

## **TITLE 216 - DEPARTMENT OF HEALTH**

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

#### **SUBCHAPTER 10 – FACILITIES REGULATION**

##### **PART 3 – Organized Ambulatory Care Facilities**

### **3.1 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 minimum requirement for the licensure of organized ambulatory care facilities in Rhode Island.

### **3.2 Incorporated Materials**

- A. These regulations hereby adopt and incorporate the Facility Guidelines Institute's "Guidelines for Design and Construction of Hospital and Outpatient Facilities" (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.
- B. These regulations hereby adopt and incorporate the U.S. Department of Health & Human Services, Office of Minority Health's "National Standards on Culturally and Linguistically Appropriate Services (CLAS)" (2013) 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.

### **3.3 Definitions**

- A. Wherever used in this Part the following terms shall be construed as follows:
  - 1. "Act" means R.I. Gen. Laws Chapter [23-17](#), entitled "Licensing of Health Care Facilities."
  - 2. "Ambulatory and urgent health care" means health care services provided to outpatients whose condition does not require emergency medical care as defined herein, by or under the supervision of a physician/dentist licensed in Rhode Island pursuant to R.I. Gen. Laws Chapters [5-37](#) and 5-31.1 respectively.

3. "Change in operator" means a transfer by the governing body or operator of an OACF 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 OACF;
  - b. Maintain and control the books and records of the OACF;
  - c. Dispose of assets and incur liabilities on behalf of the OACF; or
  - d. Adopt and enforce policies regarding operation of the OACF.
  - e. The definition is not applicable to circumstances wherein the governing body of an OACF retains the immediate authority and jurisdiction over the activities enumerated in §§ 3.3(A)(3)(a) through (d) of this Part.
4. "Change in owner" means:
  - a. In the case of an OACF 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;
  - b. In the case of an OACF which is an unincorporated sole proprietorship, the transfer of the title and property to another person;
  - c. In the case of an OACF which is a corporation:
    - (1) A sale, lease, exchange other disposition of all, or substantially all of the property and assets of the corporation; or
    - (2) A merger of the corporation into another corporation; or
    - (3) The consolidation of two or more corporations resulting in the creation of a new corporation; or
    - (4) In the case of an OACF facility which is a business corporation, any transfer of corporate stock which results in a new person acquiring a controlling interest in such corporation; or

- (5) In the case of an OACF facility which is a non-business corporation, any change in membership which results in a new person acquiring a controlling vote is such corporation.
5. "Department" means the Rhode Island Department of Health. The Department is also the "licensing agency" designated pursuant to R.I. Gen. Laws Chapter [23-17](#).
6. "Director" means the Director of the Rhode Island Department of Health.
7. "Emergency medical care" means those services provided after the onset of a medical condition that is manifested by symptoms of sufficient severity that, in the absence of immediate medical attention, could reasonably be expected to 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.
8. "Equity" means non-debt funds contributed towards the capital costs related to an initial licensure or change in owner or change in operator of an OACF 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.
9. "Initial licensure" means a review conducted pursuant to the provisions contained in § 3.4.5 of this Part.
10. "Institution based, non-public premises" means premises where the OACF provides direct care services solely to individuals who are members of a defined institution as determined by the Director.
11. "Organized ambulatory care facility" hereinafter referred to as OACF means a structurally distinct public or private health care establishment, institution or facility, primarily constituted, staffed and equipped to deliver ambulatory and urgent health care services as defined herein, to the general public and known by such terms as central service facility, treatment center, diagnostic center, rehabilitation center (outpatient), infirmary, outpatient clinic or health center which is not a part of a hospital, excluding however, OACFs owned and operated by professional service corporations as defined in [R.I. Gen. Laws Chapter 7-5.1](#), (the "Professional Services Corporation Law"), or to a private practitioner's (physician, dentist or other health care provider) office, and/or operated by an individual practitioner, alone or as an member of a partnership, professional service corporation, organization or association), and those

health care facilities otherwise licensed by or under the jurisdiction of the Department of Health and/or the Department of Mental Health, Retardation and Hospitals, or other governmental agency.

12. "Person" means any individual, trust or estate, partnership, corporation (including associations, joint stock companies), limited liability company, state, or political subdivisions or instrumentally or the state.
13. "Premises" means a tract of land and the buildings thereon where direct patient care services are provided.

