

RULES AND REGULATIONS
FOR THE LICENSING OF
FREESTANDING AMBULATORY SURGICAL CENTERS
(R23-17-FASC)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

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of the Rhode Island General Laws, as
amended)**

INTRODUCTION

These *Rules and Regulations For Licensing Of Freestanding Ambulatory Surgical Centers (R23-17-FASC)* are promulgated pursuant to the authority conferred under section 23-17-10 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting minimal standards for licensed freestanding ambulatory surgical centers in this state.

Pursuant to the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at the regulations: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) significant economic impact placed on facilities through these amended regulations. No alternative approach was identified. A duplication or overlap with one aspect of the regulations from the Department of Environmental Management was identified and DEM has taken the necessary steps to eliminate the duplication. Furthermore, the protection of the health, safety and welfare of the public necessitates the adoption of these amended regulations, despite the economic impact which may be incurred as a result of the amended regulations.

These rules and regulations shall supersede all previous *Rules and Regulations For the Licensing of Freestanding Ambulatory Surgical Centers* promulgated by the Department of Health and filed with the Secretary of State.

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PART I ***LICENSING PROCEDURES AND DEFINITIONS***

Section 1.0 ***Definitions***

Wherever used in these rules and regulations the following terms shall be construed as follows:

1.1 ***"Change of operator"*** means a transfer by the governing body or operator of a FASC to any other person (excluding delegations of authority to the medical or administrative staff of the facility) of the governing body's authority to:

- a) hire or fire the chief executive officer of the FASC;
- b) maintain and control the books and records of the FASC;
- c) dispose of assets and incur liabilities on behalf of the FASC;
- d) adopt and enforce policies regarding operation of the FASC.

This definition is not applicable to circumstances wherein the governing body of a FASC retains the immediate authority and jurisdiction over the activities enumerated in subsections (a) through (d) herein.

1.2 ***"Change in owner"*** means:

- (1) in the case of a FASC which is a partnership, the removal, addition or substitution of a partner which results in a new partner acquiring a controlling interest in such partnership.
- (2) in the case of a FASC which is a corporation:
 - a) a sale, lease, exchange or other disposition of all, or substantially all of the property and assets of the corporation; or
 - b) a merger of the corporation into another corporation; or
 - c) the consolidation of two or more corporations, resulting in the creation of a new corporation; or
 - d) in the case of a FASC which is a business corporation, any transfer of corporate stock which results in a new person acquiring a controlling interest in such corporation; or
 - e) in the case of a FASC which is a non-business corporation, and change in membership which results in a new person acquiring a controlling vote in such corporation.

- 1.3 **"Director"** shall mean the Director of the Rhode Island Department of Health.
- 1.4 **"Equity"** means non-debt funds contributed towards the capital costs related to a change in owner or change in operator of a freestanding ambulatory surgical center which funds are free and clear of any repayment or liens against the assets of the proposed owner and/or licensee and that result in a like reduction in the portion of the capital cost that is required to be financed or mortgaged.
- 1.5 **"Freestanding Ambulatory Surgical Center"** hereinafter referred to the FASC shall mean an establishment or place which may be a public or private organization equipped and operated exclusively for ambulatory patients for the purpose of performing surgical procedures which have the approval of the governing body and which in the opinion of the surgeon and anesthesiologist can be performed safely without requiring extensive anesthesia or overnight stay.
- 1.6 **"Health Services Council"** shall mean the advisory body to the Rhode Island State Department of Health established in accordance with Chapter 23-16 of the General Laws of Rhode Island, as amended, appointed and empowered in accordance with Chapter 23-17 of the General Laws of Rhode Island, as amended, to serve as the advisory body to the state agency in its review functions.
- 1.7 **"The licensed capacity"** of the FASC shall mean the number of operating rooms and recovery beds that the facility is licensed to operate.
- 1.8 **"Licensing agency"** or **"state agency"** shall mean the Rhode Island Department of Health.
- 1.9 **"Person"** shall mean any individual, trust or estate, partnership, corporation (including associations, joint stock companies), limited liability company, state, or political subdivisions or instrumentality of a state.

Section 2.0 ***General Requirements for Licensure***

- 2.1 No person acting severally or jointly with any other person, shall establish, conduct or maintain a FASC in this state without a license in accordance with the requirements of section 23-17-4 of reference 1.
- 2.2 A certificate of need is required as a precondition to the establishment of a new FASC and such other activities in accordance with reference 10.

Section 3.0 ***Application for License or for Changes in Owner, Operator, or Lessee***

- 3.1 Application for a license to conduct, maintain or operate a FASC shall be made to the licensing agency upon forms provided by it one month prior to expiration date of license and shall contain such information as the licensing agency reasonably requires which may include affirmative evidence of ability to comply with the provisions of reference 1 and the rules and regulations herein.

