# *Rhode Island Department of Health*

## PUBLIC NOTICE

The Director of the Rhode Island Department of Health has determined to amend the rules and regulations listed below to remove the specific dollar value of all fees for licensing, laboratory and administrative services provided by the Department of Health from the individual regulations and reference all such fees to a new consolidated fee regulation (to be promulgated separately). These amendments are proposed pursuant to the authority contained in Public Law 2012-241, enacted by the General Assembly on 15 June 2012, and the relevant sections of the respective professional practice and licensure acts.

**The following seventy-five (75) regulations are proposed to be amended:**

1. Food Code
2. Rules and Regulations Establishing Educational and Experience Requirements for Registration as a Sanitarian
3. Rules and Regulations for Asbestos Control
4. Rules and Regulations for Bottled Water
5. Rules and Regulations for Certifying Analytical Laboratories
6. Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Services
7. Rules and Regulations for Lead Poisoning Prevention
8. Rules and Regulations for Licensing Assisted Living Residences
9. Rules and Regulations for Licensing Athletic Trainers
10. Rules and Regulations for Licensing Birth Centers
11. Rules and Regulations for Licensing Chemical Dependency Professionals
12. Rules and Regulations for Licensing Clinical Laboratories and Stations
13. Rules and Regulations for Licensing Clinical Social Workers and Independent Clinical Social Workers
14. Rules and Regulations for Licensing Doctors of Acupuncture and Acupuncture Assistants
15. Rules and Regulations for Licensing Home Nursing Care Providers and Home Care Providers
16. Rules and Regulations for Licensing Hospice Care
17. Rules and Regulations for Licensing Interpreters for the Deaf
18. Rules and Regulations for Licensing Kidney Disease Treatment Centers
19. Rules and Regulations for Licensing Massage Therapists
20. Rules and Regulations for Licensing Mental Health Counselors and Marriage and Family Therapists
21. Rules and Regulations for Licensing Occupational Therapists and Occupational Therapy Assistants
22. Rules and Regulations for Licensing of Hospitals
23. Rules and Regulations for Licensing of Midwives
24. Rules and Regulations for Licensing of Nursing Facilities
25. Rules and Regulations for Licensing of Nursing Home Administrators
26. Rules and Regulations for Licensing Physical Therapists and Physical Therapist Assistants
27. Rules and Regulations for Licensing Psychologists
28. Rules and Regulations for Licensing Rehabilitation Hospital Centers

29. Rules and Regulations for Licensing Respiratory Care Practitioners
30. Rules and Regulations for Licensing Speech Pathologists and Audiologists
31. Rules and Regulations for Licensing Swimming and Wading Pools, Hot Tubs, and Spas
32. Rules and Regulations for Licensure and Discipline of Chiropractic Physicians
33. Rules and Regulations for Limited Medical Registration
34. Rules and Regulations for Radon Control
35. Rules and Regulations for the Certification of Administrators of Assisted Living Residences
36. Rules and Regulations for the Certification of Health Plans
37. Rules and Regulations for the Control of Radiation
38. Rules and Regulations for the Licensing of Freestanding Ambulatory Surgical Centers
39. Rules and Regulations for the Licensing of Freestanding Emergency Care Facilities
40. Rules and Regulations for the Licensing of Nurses and Standards for the Approval of Basic Nursing Education Programs
41. Rules and Regulations for the Licensing of Nursing Service Agencies
42. Rules and Regulations for the Licensing of Organized Ambulatory Care Facilities
43. Rules and Regulations for the Licensing of Podiatrists
44. Rules and Regulations for the Licensing of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants
45. Rules and Regulations for the Licensure and Discipline of Physicians
46. Rules and Regulations for the Licensure of Barbers, Hairdressers/Cosmeticians, Manicurists, Estheticians, and Instructors
47. Rules and Regulations for the Licensure of Clinical Laboratory Science Practitioners
48. Rules and Regulations for the Licensure of Physician Ambulatory Surgery Centers and Podiatry Ambulatory Surgery Centers
49. Rules and Regulations for the Licensure of Physician Assistants
50. Rules and Regulations for the Licensure of Veterinarians
51. Rules and Regulations for the Registration of Body Piercing Technicians and Body Piercing Establishments
52. Rules and Regulations for the Registration of Distributors of Controlled Substances in Rhode Island
53. Rules and Regulations for the Registration of Tanning Facilities
54. Rules and Regulations for the Registration of Tattoo Artists and Tattoo Parlors
55. Rules and Regulations for the Utilization Review of Health Care Services
56. Rules and Regulations Governing Vital Statistics
57. Rules and Regulations Pertaining to Certification of Managers in Food Safety
58. Rules and Regulations Pertaining to Dentists, Dental Hygienists, and Dental Assistants
59. Rules and Regulations Pertaining to Embalmers, Funeral Directors, and Funeral Service Establishments
60. Rules and Regulations Pertaining to Opticians
61. Rules and Regulations Pertaining to Optometrists
62. Rules and Regulations Pertaining to Permits for Screening Programs
63. Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers, and Distributors
64. Rules and Regulations Pertaining to Public Drinking Water
65. Rules and Regulations Pertaining to Rhode Island Certificates of Registration for Nursing Assistants, Medication Aides, and the Approval of Nursing Assistant and Medication Aide Training Programs
66. Rules and Regulations Pertaining to the Certification of Public Drinking Water Supply Treatment and Public Water Supply Transmission and Distribution Operators