### **3.4 Licensing Procedures**

#### **3.4.1 General Requirements for Licensure**

- A. No person or governmental unit acting severally or jointly with any other person or governmental unit shall conduct, maintain or operate or hold itself out as an OACF in Rhode Island without a license in accordance with the requirements of [R.I. Gen. Laws § 23-17-4](#), and shall meet the requirements of this Part.
  1. Notwithstanding the requirements of § 3.4.1 of this Part, a health care facility licensed as an OACF in Rhode Island, may provide services at other locations (premises) operated by that licensed OACF, without the requirement of a separate OACF license for such other locations.
  2. Each premises proposed for addition to an OACF license pursuant to § 3.4.1(A)(1) of this Part shall be approved by the Department prior to the inclusion of that premises on the OACF license and commencement of operations at that location.
- B. Each premise of a licensed OACF shall comply with all pertinent provisions of this Part consistent with the scope of services provided at such premise.
- C. Any initial licensure or any change in owner, operator, or lessee of a licensed OACF shall require prior review by the Health Services Council and approval of the Department as provided in §§ 3.4.5(A) and (B) of this Part, or for expedited reviews conducted pursuant to §§ 3.4.5(E) and (F) of this Part, as a condition precedent to the transfer, assignment or issuance of a new license.
- D. Any OACF that utilizes latex gloves shall do so in accordance with the provisions of rules and regulations pertaining to 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).

- E. Each OACF shall establish and maintain a health care facility specific electronic mail address (i.e., e-mail address) to be provided to the Department for the purposes of contacting the OACF with both routine communications and emergency notices. The OACF shall be responsible for providing notice to the Department at any time that the OACF's specific electronic mail address is changed or updated.

### **3.4.2 Application for License**

#### **A. Application for Initial License**

1. Application for an initial license to conduct, maintain or operate an OACF shall be made to the Department upon forms provided by it, and shall contain such information as the Department reasonably requires, including but not limited to, evidence of ability to comply with the provisions of R.I. Gen. Laws Chapter [23-17](#) and this Part.
2. Application to add a premises to an existing OACF license, pursuant to § 3.4.1(A)(1) of this Part, shall be made to the Department upon forms provided by it, and shall contain such information as the Department reasonably requires, including but not limited to, evidence of ability to comply with the provisions of the Act and this Part.
3. Licenses will expire at the end of each calendar year unless a renewal application is completed prior to the expiration date. Renewal applications are completed electronically on the Department web site and will be available for on-line renewal sixty (60) days prior to the expiration date.

- B. 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) by the OACF or any of the property or assets of the OACF. The list shall also include all officers, directors and other persons or any subsidiary corporation owning stock, if the OACF is organized as a corporation, and all partners if the OACF is organized as a partnership.

### **3.4.3 Issuance and Renewal of License**

- A. Upon receipt of an application for a license, the Department shall issue a license of 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 this Part. Said license, unless sooner suspended or revoked, shall expire by limitation on the 31st day of December following its issuance and may be renewed from year to year after inspection, approval and payment of all fees.

1. All applications for licenses shall be accompanied by a non-refundable, non-returnable fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title) provided that not-for-profit entities operating more than one (1) such facility shall be subject to a single annual licensure fee for all such licenses; provided, further, that non-profit charitable community health centers shall be exempt from said fee.
- B. 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.
- C. At least thirty (30) days prior to voluntary cessation of any OACF license, the Department shall be notified and provided with an acceptable plan for orderly closure, which shall include but is not limited to, notification and transfer of patients, transfer, storage or proper disposal of medical records, and notification of the public.
- D. A license shall become void and shall be returned to the Department when the OACF ceases delivering patient care.

#### **3.4.4 Application for Initial Licensure or Changes in Owner, Operator, or Lessee**

- A. Application for review for initial licensure or changes in the owner, operator, or lessee of an OACF shall be made on forms provided by the Department and shall contain but not be limited to information pertinent to the statutory purpose expressed in [R.I. Gen. Laws § 23-17-3](#) or to the considerations enumerated in § 3.4.5(B) of this Part. Three (3) paper copies and one electronic copy (as a single pdf file) of such applications are required to be provided.
  1. Each application filed pursuant the provisions of this section shall be accompanied by a non-refundable, non-returnable application fee, as set forth the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).