- 3.2 A notarized listing of names and addresses of direct and indirect owners whether individual, partnership or corporation with percentages of ownership designated shall be provided with the application for licensure and shall be updated annually. The list shall include each owner (in whole or in part) of any mortgage, deed or trust, note or other obligation.
- 3.3 Application for changes in the owner, operator, or lessee of a FASC shall be made on forms provided by the licensing agency and shall contain but not be limited to information pertinent to the statutory purpose expressed in section 23-17-3 of Chapter 23-17 or to the considerations enumerated in section 4.5 herein. Twenty-five (25) copies of such applications are required to be provided.
- 3.3.1 Each application filed pursuant the provisions of this section shall be accompanied by an application fee, made payable to the Rhode Island General Treasurer, as follows: applicants shall submit a fee equal to one tenth of one percent (0.1%) of the projected annual facility net operating revenue contained in the application; provided, however, that the minimum fee shall be five hundred dollars (\$500) and the maximum fee shall not exceed ten thousand dollars (\$10,000).

Section 4.0 *Issuance and Renewal of License*

- 4.1 Upon receipt of an application for a license, the licensing agency shall issue a license or renewal thereof for a period of no more than one (1) year if the applicant meets the requirements of reference 1 and the rules and regulations herein. Said license, unless sooner suspended or revoked, shall expire by limitation on the 31st day of December following its issuance and may be renewed from year to year after inspection and approval by the licensing agency.
- 4.2 A license shall be issued to a specific licensee for a specific location and shall not be transferable. The license shall be issued only for the premises and the individual owner, operator or lessee, or to the corporate entity responsible for its governance.
- 4.2.1 Any change in owner, operator, or lessee of a licensed FASC shall require prior review by the Health Services Council and approval of the licensing agency as provided in sections 4.4 and 4.5 as a condition precedent to the transfer, assignment or issuance of a new license.
- 4.3 A license issued hereunder shall be the property of the state loaned to such licensee and it shall be kept posted in a conspicuous place on the licensed premises.
- 4.4 Reviews of applications for changes in the owner, operator, or lessee of licensed FASC shall be conducted according to the following procedures:
- a) Within ten (10) working days of receipt, in acceptable form, of an application for a license in connection with a change in the owner, operator or lessee of an existing FASC, the licensing agency will notify and afford the public thirty (30) days to comment on such application.

- b) The decision of the licensing agency will be rendered within ninety (90) days from acceptance of the application.
- c) The decision of the licensing agency shall be based upon the findings and recommendations of the Health Services Council unless the licensing agency shall afford written justification for variance therefrom.
- d) All applications reviewed by the licensing agency and all written materials pertinent to licensing agency review, including minutes of all Health Services Council meetings, shall be accessible to the public upon request.

4.5 Except as otherwise provided in Chapter 23-17 of the General Laws of Rhode Island, as amended, a review of the Health Services Council of an application for a license in the case of a proposed change in the owner, operator, or lessee of a licensed FASC may not be made subject to any criterion unless the criterion directly relates to the statutory purpose expressed in section 23-17.3 of the General Laws of Rhode Island, as amended. In conducting reviews of such applications the Health Services Council shall specifically consider and it shall be the applicant's burden of proof to demonstrate:

4.5.1 the character, commitment, competence and standing in the community of the proposed owners, operators, or directors of the FASC as evidenced by:

- (A) In cases where the proposed owners, operators, or directors of the health care facility currently own, operate, or direct a health care facility, or in the past five years owned, operated or directed a health care facility, whether within or outside Rhode Island, the demonstrated commitment and record of that (those) person(s):
 - (i) in providing safe and adequate treatment to the individuals receiving the health care facility's services;
 - (ii) in encouraging, promoting and effecting quality improvement in all aspects of health care facility services; and
 - (iii) in providing appropriate access to health care facility services;
- (B) A complete disclosure of all individuals and entities comprising the applicant; and
- (C) The applicant's proposed and demonstrated financial commitment to the health care facility;

4.5.2 The extent to which the facility will continue, without material effect on its viability at the time of change of owner, operator, or lessee, to provide safe and adequate treatment for individuals receiving the facility's services as evidenced by:

(A) The immediate and long term financial feasibility of the proposed financing plan;

- (i) The proposed amount and sources of owner's equity to be provided by the applicant;
- (ii) The proposed financial plan for operating and capital expenses and income for the period immediately prior to, during and after the implementation of the change in owner, operator or lessee of the health care facility;
- (iii) The relative availability of funds for capital and operating needs;
- (iv) The applicant's demonstrated financial capability;
- (v) Such other financial indicators as may be requested by the state agency;

4.5.3 The extent to which the facility will continue to provide safe and adequate treatment for individuals receiving the facility's services and the extent to which the facility will encourage quality improvement in all aspects of the operation of the health care facility as evidenced by:

- (A) the applicant's demonstrated record in providing safe and adequate treatment to individuals receiving services at facilities owned, operated, or directed by the applicant; and
- (B) the credibility and demonstrated or potential effectiveness of the applicant's proposed quality assurance programs;

4.5.4 The extent to which the facility will provide or will continue to provide appropriate access with respect to traditionally underserved populations as evidenced by:

- (A) In cases where the proposed owners, operators, or directors of the health care facility currently own, operate, or direct a health care facility, or in the past five years owned, operated or directed a health care facility, both within and outside of Rhode Island, the demonstrated record of that person(s) with respect to access of traditionally under served populations to its health care facilities; and
- (B) The proposed immediate and long term plans of the applicant to ensure adequate and appropriate access to the programs and health care services to be provided by the health care facility;

4.5.5 In consideration of the proposed continuation or termination of health care services by the facility:

- (A) The effect(s) of such continuation or termination on access to safe and adequate treatment of individuals, including but not limited to traditionally underserved populations.

4.5.6 And, in cases where the application involves a merger, consolidation or otherwise legal affiliation of two or more health care facilities, the proposed immediate and long term plans of such health care facilities with respect to the health care programs to be offered and health care services to be provided by such health care facilities as a result of the merger, consolidation or otherwise legal affiliation.

- 4.6 Subsequent to reviews conducted under sections 4.4 and 4.5 of these regulations, the issuance of a license by the licensing agency may be made subject to any condition, provided that no condition may be made unless it directly relates to the statutory purpose expressed in section 23-17-3 of the General Laws of Rhode Island, as amended, or to the review criteria set forth in section 4.5 herein. This shall not limit the authority of the licensing agency to require correction of conditions or defects which existed prior to the proposed change of owner, operator, or lessee and of which notice had been given to the facility by the licensing agency.

Section 5.0 *Capacity*

- 5.1 The license for a FASC shall be issued for a specified number of operating rooms and recovery beds. The numerical capacity of the FASC shall be determined by the number of recovery beds provided.
- 5.2 The post-surgical occupancy of a facility shall not exceed the determined capacity for which a FASC is licensed.

Section 6.0 *Inspections*

- 6.1 The licensing agency shall make or cause to be made such inspections and investigations as it deems necessary and in accordance with section 23-16-10 of reference 1 and the rules and regulations herein.
- 6.2 Every FASC shall be given prompt notice by the licensing agency of any deficiencies reported as a result of an inspection or investigation.
- 6.3 Written reports and recommendations of inspections shall be maintained on file in each FASC for a period of no less than three (3) years.

Section 7.0 *Denial, Suspension, Revocation of License or Curtailment of Activities*

- 7.1 The licensing agency is authorized to deny, suspend or revoke the license or curtail activities of any FASC which: (1) has failed to comply with the rules and regulations pertaining to the licensing of FASC; and (2) has failed to comply with the provisions of reference 1.

- a) Lists of deficiencies noted in inspections conducted in accordance with section 6.0 herein shall be maintained on file in the licensing agency, and shall be considered by the licensing agency in rendering determinations to deny, suspend or revoke the license or to curtail activities of a FASC.
- 7.2 Where the licensing agency deems that operation of a FASC results in undue hardship to patients as a result of deficiencies, the licensing agency is authorized to deny licensure to a FASC not previously licensed, or to suspend for a stipulated period of time or revoke the license of a FASC already licensed or curtail activities of the FASC.
- 7.3 Whenever an action shall be proposed to deny, suspend or revoke a FASC license, or curtail its activities, the licensing agency shall notify the FASC by certified mail, setting forth reasons for the proposed action, and the applicant or licensee shall be given an opportunity for a prompt and fair hearing in accordance with section 23-16-8 of reference 1 and section 42.35.9 of reference 2.
- a) However, if the licensing agency finds that public health, safety or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the licensing agency may order summary suspension of license or curtailment of activities pending proceedings for revocation or other action in accordance with section 23-1-21 of reference 5, and section 42-35-14(c) of reference 2.
- 7.4 The appropriate state and federal placement and reimbursement agencies shall be notified of any action taken by the licensing agency pertaining to either denial, suspension or revocation of license, or curtailment of activities.

