be delineated in writing. Patients shall be made aware of such charges and services, as verified by the signature of the patient or responsible party.

E. Patients shall be permitted to use the telephone and allowed privacy when making calls.

F. Adequate safeguards shall be provided for protection and storage of patients' personal belongings.

G. Patient rights shall be guaranteed, prominently displayed, and the facility shall inform the patient of these rights, to include, at a minimum:

1. The care, treatment, procedures, surgery, and/or services to be provided;
2. Informed consent for care, treatment, procedures, surgery, and/or services;
3. Respect for the patient's property;
4. Freedom from mental and physical abuse and exploitation;
5. Privacy while being treated and while receiving care;
6. Respect and dignity in receiving care, treatment, procedures, surgery, and/or services;
7. Refusal of treatment. The patient shall be informed of the consequences of refusal of treatment, and the reason shall be reported to the physician and documented in the patient record;
8. Refusal of experimental treatment and drugs. The patient's written consent for participation in research shall be obtained and retained in his or her patient record;
9. Confidentiality and privacy of records. Written consent by the patient shall be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's responsible party. The facility shall establish policies to govern access and duplication of the patient's record.

H. Except in emergencies, documentation regarding informed consent shall be properly executed prior to surgery/procedure.

SECTION 1000

MEDICATION MANAGEMENT

1001. General (I).

A. Medications, including controlled substances, medical supplies, intravenous solutions, and those items necessary for the rendering of first aid shall be properly managed in accordance with local, state, and federal laws and regulations, to include the securing, storing, and administering of medications, medical

supplies, first aid supplies, biologicals and their disposal when discontinued or expired, or at discharge, death, or transfer of a patient.

B. Non-legend medications that can be obtained without a prescription may be retained and labeled as stock in the facility for administration as ordered by a physician or other legally authorized healthcare provider.

C. If controlled substances are to be used, a controlled substances registration from the Department's Bureau of Drug Control and a controlled substance registration from the federal Drug Enforcement Administration (DEA) shall be obtained. The registration(s) shall be displayed in a conspicuous location within the facility.

D. Each facility shall maintain, upon the advice and written approval of the Medical Director or consultant pharmacist, an emergency kit/cart of lifesaving medicines and equipment for the use of physicians or other legally authorized healthcare providers in treating the emergency needs of patients.

1. The kit/cart shall be sealed and stored in such a manner as to prevent unauthorized access and to ensure a proper environment for preservation of the medications within, but in such a manner as to allow immediate access.

2. The exterior of each emergency medication kit/cart shall have displayed the following information:

a. "For Emergency Use Only";

b. Name, address, and telephone number of the consultant pharmacist.

3. Whenever the kit/cart is opened, it shall be restocked and resealed within a reasonable time to prevent risk of harm to a patient.

4. Medications used from the kit/cart shall be replaced pursuant to orders from a physician or other legally authorized healthcare provider according to facility policy.

5. Contents of each section of the kit/cart shall be listed and maintained on or in the kit/cart, and shall correspond to the list. Documentation of monthly checks of expiration dates of medications and supplies is to be retained by the facility for a period of two years or until the Department's next inspection, whichever is longer.

E. Medications shall not be expired.

F. Applicable reference materials published within the previous year shall be available at the facility in order to provide staff members with adequate information concerning medications.

1002. Medication Orders (I).

A. Medications, to include oxygen, shall be administered in the facility to patients only upon orders of a physician or other legally authorized healthcare provider.

B. All orders (including verbal) shall be received only by licensed nurses or authorized healthcare providers, and shall be authenticated and dated by a physician or other legally authorized healthcare provider pursuant to the facility's policies and procedures, but no later than 72 hours after the order is given. Verbal orders received shall include the time of receipt of the order, description of the order, and

identification of the physician or other legally authorized healthcare provider and the individual receiving the order.

C. Medications and medical supplies ordered for a specific patient shall not be provided to or administered to any other patient.

1003. Administering Medication (I).

A. Each medication dose administered shall be properly recorded in the patient's record as the medication is administered. The medication administration record shall include the name of the medication, dosage, mode of administration, date, time, and the signature of the individual administering the medication. Initials may be utilized when recording administration, provided identification of the individual's initials is located within the record.

