

**216-RICR-40-10-13**

## **TITLE 216 – DEPARTMENT OF HEALTH**

### **CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION**

#### **SUBCHAPTER 10 – FACILITY REGULATION**

PART 13 – Licensure of Physician Ambulatory Surgery Centers and Podiatry Ambulatory Surgery Centers

#### **13.1 Authority**

These regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws § [23-17-10](#), and are established for the purpose of adopting minimal standards for the licensure of physician ambulatory surgery centers and podiatry ambulatory surgery centers in this state.

#### **13.2 Incorporated Materials**

- A. These regulations hereby adopt and incorporate American National Standards Institute, Inc.'s "Specifications for Making Buildings and Facilities Accessible to and Usable by, The Physically Handicapped" (1980) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
- B. These regulations hereby adopt and incorporate the American Society of Anesthesiologists' "The ASA Physical Status Classification System" (1999) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
- C. These regulations hereby adopt and incorporate the American Society of Anesthesiologists' "Basic Standards for Preanesthesia Care, Standards for Basic Anesthetic Monitoring, and Standards for Postanesthesia Care" (2015) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
- D. These regulations hereby adopt and incorporate the American Society of Anesthesiologists' "Guidelines for Office-Based Anesthesia," (2014) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
- E. These regulations hereby adopt and incorporate the American Institute of Architects Academy of Architecture for Health's "Guidelines for Design and Construction of Hospital and Health Care Facilities" (2001), by reference, not

including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

### **13.3 Definitions**

- A. Wherever used in these rules and regulations the following terms shall be construed to mean:
1. "Accreditation agency" means an entity, approved by the Director, which grants accreditation to physician ambulatory surgery centers and podiatry ambulatory surgery centers. Accreditation agencies approved by the Director include: the Joint Commission on Accreditation of Healthcare Organizations, the American Association for Accreditation of Ambulatory Surgery Facilities, Inc., and the Accreditation Association for Ambulatory Health Care, Inc.
  2. "Anesthesiologist" means a physician licensed in Rhode Island who is board certified, or becoming so, in anesthesia and has privileges to administer anesthesia in a Rhode Island licensed health care facility.
  3. "Certified registered nurse anesthetist" means a registered nurse who has successfully met the requirements for licensure which are set forth in the "Rules and Regulations for Licensing of Nurses and Standards for the Approval of Basic Nursing Education Programs".
  4. "The practice of certified registered nurse anesthesia" means providing certain health care services under the supervision of anesthesiologists, licensed physicians, or licensed dentists, in accordance with R.I. Gen. Laws § 5-31.1-1(g) which requires substantial specialized knowledge, judgement and skill related to the administration of anesthesia, including pre-operative and post-operative assessment of patients; administration of anesthetics; monitoring patients during anesthesia; management of fluid in intravenous therapy and respiratory care.
  5. "Conscious sedation" means a drug-induced depression of consciousness during which patients respond purposefully (reflex withdrawal from a painful stimulus is not considered a purposeful response) to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
  6. "Director" means the Director of the Rhode Island Department of Health.
  7. "Employee", as used in § 13.4.1(E) of this Part, means an individual who is required to comply with instructions about when, where, and how to work, both as to the final results and as to the details of when, where, and how the work is to be done. The employer need not actually exercise this

control; it is sufficient that he has the right to do so. When the employer does not possess this control, the individual involved is not an employee, but an independent contractor.

8. "Exempt procedures" means:
  - a. Minor surgical procedures such as excision of skin lesions, moles, warts, lipomas and repair of lacerations, incision and drainage of superficial abscesses, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug induced alteration of consciousness other than minimal pre-operative tranquilization of the patient;
  - b. Procedures not requiring or using conscious sedation techniques or pre-operative medications other than minimal pre-operative tranquilization of the patient;
  - c. Procedures requiring or using only local, topical, or no anesthesia.
9. "General anesthesia" means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.
10. "The licensed capacity" of the physician ambulatory surgery center and/or podiatry ambulatory surgery center means the number of operating/procedure rooms that the physician ambulatory surgery center and/or podiatry ambulatory surgery center is licensed to operate.
11. "Licensing agency" or "state agency" means the Rhode Island Department of Health.
12. "Local anesthesia" means the injection of a local anesthetic agent (e.g., Lidocaine) into and around the operative site to achieve numbness in the area where a painful procedure is to be performed. This type of anesthesia does not involve any systemic sedation.
13. "Operating room or procedure room" means the area of the office operatory wherein a surgical treatment is performed.
14. "Person" means any individual, trust or estate, partnership, corporation (including associations, joint stock companies), limited liability company, state, or political subdivisions or instrumentality of a state.

15. "Physician" means a person licensed to practice allopathic or osteopathic medicine in this state, pursuant to the provisions of R.I. Gen. Laws Chapter 5-37.
16. "Physician ambulatory surgery center," means an office or portion thereof owned and/or operated by a physician-controlled professional services corporation as defined in R.I. Gen. Laws Chapter 7-5.1 or a private physician's office or group of physicians' offices (whether owned and/or operated by an individual practitioner, alone or as a member of a partnership, professional service corporation, organization, or association) which is utilized for the purpose of furnishing surgical services to said owner and/or operator's own patients on an ambulatory basis.
17. "Podiatrist" means a person with a license to practice podiatric medicine and surgery in this state under the provisions of R.I. Gen. Laws Chapter 5-29.
18. "Podiatry ambulatory surgery center" means an office or portion of an office owned and/or operated by a podiatrist controlled professional service corporation as defined in R.I. Gen. Laws Chapter 7-5.1 or a private podiatrist's office or group of the podiatrists' offices (whether owned and/or operated by an individual practitioner, alone or as a member of a partnership, professional service corporation, organization, or association) which is utilized for the purpose of furnishing surgical services to the owner and/or operator's own patients.
19. "Regional anesthesia" means the use of local anesthetic agents to block nerves leading to the area where a painful procedure is to be done. There are many examples of regional anesthesia, including, but not limited to, spinal, interscalene, ankle, etc. Generally, regional anesthesia involves more of a physiological reaction because of the larger area blocked and/or the dose of local anesthesia. This type of anesthesia may or may not involve sedation.
20. "Registered nurse" means a person licensed under the provisions of R.I. Gen. Laws Chapter 5-34.
21. "Surgery" means the excision or resection partial/complete, destruction, incision or other structural alteration of human tissue by any means. Surgery shall have the same meaning as "operate."