#### **3.4.5 Initial Licensure and Change in Owner, Operator, or Lessee Review**

- A. Except for expedited reviews conducted pursuant to §§ 3.4.5(E) and (F) of this Part, reviews of applications for initial licensure or for changes in the owner, operator, or lessee of licensed OACF's shall be conducted according to the following procedures:
  1. 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 OACF, the Department will notify and afford the public thirty (30) days to comment on such application.

2. The decision of the Department will be rendered within ninety (90) days from acceptance of the application.
  3. The decision of the Department shall be based upon the findings and recommendations of the Health Services Council unless the Department shall afford written justification for variance therefrom.
  4. All applications reviewed by the Department and all written materials pertinent to Department review, including minutes of all Health Services Council meetings, shall be accessible to the public upon request.
- B. Except as otherwise provided in R.I. Gen. Laws Chapter [23-17](#), 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 OACF may not be made subject to any criterion unless the criterion directly relates to the statutory purpose expressed in R.I. Gen. Laws Chapter [23-17-3](#). 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:
1. The character, commitment, competence, and standing in the community of the proposed owners, operators or directors of the OACF as evidenced by:
    - a. In cases where the proposed owners, operators, or directors of the OACF 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):
      - (1) In providing safe and adequate treatment to the individuals receiving the health care facility's services;
      - (2) In encouraging, promoting and effecting quality improvement in all aspects of health care facility services; and
      - (3) In providing appropriate access to health care facility services for traditionally underserved populations, which include but are not limited to Medical Assistance beneficiaries and uninsured and underinsured populations;

- b. A complete disclosure of all individuals and entities comprising the applicant; and
  - c. The applicant's proposed and demonstrated financial commitment to the OACF.
- 2. The extent to which the OACF 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 OACF's services as evidenced by:
  - a. The immediate and long term financial feasibility of the proposed financing plan:
    - (1) The proposed amount and sources of owner's equity to be provided by the applicant;
    - (2) 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 OACF;
    - (3) The relative availability of funds for capital and operating needs;
    - (4) The applicant's demonstrated financial capability; and
    - (5) Such other financial indicators as may be requested by the state agency.
- 3. The extent to which the facility will provide or will continue to provide safe and adequate treatment for individuals receiving the OACF's services and the extent to which the OACF will encourage quality improvement in all aspects of the operation of the OACF as evidenced by:
  - a. The applicant's demonstrated record in providing safe and adequate treatment to individuals receiving services at facilities owned, operated, or directed by the applicant; and
  - b. The credibility and demonstrated or potential effectiveness of the applicant's proposed quality assurance programs.
- 4. The extent to which the facility will provide or will continue to provide appropriate access with respect to traditionally underserved populations as evidenced by:



- a. In cases where the proposed owners, operators, or directors of the OACF currently own, operate, or direct a health care facility, or in the past five (5) 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 underserved populations, which include but are not limited to Medical Assistance beneficiaries and uninsured and underinsured 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 OACF for traditionally underserved populations, which include but are not limited to Medical Assistance beneficiaries and uninsured and underinsured populations.
- 5. In consideration of the proposed continuation or termination of primary care and/or other core health care services by the OACF:
  - 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 traditionally underserved populations.
- 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.
- C. Subsequent to reviews conducted under §§ 3.4.5(A), (B), (E), and (F) of this Part, the issuance of a license by the Department may be made subject to any condition, provided that no condition may be made unless it directly relates to the statutory purpose expressed in R.I. Gen. Laws § 23-17-3 or to the review criteria set forth in § 3.4.5(B) of this Part. This shall not limit the authority of the Department to require correction of conditions or defects which existed prior to the proposed change in owner, operator, or lessee and of which notice had been given to the OACF by the Department.
- D. A license issued under this Part shall be the property of the State of Rhode Island and loaned to such licensee, and it shall be kept posted in a conspicuous place on the licensed premises.