B. Expired medications shall not be administered to patients.

1004. Pharmacy Services (I).

Facilities that maintain stocks of legend medications and biologicals for patient use within the facility shall obtain and maintain from the S.C. Board of Pharmacy a valid, current, nondispensing drug outlet permit, displayed in a conspicuous location in the facility, and have a consultant pharmacist on-call during facility operating hours.

1005. Medication Containers (I).

Medications for each patient shall be dispensed from their original container(s), to include unit dose systems. There shall be no transferring between containers or opening blister packs to remove medications for destruction or adding new medications for administration, except by direction of a pharmacist.

1006. Medication Storage (I).

A. Medications shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety and security. Medications shall be stored in accordance with manufacturer's directions and in accordance with all applicable state and federal laws and regulations.

B. Medications shall be properly stored and safeguarded to prevent access by unauthorized persons. Expired or discontinued medications shall not be stored with current medications. Storage areas shall be of sufficient size for clean and orderly storage, and shall be locked when not under direct observation by a licensed healthcare provider. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf-life.

C. Medications requiring refrigeration shall be stored in a refrigerator at the temperature established by the U. S. Pharmacopeia (36 - 46 degrees F.). Food and drinks shall not be stored in the same refrigerator in which medications and biologicals are stored. Blood and blood products may be stored in the same refrigerator with medications and biologicals if stored in a separate compartment from the medications and biologicals.

D. Medications shall be stored:

1. Separately from poisonous substances, blood, or body fluids;

2. In a manner that provides for separation between oral and topical medications;
3. Separately from food.

E. Records shall be maintained of all stock controlled substances that indicate an accounting of all items received and/or administered in such a manner that the disposition of each dose of any particular item may be readily traced. Records shall be maintained for a minimum of two years or until the next inspection by the Department, whichever is longer.

F. Review of medication storage areas shall be conducted by the consultant pharmacist or his or her designee on at least a monthly basis. Records of such reviews shall be retained by the facility for at least two years or until the Department's next inspection, whichever is longer.

1007. Disposition of Medications (I).

A. Medications shall not be retained in stock after the expiration date on the label and no contaminated or deteriorated medications shall be maintained. Expired, damaged, or deteriorated medications and biologicals shall be disposed of in the following manner:

1. When noncontrolled legend medications are destroyed, the following shall be documented: date of destruction, medication name, strength, quantity, mode of destruction, and the names of the individual performing the destruction and a witness. (This shall not be applicable to partial unused doses of medications.) The medications may also be disposed of by returning them to the dispensing pharmacy and obtaining a receipt from the pharmacy.

2. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.61-4.

B. Destruction records shall be retained by the facility for at least two years or until the Department's next inspection, whichever is longer.

SECTION 1100

MEAL SERVICE

1101. General (II).

A. All facilities that prepare food on-site shall be approved by the Department, and shall be regulated, inspected, and graded pursuant to R.61-25.

B. When meals or snacks are catered to a facility, such meals shall be obtained from a food service establishment graded by the Department, pursuant to R.61-25, and there shall be a written executed contract with the food service establishment.

1102. Food Storage (II).

A. All food items shall be stored at a minimum of six inches above the floor on clean surfaces and in such a manner as to be protected from splash and other contamination.

B. Food stored in the refrigerator or freezer shall be covered, labeled, and dated. Prepared food shall not be stored in the refrigerator for more than 72 hours.

1103. Food Equipment and Utensils (II).

The equipment and utensils utilized, and the cleaning, sanitizing, and storage of such shall be in accordance with R.61-25.

1104. Ice and Drinking Water (II).

A. Ice from a water system that is in accordance with R.61-58, shall be available and precautions taken to prevent contamination. The ice scoop shall be stored in a sanitary manner outside of the ice container.

B. Potable drinking water shall be available and accessible to patients at all times.

C. The use of common drinking cups shall be prohibited.

D. Ice delivered to patient areas in bulk shall be in nonporous, covered containers that shall be cleaned after each use.

1105. Equipment (II).

A. Liquid or powder soap in dispensers and sanitary paper towels shall be available at each food service handwash lavatory.

B. The facility shall include a separate handwash sink, convenient to serving, food preparation, and dishwashing areas.

C. All walk-in refrigerators and freezers shall be equipped with opening devices that will permit opening of the door from the inside at all times. (I)

1106. Refuse Storage and Disposal (II).

Refuse storage and disposal shall be in accordance with R.61-25.