## **13.4 Licensure Procedures**

### **13.4.1 General Requirements for Licensure**

- A. No person acting severally or jointly with any other person, shall establish, conduct or maintain a physician ambulatory surgery center in this state without a

license in accordance with the requirements of R.I. Gen. Laws § 23-17-4. Physician ambulatory surgery center licensure shall not be required for the performance of exempt procedures as defined herein.

- B. On or after January 6, 2003 , no person acting severally or jointly with any other person, shall establish, conduct or maintain a podiatry ambulatory surgery center in this state without a license in accordance with the requirements of R.I. Gen. Laws § 23-17-4. Podiatry ambulatory surgery center licensure shall not be required for the performance of exempt procedures as defined herein.
- C. Exemption from the requirements of certificate of need for a single-practice physician or podiatry ambulatory surgery center is pursuant to R.I. Gen. Laws § 23-15-2(4)(i).
- D. Initial licensure and/or changes in owner, operator or lessee of a physician ambulatory surgery center or podiatry ambulatory surgery center are subject to approval of the licensing agency.
- E. Surgery provided within the physician ambulatory surgery center/ podiatry ambulatory surgery center shall be provided solely by physicians or podiatrists, respectively, who are or who comprise, or are employees of, the person to whom the license is issued.

#### **13.4.2 Application for License**

- A. Application for a license to conduct, maintain or operate a physician ambulatory surgery center/ podiatry ambulatory surgery center shall be made to the licensing agency upon forms provided by it one (1) 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 R.I. Gen. Laws Chapter 23-17 and the rules and regulations herein.
  - 1. Each application shall be accompanied by a non-refundable application fee as set forth in the rules and regulations pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
- B. A 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 upon any change to such ownership information.
  - 1. The licensing agency shall be informed forthwith of any change in owner of a licensed physician ambulatory surgery center/ podiatry ambulatory surgery center.

#### **13.4.3 Issuance and Renewal of License**

- A. 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 R.I. Gen. Laws Chapter 23-17 and the rules and regulations herein. Said license, unless sooner suspended or revoked, shall expire by limitation on the 31st day of December beginning in the year 2001 (2003 for podiatry ambulatory surgery centers) and may be renewed from year to year after inspection and approval by the licensing agency.
  - 1. All renewal applications shall be accompanied by a non-refundable application fee as set forth in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
- B. A license shall be issued to a specific licensee for a specific location and shall not be transferable.
- C. 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.

#### **13.4.4 Capacity**

- A. The license for a physician ambulatory surgery center/ podiatry ambulatory surgery center shall be issued for a specified number of operating/procedure rooms.
- B. The post-surgical recovery area of a physician ambulatory surgery center/ podiatry ambulatory surgery center shall be adequate to meet patients' needs.

#### **13.4.5 Inspections**

- A. The licensing agency shall make or cause to be made such inspections and investigations as it deems necessary and in accordance with R.I. Gen. Laws § 23-17-10 and the rules and regulations herein.
  - 1. Within nine (9) months of initial licensure, the physician ambulatory surgery center/ podiatry ambulatory surgery center shall file an acceptable application with an accreditation agency, as defined herein.
  - 2. Within twenty four (24) months of initial licensure, the physician ambulatory surgery center/ podiatry ambulatory surgery center shall attain appropriate certification from an accreditation agency, as defined in herein.
  - 3. Each physician ambulatory surgery center/ podiatry ambulatory surgery center, having obtained accreditation pursuant to § 13.4.5(A)(2) of this Part, shall maintain such certification as a condition of licensure.

4. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall provide the state agency with complete copies of all correspondence received from or mailed to any accreditation agency related to certification from the accreditation agency. Said copies shall be supplied to the state agency within three (3) days of receipt or mailing of the correspondence.
- B. Every physician ambulatory surgery center/ podiatry ambulatory surgery center shall be given prompt notice by the licensing agency of any deficiencies reported as a result of an inspection or investigation.
- C. Written reports and recommendations of inspections, including such materials from the state agency and the accreditation agency, shall be maintained on file in each physician ambulatory surgery center/ podiatry ambulatory surgery center for a period of no less than three (3) years. Physician ambulatory surgery center/ podiatry ambulatory surgery center plans for the correction of identified deficiencies shall also be maintained on file for a period of no less than three (3) years.
- D. All materials required pursuant to § 13.4.5 of this Part shall be deemed to be public records and shall be made available by the physician ambulatory surgery center/ podiatry ambulatory surgery center to members of the public on request.

#### **13.4.6 Denial, Suspension, Revocation of License or Curtailment of Activities**

- A. The licensing agency is authorized to deny, suspend or revoke the license or curtail activities of any physician ambulatory surgery center/ podiatry ambulatory surgery center which:
  1. Has failed to comply with the rules and regulations pertaining to the licensing of physician ambulatory surgery center/ podiatry ambulatory surgery centers; and
  2. Has failed to comply with the provisions of R.I. Gen. Laws Chapter 23-17.
  3. Lists of deficiencies noted in inspections conducted in accordance with § 13.4.5 of this Part 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 physician ambulatory surgery center/ podiatry ambulatory surgery center.
- B. Where the licensing agency deems that operation of a physician ambulatory surgery center/ podiatry ambulatory surgery center results in undue hardship to patients as a result of deficiencies, the licensing agency is authorized to deny licensure to a physician ambulatory surgery center/ podiatry ambulatory surgery center not previously licensed, or to suspend for a stipulated period of time or revoke the license of a physician ambulatory surgery center/ podiatry ambulatory

surgery center already licensed or curtail activities of the physician ambulatory surgery center/ podiatry ambulatory surgery center.