- E. Applicants for initial licensure may, at the sole discretion of the Department, be reviewed under expedited review procedures established in § 3.4.5(F) of this Part if the Department determines:
1. 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 [R.I. Gen. Laws Chapter 23-17](#) whose records of compliance with licensure standards and requirements are deemed by the Department to demonstrate the legal entity's ability and commitment to provide quality health services; and
  2. That the licensure application demonstrates complete and satisfactory compliance with the review criteria set forth in § 3.4.5(B) of this Part.
- F. Expedited reviews of applications for initial licensure of OACFs shall be conducted according to the following procedures:
1. Within ten (10) working days of receipt, in acceptable form, of an application for initial licensure the Department will determine if such application will be granted expedited review and the Department will notify the public of the Department's initial assessment of the application materials with respect to the review criteria in § 3.4.5(B) of this Part as well as the Department's intent to afford the application expedited review. At the same time the Department will afford the public a twenty (20) day period during which the public may review and comment on the application and the Department's initial assessment of the application materials and the proposal to afford the application expedited review.
  2. 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 Department may propose a preliminary report on such application provided such proposed report incorporates findings relative to the review criteria set forth in § 3.4.5(B) of this Part. The Health Services Council may consider such proposed report and may provide its advisory to the Director 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 §§ 3.4.5(E) and (F) of this Part. 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 § 3.4.5(A) of this Part 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. The final decision either to grant or to deny expedited review cannot be appealed.

### **3.4.6 Inspections**

- A. The Department shall make or cause to be made such inspections and investigations as it deems necessary, including health care records, in accordance with [R.I. Gen. Laws § 23-17-10](#) and this Part.
- B. A duly authorized representative of the Department shall have the right to enter at any time without prior notice to inspect the entire premises and services, including all records of any OACF for which an application has been received or for which a license has been issued. Any application shall constitute permission for and willingness to comply with such inspections.
- C. Refusal to permit inspections shall constitute a valid ground for license revocation.
- D. Every OACF shall be given notice within fifteen (15) business days by the Department of any deficiencies reported as a result of an inspection or investigation.
- E. Written reports and recommendations of inspections and inspection logs or journals shall be maintained on file in each OACF for a period of no less than three (3) years.

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

- A. The Department is authorized to deny, suspend or revoke the license of or to curtail the activities of any OACF which:
  - 1. Has failed to comply with this Part; and

2. Has failed to comply with the provisions of R.I. Gen Laws Chapter [23-17](#).
  3. Reports of deficiencies noted in inspections conducted in accordance with § 3.4.6 of this Part shall be maintained on file in the Department, and shall be considered by the Department in rendering determinations to deny, suspend or revoke the license or to curtail activities of an OACF.
- B. Whenever an action shall be proposed to deny, suspend or revoke the license of or to curtail the activities of an OACF, the Department shall notify the OACF 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](#) and pursuant to the provisions of § 3.8.1 of this Part.
1. However, if the Department finds that public health, safety or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the Department 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\(c\)](#).
- C. The appropriate state and federal agencies shall be notified of any action taken by the Department pertaining to either denial, suspension, or revocation of license or curtailment of activities of any OACF.

### **3.5 Organization and Management**

#### **3.5.1 Governing Body or Other Legal Authority**

- A. Each OACF shall have an organized governing body or other legal authority, ultimately responsible for:
1. The management and fiduciary control of the operation and maintenance of the OACF;
  2. The conformity of the OACF with all federal, state and local laws and rules and regulations pertaining to fire, safety, sanitation, communicable and reportable diseases, patient care and other relevant health and safety requirements and this Part.
  3. The administration of a policy of non-discrimination in the provision of services to patients and the employment of persons without regard to race, color, creed, national origin, gender, religion, sexual orientation, age, handicapping condition or degree of handicap, in accordance with Title VI of the Civil Rights Act of 1964; U.S. Executive Order #11246 entitled

“Equal Employment Opportunity”, U.S. Department of Labor regulations; Title V of the Rehabilitation Act of 1973, the Rhode Island Fair Employment Practices Act, R.I. Gen. Laws Chapter 28-5 *et seq.*; the Americans with Disabilities Act; and any other federal or state laws relating to discriminatory practices.