SECTION 1200

EMERGENCY PROCEDURES/DISASTER PREPAREDNESS

1201. Emergency Services (I).

A. Appropriate equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer to a hospital. The emergency equipment must meet the following requirements:

1. Be immediately available for use during emergency situations;

2. Be appropriate for the facility's patient population; and

3. Be maintained by appropriate personnel in accordance with manufacturer's instructions.

~~B. The facility shall have the capability of obtaining blood and blood products to meet emergency situations.~~

1202. Disaster Preparedness (II).

A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

1203. Emergency Call Numbers (I).

Although the facility may have access to “911,” emergency call data shall be immediately available and shall include, at a minimum, the telephone numbers of fire and police departments, ambulance service, and the Poison Control Center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

1204. Continuity of Essential Services (II).

There shall be a written plan to be implemented to assure the continuation of essential patient support services for reasons such as power outage, water shortage, or in the event of the absence of any portion of the staff resulting from inclement weather or other causes.

SECTION 1300

FIRE PREVENTION

1301. Arrangements for Fire Department Response/Protection (I).

A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire, *i.e.*, fire plan and evacuation plan.

B. Facilities located outside a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. A copy of the agreement shall be kept on file in the facility.

1302. Tests and Inspections (I).

A. Fire protection and suppression systems shall be maintained and tested in accordance with NFPA 10, 13, 14, 15, 25, 70, 72, and 96.

B. Fire alarm systems shall be maintained in a safe, operable condition in accordance with NFPA 70 and 99 and shall be inspected at least annually.

1303. Fire Response Training (I).

A. Each staff member shall receive training within 24 hours of his or her first day of employment in the facility and at least annually thereafter, addressing at a minimum, the following:

1. Fire plan;
2. Reporting a fire;
3. Use of the fire alarm system, if applicable;

4. Location and use of fire-fighting equipment;
5. Methods of fire containment; and
6. Specific responsibilities, tasks, or duties of each staff member.

B. A plan for the evacuation of patients, staff members, and visitors, to include evacuation routes and procedures in case of fire or other emergencies, shall be established and posted in conspicuous public areas throughout the facility.

1304. Fire Drills (I).

A. An unannounced fire drill shall be conducted at least quarterly for all shifts. Each staff member shall participate in a fire drill at least once each year. Records of drills shall be maintained at the facility, indicating the date, time, shift, description and evaluation of the drill, and the names of staff members directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, the provisions of the statute or regulation shall be complied with and shall supersede the requirements of this section.

B. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1303 above.

SECTION 1400

MAINTENANCE

1401. General (II).

A. The structure, including its component parts and equipment, shall be properly maintained to perform the functions for which it is designed.

B. The facility shall keep its component parts and all equipment in good repair and operating condition and documented.

1402. Equipment (II).

A. Equipment used in the provision of care, treatment, procedures, surgery, and/or services shall meet appropriate specifications and calibrations and shall be monitored and operated in accordance with the manufacturer's guidelines and with local, State, and Federal laws.

B. If utilized, all equipment for the administration of anesthesia shall be readily available, clean or sterile, and operating properly.

1. Anesthesia apparatus shall be equipped with a device to measure the oxygen component of the gas being inhaled by the patient. The device shall emit audible and visual alarms should the proportion of oxygen fall below a safe level. (I)

2. Inspections shall be made prior to each use of the anesthesia equipment, as well as a record of all service and repair performed on all anesthesia machines, vaporizers, and ventilators, shall be maintained and retained for a minimum of two years or until the next Department's inspection, whichever is longer.

1403. Preventive Maintenance of Life Support Equipment (II).

A. A written preventive maintenance program shall be developed and implemented for all life support equipment, to include, but not be limited to:

1. Patient monitoring equipment;
2. Isolated electrical systems;
3. Patient ground systems; and
4. Medical gas systems.

B. This equipment shall be calibrated, if applicable, and/or tested at periodic intervals, but not less than annually, to insure proper operation. After repairs and/or alterations are made to any equipment or system, thorough testing for proper operation shall be accomplished prior to returning it to service. (I)

C. Records shall be maintained on all life support equipment to indicate its history of testing and maintenance.

SECTION 1500

INFECTION CONTROL AND ENVIRONMENT

1501. Staff Practices (I).

Staff and volunteer practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and practices shall be in compliance with applicable guidelines of the Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; the Centers for Disease Control and Prevention (CDC) Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee; the Department's *Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*, and R.61-105; and other applicable federal, state, and local laws and regulations.