PART II ***ORGANIZATION AND MANAGEMENT***

Section 8.0 ***Governing Body and Management***

- 8.1 Each facility shall have an organized governing body or other legal authority, responsible for: (1) the management and control of the operation; (2) the assurance of the quality of care and services; (3) the conformity of the facility with all federal, state and local laws and regulations relating to fire, safety, sanitation, infection control; and (4) other relevant health and safety requirements and with all the rules and regulations herein.
- 8.2 The governing body or other legal authority shall provide appropriate personnel, physical resources, and equipment based on the scope of services provided.
- 8.3 The governing body or other legal authority shall designate: (a) an administrator who shall be responsible for the management and operation of the facility; and (b) a medical director to ensure achievement and maintenance of quality standards of professional practice.
- 8.4 The governing body shall adopt and maintain by-laws defining responsibilities for the operation and performance of the organization, identifying purposes and means of fulfilling such, and in addition the by-laws shall include but not be limited to:
- a) a statement of qualifications and responsibilities of the medical director and administrator;
 - b) a statement of the governing body's responsibility for the quality of care and services;
 - c) a statement relating to development and implementation of long and short range plans;
 - d) a statement of policy establishing the criteria for the selection and admission of patients;
 - e) a statement relating to conflict of interest on the part of the governing body, medical staff and employees;
 - f) a policy statement concerning the publication of an annual report, including a certified financial statement; and
 - g) such other matters as may be relevant to the organization of the FASC.
- 8.5 When a majority of the members of the governing body are physicians, the governing body, either directly or by delegation, shall make initial appointments, and assignment or curtailment of surgical privileges, based on the education, training, experience and evidence of competence of the physician, dentist or podiatrist consistent with state law; or when a majority of the members of the governing body are not physicians the organization's by-laws or similar rules and regulations shall specify a procedure for establishing medical review for the purpose of making initial appointments, reappointments, and assignment or curtailment of medical

privileges, based on the education, training, experience and evidence of current competence of the physician, dentist or podiatrist, and consistent with state law.

- 8.6 A health care facility shall require all persons, including students, who examine, observe, or treat a patient or resident of such facility to wear a photo identification badge which states, in a reasonably legible manner, the first name, licensure/registration status, if any, and staff position of such person.

Section 9.0 *Administrator*

- 9.1 The governing body shall appoint a qualified administrator who may be the medical director, who shall be responsible for: (1) the management and operation of the FASC; (2) the enforcement of policies, rules and regulations and statutory provisions pertaining to the health and safety of patients; (3) serving as liaison between the governing body and the staff; and (4) the planning, organizing and directing of such other activities as may be delegated by the governing body.

Section 10.0 *Medical Director*

- 10.1 The surgical services of the FASC shall be under the direction of a physician licensed in Rhode Island, who meets the qualifications set forth by the governing body in accordance with section 8.0 herein, and who shall be responsible for no less than the following.
- a) the coordination, supervision and functioning of services;
 - b) the establishment of provisions for infection control;
 - c) the achievement and maintenance of quality assurance of professional practices through a mechanism of peer review; and
 - d) the establishment of policies and procedures for surgical and anesthesia services and other related health care services.

10.2 *Personnel Health Requirements*

- 10.2 Employment health examination shall be required for each employee and shall include a physician's certification, i.e., documented evidence which shall include but not be limited to:
- a) ***Tuberculosis:*** a licensed physician must certify that the prospective employee is free of tuberculosis based on a physical examination and a negative (<10 mm Mantoux (PPD) tuberculin skin test.
 - i. If the Mantoux test done at the time of employment is positive (>10mm induration) or a previous one is known to have been positive, the physician's certification shall be based on documentation of adequate chemotherapy for tuberculosis or on a chest x-ray taken not more than six (6) months prior to the physician's certification;

- b) ***Rubella:*** Documented evidence of acquired immunity (natural or prior immunization) on or after 12 months of age of the prospective employee shall be required. If the individual is unable to provide documentation of immunity, and is not pregnant, the individual must be immunized with live rubella virus vaccine prior to their contact with patients in lieu of serologic testing in order to determine susceptibility. Vaccination is recommended as preferred alternative to testing for women who are not pregnant and who have no proof of rubella vaccination; and
- c) ***Measles:*** Any person born prior to 1956 shall be considered immune. Persons born after 1956:
 - 1) Must have documented evidence of natural immunity via physician diagnosed measles; or
 - 2) Must have been immunized against measles with a live virus vaccine on or after 12 months of age. (Persons vaccinated prior to 1968 must be revaccinated). or
 - 3) Must have documentation that he/she is not a fit subject for immunization for medical reasons.

Vaccination is preferred in lieu of serologic testing for immunity for women who are not pregnant.

- d) Such other appropriate test(s) to control communicable diseases as may be prescribed by the Director of Health.

10.3 Subsequent employee health examination shall be such as are necessary as determined by the Department of Health or the facility to document that employees are physically able to perform their duties and show no evidence of communicable disease.

- i. Repeat Mantoux skin testing is recommended for employees who are at high risk of acquiring tuberculosis infection in accordance with the guidelines of reference 12.
- ii. Whenever an employee develops a chronic cough or other symptoms suggestive of tuberculosis, the procedure outlined in section 10.2(a) above shall be repeated.
- iii. If communicable tuberculosis is discovered, an investigation of transmission shall be conducted and reported to the Rhode Island Department of Health.
- iv. Documented evidence of rubella and measles immunization or exemption, consistent with sections 10.2(b) and (c) shall be confirmed.