67. Rules and Regulations Pertaining to the Licensing of Dietitians/Nutritionists
68. Rules and Regulations Pertaining to the Medical Examiner System
69. Rules and Regulations Pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and the Newborn Hearing Loss Screening Program
70. Rules and Regulations Pertaining to the Processing and Distribution of Shellfish
71. Rules and Regulations Prescribing Minimum Standards for Processing, Storage and Transportation of Fish and Fishery Products
72. Rules and Regulations Related to the Licensure of Hearing Aid Dealers and Fitters
73. Rules and Regulations Related to the Medical Marijuana Program
74. Rules and Regulations Related to the Practice of Electrolysis
75. Rules and Regulations Relating to Emergency Medical Services

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Notice is hereby given in accordance with the provisions of §42-35-3(a)(2) of the Rhode Island General Laws, as amended, that the Director is affording all interested persons the opportunity to submit data, views, or arguments in writing on this matter. Opportunity for public hearing shall be granted if requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members. *Otherwise, no hearing shall be convened*. Should a hearing be requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members, *a hearing shall be scheduled only for the regulation(s) for which the request for hearing was received*. All regulations for which a public hearing is not requested will be filed with the Rhode Island Secretary of State pursuant to Chapter 42-35 of the Rhode Island General Laws, as amended, shortly after the 10 September 2012 deadline (as below).

Such input or requests for public hearing must be received in writing **no later than Monday, 10 September 2012**. Such input or requests should be addressed to: Michael Fine, M.D., Director, Rhode Island Department of Health, Three Capitol Hill, Room #401, Providence, Rhode Island 02908-5097.

In the development of these amendments, consideration was given to the following: (1) alternative approaches; and (2) overlap or duplication with other statutory and regulatory provisions. No alternative approach, duplication, or overlap was identified based upon available information.

Copies of all regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, Three Capitol Hill, Providence, Rhode Island 02908-5097, on the Secretary of State's website: http://www.sos.ri.gov/rules/, by calling 401-222-7767, or by e-mail to Bill.Dundulis@health.ri.gov.