1502. Vaccinations (I).

A. Hepatitis B.

1. All direct care staff who perform tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps shall have the hepatitis B vaccination series unless the vaccine is contraindicated or an individual is offered the series and declines. In either case the decision shall be documented.

2. Each staff member who elects vaccination shall have completed the initial dose of the three-dose series within 30 days of employment.

B. Influenza. All direct care staff shall have an annual influenza vaccination unless contraindicated or offered and declined. In either case the decision shall be documented.

C. MMR and Varicella. All direct care staff shall have been vaccinated or have evidence of immunity for measles, rubella, and varicella prior to patient contact unless contraindicated or offered and declined. In either case the decision shall be documented. Immunity to mumps is recommended.

1503. Live Animals.

Live animals shall not be permitted in facilities.

EXCEPTION: This standard does not apply to patrol dogs accompanying security or police officers, guide dogs, or other service animals accompanying individuals with disabilities.

1504. Sterilization Procedures (I).

A. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and operating room materials as well as laboratory equipment and supplies. The sterilizing equipment shall have approved control and safety features. The accuracy of instrumentation and equipment shall be tested at least quarterly; periodic calibration and/or preventive maintenance shall be provided as necessary and a history of testing and service maintained.

B. The dates of sterilization and expiration shall be marked on all supplies sterilized in the facility.

EXCEPTION: Facilities may utilize “event-related” methodologies for determining sterile integrity in lieu of “time-related” methods provided there is an established policy and procedure.

C. The facility shall provide for appropriate storage and distribution of sterile supplies and equipment pursuant to facility policies and procedures.

D. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area, appropriate to the area and the equipment’s purpose or use, shall be accomplished. A recognized method of monitoring disinfectant performance shall be employed. Disinfectants, *e.g.*, glutaraldehyde, Cidex, Sporox, hydrogen peroxide, shall be tested and maintained according to manufacturer’s instructions and shall include, at a minimum, a record of readings/testings and change dates of the disinfectant solution.

E. Collection, transportation, and storage of contaminated or used equipment must be performed in a safe manner and in accordance with approved policies and procedures of the Facility.

1505. Tuberculosis Risk Assessment (I).

A. All facilities shall conduct an annual tuberculosis risk assessment in accordance with CDC guidelines (See Section 102.B.6) to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

B. The risk classification, *i.e.*, low risk, medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff and patients and the frequency of screening. A risk classification shall be determined for the entire facility. In certain settings, *e.g.*, healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, patient population, job type, or location within the setting may have separate risk classifications.

1506. Staff Tuberculosis Screening (I).

A. Tuberculosis Status. Prior to date of hire or initial patient contact, the tuberculosis status of direct care staff shall be determined in the following manner in accordance with the applicable risk classification:

B. Low Risk:

1. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All staff (within three (3) months prior to contact with patients) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified.

Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8-10) weeks after that exposure to *M. tuberculosis* ended.

C. Medium Risk:

1. Baseline two-step TST or a single BAMT: All staff (within three (3) months prior to contact with patients) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic testing (with TST or BAMT): Annually, of all staff who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, staff with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the staff about symptoms of TB disease (including the staff and/or direct care volunteers responses), documenting the questioning of the staff about the presence of symptoms of TB disease, and instructing the staff to report any such symptoms immediately to the administrator or director of nursing. Treatment for latent TB infection (LTBI) shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8-10) weeks after that exposure to *M. tuberculosis* ended.

D. Baseline Positive or Newly Positive Test Result:

1. Staff with a baseline positive or newly positive test result for *M. tuberculosis* infection (*i.e.*, TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, *e.g.*, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). These staff members will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (*i.e.*, the Department's TB Control program).

2. Staff who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician or legally authorized healthcare provider, and permitted to return to work only with approval by the Department TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB diseases develop or unless recommended by a physician or legally authorized healthcare provider.

1507. Housekeeping (II).

The facility and its grounds shall be uncluttered, clean, and free of vermin and offensive odors.

A. Interior housekeeping shall at a minimum include:

1. Cleaning each specific area of the facility (dry sweeping and dusting shall be prohibited in restricted areas as identified in facility policies and procedures);
2. Cleaning of operating/procedure rooms in accordance with established written procedures after each operation/procedure.