- C. Whenever an action shall be proposed to deny, suspend or revoke a physician ambulatory surgery center/ podiatry ambulatory surgery center license, or curtail its activities, the licensing agency shall notify the physician ambulatory surgery center/ podiatry ambulatory surgery center 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 R.I. Gen. Laws §§ 23-17-8 and 42-35-9.
- D. 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 R.I. Gen. Laws §§ 23-1-21 and 42-35-14(c).
- E. The appropriate state and federal placement and reimbursement agencies and the relevant accreditation agency(ies) shall be notified of any action taken by the licensing agency pertaining to denial, suspension or revocation of license, or curtailment of activities.

## **13.5 Organization and Management**

### **13.5.1 Control and Management**

- A. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall be 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 physician ambulatory surgery center/ podiatry ambulatory surgery center 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.
- B. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall provide appropriate personnel, physical resources, and equipment based on the scope of services provided.
- C. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall designate:



1. an administrator who shall be responsible for the management and operation of the physician ambulatory surgery center/ podiatry ambulatory surgery center; and
  2. a medical director to assure achievement and maintenance of quality standards of professional practice.
  3. The administrator and the medical director may be the same individual.
- D. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall adopt and maintain policies/procedures defining responsibilities for the operation and performance of the physician ambulatory surgery center/ podiatry ambulatory surgery center, identifying purposes and means of fulfilling such, and in addition the policies/procedures shall include but not be limited to:
1. A statement of qualifications and responsibilities of the medical director and administrator;
  2. A statement of the physician ambulatory surgery center/ podiatry ambulatory surgery center's responsibility for the quality of care and services;
  3. A statement of physician ambulatory surgery center/ podiatry ambulatory surgery center's policy establishing the criteria for the selection and admission of patients;
  4. Such other matters as may be relevant to the organization of the physician ambulatory surgery center/ podiatry ambulatory surgery center.
- E. All policies and procedures adopted by the physician ambulatory surgery center/ podiatry ambulatory surgery center shall be reviewed annually.

### **13.5.2 Personnel Requirements**

- A. The appointment of all personnel shall be documented in writing. The job description of each member of the physician ambulatory surgery center/ podiatry ambulatory surgery center shall be documented in writing and shall include directives related to responsibilities and discipline.
- B. A timely written performance evaluation shall be required for all employees.
- C. 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. All personnel, such as nurses, shall be licensed as required by the R.I. Gen. Laws.
- D. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall make initial appointments, and assignment or curtailment of surgical

privileges, based on the education, training, experience and evidence of competence of the licensed professional staff person providing surgical services, consistent with state law. (See also § 13.6.5(B) of this Part).

- E. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall clearly define in writing the responsibilities and supervision of any student personnel utilized in the physician ambulatory surgery center/ podiatry ambulatory surgery center.
- F. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall adhere to a written procedure for granting and renewing privileges for anesthesiologists or certified registered nurse anesthetists that specifies the required training, experience, board certification, and/or other factors that indicate acceptable proficiency.
- G. A physician ambulatory surgery center/ podiatry ambulatory surgery center shall require all persons, including students, who examine, observe, or treat a patient of such office operatory to wear photo identification badge which states, in a reasonably legible manner, the first name, licensure/registration status, if any, and staff position of such person.
- H. All surgical personnel, pre-operative, and recovery personnel shall be trained in basic life support (CPR) at least every two (2) years.
- I. All surgical personnel shall be trained in basic aseptic techniques.
- J. All surgical personnel shall wear suitable attire.
- K. Administrator. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall appoint a qualified administrator who may be the medical director, who shall be responsible for:
  - 1. The management and operation of the physician ambulatory surgery center/ podiatry ambulatory surgery center;
  - 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 physician ambulatory surgery center/ podiatry ambulatory surgery center and the staff; and
  - 4. The planning, organizing and directing of such other activities as may be delegated by the physician ambulatory surgery center/ podiatry ambulatory surgery center.
- L. Medical Director

1. The surgical services of the physician ambulatory surgery center/ podiatry ambulatory surgery center shall be under the direction of a physician licensed under the provisions of R.I. Gen. Laws Chapter 5-37, or a podiatrist licensed under the provisions of R.I. Gen. Laws Chapter 5-29, respectively, who meets the qualifications set forth by the physician ambulatory surgery center/ podiatry ambulatory surgery center in accordance with § 13.5.1 of this Part, 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 acceptable to the Director; and
  - d. The establishment of policies and procedures for surgical and anesthesia services and other related health care services.

M. Health Screening

1. Upon hire and prior to delivering services, a pre-employment health screening shall be required for each individual who has or may have direct contact with a patient in the physician ambulatory surgery center/ podiatry ambulatory surgery center. Such health screening shall be conducted in accordance with the rules and regulations pertaining to Immunization, Testing, and Health Screening for Health Care Workers (Part 20-15-7 of this Title) promulgated by the Department of Health.

**13.5.3 Quality Assurance**

The office operator shall establish a formal mechanism for quality assurance for all surgical services provided by all physicians or podiatrists performing surgical procedures in the physician ambulatory surgery center/ podiatry ambulatory surgery center. The quality assurance mechanism shall be in accordance with the requirements established by the accreditation agency.

**13.5.4 Peer Review**

- A. An organized process of peer review shall be conducted in accordance with the requirements of the accreditation agency. At a minimum, peer review shall provide for:
  1. Regular review of reportable events (see § 13.6.3(E) of this Part) with formal determination of strategies to improve outcomes and assessment of change accomplished; and

2. Formal review of credentials and privileges of all surgeons, certified registered nurse anesthetists, and anesthesiologists.
- B. Medical peer review shall be conducted in accordance with R.I. Gen. Laws §§ 5-37-1(10)(a) and (b) and subject to the confidentiality provisions of R.I. Gen. Laws § 5-37.3-7.

### **13.5.5 Administrative Records**

- A. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall maintain such administrative records as may be deemed necessary for the business operation of the physician ambulatory surgery center/ podiatry ambulatory surgery center, in addition to the following:
1. Monthly statistical summary of numbers of surgical procedures performed, appropriately classified;
  2. Controlled substances register if such are maintained at the physician ambulatory surgery center/ podiatry ambulatory surgery center;
  3. An operating/procedure room log book maintained in chronological sequence of admissions which shall include pertinent information such as patient's name, pre-op and post-op diagnosis, name of operating physician and person administering anesthesia, circulating nurse, surgical procedures performed, specimen sent for pathological examination, type of anesthesia and complications (if any); and
  4. A record of all transfers to a hospital for post-surgical care.