Section 11.0 ***Rights of Patients***

- 11.1 Each FASC shall observe the standards enumerated in section 23-16-19.1 of reference 1 with respect to each patient admitted on its facility.
- 11.2 Each facility shall display in a conspicuous place in the licensed FASC a copy of the "Rights of Patients."

Section 12.0 ***Disaster Preparedness***

- 12.1 Each FASC shall develop and maintain a written disaster preparedness plan which shall include specific provisions and procedures for the emergency care of patients in the event of fire, natural disaster or functional failure of equipment.
 - a) Such a plan shall be developed and coordinated with appropriate state and local agencies and representatives concerned with emergency safety and rescue;
 - b) A copy of the plan shall be submitted to the licensing agency;
 - c) Simulated drills testing the effectiveness of the plan shall be conducted at least semi-annually. Written reports and evaluation of all drills shall be maintained by the FASC and available for review by the licensing agency;
- 12.2 Emergency steps of action shall be clearly outlined and posted in conspicuous locations throughout the facility.

Section 13.0 ***Administrative Records***

- 13.1 Each FASC shall maintain such administrative records as may be deemed necessary for the business operation of the facility, in addition to the following;
 - a) monthly statistical summary of numbers of surgical procedures performed, appropriately classified;
 - b) narcotic register;
 - c) an operating room log book maintained in chronological sequence of admissions which shall include pertinent information such as patient's name, name of surgeon and anesthesiologist, circulating nurse, surgical procedures performed, type of anesthesia and complications (if any); and
 - d) a record of all transfers to a hospital for post-surgical care.

Section 14.0 ***Uniform Reporting System***

- 14.1 Each FASC shall establish and maintain records and data in such a manner as to make uniform

the system of periodic reporting. The manner in which the requirements of this regulation may be met shall be prescribed from time to time in directives promulgated by the Director with the advice of the Health Services Council.

- 14.2 Each FASC shall report to the licensing agency detailed financial and statistical data pertaining to its operations, services, and facility. Such reports shall be made at such intervals and by such dates as determined by the Director and shall include but not be limited to the following:
- a) utilization of FASC services;
 - b) unit cost of services;
 - c) charges for services;
 - d) financial condition of the FASC; and
 - e) quality of care.
- 14.3 The licensing agency is authorized to make the reported data available to any state agency concerned with or exercising jurisdiction over the reimbursement of the FASC.
- 14.4 The directives promulgated by the Director pursuant to these regulations shall be sent to each FASC to which they apply. Such directives shall prescribe the form and manner in which the financial and statistical data required shall be furnished to the licensing agency.

PART III *PATIENT CARE SERVICES*

Section 15.0 *Admission, Transfer and Discharge*

- 15.1 Each FASC shall have written admission, transfer and discharge policies and procedures pertaining to at least the following:
- a) types of surgical procedures and conditions acceptable for admission;
 - b) emergency admission;
 - c) requirements for pre-admission history in accordance with section 19.3 herein;
 - d) transfer of patients for continuity of care or emergency care;
 - e) discharge of patient with responsible adult, as indicated;
 - f) constraints imposed by limitations of services, physical facilities; and
 - g) instruction of patients on self care upon discharge.

Section 16.0 *Patient Care Management*

- 16.1 Each patient shall be under the continuing supervision of a physician and provisions shall be made to assure the availability of a physician through the period of a patient's stay in the FASC.
- 16.2 A mechanism shall be established for the development and periodic review and revision of patient care policies and procedures which shall pertain to no less than:
- a) scope of services provided either directly or per contractual arrangements;
 - b) criteria for admission, transfer and discharge;
 - c) physician services and consultation services;
 - d) radiology and laboratory services; and
 - e) counseling services, if indicated.
- 16.3 The names and telephone number(s) of physicians to be called in an emergency including rescue or ambulance services shall be posted and easily accessible.
- 16.4 No medication shall be given except on the signed order of a lawfully authorized person. Emergency telephone orders shall be signed within twenty-four (24) hours.

Section 17.0 *Anesthesia Service*

- 17.1 A qualified anesthesiologist shall be on the staff.
- 17.2 There shall be written policies and procedures regarding: (1) privileges of staff for anesthesiology established in accordance with section 8.5 herein; (2) emergency coverage; (3) administration of anesthetics; (4) the maintenance of safety controls; and (5) qualifications and supervision of non-physician anesthetists. In addition, the policies shall include provisions for at least the following:
- a) pre-anesthesia evaluation by a physician;
 - b) safety of the patient during the anesthesia period;
 - c) review of patient's condition prior to induction of anesthesia and post-anesthetic evaluation; and
 - d) recording of all events related to each phase of anesthesia care.