Signed this 3rd day of August 2012

*Original signed by Michael Fine, MD*

Michael Fine, M.D., Director of Health

# RULES AND REGULATIONS

# FOR THE LICENSING OF

# FREESTANDING EMERGENCY CARE FACILITIES

(R23-17-FECF)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health

December 1981

***As amended***:

| | |
|---|---|
| June 1981 (E) | February 1998 |
| October 1981(E) | January 2000 |
| April 1982 | January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended) |
| August 1982 | July 2002 |
| February 1984 (E) | March 2005 |
| June 1984 (E) | January 2007 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended) |
| February 1985 | January 2012 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended) |
| September 1987 | **August 2012 (Proposed)** |
| January 1991 (E) | |
| April 1991 | |
| December 1993 | |

**COMPILER'S NOTES:**
**Proposed Additions: Underlined**
**Proposed Deletions: ~~Strikeouts~~**

## *INTRODUCTION*

These *Rules and Regulations for the Licensing of Freestanding Emergency Care Facilities (R23-17-FECF)* 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 the licensing of freestanding emergency care facilities 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: (a) alternative approaches to the regulations; (b) duplication or overlap with other state regulations; and (c) significant economic impact on facilities. No alternative approach was identified. The protection of the health, safety and welfare of the public necessitates the adoption of the regulations despite the economic impact which may be incurred as a result of the regulations.

These rules and regulations shall supersede any previous rules and regulations 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 ***"Freestanding Emergency Care Facility"*** hereinafter referred to as FECF, means an establishment, place or facility which may be a public or private organization, structurally distinct and separate from a hospital, staffed, equipped and operated to provide prompt emergency medical care as defined in section 1.2 herein.

1.2 ***"Emergency Medical Care"*** shall mean services provided for a medical condition that is manifested by symptoms of sufficient severity that, in the absence of immediate medical attention, could result in placing health in jeopardy, serious impairment to bodily functions, serious dysfunction of any bodily organ or part, or development or continuance of severe pain.

1.3 ***"Director"*** shall mean the Director of the Rhode Island Department of Health.

1.4 ***"Licensing Agency"*** shall mean the Rhode Island Department of Health.

1.5 ***"Person"*** shall mean any individual, trust or state, partnership, corporation (including associations, joint stock companies) state, or political subdivisions or instrumentality of the state.

1.6 ***"Physician"*** shall mean an individual licensed under the provisions of Chapter 5-37 of the General Laws of Rhode Island, as amended, to practice medicine or osteopathy in this state.

1.7 ***"Change in owner"*** means:

(1) in the case of an FECF 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 an FECF which is an unincorporated solo proprietorship, the transfer of the title and property to another person;

(3) in the case of an FECF 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 an FECF 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 an FECF facility which is a non-business corporation, any change in membership which results in a new person acquiring a controlling vote in such corporation.

1.8 ***"Change in operator"*** means a transfer by the governing body or operator of an FECF 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 FECF;

b) maintain and control the books and records of FECF;

c) dispose of assets and incur liabilities on behalf of the FECF; or

d) adopt and enforce policies regarding operation of the FECF.

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

1.9 ***"Equity"*** means non-debt funds contributed towards the capital costs related to an initial licensure or change in owner or change in operator of a freestanding emergency care facility 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.

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 FECF in this state without a license in accordance with the requirements of section 23-17-4 of reference 1 and section 23-15-4 of reference 14, and shall meet the requirements of the rules and regulations herein.

2.2 a) No person or facility shall represent itself as a Freestanding Emergency Care Facility or except in the case of licensed hospitals, shall use the term "emergency" in its title, advertising, publications or other form of communication, unless licensed as a freestanding emergency care facility in accordance with the provisions herein.

b) A facility licensed as a Freestanding Emergency Care Facility must include in a prominent manner in all its advertising, publications, signs or other forms of communication the following:

i. the term "freestanding", to distinguish the emergency care facility from that of a hospital emergency care service of reference 15; and

ii. days and hours of the facility's operation.

2.3 Pursuant to section 23-17-26 of reference 1, a freestanding emergency care facility shall provide to every person prompt lifesaving medical care treatment in an emergency without discrimination on account of economic status or source of payment and without delaying treatment for the purpose of prior discussion of source of payment unless such delay can be imposed without material risk to the health of the person.

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

3.1 Application for a license to conduct, maintain or operate, a FECF shall be made to the licensing agency upon forms provided by it, and shall contain such information as the licensing agency reasonably requires, including but not limited to 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 secured (in whole or in part) by the FECF or any of the property or assets of the FECF. The list shall also include all officers, directors and other persons or any subsidiary corporation owning stock, if the FECF is organized as a corporation, and all partners if the FECF is organized as a partnership.