### **13.5.6 Disaster Preparedness**

- A. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall develop and maintain a written disaster preparedness plan that shall include specific provisions and procedures for the emergency care of patients in the event of fire, loss of utilities, bomb threat, natural disaster or functional failure of equipment.
1. Such a plan shall be developed and coordinated with appropriate state and local agencies and representatives concerned with emergency safety and rescue;
  2. A copy of the plan shall be submitted to the licensing agency;
  3. 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 physician ambulatory surgery center/ podiatry ambulatory surgery center and available for review by the licensing agency.

- B. Emergency action steps shall be clearly outlined and posted in conspicuous locations throughout the physician ambulatory surgery center/ podiatry ambulatory surgery center.

### **13.5.7 Uniform Reporting System**

Each physician ambulatory surgery center/ podiatry ambulatory surgery center 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.

## **13.6 Patient Care Services**

### **13.6.1 Rights of Patients**

- A. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall observe the standards enumerated in R.I. Gen. Laws § 23-17-19.1 with respect to each patient admitted to its physician ambulatory surgery center/ podiatry ambulatory surgery center.
- B. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall display in a conspicuous place in the licensed physician ambulatory surgery center/ podiatry ambulatory surgery center a copy of the "Rights of Patients."

### **13.6.2 Admission, Transfer and Discharge**

- A. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall have and implement written admission, transfer and discharge policies and procedures pertaining to at least the following:
  1. Types of surgical procedures and conditions acceptable for admission;
  2. Requirements for pre-admission history;
  3. Transfer of patients for continuity of care or emergency care accompanied by the "Rhode Island Department of Health Continuity of Care Short Form" available on-line: [www.healthri.org](http://www.healthri.org);
  4. Emergency instructions shall be posted at each telephone. The names and telephone numbers to be called in an emergency shall be posted and easily accessible (including, but not limited to, "911", physicians to be called in an emergency, nearest hospital emergency department).
  5. Emergency transfer of patients to the nearest full-service emergency department of an acute care hospital. When indicated, a physician, physician assistant, or nurse shall accompany the patient.

6. Discharge of patient with responsible adult, as indicated;
7. Constraints imposed by limitations of services, physical facilities; and
8. Instruction of patients on self-care upon discharge.

### **13.6.3 Patient Care Management**

- A. Each patient shall be under the continuing supervision of a physician or podiatrist on-site throughout the period of a patient's stay in the physician ambulatory surgery center/ podiatry ambulatory surgery center.
- B. A physician, podiatrist, registered nurse, physician assistant, advanced practice nurse, or midwife shall care for the patient at all times while in the recovery area.
- C. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall have and implement written patient care management policies and procedures pertaining to at least the following:
  1. Scope of services provided either directly or per contractual arrangements;
  2. Criteria for admission, transfer and discharge;
  3. Management of patients with known or suspected infectious diseases, including the exclusion of patients who are known or suspected of having airborne infectious diseases;
  4. Physician services and consultation services;
  5. Staffing plan that delineates the personnel required to be present in the physician ambulatory surgery center/ podiatry ambulatory surgery center in order to provide effective safe patient care and all other related services;
  6. Radiology and laboratory services, including the facility's required minimum specific testing; and
  7. Counseling services, if indicated.
- D. All orders for medications or treatments must be in writing. An order is considered to be in writing if:
  1. It is written and signed by a lawfully authorized person; or
  2. It is dictated to and transcribed by a registered nurse or other appropriately licensed person onto the order form. Additionally, the registered nurse or other appropriately licensed person must:

- a. Date the order and identify the verbal order by the name and title of the authorized individual who gave the order; and
  - b. Sign the order entry with his/her own name and title. All verbal orders must be appropriately signed within twenty-four (24) hours.
- E. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall, within seventy-two (72) hours of receipt of such information, notify the licensing agency of any reportable event as follows:
1. Transfer of the patient from the physician ambulatory surgery center/ podiatry ambulatory surgery center to a hospital emergency department;
  2. Unscheduled hospital admission of the patient within seventy-two (72) hours of discharge from the physician ambulatory surgery center/ podiatry ambulatory surgery center;
  3. Extension of the surgical procedure beyond four (4) hours;
  4. Unplanned readmission to the physician ambulatory surgery center/ podiatry ambulatory surgery center within seventy-two (72) hours;
  5. Death of the patient within thirty (30) days;
  6. Subjecting a patient to a procedure not ordered or intended by the patient's physician, excluding: procedures not requiring a physician's order, medication errors, and collection of specimens, for laboratory study, obtained by non-invasive means or routine phlebotomy;
  7. Or any other incident reported to the malpractice insurance carrier.

#### **13.6.4 Anesthesia Service**

- A. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall have and implement written anesthesia service policies and procedures pertaining to at least the following:
1. Staff privileges for anesthesia services established in accordance with §§ 13.5.2(D) and (F) of this Part;
  2. Emergency coverage;
  3. Administration of anesthetics;
  4. The maintenance of safety controls, including, but not limited to, inspection, maintenance, and calibration of equipment;
  5. Qualifications and supervision of non-physician anesthetists;