B. Exterior housekeeping shall at a minimum include:

1. Cleaning of all exterior areas, *e.g.*, porches and ramps, and removal of safety impediments such as snow and ice;
2. Keeping facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin.

1508. Infectious Waste (I).

Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in a manner compliant with OSHA Bloodborne Pathogens Standard, the Department's Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings, and R.61-105.

1509. Clean/Soiled Linen and Surgical Clothing (II).

A. A supply of clean, sanitary linen/surgical clothing shall be available at all times. In order to prevent the contamination of clean linen/surgical clothing by dust or other airborne particles or organisms, it shall be stored and transported in a sanitary manner, *i.e.*, enclosed and covered. Linen/Surgical clothing storage rooms shall be used only for the storage of linen/surgical clothing. Clean linen/Surgical clothing shall not be stored with other items.

B. Soiled linen/Surgical clothing.

1. Provisions shall be made for collecting, transporting, and storing soiled linen and surgical clothing;
2. Soiled linen/Surgical clothing shall be kept in enclosed/covered containers.

SECTION 1600

QUALITY IMPROVEMENT PROGRAM

1601. General (II).

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care, treatment, procedures, surgery, and/or services provided by the facility.

B. The quality improvement program, at a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is systematically, objectively, and regularly accomplished at a frequency as determined by the facility to ensure that policies and procedures and this regulation are met, but not less than every three months;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Establish ways to measure the quality of patient care and staff performance as well as the degree to which the policies and procedures are followed;

5. Analyze the necessity of care, treatment, procedures, surgery, and/or services rendered;

6. Analyze the effectiveness of the fire plan;

7. Analyze all serious incidents and accidents, to include all patient deaths and significant medication errors;

8. Analyze any other unusual occurrences that threaten the health, safety, or well-being of the patients;

9. At least every three months, review an established percentage of patient records to verify the accuracy and integrity of the system, and take corrective action as needed;

10. Establish a systematic method of obtaining feedback from patients and other interested persons, *e.g.*, family members and peer organizations, as expressed by the level of satisfaction with care, treatment, procedures, surgery, and/or services received.

C. The governing body must ensure the quality improvement program:

1. Is defined, implemented, and maintained by the Facility;

2. Addresses the Facility's priorities and that all improvements are evaluated for effectiveness;

3. Specifies data collection methods, frequency, and details;

4. Clearly establishes its expectations for safety; and

5. Adequately allocates sufficient staff, time, information systems, and training to implement the quality improvement program.

SECTION 1700

DESIGN AND CONSTRUCTION

1701. General (II).

A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each patient.

1702. Local and State Codes and Standards (II).

Buildings shall comply with pertinent local and state laws, codes, ordinances, and standards with reference to design and construction. No facility shall be licensed unless the Department has assurance that responsible local officials (zoning and building) have approved the facility for code compliance.

1703. Applicable Code Editions (II).

A. Facility design and construction shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to ambulatory surgical facilities.

B. Unless specifically required otherwise by the Department, all facilities shall comply with the construction codes and construction regulations applicable at the time its license was issued.

C. Any facility that closes, has its license revoked, or surrenders its license, and applies for re-licensure at the same site, shall be considered a new building and shall meet the current codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of application for re-licensing.

1704. Submission of Plans and Specifications.

A. Plans and specifications shall be submitted to the Department for review and approval for new construction, additions or alterations to existing buildings, replacement of major equipment, buildings being licensed for the first time, buildings changing license type, and for facilities increasing occupant load or licensed capacity. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. Unless directed otherwise by the Department, submit plans at the schematic, design development, and final stages. All plans shall be drawn to scale with the title, stage of submission and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for observation and inspections. Upon approval of the Department, construction administration may be performed by an entity other than the architect. The Department shall conduct periodic inspections throughout each project.

B. Plans and specifications shall be submitted to the Department for review and approval for projects that have an effect on:

1. The function of a space;
2. The accessibility to or of an area;

3. The structural integrity of the facility;
4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);
5. Doors;
6. Walls;
7. Ceiling system assemblies;
8. Exit corridors;
9. Life safety systems; or
10. That increases the occupant load or licensed capacity of the facility.

C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.

D. Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the facility and made available to the Department.

E. Any construction work which violates codes or standards will be required to be brought into compliance. All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.

1705. Construction Inspections.

All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.