- B. The governing body or other legal authority shall provide appropriate personnel, physical resources, and equipment to facilitate the delivery of ambulatory health care services, during established hours of operation.
- C. The governing body or other legal authority shall adopt by-laws defining the responsibilities for the operation and performance of the OACF and identifying purposes and means of fulfilling such. In addition, the governing body or equivalent legal authority shall establish administrative/clinical policies pertaining to no less than the following:
  - 1. The qualifications and responsibilities of the administrator;
  - 2. The scope of health and medical services to be provided;
  - 3. Maintain linkages and referrals with other health care facilities to assure continuity of care;
  - 4. Quality assurance for patient care and services;
  - 5. Provisions for a program permitting selected individuals other than physicians or other licensed, registered or certified personnel to perform extended, defined patient care functions. Said functions shall not otherwise require a license, certification or registration by state law. Such program shall include written systems of credentials review, selection, training, formal authorization of specific functions, and maintenance of a current register; and
  - 6. Such other matters as may be relevant to the organization and operation of the OACF.
- D. The governing body shall be responsible to establish a mechanism through the organization's by-laws or policies and procedures to assure that duly qualified physicians and other professionals are assigned to agency services based on appropriate education, training, experience and evidence of current professional practice and licensure as may be required by law.

### **3.5.2 Quality Improvement Program**

- A. The governing body shall ensure that there is an effective, ongoing, OACF-wide quality improvement program to evaluate the provision of patient care.
- B. The organized OACF-wide quality improvement program shall be ongoing and shall have a written plan of implementation. The written quality improvement plan shall include at least the following:
  - 1. Program objectives;
  - 2. Organization(s) involved;
  - 3. Oversight responsibility (e.g., reports to the governing body);
  - 4. Facility-wide scope;
  - 5. Program administration and coordination;
  - 6. Involvement of all patient care disciplines/services;
  - 7. Methodology for monitoring and evaluating quality of care;
  - 8. Priority setting and problem resolution;
  - 9. Determination of the effectiveness of action(s) taken;
  - 10. Documentation of the quality improvement plan review.
- C. All patient care services, including services rendered by a contractor, shall be evaluated.
- D. Nosocomial infections and medication therapy shall be evaluated.
- E. All medical and surgical services performed in the OACF shall be evaluated for appropriateness in diagnosis and treatment.
- F. The OACF shall take and document appropriate remedial action to address problems identified through the quality improvement program. The outcome(s) of the remedial action shall be documented.
- G. The provisions of §§ 3.5.2(A) through (F) of this Part ("Quality Improvement") shall be deemed to have been met if the OACF has met similar requirements of a national accrediting body, as approved by the Director.

### **3.5.3 Pending and Actual Labor Disputes/Actions**

OACFs shall provide the Department with prompt notice of pending and actual labor disputes/actions which would impact delivery of patient care services

including, but not limited to, strikes, walk-outs, and strike notices. OACFs shall provide a plan, acceptable to the Director, for continued operation of the facility, suspension of operations, or closure in the event of such actual or potential labor dispute/action.

#### **3.5.4 Administrator**

- A. The governing body or other legal authority of the OACF shall appoint an administrator who shall be operationally responsible for:
  - 1. The management and operation of the OACF;
  - 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 or equivalent legal authority and the staff; and
  - 4. The planning, organizing and directing of such other activities as may be delegated by the governing body.

#### **3.5.5 Medical or Dental Director**

The governing body or other legal authority of the OACF shall appoint a medical or dental director (as appropriate), licensed in Rhode Island to ensure the achievement and maintenance of the quality of health care services and the establishment of policies and procedures for health care services based on recognized standards of practice in accordance with this Part.

#### **3.5.6 Personnel**

- A. The OACF shall be staffed with appropriate professional and ancillary personnel who shall be assigned duties and responsibilities which are consistent with licensure/ certification requirements, their training and experience, and services rendered. Staff performing functions requiring certification and/or licensure shall be duly licensed in Rhode Island as required by statute.
- B. National criminal background checks shall be conducted in accordance with R.I. Gen. Laws §§ 23-17.7.1-17 and 23-17.7.1-20 for OACF personnel whose employment involves routine contact with a patient.
- C. Each OACF shall have at least one appropriate qualified health professional staff person on duty at all times during the hours of operation when services are provided.

- D. The OACF shall have a physician or dentist, as appropriate, licensed in Rhode Island, who is accessible during hours of operation.
- E. An OACF shall require all persons, including students, who examine, observe, or treat a patient 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.
- F. 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 OACF. 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).

### **3.5.7 Rights of Patients**

- A. Each OACF shall observe the standards of R.I. Gen. Laws § [23-17-19.1](#) with respect to each patient.
- B. In accordance with R.I. Gen. Laws § 23-17-19.2 each OACF shall display in a conspicuous place in the licensed OACF a copy of the "Rights of Patients" as defined in R.I. Gen. Laws § 23-17-19.1.