6. Qualifications of the supervising physician;
  7. Anesthesia monitoring standards of § 13.2(C) of this Part.
- B. In addition, the policies shall include provisions for at least the following:
1. Pre-anesthesia evaluation by a physician;
  2. Safety of the patient during the anesthesia period;
  3. Review of patient's condition prior to induction of anesthesia and post-anesthetic evaluation in accordance with the standards cited in § 13.2(C) of this Part; and
  4. Recording of all events related to each phase of anesthesia care.
- C. A board-certified anesthesiologist or a board-certified anesthesiologist, in conjunction with a certified registered nurse anesthetist, if the facility utilizes certified registered nurse anesthetists to administer anesthesia shall be responsible for developing the policies and procedures cited in §§ 13.6.4(A) and (B) of this Part.
- D. General anesthesia shall be permitted only in those licensed physician ambulatory surgery centers/ podiatry ambulatory surgery centers that meet the requirements of §§ 13.6.4(E), (G), and 13.6.7(D) of this Part. If any type of anesthesia is administered that may fail mid-procedure necessitating the use of general anesthesia, the physician ambulatory surgery center/ podiatry ambulatory surgery center shall be in compliance with §§ 13.6.4(E), (G), and 13.6.7(D) of this Part at all times.
- E. No explosive anesthetics shall be utilized in any physician ambulatory surgery center/ podiatry ambulatory surgery center.
- F. The administration of anesthesia, with or without sedation or a dissociative drug, shall be under the direct supervision of a qualified physician.
- G. In a licensed physician ambulatory surgery center/ podiatry ambulatory surgery center administering general anesthesia, an anesthesiologist or a certified registered nurse anesthetist shall administer the anesthesia.
- H. In a licensed physician ambulatory surgery center/ podiatry ambulatory surgery center administering all types of anesthesia, other than general anesthesia, an anesthesiologist, a certified registered nurse anesthetist, or a physician shall administer anesthesia.
- I. The person administering anesthesia shall not function in any other capacity during the surgical procedure.



### 13.6.5 Surgical Service

- A. Written staff rules and regulations and policies shall be established and implemented to govern surgical services that shall include surgical staff privileges, supporting services of professional and paramedical personnel, provisions for emergency coverage and operating suite procedures.
- B. Surgical procedures shall be performed only by physicians or podiatrists who have current surgical privileges for the same or a similar class of procedures at a nearby hospital.
- C. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall schedule elective surgery only.
- D. Discharge of the patient shall be the responsibility of the operating physician or podiatrist and shall take place only after direct evaluation by the physician or podiatrist, determining the patient is adequately recovered to function independently (i.e., vital signs stable, full responsiveness and orientation, ability to move voluntarily). If sedation, regional block, or general anesthesia has been utilized, a responsible adult shall accompany the patient and be instructed about the patient's care.
- E. Surgical procedures performed in the physician ambulatory surgery center/ podiatry ambulatory surgery center shall:
  - 1. Be performed only on patients determined in writing by the operating physician or podiatrist prior to surgery to be classified as ASA Class 1, ASA Class 2, or ASA Class 3 under the American Society of Anesthesiology "Physical Status Classification". For ASA Class 3 patients, surgical procedures utilizing planned general anesthesia, or planned epidurals, spinals, or brachial plexus blocks, may be performed only when the operating physician or podiatrist and a board-certified anesthesiologist concur (in writing prior to the surgery) that the patient is an acceptable candidate for a surgical procedure in the physician ambulatory surgery center/ podiatry ambulatory surgery center setting;
  - 2. Not exceed an expected duration of two (2) hours, as documented in writing prior to the initiation of the procedure by the operating physician or podiatrist; Surgical procedures exceeding two (2) hours in duration shall be peer-reviewed and documented in accordance with the requirements set forth in § 13.5.4(A) of this Part.
  - 3. Be permitted only when at least one (1) physician, podiatrist, or a certified registered nurse anesthetist currently trained in Advanced Cardiac Life Support (ACLS) is available and will continue to be available in the recovery area until the patient is discharged from the physician ambulatory surgery center/ podiatry ambulatory surgery center.

- F. No overnight stays shall be permitted in the physician ambulatory surgery center/ podiatry ambulatory surgery center under any circumstances.
- G. If termination of pregnancy procedures are performed in a physician ambulatory surgery center, the requirements of the rules and regulations for the Termination of Pregnancy (Part 20-10-6 of this Title) shall also apply.
- H. Each operating/procedure room suite shall have policies and procedures pertaining to safety controls prominently posted.
- I. All tissues/specimens removed at surgery shall be submitted for pathological examination except those exempted in writing by the operating physician or podiatrist.
- J. The patient's medical record shall be available in the operating/procedure room at the time of surgery.
- K. An accurate and complete description of operative procedure shall be recorded by the operating physician or podiatrist within a timely fashion following completion of surgery.
- L. Areas for the processing of clean and dirty supplies and equipment shall be separated by physical barriers.
- M. Written procedures shall be adhered to for all sterilization and for the appropriate disposal of wastes and contaminated supplies.
- N. Reports of bacteriological tests and inspection records shall be maintained on the premises.

#### **13.6.6 Infection Control**

- A. A mechanism shall be established by the medical director for the development of infection control policies that shall pertain to no less than:
  - 1. Infection surveillance activities;
  - 2. Sanitation and asepsis;
  - 3. Handling and disposal of waste and contaminants;
  - 4. Sterilization, disinfection, and laundry;
  - 5. Reporting, recording and evaluation of occurrences of infections; and
  - 6. Documentation of infection rate.

- B. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall report promptly to the licensing agency infectious diseases that may present a potential hazard to patients, personnel, and the public. Included are the reportable diseases cited in the rules and regulations regarding "Rules and Regulations Pertaining to Reporting of Infectious, Environmental and Occupational Diseases [R23-10-DIS]" and the occurrences of other diseases in outbreak form.