3.3 Application for initial licensure or change in owner, operator, or lessee of an FECF 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 the considerations enumerated in section 4.4 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 a non-returnable, non-refundable application fee, ~~made payable to the Rhode Island General Treasurer, as follows: applicants shall submit a fee equal to two tenths of one percent (0.2%) of the projected annual facility net operating revenue contained in the application; provided, however, that the minimum fee shall be fifteen hundred dollars ($1,500) and the maximum fee shall not exceed twenty thousand dollars ($20,000).~~ 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.*

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 subject to 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 initial license or any change in owner, operator, or lessee of a licensed FECF shall require prior review by the Health Services Council and approval of the licensing agency as provided in section 4.3 and 4.4, or for expedited reviews conducted pursuant to sections 4.7 and 4.8, as a condition precedent to the transfer, assignment, or issuance of a new license.

4.3 Except for expedited reviews conducted pursuant to sections 4.7 and 4.8, reviews of applications for initial licensure or for changes in the owner, operator, or lessee of licensed FECF shall be conducted according to the following procedures:

a) Within ten (10) working days of receipt, in acceptable form, of an application for initial licensure or for a license in connection with a change in the owner, operator or lessee of an existing FECF, 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.

4.4 Except as otherwise provided in Chapter 23-17 of the General Laws of Rhode Island, as amended, a review by the Health Services Council of an application for an initial license or for a license in the case of a proposed change in the owner, operator, or lessee of a licensed Freestanding Emergency Care Facility 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. 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:

4.4.1 the character, commitment, competence, and standing in the community of the proposed owners, operators, or directors of the FECF 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;

4.4.2 the extent to which the facility will provide or 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 FECF 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;

4.4.3 the extent to which the facility will provide or will continue to provide safe and adequate treatment for individuals receiving the FECF 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 credibility and demonstrated or potential effectiveness of the applicant's proposed quality assurance programs;

4.4.4 the extent to which the facility will provide or will continue to provide appropriate access with respect to traditionally undeserved 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.

4.4.5 in consideration of the proposed continuation or termination of emergency, primary and/or other core health care services by the FECF:

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

4.4.6 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.

4.5 Subsequent to reviews conducted under sections 4.3, 4.4, 4.7, and 4.8 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 Rhode Island General Laws, as amended, or to the review criteria set forth in section 4.4 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 has been given to the FECF by the licensing agency.

4.6 A license issued hereunder shall be the property of the state and loaned to such licensee and it shall be kept posted in a conspicuous place on the licensed premises.

4.7 Applicants for initial licensure may, at the sole discretion of the licensing agency, be reviewed under expedited review procedures established in section 4.8 if the licensing agency determines (a) that the legal entity seeking licensure is the licensee for one or more health care facilities licensed in Rhode Island pursuant to the provisions of Chapter 23-17 whose records of compliance with licensure standards and requirements are deemed by the licensing agency to demonstrate the legal entity's ability and commitment to provide quality health services; and (b) that the licensure application demonstrates complete and satisfactory compliance with the review criteria set forth in set forth in section 4.4 herein.

4.8 Expedited reviews of applications for initial licensure of freestanding emergency care facilities shall be conducted according to the following procedures:

a) Within ten (10) working days of receipt, in acceptable form, of an application for initial licensure the licensing agency will determine if such application will be granted expedited review and the licensing agency will notify the public of the licensing agency's initial assessment of the application materials with respect to the review criteria in section 4.4 as well as the licensing agency's intent to afford the application expedited review. At the same time the licensing agency will afford the public a twenty (20) day period during which the public may review and comment on the application and the licensing agency's initial assessment of the application materials and the proposal to afford the application expedited review.