Section 18.0 *Counseling and Referral Service*

- 18.1 When irreversible procedures are to be performed, such as human sterilization or termination of pregnancy, or when indicated in other situations, counseling service shall be provided through physicians, qualified nurses, social workers or trained counselors or a list of counseling agencies shall be made available to patients.

Section 19.0 *Nursing Care Service*

- 19.1 Nursing care service shall be under the direction of a full time licensed registered nurse who has training and experience in surgical nursing, and who shall be responsible for the supervision of nursing care needs of patients in preparation for and during the surgical procedure, and during the recovery period until discharged from the FASC by the responsible physician.
- 19.2 The number and type of registered nurses and ancillary personnel shall be based on the scope of services provided and staff capabilities, to ensure direct patient care as needed throughout the period of the patient(s) stay.
- 19.3 It shall be the responsibility of the registered nurse to obtain directly from the patient, per telephone if possible, a pre-admission history, distinct from the history obtained by the private physician.

Section 20.0 *Infection Control*

- 20.1 A mechanism shall be established by the Medical Director for the development of infection control policies which shall pertain to no less than:

- a) infection surveillance activities
- b) sanitation and asepsis;
- c) isolation of patients with known or suspected infectious diseases;
- d) handling and disposal of waste and contaminants;
- e) sterilization, disinfection and laundry;
- f) reporting, recording and evaluation of occurrences of infections; and
- g) documentation of infection rate.

20.2 The facility shall report promptly to the licensing agency infectious diseases which may present a potential hazard to patients, personnel and the public. Included are the reportable diseases and the occurrences of other diseases in outbreak form.

Section 21.0 *Surgical Service*

- 21.1 Written staff rules and regulations and policies shall be established to govern surgical services which shall include surgical staff privileges, supporting services of professional and paramedical personnel, provisions for emergency coverage and operating suite procedures.
- 21.2 Surgical procedures shall be performed only by physicians, dentists or podiatrists who are licensed in the state and who have been granted privileges to perform those procedures by the governing body of the FASC in accordance with section 8.5 herein.
- 21.3 Each FASC shall have a written transfer agreement for transferring patients to a nearby hospital when hospitalization is indicated, or shall permit elective surgery only by licensed practitioners who have similar privileges at a nearby licensed hospital and approved by the governing body of the FASC.
- 21.4 Surgical procedures performed in the FASC shall be limited to those procedures and approved by the governing body.
- 21.5 If termination of pregnancy procedures are performed in a FASC the requirements of the rules and regulations of reference 7 shall apply.
- 21.6 An anesthesiologist or another physician qualified in resuscitative technique shall be present or immediately available until all patients operated on a given day have been discharged.
- 21.7 Each operating room suite shall be:
 - a) under the supervision of a person qualified by training and experience in operating room service;

- b) designed and equipped so that the types of surgery conducted and the type of anesthesia utilized (general or local) shall meet the fire and safety requirements of sections 30.3 and/or 30.4 herein;
 - c) designed to include recovery rooms, proper scrubbing, sterilizing and dressing room facilities, storage for anesthetic agents;
 - d) equipped to carry out all necessary and emergency procedures; and
 - e) provided with prominently posted policies and procedures pertaining to safety controls.
- 21.8 All tissues/specimens removed at surgery shall be submitted for pathological examination except those exempted by the surgeon in writing.
- 21.9 Procedures shall be established to obtain blood or blood substitutes on a timely basis.
- 21.10 The patient's medical record shall be available in the operating room at the time of surgery and shall contain no less than the following information:
- a) a medical history and physical examination;
 - b) a urinalysis and CBC;
 - c) a signed consent form for surgical procedure; and
 - d) a pre-operative diagnosis.
- 21.11 An accurate and complete description of operative procedure shall be recorded by the operating surgeon immediately following completion of surgery.
- 21.12 Areas for the processing of clean and dirty supplies and equipment shall be separated by physical barriers.
- 21.13 Written procedures shall be established for all sterilization and for the appropriate disposal of wastes and contaminated supplies.
- 21.14 Reports of bacteriological tests and dated recordings of thermometer charts and inspection records shall be maintained on the premises.

Section 22.0 *Supplies and Equipment*

- 22.1 Supplies of appropriate sterile linens, gloves, dressings and so forth, shall be maintained in sufficient quantities for regular and emergency use.
- 22.2 Such surgical instruments, accessory and operating room lights and resuscitation equipment as

are appropriate for the types of surgery and surgical risks which may be encountered in a FASC shall be provided and maintained in clean and sterile condition.

- 22.3 Supplies of appropriate drugs, medications, fluids, electrolyte solutions, etc. shall be maintained in sufficient quantities for regular and emergency use.