### **3.5.8 Administrative Records**

- A. Each OACF shall maintain such administrative records as may be deemed necessary by the Department. These records shall include but not be limited to:
  - 1. Monthly statistical summary of numbers of visits and number of patients seen;
  - 2. An administrative record, log book or appointment book containing pertinent data such as patient's name, record number, age, sex, date and stated reason for the appointment and time of visit and the name of the provider of service; and
  - 3. A triage plan for the screening and classification of patients to determine priority needs and to utilize staff personnel and equipment efficiently.

### **3.5.9 Uniform Reporting System**

- A. Each OACF 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 the regulation may be met shall be prescribed from time to time in directives promulgated by the Director.

- B. Each OACF shall make available for review upon request of the Department detailed statistical data pertaining to its operation, services provided, including numbers of patients, range of problems presented and treated, and facility. Such reports and data shall be made at such intervals and by such dates as determined by the Director.

## **3.6 Health Care Services**

### **3.6.1 Management of Services**

- A. Each OACF shall be organized to provide services with adequate professional and ancillary staff to ensure that all persons are treated and released within a reasonable and appropriate length of time. No patients shall be held overnight.
- B. Policies and procedures pertaining to the provision of services and supported by appropriate manuals and reference material shall be established by the appropriate professional staff and approved by the administrator and the governing body. Such policies and procedures shall pertain to no less than the following:
  - 1. The responsibility of the physician(s) or dentist, as appropriate, for the provision of health care services;
  - 2. The designation of personnel authorized to deliver health care services in accordance with licensure and/or certification requirements and the provisions of § 3.5.1(C)(5) of this Part;
  - 3. Standards of practice for each health care service provided;
  - 4. Procedures that may and may not be performed;
  - 5. Procurement and storage of drugs and medications in accordance with R.I. Gen. Laws Chapters [21-28](#) and [21-31](#);
  - 6. Designation of personnel authorized to prescribe, administer, or dispense drugs;
  - 7. Disposal of hypodermic needles, syringes and instruments in accordance with the requirements of the rules and regulations for Hypodermic Needles, Syringes, and Other Such Instruments (Part 20-15-6 of this Title);

8. Delineation of clinical privileges of non-physician practitioners;
9. Disclosure of patient information in accordance with federal and state law; and
10. Such other conditions as may be deemed appropriate.

C. Financial Interest Disclosure

1. Any OACF licensed pursuant to R.I. Gen. Laws Chapter [23-17](#), which refers clients to another such licensed health care facility or to a residential care/assisted living facility licensed pursuant to R.I. Gen. Laws Chapter [23-17.4](#) or to a certified adult day care program in which the referring entity has a financial interest shall, at the time a referral is made, disclose in writing the following information to the client:
  - a. That the referring entity has a financial interest in the facility or provider to which the referral is being made; and
  - b. That the client has the option of seeking care from a different facility or provider which is also licensed and/or certified by the state to provide similar services to the client.
2. The referring entity shall also offer the client a written list prepared by the Department of all such alternative licensed and/or certified facilities or providers. Said written list may be obtained by contacting:

Rhode Island Department of Health,

Center for Health Facilities Regulation, 3 Capitol Hill, Room 306

Providence, RI 02908

401.222.2566
3. Non-compliance with §§ 3.6.1(C)(1) and (2) of this Part shall constitute grounds to revoke, suspend or otherwise discipline the licensee or to deny an application for licensure by the Director, or may result in imposition of an administrative penalty in accordance with R.I. Gen. Laws Chapter [23-17.10](#).

### 3.6.2 Radiology and Laboratory Services

- A. Any OACF providing diagnostic radiology services must meet the requirements of the regulations for Radiation (Subchapter 40-20 of this Title).
  - 1. Mammography:
    - a. All aspects of mammography services shall be managed in accordance with the requirements of the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900.
    - b. Pursuant to R.I. Gen. Laws § 23-4.9-1, each mammographic imaging facility that takes a mammography x-ray of any individual within Rhode Island shall keep and maintain that mammography x-ray for the life of the individual. However, any mammography x-ray may be destroyed if the individual has had no contact with the mammographic imaging facility for a period exceeding fifteen (15) years.
- B. Clinical laboratory services may be provided on the premises of the OACF subject to the provisions of R.I. Gen. Laws § [23-16.2-3](#) and Federal CLIA requirements (42 C.F.R. § 493).