### **13.6.7 Supplies and Equipment**

- A. Supplies of appropriate sterile linens, gloves, dressings and so forth, shall be maintained in sufficient quantities for routine and emergency use.
- B. Such surgical instruments, accessory and operating/procedure room lights, and resuscitation equipment as are appropriate for the types of surgery and surgical risks that may be encountered in a physician ambulatory surgery center/ podiatry ambulatory surgery center shall be provided and maintained in clean, safe, and sterile condition.
  - 1. An adequately-stocked cardiopulmonary resuscitative cart shall be available for emergencies and shall include, at a minimum, an Ambu Bag, a laryngoscope, airway management equipment, and a medication kit. The medication kit shall include appropriate medications for the treatment of anaphylaxis, cardiac arrhythmias, cardiac arrest, and malignant hyperthermia.
- C. When anesthesia is utilized, appropriate monitoring equipment shall be available, shall be maintained in proper working condition, shall meet the requirements of the guidelines of § 13.2(D) of this Part incorporated above in this Part, and shall include monitors for pulse oximeter, non-invasive blood pressure, and EKG.
- D. In those physician ambulatory surgery centers/ podiatry ambulatory surgery centers administering general anesthesia, the following monitoring equipment shall be present in the facility: blood pressure apparatus, EKG oscilloscope, defibrillator, pulse oximeter with alarm, oxygen analyzer with alarm, and CO2 monitor.
- E. Defibrillating equipment shall be available.
- F. Supplies of appropriate drugs, medications, fluids, electrolyte solutions, etc. shall be maintained in sufficient quantities for routine and emergency use.
- G. Any physician ambulatory surgery center/ podiatry ambulatory surgery center that utilizes latex gloves shall do so in accordance with the provisions of the Use of Latex Gloves by Health Care Workers, in Licensed Health Care Facilities, and by Other Persons, Firms, or Corporations Licensed or Registered by the Department (Part 20-15-3 of this Title) promulgated by the Department of Health.

### **13.6.8 Laboratory, Radiology, and Pharmaceutical Services**

- A. Each physician ambulatory surgery center/ podiatry ambulatory surgery center may perform on the premises limited procedures such as urinalysis and CBC, provided that personnel are qualified by training and are under the supervision of a physician.
- B. The requirements of the "Rules and Regulations for the Control of Radiation" pertaining to radiology shall apply to those office operator providing such services.
- C. Each physician ambulatory surgery center/ podiatry ambulatory surgery center performing laboratory testing shall be in compliance with the requirements of 42 C.F.R. Part 493.
- D. Pharmaceutical services, if provided by the physician ambulatory surgery center/ podiatry ambulatory surgery center, shall be provided in accordance with prevailing standards of professional practice and shall be supervised by a pharmacist licensed in Rhode Island, by an operating physician, or by a podiatrist who is qualified to assume professional, organization, and administrative responsibility for the quality of services rendered.
- E. Record-keeping and security measures shall be maintained to assure the control and safe dispensing of drugs in compliance with all state and federal laws.
- F. Provisions for secure storage and proper record-keeping of all controlled substances shall be in accordance with R.I. Gen. Laws Chapter 21-28.
- G. Dispensing and labeling of all pharmaceuticals shall be in accordance with R.I. Gen. Laws Chapter 21-31.
- H. The quality and appropriateness of medication usage shall be monitored and evaluated as part of the quality assurance program required herein.

### **13.6.9 Medical Records**

- A. An individual shall be designated to supervise the medical records and to ensure proper documentation, completion, indexing, filing, retrieval, and safe storage.
- B. A medical record shall be established and maintained for every patient cared for in the physician ambulatory surgery center/ podiatry ambulatory surgery center. Said medical record may be the same patient record maintained in the physician's/podiatrist's office, provided that the information stipulated in § 13.6.9(C) of this Part is included.
- C. Each medical record shall contain sufficient information and data to support the diagnosis, plan of treatment, and shall contain no less than the following:

1. Patient identification, (name, address, birth date, etc.);
2. Medical history and physical examination;
3. Pre-operative and final diagnosis;
4. Results of all appropriate, minimum specific tests for the procedure(s) to be performed;
5. A signed consent form for surgical procedure;
6. A signed consent form for anesthesia;
7. The expected duration of the surgical procedure(s);
8. The type(s) of anesthesia to be used and the expected duration of each;
9. The patient's pre-operative ASA classification(s) as determined by:
  - a. the operating physician;
  - b. any consulting physician(s);
  - c. physician assistant(s) in collaboration with a physician; and
  - d. the anesthesiologist or certified registered nurse anesthetist;
  - e. For ASA Class 3 patients who are undergoing surgical procedures utilizing planned general anesthesia, or planned epidurals, spinals, or brachial plexus blocks, a written statement from a board-certified anesthesiologist concurring that the patient is an acceptable candidate for a surgical procedure in the physician ambulatory surgery center/ podiatry ambulatory surgery center setting shall also be required. (See § 13.6.5(E)(1) of this Part).
10. Nurses' notes;
11. Anesthesiologist's and/or certified registered nurse anesthetist's reports, including pre- anesthesia evaluation, intra-operative anesthesia record, and post-anesthesia evaluation;
12. Medical consultation, and counseling (if any);
13. Operating physician's/podiatrist's operative notes, progress reports, and discharge notes;
14. Instructions given patient upon discharge; and
15. Other related reports.

D. Medical Consultation

1. Consultation and assistance in specialty fields shall be readily available and used as indicated prior to and/or following a surgical procedure. A physician ambulatory surgery center/ podiatry ambulatory surgery center shall maintain a current list of consultants available.

## **13.7 Environmental Maintenance**

### **13.7.1 Environment**

- A. The physician ambulatory surgery center/ podiatry ambulatory surgery center shall be maintained and equipped to provide a functional sanitary, safe and comfortable environment, with all furnishings in good repair. The premises shall be kept free of hazards.
- B. 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.
- C. Equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe, sanitary condition.
- D. 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.
- E. Cleaning shall be performed in a manner that minimizes the spread of pathogenic organisms in the atmosphere.
- F. Operating/procedure rooms shall be thoroughly cleaned after each operation.
- G. Smoking shall not be permitted.

## **13.8 Physical Plant and Equipment**

### **13.8.1 New Construction**

- A. All new construction shall be subject to the provisions of R.I Gen. Laws Chapters 23-28.1 and 23-27.3, and § 13.2(A) of this Part above.
- B. 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 more stringent standard shall apply.
- C. All plans for new construction or the renovation, alteration, extension, modification or conversion of an existing facility that may affect compliance with § 13.8.2 of this Part shall be reviewed by a licensed architect, acceptable to the

Director. Said architect shall certify that the plans conform to the construction requirements of § 13.8.2 of this Part, prior to construction. The facility shall maintain a copy of the plans reviewed and the architect's signed certification, for review by the Department of Health upon request.