Section 23.0 *Deficiencies and Plans of Correction*

- 23.1 The licensing agency shall notify the governing body or other legal authority of a facility of violations of individual standards through a notice of deficiencies which shall be forwarded to the facility within fifteen (15) days of inspection of the facility unless the director determines that immediate action is necessary to protect the health, welfare, or safety of the public or any member thereof through the issuance of an immediate compliance order in accordance with Section 23-1-21 of the General Laws of Rhode Island, as amended.
- 23.2 A facility which received a notice of deficiencies must submit a plan of correction to the licensing agency within fifteen (15) days of the date of the notice of deficiencies. The plan of correction shall detail any requests for variances as well as document the reasons therefore.
- 23.3 The licensing agency will be required to approve or reject the plan of correction submitted by a facility within fifteen (15) days of receipt of the plan of correction.
- 23.4 If the licensing agency rejects the plan of correction, or if the facility does not provide a plan of correction or if a facility whose plan of correction has been approved by the licensing agency fails to execute its plan within a reasonable time, the licensing agency may invoke the sanctions enumerated in Section 7.0 herein. If the facility is aggrieved by the action of the licensing agency, the facility may appeal the decision and request a hearing in accordance with Chapter 42.35.

Section 24.0 *Laboratory and Radiology Services*

- 24.1 Each FASC may perform on the premises limited procedures such as urinalysis and CBC, provided that personnel are qualified by training and are under supervision of a physician.
- 24.2 The requirements of reference 9 pertaining to radiology shall apply to those FASC providing such services.

24.2.1 *Mammography:*

All aspects of mammography services shall be managed in accordance with the provisions of the *Rules & Regulations related to Quality Assurance Standards for Mammography* (R23-1-MAM) of the Rhode Island Department of Health.

Section 25.0 *Medical Records*

- 25.1 A member of the professional staff shall be designated to supervise the medical records and to

ensure proper documentation, completion, indexing, filing, retrieval and safe storage.

25.2 A medical record shall be established and maintained for every patient cared for in the FASC.

25.3 Each medical record shall contain sufficient information and data to support the diagnosis, plan of treatment and shall contain no less than the following:

- a) patient identification, (name, address, birth date, etc.);
- b) medical history and physical examination;
- c) pre-operative and final diagnosis;
- d) nurses' notes;
- e) anesthesiologists reports, medical consultation, and counseling (if any);
- f) surgeon's operative notes, progress report and discharge notes;
- g) instructions given patient upon discharge; and
- h) other related reports.

Section 26.0 ***Medical Consultation***

26.1 Consultation and assistance in specialty fields shall be readily available and used as indicated prior to and when necessary following a surgical procedure. A facility shall maintain a current list of consultants available.

Section 27.0 ***Emergency Transfer***

27.1 Each FASC shall have resources available for the emergency transfer of patients to a hospital. When indicated, a physician or nurse shall accompany the patient.

PART IV *ENVIRONMENTAL MAINTENANCE*

Section 28.0 *Environment*

- 28.1 The FASC shall be maintained and equipped to provide a functional sanitary, safe and comfortable environment, with all furnishings in good repair, and the premises shall be kept free of hazards.
- 28.2 Written policies and procedures shall be established pertaining to environmental controls to assure comfortable, safe and sanitary environment with well-lighted space for the services provided.
- 28.3 Equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe, sanitary condition.
- 28.4 Hazardous cleaning solutions, compounds and substances shall be labeled, stored in a safe place and kept in an enclosed section separate from other cleaning materials.
- 28.5 Cleaning shall be performed in a manner which minimizes the spread of pathogenic organisms in the atmosphere.
- 28.6 Operating rooms shall be thoroughly cleaned after each operation.
- 28.7 Smoking shall be permitted only in restricted areas.

PART V *PHYSICAL PLANT AND EQUIPMENT*

Section 29.0 *New Construction*

- 29.1 All new construction shall be subject to the provisions of references 3, 4, and 6.
- 29.2 In addition, any other applicable state and local laws, codes and regulations shall apply. Where there is a difference between codes, the code having the higher standard shall apply.

Section 30.0 *Physical Facility*

- 30.1 Patient examination, waiting, procedure and recovery rooms shall be designed and equipped to provide good and safe care, as well as to provide privacy and comfort for patients.
- 30.2 Sufficient space shall be provided in the patient recovery areas to accommodate the patient load with a planned recovery period and to accommodate emergency equipment and staff to move freely.
- 30.3 If flammable agents are present in an operating room, the room shall be constructed and equipped in accordance with the standards of publication No. 56A, (1973) of reference 8.
- 30.4 If only non-flammable agents are present in an operating room, the room shall be constructed and equipped in compliance with standards of publication No. 56G, (1975) of reference 8.
- 30.5 Heating and ventilation systems shall be capable of maintaining comfortable temperatures.
- 30.6 Each FASC shall meet the fire and safety provisions of reference 3 and shall conform with all state and local building codes.
- 30.7 An elevator shall be provided where patient care is provided at different floor levels. The cab size of the elevator shall be large enough to accommodate a stretcher and an attendant.
- 30.8 Medication and storage areas shall be provided and equipped with locks to ensure the safe keeping of drugs and biologicals.