b) Written objections from affected parties directed to the processing under the expedited procedures and/or the satisfaction of the review criteria shall be accepted during the twenty (20) day comment period. Objections must provide clear, substantial and unequivocal rationale as to why the application does not satisfy the review criteria and/or why the application ought not to be processed under the expedited review mechanism. The licensing agency may propose a preliminary report on such application provided such proposed report incorporates findings relative to the review criteria set forth in section 4.4. The Health Services Council may consider such proposed report

and may provide its advisory to the Director of Health by adopting such report in amended or unamended form. The Health Services Council, however, is not bound to recommend to the Director that the application be process under the provisions for expedited review as delineated in sections 4.7 and 4.8. The Health Services Council shall take under advisement all objections both to the merits of the application and to the proposed expedited processing of the proposed application and shall make a recommendation to the Director regarding each. Should the Health Services Council not recommend to the Director that the application be processed under expedited review procedures as initially proposed, such application may continue to be processed consistent with the time frames and procedures for applications not recommended for expedited review. If expedited review is not granted, then the comment period may be forthwith extended consistent with the time frames in section 4.3 for applications not proposed for expedited review. The Director, with the advice of the Health Services Council, shall make the final decision either to grant or to deny expedited review and shall make the final decision to grant or to deny the application on the merits within the expedited review mechanism and time frames.

Section 5.0 ***Inspections***

5.1 The licensing agency shall make or cause to be made such inspections and investigations, as it deems necessary, in accordance with section 23-17-10 of reference 1 and the rules and regulations herein.

5.2 Every FECF shall be given prompt notice by the licensing agency of any deficiencies reported as a result of an inspection or investigation.

Section 6.0 ***Denial, Suspension, Revocation of License or Curtailment of Activities***

6.1 The licensing agency is authorized to deny, suspend or revoke the license of or to curtail the activities of any FECF which:

(1) has failed to comply with the rules and regulations pertaining to the licensing of FECFs; and

(2) has failed to comply with the provisions of reference 1.

6.1.1 Reports of deficiencies noted in inspections conducted in accordance with section 5.0 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 FECF.

6.2 Whenever an action shall be proposed to deny, suspend or revoke the license of or to curtail the activities of a FECF, the licensing agency shall notify the FECF 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 23-17-8 of reference 1 and section 42-35-9 of reference 11 and in accordance with the provisions of section 23.0 herein.

6.2.1 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 12 and section 42-35-14 (c) of reference 11.

6.3 The appropriate state and federal 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 7.0 ***Governing Body and Management***

7.1 Each facility shall have an organized governing body or equivalent legal authority ultimately responsible for: (1) the management and control of the operation; (2) the assurance of the quality of care and services; (3) the compliance with all federal, state and local laws and regulations; and (4)other relevant health and safety requirements including the rules and regulations herein.

7.2 The governing body or equivalent legal authority shall provide appropriate personnel, physical resources, and equipment for the delivery of safe and effective emergency medical care.

7.3 The governing body or equivalent 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.

7.4 The governing body or equivalent legal authority shall adopt and maintain by-laws defining responsibilities for the operation and performance of the organization, identifying purposes and means of fulfilling each. In addition, the governing body shall establish administrative policies pertaining to no less than the following:

a) qualifications and responsibilities of the medical director and administrator;

b) the plan of the governing body for the implementation of long and short range plans as prescribed by the Director in accordance with reference 1; and

c) such other matters as may be relevant to the organization and operation of the FECF.

7.5 The governing body or other legal authority shall be responsible through the organization's by-laws, policies, or other mechanism to determine the qualifications of physicians and other professionals as required herein, considering such factors as education, training, experience, board certification, eligibility to sit for examination of specialty board, evidence of current professional practice and licensure as may be required by law or regulation, the relevant qualifications required in section 10.0 herein and such other relevant factors as may be deemed necessary.

### Section 8.0 ***Administrator***

8.1 The governing body or equivalent legal authority shall appoint an administrator (who may also be the medical director), who shall be operationally responsible for: (1) the management and operation of the FECF; (2) the compliance with 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 9.0 ***Medical Director***

9.1 The FECF shall have a physician licensed in this state, who shall serve as Medical Director and be responsible for no less than the following:

a) coordination and supervision of emergency medical care services;

b) the achievement and maintenance of quality assurances of professional practice through a mechanism of peer review; and

c) the establishment of policies and procedures for emergency medical care services and other related emergency health care services.