1. In the event of non-conformance for which the facility seeks a variance, the general procedures outlined in § 13.9.2 of this Part shall be followed. Variance requests shall include a written description of the entire project, details of the non-conformance for which the variance is sought and alternate provisions made, as well as detailing the basis upon which the request is made. The Department may request additional information while evaluating variance requests.
  2. If variances are granted, a licensed architect shall certify that the plans conform to all construction requirements of § 13.8.2 of this Part, except those for which variances were granted, prior to construction. The facility shall maintain a copy of the plans reviewed, the variance(s) granted and the architect's signed certification, for review by the Department upon request.
- D. Upon completion of construction, the facility shall provide written notification to the Department describing the project, and a copy of the architect's certification. The facility shall obtain authorization from the Department prior to occupying/re-occupying the area. At the discretion of the Department, an on-site visit may be required.

### **13.8.2 Physical Facility**

- A. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall meet the fire and safety provisions of R.I Gen. Laws Chapters 23-28.1 and shall conform to all state and local building codes.
- B. A building entrance shall be located at grade level and able to accommodate wheelchairs.
- C. An elevator shall be provided where patient care is provided at other than street level. The cab size shall be large enough to accommodate a stretcher and an attendant.
- D. Administrative and public areas shall include at least the following:
  1. A lobby area including a waiting area, conveniently accessible wheelchair storage;
  2. Reception/information desk, accessible public toilets, public telephone(s) and drinking fountain(s);
  3. Interview space for private interviews relating to admission, credit, etc.;

4. General and individual office space for business transactions, records and administrative and professional staff. These shall be separate from public and patient areas with provisions for confidentiality of records. Enclosed office spaces for administration and consultation shall be provided.
  5. General storage facilities.
- E. A system for sterilizing equipment and supplies shall be provided. When sterilization is provided off-site, adequate sterile supplies shall be provided. If on-site processing facilities are provided, they shall include the following:
1. Soiled workroom: This room shall be physically separated from all other areas of the facility. Work space shall be provided to handle the cleaning and terminal sterilization/disinfection of all medical/surgical instruments and equipment. The soiled workroom shall contain work table(s), sink(s), flush-type device(s) and washer/sterilizer decontaminator(s) or other decontamination equipment. Pass-through doors and washer/sterilizer decontaminators should deliver into clean processing areas/workrooms.
  2. Clean Assembly/Workroom and Sterilization Area: Clean and soiled work areas should be physically separated. This room is exclusively for the inspection, assembly and packaging and sterilization of medical/surgical supplies and equipment. The room shall contain handwashing facilities, work space and equipment for terminal sterilizing of medical and surgical equipment and supplies. The assembly work area should contain work tables, counter, storage facilities for back-up supplies and a drying cabinet or equipment. Access to the sterilization room should be restricted.
  3. Alternatively, based on the scope of the practice, a single utility room may be adequate for clean and soiled activities, provided the room includes a sink for cleaning instruments/equipment, a hand wash sink, adequate work counter space, and allow for instrument/equipment processing to flow from soiled area, to clean area, to sterilization, and finally to storage, without crossing paths.
    - a. Clean/Sterile Supplies – Storage: Storage for packs, etc., shall include provisions for ventilation, humidity, and temperature control.
- F. Provisions shall be made to separate pediatric from adult patients. This shall include pre- and post-operative care areas and should allow for parental presence.
- G. At least one room shall be provided for examination and testing of patients prior to surgery, assuring both visual and audible privacy. Exam rooms shall have a minimum floor area of 80 square feet, excluding vestibules, toilets and closets. Room arrangement should permit at least 2 feet 8 inches clearance at each side



and the foot of the examination table. A handwashing fixture and a counter or shelf space for writing shall be provided.

- H. Each operating room shall have a minimum clear area of 250 square feet, exclusive of cabinets and shelves. Additional clear area may be required to accommodate the functional plan, which may require additional staff or equipment. There shall be at least one x-ray film illuminator in each room.
- I. A room for post-anesthesia recovery shall be provided as required by volumes and procedure type. At least 3 feet shall be provided at each side and at the foot of each bed. If pediatric surgery is part of the program, separation from the adult section and space for parents shall be provided. Bedpans and bedpan-cleaning facilities shall be provided in this area.
- J. A designated supervised recovery lounge shall be required for patients who do not require post-anesthesia recovery but need additional time for their vital signs to stabilize before safely leaving the facility. This lounge shall contain space for staff and family members and provisions for privacy. It shall have convenient access to toilets. Hand washing and nourishment facilities must be provided.
- K. The surgical service area must include a drug distribution station. Provisions shall be made for storage and preparation of medications administered to patients. Locked storage, including a refrigerator and double-locked storage for controlled substances shall be provided. Convenient access to handwashing facilities shall be provided.
- L. Scrub facilities shall be provided near the entrance to each operating room and may service two operating rooms if needed. Scrub facilities shall be arranged to minimize incidental splatter on nearby personnel or supplies.
- M. The surgical service area must include a soiled work area, containing a clinical sink or equivalent flushing-type fixture, a work counter sink for handwashing and waste receptacle(s).
- N. Fluid waste disposal facilities shall be provided, convenient to operating rooms. A clinical sink or equivalent equipment in a soiled workroom shall meet this standard.
- O. Provisions shall be made for cleaning, testing, and storing anesthesia equipment. If a separate workroom, it shall contain a work counter, sink and racks for cylinders. Provisions shall be made for the separate storage of clean and soiled items. Provisions shall be made for the separate storage of reserve gas cylinders.
  - 1. If flammable agents are present in an operating/procedure room, the room shall be constructed and equipped in accordance with the standards of

publication number 56A, (1975) of the National Fire Protection Association.