### **3.6.3 Infection Control**

- A. An OACF shall establish policies and procedures governing infection control and reporting techniques which address §§ 3.6.3(B) through (F) of this Part, as applicable.
- B. The medical/dental director in cooperation with other disciplines shall establish a team which shall be responsible for no less than the following:
  - 1. Establishing and maintaining a facility-wide infection surveillance program which shall include an infection surveillance officer to conduct all infection surveillance activities;
  - 2. Developing and implementing written policies and procedures for the surveillance, prevention, and control of infections;
  - 3. Developing, evaluating and revising on a continuing basis infection control policies, procedures and techniques for all appropriate phases of facility operation and services.
- C. Infection control provisions shall be established for the mutual protection of patients, employees and the public.

- D. A continuing education program on infection control shall be conducted at intervals not to exceed twelve (12) months for all staff.
- E. Reporting of Communicable Diseases:
  - 1. The OACF shall promptly report to the Department cases of communicable diseases designated as "reportable diseases" by the Director, when such cases are diagnosed in the OACF in accordance with the rules and regulations pertaining to the Reporting and Testing of Infectious, Environmental and Occupational Diseases (Part 30-05-1 of this Title).
  - 2. When infectious diseases present a potential hazard to patients or personnel, these shall be reported to the Department, even if not designated as "reportable diseases."
- F. Reporting by Laboratories:
  - 1. Laboratories shall report communicable diseases and submit specimens in accordance with the Department's Clinical Specimen Submission Guidance(available on-line <http://www.health.ri.gov/programs/laboratory/biological/about/specimensubmission/>) .
  - 2. Facilities must, in addition, comply with all other laboratory reporting requirements for TB, HIV/AIDS, sexually transmitted diseases, childhood lead poisoning and occupational diseases as outlined in the rules and regulations pertaining to the Reporting and Testing of Infectious, Environmental and Occupational Diseases (Part 30-05-1 of this Title).

#### **3.6.4 Health Care Records**

- A. Each OACF shall maintain a health care record on every patient seeking health care services.
- B. For each visit to the OACF the health care record shall contain documentation relating to the following:
  - 1. Patient identification (name, address, age and sex);
  - 2. Pertinent health history and physical findings;
  - 3. Diagnostic and therapeutic orders;
  - 4. Reports of procedures, tests and findings of each visit;

5. Diagnostic impressions; and
  6. Such other pertinent data as may be necessary to insure continuity of patient care.
- C. Each OACF shall make provisions for the appropriate release or transfer of patient care information in accordance with the legal requirements governing confidentiality of health care information.
  - D. All medical records, either originals 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 eighteen (18) years.

### **3.6.5 Medical and/or Dental Equipment**

Medical and/or dental 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.

## **3.7 Physical Plant and Equipment**

### **3.7.1 Physical Facility**

- A. All construction shall be subject to the laws, rules, regulations and codes of R.I. Gen. Laws Chapters [23-17](#), [23-28.1](#), and “Guidelines for Design and Construction of Hospital and Outpatient Facilities” incorporated above at § 3.2(A) of this Part, and all other appropriate state and local laws, codes, regulations and ordinances. Where there is a difference between codes, the code having the more stringent standard shall apply.
- B. All plans for new construction or the renovation, alteration, extension, modification or conversion of an existing facility that may affect compliance with “Guidelines for Design and Construction of Hospital and Outpatient Facilities” incorporated above at § 3.2(A) 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 “Guidelines for Design and Construction of Hospital and Outpatient Facilities” incorporated above at § 3.2(A) 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 upon request.
  1. In the event of non-conformance for which the facility seeks a variance, the general procedures outlined in § 3.8.1 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 "Guidelines for Design and Construction of Hospital and Outpatient Facilities" incorporated above at § 3.2(A) 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.
- C. 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.

### **3.7.2 Environmental Maintenance**

- A. The OACF 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.
- B. Written policies and procedures shall be established to assure a comfortable, safe and sanitary environment and appropriate lighting throughout the facility.
- C. Appropriate equipment and supplies to clean the facility 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. Smoking shall be permitted only in areas designated pursuant to R.I. Gen. Laws Chapter [23-20.10](#).
- F. Waste Disposal
  1. Regulated Medical Waste:
    - a. Regulated medical waste, as defined in the Medical Waste Regulations (250-RICR-140-15-1.2(C)) shall be managed in accordance with the provisions of the aforementioned regulations.