Section 10.0 ***Personnel***

10.1 Each FECF shall be staffed by a licensed physician(s) who has certification, as defined in section 10.2 herein, and full licensure and who shall be present within the facility during the hours of operation.

10.2 At least one physician on duty during the hours of operation shall be:

a) Certified or Board Eligible by the American Board of Emergency Medicine or the American Board of Osteopathic Emergency Medicine; OR

b) Certified or Board Eligible to sit for the examination of one of the following boards: Internal Medicine, Family Practice, or Surgery; AND must hold a certificate from the following approved programs: Advanced Coronary Life Support; Advanced Trauma Life Support; Pediatric Advanced Life Support.

10.3 No less than one licensed registered nurse who has training and experience in emergency care shall be on duty during the hours of operation.

10.4 Every freestanding emergency care facility shall have a person qualified by training and experience on the premises during the hours of operation who shall determine the nature, level and urgency of care required of all persons seeking treatment and to categorize them accordingly, assuring that serious cases are accorded priority treatment. If such person is a non-physician, he or she shall serve under the supervision of the physician-in-charge and in accordance with policies and procedures acceptable to the governing body or other legal authority.

10.5 Each FECF shall establish a protocol to govern the interpretation by a radiologist, of diagnostic images produced by x-ray or other modalities, including a procedure for the prompt communication of the radiologist's interpretation to the facility.

10.6 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.

***Health Screening***

10.7 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 freestanding emergency care facility. Such health screening shall be conducted in accordance with the *Rules and Regulations Pertaining to Immunization, Testing, and Health Screening for Health Care Workers (R23-17-HCW)* promulgated by the Department of Health.

Section 11.0 ***Rights of Patients***

11.1 Each FECF shall observe the standards of section 23-17-19.1 of reference 1 with respect to each patient.

11.2 Each facility shall display in a conspicuous place in the licensed FECF a copy of the "Rights of Patients."

Section 12.0 ***Disaster Preparedness***

12.1 Each FECF shall develop and maintain a written disaster preparedness plan which shall include specific provisions and procedures for the emergency medical care of patients in the event of an external disaster or internal functional failure of equipment.

a) Such plan shall be developed in cooperation with appropriate state and local agencies.

b) A copy of the plan shall be submitted to the licensing agency.

Section 13.0 ***Administrative Records***

13.1 Each FECF shall maintain such administrative records as may be deemed necessary by the licensing agency. These records shall include but not be limited to:

a) monthly statistical summary of numbers of patients seen appropriately classified as to the nature of the conditions;

b) a copy of the long and short range plans;

c) an administrative record of log book containing pertinent data such as patient's name, record number, age, sex, date and time of arrival and discharge, type of care, diagnosis and disposition, and provider of service.

d) a record of all transfers to other health facilities.

Section 14.0 ***Uniform Reporting System***

14.1 Each FECF 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.

14.2 Each FECF shall make available for review upon request of the licensing agency detailed statistical data pertaining to its operations, services, and facility. Such reports and data shall be made at such intervals and by such dates as determined by the Director.

14.3 The licensing agency is authorized to make the reported data available to any state or federal agency concerned with or exercising jurisdiction over the FECF.

14.4 The directives promulgated by the Director pursuant to these regulations shall be sent to each FECF to which they apply. Such directives shall prescribe the form and manner in which the statistical data required shall be furnished to the licensing agency.

## PART III *EMERGENCY CARE SERVICES*

### Section 15.0 ***Management Services***

15.1 Each FECF shall provide emergency care service with professional and ancillary staff to ensure that all persons treated are released or transferred within a reasonable and appropriate length of time. No patient shall be held over-night.