SECTION 1800

FIRE PROTECTION EQUIPMENT AND SYSTEMS

1801. Fire Alarms (I).

A. A facility shall include a partial, manual, automatic, supervised fire alarm system. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. There must be a fire alarm pull station at each required exit and in or near each nurses station.

C. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.

1802. Gases (I).

Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously inside the facility and on oxygen cylinders. All cylinders shall be properly secured in place.

SECTION 1900

ELECTRICAL

1901. Signal System.

A. All facilities shall have a signal system consisting of a call button for each bed, bath, toilet and treatment/examination room. A light shall be at or over each patient room door visible from the corridor. There shall be an audio-visual master station in a location continuously monitored by staff.

B. Activation of signal system shall be by pull cord or electronic device. Pull cord shall hang to a maximum of four (4) inches above finished floor.

1902. Emergency Generator Service (I).

A. With concurrence of the local authority having jurisdiction, facilities shall have an emergency generator with a ten (10) second startup and six (6) hour run time based on the maximum load rating of the generator. As a minimum, emergency power shall be provided for but not limited to:

1. Emergency and Exit lighting;
2. Lighting for staff work areas;
3. All lighting and power at patient care areas;
4. Fire alarm telephone and signal systems;
5. At least one (1) elevator where required;
6. Fire pump and associated equipment;
7. Public toilet rooms;
8. All HVAC equipment serving patient areas; and
9. All patient life safety equipment;

EXCEPTION: In endoscopy facilities, an emergency power supply system is not required.

B. An Uninterruptible Power System (UPS) is not acceptable as an alternative to the generator system.

C. In the event of natural disaster or electrical power failure, no new surgery/procedures shall commence, and surgery/procedures in progress shall be concluded as soon as possible.

SECTION 2000

PHYSICAL PLANT

2001. Surgical Suite(s).

The size and design of the surgical suite(s) shall be in accordance with individual programs and this regulation. The following basic elements, designed to ensure no flow of through traffic, shall be incorporated in all facilities:

A. Operating/Procedure Room(s).

1. The number shall depend on the projected caseload and types of procedures to be performed. Rooms shall have adequate space to accommodate necessary equipment and staff.

2. Each operating room shall have a minimum clear area of 180 square feet exclusive of fixed and movable cabinets and shelves. The minimum width shall be 12 feet.

3. Each procedure room shall have a minimum clear area of 140 square feet exclusive of fixed and movable cabinets and shelves. The minimum width shall be 10 feet.

4. Additional clear area may be required as described in the narrative program to accommodate special functions in one or more of these rooms.

5. The facility shall include an emergency communication system connecting with the surgical suite work station.

B. Surgery/Procedure and Recovery Equipment and Supplies

1. Each operating/procedure room shall be completely equipped and supplied for the types of procedures to be performed. (I)

2. The center's medical staff and governing body shall develop policies and procedures to specify the types of emergency equipment required for use in the Ambulatory Surgical Facility's operating room(s). The equipment must meet the following requirements: (I)

- (a) Be immediately available for use during emergency situations;
- (b) Be appropriate for the facility's patient population; and
- (c) Be maintained by appropriate personnel.

C. Surgical/Procedure Service Areas. The facility shall include the following:

1. A work station located to permit visual surveillance of persons entering the surgical/procedure areas and the recovery area;

2. Sterilizing equipment with autoclave(s) conveniently located to serve all operating rooms;

EXCEPTION: Sterilizing equipment is not required in endoscopy facilities; however, a high-level disinfection of equipment is required in such facilities.

3. A medication distribution station provided for storage and preparation of medication to be administered to patients;

4. Scrub facilities provided near the entrance to each operating room. Scrub facilities with foot or knee controls shall be arranged to minimize any incidental splatter on nearby staff or supply carts. At a minimum, the facility shall include the following:

- a. Scrub sink with knee, elbow, or foot controls;
- b. Soap dispenser.

EXCEPTION: For endoscopy facilities, in lieu of scrub facilities, there shall be a handwash sink in each procedure room that is equipped with valves that can be operated without the use of hands.

5. A soiled workroom for the exclusive use of the surgical suite staff. The soiled workroom shall contain a clinical sink or equivalent flushing type fixture, waste receptacle, and covered soiled receptacle, unless there is a separate soiled linen storage room;

EXCEPTION: In endoscopy facilities, a designated soiled work area will suffice in lieu of a soiled workroom.