2. If only non-flammable agents are present in the operating/procedure room, the room shall be constructed and equipped in accordance with the standards of publication number 56G, (1975) of the National Fire Protection Association.
- P. Equipment storage area(s) for equipment and supplies used in the surgical service shall be provided.
- Q. Appropriate change areas shall be provided for staff working within the surgical area. Change area(s) shall contain toilets, lavatories for handwashing, and space for donning scrub attire.
- R. Provisions shall be made for patients to change from street clothing into hospital gowns, if required by the functional program, and prepare for surgery. This should include waiting areas, toilets, changing areas, and space for administration of medication. Provisions shall be made for securing patients' clothing and personal effects.
- S. If stretcher storage provided, at least the following minimal facilities shall be provided:
1. Laboratory work counter with sink, vacuum, gas and electrical services.
  2. Lavatory or counter sink equipped for handwashing. shall be provided, convenient for use and out of the way of normal traffic.
- T. Physician ambulatory surgery centers/ podiatry ambulatory surgery centers having three (3) or more operating rooms shall provide a lounge area for surgical staff and a staff toilet room shall be provided near the recovery area.
- U. Space containing a floor receptacle or service sink and storage space for housekeeping supplies and equipment shall be provided.
- V. Provisions shall be made for convenient access to and use of emergency equipment at both surgical and recovery areas.
1. If laboratory services are
  2. Storage cabinet(s) or closet(s).
  3. Specimen collection facilities.
- W. If radiology services are provided, at least the following minimal facilities shall be provided:

1. Radiographic room(s)
  2. Film processing facilities
  3. Viewing areas
  4. Storage facilities for exposed film
  5. Dressing rooms, as required by services provided, with convenient toilet access.
- X. Heating and ventilation systems shall be capable of maintaining adequate ventilation and temperature for the comfort and safety of patients and staff.
- Y. If the physician ambulatory surgery center/ podiatry ambulatory surgery center includes an endoscopy suite, the following minimal facilities must be provided:
1. Each procedure room shall have a minimum clear area of 200 square feet, exclusive of fixed cabinets and built-in shelves, and be designed for visual and acoustical privacy. Oxygen, vacuum and medical air shall be provided.
  2. Dedicated processing room(s) for cleaning and disinfecting instrumentation must be provided. Cleaning rooms should allow for the flow of instrumentation from the contaminated area to the clean area, and, finally, to storage.
  3. The decontamination room shall be equipped with the following: two utility sinks remote from each other; freestanding handwashing fixture; work counter space: space and plumbing for automatic endoscope cleaners, sonic processor and flash sterilizer (where required); and outlets for vacuum and compressed air. Negative pressure shall be maintained in the decontamination room and all air should be vented to the outside to avoid recirculation within the physician ambulatory surgery center/ podiatry ambulatory surgery center.

### **13.8.3 Emergency Power**

- A. Each physician ambulatory surgery center/ podiatry ambulatory surgery center shall be equipped with an alternate emergency energy power source with a minimum two (2) hour capability.
- B. The emergency electrical power system shall have a sufficient capacity to supply power to maintain the operation of the operating/procedure room and other life-support systems, and lighting of egress, fire detection equipment, alarm and extinguishing systems.

- C. Monthly testing of emergency power shall be documented and reports retained for at least three (3) years.

#### **13.8.4 Lighting and Electrical Services**

All electrical and other equipment used in the physician ambulatory surgery center/ podiatry ambulatory surgery center shall be maintained free of defects that 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 for at least three (3) years.

#### **13.8.5 Plumbing**

- A. All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of R.I. Gen. Laws Chapter 23-27.3.
- B. All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections between potable and non-potable water supplies.

#### **13.8.6 Water Supply**

Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the physician ambulatory surgery center/ podiatry ambulatory surgery center and shall be adequate in volume and pressure for all purposes including fire fighting.

#### **13.8.7 Medical Waste Disposal**

Medical waste as defined in the Medical Waste Regulations, 250-RICR-140-15-1, promulgated by the Rhode Island Department of Environmental Management, shall be managed in accordance with the provisions of the aforementioned regulations.

#### **13.8.8 Waste Water Disposal**

If a municipal sanitary sewer system is available, the physician ambulatory surgery center/ podiatry ambulatory surgery center shall be connected to the system, if feasible. If a municipal sanitary sewer system is not available, the physician ambulatory surgery center/ podiatry ambulatory surgery center shall meet the standards set forth by the Department of Environmental Management.

### **13.9 Deficiencies, Variance, and Severability**

#### **13.9.1 Deficiencies and Plans of Correction**

- A. The licensing agency shall notify the physician ambulatory surgery center/ podiatry ambulatory surgery center of violations of individual standards through a notice of deficiencies which shall be forwarded to the physician ambulatory

surgery center/ podiatry ambulatory surgery center within fifteen (15) days of inspection of the physician ambulatory surgery center/ podiatry ambulatory surgery center 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 R.I. Gen. Laws § 23-1-21.

- B. A physician ambulatory surgery center/ podiatry ambulatory surgery center that 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 therefor.
- C. The licensing agency will be required to approve or reject the plan of correction submitted by a physician ambulatory surgery center/ podiatry ambulatory surgery center within fifteen (15) days of receipt of the plan of correction.
- D. If the licensing agency rejects the plan of correction, or if the physician ambulatory surgery center/ podiatry ambulatory surgery center does not provide a plan of correction or if a physician ambulatory surgery center/ podiatry ambulatory surgery center 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 § 13.9 of this Part. If the physician ambulatory surgery center/ podiatry ambulatory surgery center is aggrieved by the action of the licensing agency, the physician ambulatory surgery center/ podiatry ambulatory surgery center may appeal the decision and request a hearing in accordance with R.I. Gen. Laws Chapter 42-35.

### **13.9.2 Variance Procedure**

- A. The licensing agency may grant a variance upon request of the applicant from the provisions herein, if it finds in specific cases, that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such a variance will not be contrary to the public interest.
- B. A request for a variance shall be filed by an applicant in writing, setting forth in detail the basis upon which the request is made.
  - 1. Upon filing of each request for variance with the licensing agency and within a reasonable time thereafter, the licensing agency shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the facility appeals the denial. Such hearing must be held in accordance with the provisions of § 13.9.3 of this Part.

### **13.9.3 Rules Governing Practices and Procedures**

All hearings and reviews required under the provisions of R.I. Gen. Laws Chapter 23-17 shall be held in accordance with the provisions of the "Rules and Regulations Pertaining to Practices and Procedures Before the Rhode Island Department of Health [R42-35-PP]".