Section 31.0 *Emergency Power*

- 31.1 Each FASC shall be equipped with an alternate emergency power source.
- 31.2 The emergency electrical power system shall have a sufficient capacity to supply power to maintain the operation of the operating room and other life-support systems, and lighting of egress, fire detection equipment, alarm and extinguishing systems.
- 31.3 Monthly testing of emergency power shall be documented and reports retained for at least three (3) years.

Section 32.0 *Lighting and Electrical Services*

- 32.1 All electrical and other equipment used in the FASC shall be maintained free of defects which could be a potential hazard to patients or personnel. Periodic calibration and/or preventive maintenance of equipment shall be provided and documentation of all testing shall be maintained.

Section 33.0 *Plumbing*

- 33.1 All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of reference 4.
- 33.2 All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections between potable and non-potable water supplies.

Section 34.0 *Water Supply*

- 34.1 Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the facility and shall be adequate in volume and pressure for all purposes including fire fighting.

Section 35.0 *Waste Disposal*

35.1 *Medical Waste*

Medical waste as defined in the *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste (DEM-DAH-MW-01-92)*, promulgated by the Rhode Island Department of Environmental Management, shall be managed in accordance with the provisions of the aforementioned regulations.

35.2 *Other Waste:*

Wastes which are not classified as infectious waste, hazardous wastes, or which are not otherwise regulated by law or rule may be disposed in dumpsters or load packers provided the following precautions are maintained:

- a) Dumpsters shall be tightly covered, leak proof, inaccessible to rodents and animals, and placed on concrete slabs preferably graded to a drain. Water supply shall be available within easy accessibility for washing down of the area. In addition, the pick-up schedule shall be maintained with more frequent pick-ups when required. The dumping site of waste materials must be in sanitary landfills approved by the Department of Environmental Management.

- b) Load packers must conform to the same restrictions required for dumpsters and in addition, load packers shall be:
 - a) high enough off the ground to facilitate the cleaning of the underneath areas of the stationary equipment; and
 - b) the loading section shall be constructed and maintained to prevent rubbish from blowing from said area site.

Section 36.0 *Waste Water Disposal*

- 36.1 If a municipal sanitary sewer system is available, the facility shall be connected to the system, if feasible. If a municipal sanitary sewer system is not available the facility shall meet the standards set forth by the Department of Environmental Management.

PART VI ***EXCEPTION AND SEVERABILITY***

Section 37.0 ***Exception***

- 37.1 Modification of any individual standards herein, for experimental or demonstration purposes, or any other purpose, shall require advance written approval from the licensing agency.

Section 38.0 ***Rules Governing Practices and Procedures***

- 38.1 All hearings and reviews required under the provisions of Chapter 23-17 of the General Laws of Rhode Island, as amended, shall be held in accordance with the provisions of the *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)*.

Section 39.0 ***Severability***

- 39.1 If any provision of these regulations or the application thereof to any facility or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.

PART VII *REFERENCES*

1. "Health Care Facility Licensing Act of Rhode Island," Chapter 23-16 of the General Laws of Rhode Island, as amended.
2. "Administrative Procedures Act," Chapter 42-35 of the General Laws of Rhode Island, as amended.
3. "Rhode Island State Fire Safety Code," Chapter 23-28.1 of the General Laws of Rhode Island, as amended.
4. "Rhode Island State Building Code," Chapter 23-27.3 of the General Laws of Rhode Island, as amended.
5. "Department of Health," Chapter 23-1 of the General Laws of Rhode Island, as amended.
6. The American National Standard - Specifications for Making Buildings and Facilities Accessible to and Usable by, The Physically Handicapped," American National Standards Institute, Inc., 1430 Broadway, New York, New York 10013.
7. *Rules and Regulations for the Termination of Pregnancy*, Rhode Island Department of Health.
8. "National Fire Protection Association," 470 Atlantic Avenue, Boston, Massachusetts 02110.
9. *Rules and Regulations for the Control of Radiation*, Radiation Control Agency, Rhode Island Department of Health.
10. "Health Care Certificate of Need Act of Rhode Island", Chapter 23-15 of the Rhode Island General Laws, as amended.
11. *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste in Rhode Island (DEM-DAH-MW-01-92)*, Rhode Island Department of Environmental Management, April 1994.
12. "Guidelines for Prevention of Tuberculosis Transmission in Hospitals", U.S. Department of Health and Human Services, HHS Publication, No. (CDC) 82-8371, January 1982.