6. A clean workroom when clean materials are assembled within the surgical suite prior to use. The workroom shall contain a work counter, a sink equipped for handwashing and space for clean and sterile supplies;

EXCEPTION: In endoscopy facilities, a designated clean work area will suffice in lieu of a clean workroom.

7. An area for cleaning, testing, and storing anesthesia equipment in accordance with accepted principles of aseptic technique.

EXCEPTION: An anesthesia area is not required in endoscopy facilities.

8. Staff change areas that shall contain adequate dressing space for changing of scrubs and shall contain lockers, showers, toilets, lavatories, and receptacles and facilities for the appropriate disposition of soiled scrubs; these areas shall be arranged to allow a restricted traffic pattern of authorized staff from outside the surgical suite to change into appropriate attire and enter the surgical suite;

EXCEPTION: Showers and areas for donning of scrub suits and boots are not required in endoscopy facilities.

9. Provisions for emergency eye-washing.

D. Recovery Area. The facility shall include the following:

1. An area for recovery of patients;
2. Handwashing facilities, secured medication storage space, clerical work space, and sufficient storage space for supplies and equipment;

3. At least four feet between beds or stretchers (two feet if next to a wall) and adequate space at the foot of the bed or stretcher as needed for work and staff circulation;
4. Partitions, walls and/or cubicle curtains (on built-in tracks) to afford visual privacy for each patient;
5. Recovery beds or reclining type of vinyl upholstered chairs or recovery stretchers;
6. Equipment for oxygen, resuscitation, and suction.

2002. Soiled Utility Room.

Facilities shall have at least one soiled utility room per floor containing a clinical sink, work counter, waste receptacle and soiled linen receptacle.

2003. Clean Utility Room.

Facilities shall have at least one clean utility room per floor containing a counter with handwashing sink and space for the storage and assembly of supplies for nursing procedures.

2004. Corridors (II).

A. Minimum public corridor width shall be five feet.

B. There shall be at least one corridor that is no less than eight feet clear width between doors from the recovery area and/or operating/procedure rooms and an exit door. In a one-story building or on the ground floor of a multi-story building, if there is less than eight feet clear width, the corridors shall be so arranged as to allow a stretcher to exit from the recovery area or operating rooms directly into the corridor without turning and move to the required exit without having to make a turn. Minimum width shall be five feet.

C. The location of items such as drinking fountains, telephone booths, vending machines, and portable equipment shall not restrict corridor traffic or reduce the required corridor width. (II)

2005. Handrails/Guardrails (II).

The facility shall have handrails on at least one side of each corridor/hallway, and on all stairways, ramps, and porches with two or more steps. Ends of all installed handrails shall return to the wall.

2006. Restrooms (II).

A. There shall be an appropriate number of restrooms in the facility, to accommodate patients, staff, and visitors.

B. The restrooms shall be accessible during all operating hours of the facility.

C. A restroom(s) shall be equipped with at least one toilet fixture, toilet paper installed in a holder, a lavatory supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a covered waste receptacle.

D. The waiting/lobby area must have at least one restroom.

E. The facility shall have toilet fixtures in restrooms for patient use in ample number, located within or adjacent to the recovery area. The minimum requirement is one toilet fixture for every ~~surgical and procedure room~~ eight pre-operative and post-operative beds.

F. All toilet fixtures used by patients shall have approved grab bars securely fastened in a usable fashion.

G. Privacy shall be provided at toilet fixtures and urinals.

2007. Janitor's Closets.

A. The facility shall include at least one (1) lockable janitor's closet throughout the facility.

B. Each shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies, *e.g.*, mops.

2008. Storage Areas.

A. Adequate general storage areas shall be provided for patient and staff/volunteer belongings, equipment, and supplies as well as clean linen, soiled linen, wheelchairs, and general supplies and equipment.

B. Soiled linen shall be stored in an enclosed room. This room may also be the soiled workroom.

C. Storage buildings on the premises shall meet the requirements of the current building code regarding distance from the licensed building. Storage in buildings other than on the facility premises shall be secure and accessible. An appropriate controlled environment shall be provided if necessary for storage of items requiring such an environment.

D. Supplies/Equipment shall not be stored directly on the floor. Supplies/Equipment susceptible to water damage/contamination shall not be stored under sinks or other areas with a propensity for water leakage.