15.2 Policies and procedures pertaining to the provision of emergency medical care services and supported by appropriate manuals and reference material shall be established by the Medical Director and approved by the governing body. Such policies and procedures shall pertain to no less than the following:

a) the responsibility of the medical staff for emergency patient care;

b) medical circumstances under which definitive care cannot be provided and procedures for referral;

c) procedures that may and may not be performed in the FECF;

d) procurement, storage and administration of drugs and medications in accordance with references 8 and 9;

e) disposal of hypodermic needles, syringes and instruments in accordance with the requirements of reference 10;

f) handling of persons who are emotionally ill, under the influence of drugs or alcohol, dead on arrival, or other categories of special care;

g) procedures for early transfer of severely ill or injured to hospital;

h) written instructions to be given to the patient to assure continuity of care;

i) notification of patient's personal physician and transmission of relevant reports per written consent of patient;

j) disclosure of patient information in accordance with federal and state law;

k) location and storage of supplies and special equipment; and

l) pursuant to section 23-17-26 of reference 1 the provision of prompt emergency medical care for every person in an emergency without discrimination on account of economic status or source of payment and without delaying treatment for the purpose of prior discussion of source of payment unless such delay can be imposed without material risk to the health of the person.

Section 16.0 ***Supportive Services***

16.1 Each FECF shall provide on the premises during hours of operation, the following:

a) clinical laboratory services: - must be provided on the premises of the FECF subject to the provisions of section 23-16.2-3 of the General Laws of Rhode Island, as amended; and

b) diagnostic radiology services which meet the requirements of section 10.4 herein and reference 3.

i) Mammography

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

Section 17.0 ***Medical Records***

17.1 A medical record shall be maintained on every patient provided emergency care.

17.2 For each visit to the emergency facility the medical record shall contain documentation relating to the following:

a) patient identification (name, address, age and sex);

b) time and means of arrival;

c) pertinent medical history of the illness or injury and physical findings;

d) emergency care given before arrival;

e) diagnostic and therapeutic orders;

f) reports of procedures, tests and findings;

g) diagnostic impression;

h) conclusion at termination of evaluation/treatment, including final disposition of patient's condition on discharge or transfer and any instructions given for follow-up care;

i) a patient's leaving against medical advice; and

j) origin of incoming patient and destination of patient at discharge.

17.3 All medical records either original or accurate reproductions shall be preserved for a minimum of five (5) years, except that records of minors shall be kept for at least five (5)years after such minor shall have reached the age of 18 years.

Section 18.0 ***Medical Equipment and Supplies***

18.1 No less than the following special supplies and equipment shall be available and located within the emergency service area:

i. oxygen;

ii. electrocardiograph;

iii. cardiac monitor and defibrillator with battery pack;

iv. pacemaker insertion set-up; external pacemaker

v. central venous catheter set-up;

vi. gastric lavage equipment;

vii. suction device;

viii. intravenous fluids and administration devices;

ix. endotracheal intubation, and tracheostomy trays; and

x. emergency obstetrical pack.

18.2 Medical equipment and supplies for the reception, appraisal, examination, treatment and observation of patients shall be determined by the amount, type and extensiveness of services provided.

18.3 The emergency drug cart(s) and adjunctive emergency equipment shall be checked by an appropriate, designated individual as per written procedures after each use to assure that all items required for immediate availability are actually contained in the cart and are in usable condition.

## PART IV ***PHYSICAL PLANT AND EQUIPMENT***

### Section 19.0 ***New Construction***

19.1 All new construction shall be subject to the provisions of references 2, 4, 5, and 6.

19.2 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 more stringent standard shall apply.)

### Section 20.0 ***Physical Facility***

20.1 The FECF shall be designed and equipped to facilitate the reception, examination, treatment and observation of patients, in accordance with prevailing standards, safeguarding the dignity and privacy of patients and their families to the extent consistent with providing emergency medical care and with efficient administration.

20.2 In existing facilities, unless a variance is granted by the licensing agency, the same standards as specified above in section 19.0 for new construction shall apply.

20.3 The entrance of the FECF shall be clearly identified externally and shall be accessible to emergency vehicles and pedestrian traffic. All entrance doors shall be well lighted, wide enough to accommodate patients, attendants and equipment. A ramp shall be provided for wheelchair and stretcher patients when the use of stairs would be required otherwise.