E. Chemicals indicated as harmful on the product label, cleaning materials, and supplies shall be safely stored in cabinets or well-lighted closets/rooms.

2009. Elevators (II).

Elevators shall be inspected and tested upon installation, prior to first use, and annually thereafter by a certified elevator inspector.

2010. Telephone Service.

At least one land-line telephone shall be available on each floor of the facility for use by patients and/or visitors for their private, discretionary use; pay phones for this purpose are acceptable

2011. Location.

A. Transportation. The facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The facility shall have a parking area to reasonably satisfy the needs of patients, staff members, and visitors.

C. Access to firefighting equipment. Facilities shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

2012. Incinerators (I).

If the facility has an incinerator, it shall conform to the requirements of the Department.

2013. Furnishings/Equipment (I).

A. The facility shall maintain the physical plant free of fire hazards and impediments to fire prevention.

B. No portable electric or unvented fuel heaters shall be permitted in the facility except as permitted by the State Fire Marshal Regulations.

C. Wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant in accordance with the applicable code in Section 1700.

2014. Water Requirements.

A. The facility shall establish written policies and procedures to prevent waterborne microbial contamination within the water distribution system.

B. The facility shall ensure the practice of hand hygiene to prevent the hand transfer of pathogens, and the use of barrier precautions (e.g. gloves) in accordance with established guidelines.

C. The facility shall eliminate contaminated water or fluid from environmental reservoirs (e.g. in equipment or solutions) wherever possible.

D. The facility shall not place decorative fountains and fish tanks in patient-care areas. If decorative fountains are used in separate public areas, the facility shall ensure they are disinfected in accordance with manufacturer's instructions and safely maintained.

E. The facility plumbing fixtures that require hot water and are accessible to patients shall be supplied with water which thermostatically controlled to a temperature of at least 100 degrees F. (37.8 degrees C) and not exceeding 125 degrees F. (51.7 degrees C.) at the fixture.

F. The facility shall have a written plan to respond to disruptions in water supply. The plan must include a contingency plan to estimate water demands for the entire facility in advance of significant water disruptions (i.e., those expected to result in extensive and heavy microbial or chemical contamination of the potable water), sewage intrusion, or flooding.

G. When a significant water disruption or an emergency occurs, the facility shall:

1. Adhere to any advisory to boil water issued by the municipal water utility;

2. Alert patients, families, employees, volunteers, students and visitors not to consume water from drinking fountains, ice, or drinks made from municipal tap water, while the advisory is in effect, unless the water has been disinfected;

3. After the advisory is lifted, run faucets and drinking fountains at full flow for greater than 5 minutes, or use high-temperature water flushing or chlorination;

4. All ice and drinks that may have been contaminated must be disposed and storage containers cleaned; and

5. Decontaminate the hot water system as necessary after a disruption in service or a cross-connection with sewer lines has occurred.

H. The facility shall follow appropriate recommendations to prevent cross connection and other sources of contamination of ice for human consumption and to prevent contamination of hydrotherapy equipment and medical equipment connected to water systems (e.g. automated endoscope reprocessors).

I. The facility shall maintain and implement policies and procedures addressing the management of failure of waste water systems.

J. Patient and staff handwashing lavatories and showers, if any, shall include hot and cold water at all times.

2015. Panelboards (II).

The directory shall be labeled to conform to the actual room designations. Clear access of stored materials shall be maintained to the panel. The panelboard directory shall be labeled to conform to the actual room numbers or designations.

2016. Lighting.

A. Spaces occupied by persons, machinery, equipment within buildings, approaches to buildings, and parking lots shall be lighted. (II)

B. The facility shall have adequate artificial light to include sufficient illumination for reading, observation, and activities.

2017. Heating, Ventilation, and Air Conditioning (HVAC) (II).

A. The HVAC system shall be inspected at least once a year by a certified/licensed technician.

B. No HVAC supply or return grill shall be installed within three feet of a smoke detector. (I)

C. Intake air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials.

D. Each bath/restroom shall have either operable windows or have approved mechanical ventilation.

SECTION 2100

SEVERABILITY

2101. General.

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 2200

GENERAL

2201. General.

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

Fiscal Impact Statement:

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any requirements of this regulation.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(A)(3)(h):

These revised regulations are updated to implement new statutory requirements concerning uncompensated indigent/charity care, and to ensure the safety and wellbeing of patients of ambulatory surgical facilities.