### Section 21.0 ***Environmental Maintenance***

21.1 The FECF shall be maintained and equipped to provide a sanitary, safe and comfortable environment, with all furnishings in good repair, and the premises shall be kept free of hazards.

21.2 Written policies and procedures shall be established to assure comfortable, safe and sanitary environment and appropriate lighting throughout the facility.

21.3 Appropriate equipment and supplies to clean the facility shall be maintained in a safe, sanitary condition.

21.4 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.

21.5 Smoking shall be permitted only in designated areas.

### Section 21.6 ***Waste Disposal***

#### 21.6.1 ***Infectious Waste***

Infectious waste as defined in the *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management & Disposal of Regulated Medical Waste in Rhode Island (DEM-DAH-MW-01-92*),Rhode Island Department of Environmental Management

(June 1994), shall be managed in accordance with the provisions of the aforementioned regulations.

21.6.2 ***Other Waste***

Wastes which are not classified as infectious waste, hazardous wastes, or which are not otherwise regulated bylaw 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:

c) high enough off the ground to facilitate the cleaning of the underneath areas of the stationary equipment; and

d) the loading section shall be constructed and maintained to prevent rubbish from blowing from said area site.

## PART V ***PRACTICES AND PROCEDURES, CONFIDENTIALITY AND SEVERABILITY***

### Section 22.0 ***Variance Procedure***

22.1 The licensing agency may grant a variance either upon its own motion or upon request of the applicant from the provisions of any rules and regulation 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, public health and/or health and safety of patients.

22.2 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.

22.2.1 Upon filing of each request for variance with the licensing agency and within thirty (30) days 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 section 23.0 herein.

### 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 within the fifteen (15) day period, 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 6.0 herein. If the facility is aggrieved by the action of the licensing agency, the facility may appeal the decision regarding sanctions and request a hearing in accordance with Chapter 42-35 of the General Laws.

### Section 24.0 ***Rules Governing Practices and Procedures***

24.1 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 promulgated by the Rhode Island Department of Health entitled *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*) of reference 13.

Section 25.0 ***Confidentiality***

25.1 Disclosure of any health care information relating to individuals shall be subject to the provisions of the Confidentiality Act of reference 7 and other relevant statutory and federal requirements.

Section 26.0 ***Severability***

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

## PART VI ***REFERENCES***


1. "Licensing of Health Care Facilities," Chapter 23-17 of the General Laws of Rhode Island as amended.

2. "NFPA Publication 56A, 1975," National Fire Protection Association, 470 Atlantic Avenue, Boston, Massachusetts 02210.

3. *Rules and Regulations for the Control of Radiation*, Radiation Control Agency, Rhode Island Department of Health.

4. "Rhode Island State Fire Safety Code," Chapter 23-28.1 of the General Laws of Rhode Island as amended.

5. "Rhode Island State Building Code," Chapter 23-27.3 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. "Confidentiality of Health Care Information, "Chapter 5-37.3 of the General Laws of Rhode Island, as amended.

8. "Uniform Controlled Substances Act," Chapter 21-28 of the General Laws of Rhode Island, as amended.

9. "Rhode Island Food, Drugs and Cosmetics Act," Chapter 21-31 of the General Laws of Rhode Island, as amended.

10. *Rules and Regulations for Governing Hypodermic Needles, Syringes and Other Such Instruments,* Rhode Island Department of Health.

11. "Administrative Procedures Act," Chapter 42-35 of the General Laws of Rhode Island, as amended.

12. "Department of Health," Chapter 23-1 of the General Laws of Rhode Island, as amended.

13. *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*), Rhode Island Department of Health.

14. "Determination of Need for New Health Care Equipment and New Institutional Health Services," Chapter 23-15 of the General laws of Rhode Island, as amended.

15. *Rules and Regulations for Licensing of Hospitals (R23-17-HOSP),* Rhode Island Department of Health.

16. *Rules and Regulations Pertaining to Immunization, Testing, and Health Screening for Health Care Workers (R23-17-HCW)*, Rhode Island Department of Health.

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*Monday, 30 July 2012*