2. Other Waste:
  - a. Wastes which are not classified as infectious waste, hazardous wastes or which are not otherwise regulated by law or rule may be disposed in dumpsters or load packers provided the following precautions are maintained:
3. 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.
4. Load packers must conform to the same restrictions required for dumpsters and, in addition, load packers shall be:
  - a. High enough off the ground to facilitate the cleaning of the underneath areas of the stationary equipment; and
  - b. The loading section shall be constructed and maintained to prevent rubbish from blowing from said area site.

### **3.7.3 Disaster Preparedness**

- A. Each facility shall develop and maintain a written disaster preparedness plan which shall include plans and procedures to be followed in case of fire and/or other emergencies.
- B. The plan and procedures shall be developed with the assistance of qualified safety, emergency management, and/or other appropriate experts.
- C. The plan shall include procedures to be followed pertaining to no less than the following:
  1. Fire, explosion, hurricane, loss of power and/or water, flooding, failure of internal systems or equipment, and other calamities;
  2. Transfer of casualties;
  3. Location and use of alarm systems, signals and firefighting equipment;
  4. Containment of fire;
  5. Notification of appropriate persons;

6. Relocation of patients and evacuation routes;
  7. Handling of drugs and biologicals; and
  8. Any other essentials as may be warranted.
- D. A copy of the plan shall be available to all personnel.
  - E. Emergency steps of action shall be clearly outlined and posted in conspicuous locations throughout the facility.
  - F. Simulated drills testing the effectiveness of the plan shall be conducted for all personnel at least twice a year. Written reports and evaluation of all drills shall be maintained by the facility.
  - G. All personnel shall receive training in disaster preparedness as part of their employment orientation.

#### **3.7.4 Fire Safety**

- A. Each facility shall meet the requirements of R.I. Gen. Laws Chapter [23-28.1](#) pertaining to fire and safety.
- B. A monitoring program for the internal enforcement of all applicable fire safety laws and regulations shall be established. Such program shall include written procedures for the implementation of policies, regulations, and statutes. A log of such monitoring shall be maintained.

### **3.8 PRACTICES AND PROCEDURES, CONFIDENTIALITY**

#### **3.8.1 Variance Procedures**

- A. The Department may grant a variance either upon its own motion or upon request of the applicant from the provisions of any rule or regulation in a specific case if it finds 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.
- 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 the filing of each request for variance with the Department, and within a reasonable time thereafter, the Department 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 and in accordance with the provisions of § 3.8.2 of this Part.



### **3.8.2 Deficiencies and Plans of Correction**

- A. The Department shall notify the governing body or other legal authority of an OACF of violations of individual standards through a notice of deficiencies which shall be forwarded to the OACF f within fifteen (15) days of inspection of the OACF 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. An OACF which received a notice of deficiencies must submit a plan of correction to the Department 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.
- C. The Department will be required to approve or reject the plan of correction submitted by an OACF in accordance with § 3.8.2(B) of this Part within fifteen (15) days of receipt of the plan of correction.
- D. If the Department rejects the plan of correction, or if the OACF does not provide a plan of correction within the fifteen (15) day period stipulated in § 3.8.2(C) of this Part, or if an OACF whose plan of correction has been approved by the Department fails to execute its plan within a reasonable time, the Department may invoke the sanctions enumerated in § 3.4.7 of this Part. If the OACF is aggrieved by the action of the Department, the OACF may appeal the decision and request a hearing in accordance with [R.I. Gen. Laws Chapter 42-35](#) .
- E. The notice of the hearing to be given by the Department shall comply in all respects with the provisions of R.I. Gen. Laws Chapter [42-35](#) . The hearing shall in all respects comply with the provisions therein.

### **3.8.3 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 regarding Practices and Procedures Before the Department of Health (Part 10-05-4 of this Title) and Access to Public Records (Part 10-05-1 of this Title).

### **3.8.4 Confidentiality**

Disclosure of any health care information relating to individuals shall be subject to the provisions of the Confidentiality Act of R.I. Gen. Laws Chapter [5-37.3](#) and other relevant statutory and federal requirements.

**216-RICR-40-10-3**

**TITLE 216 - DEPARTMENT OF HEALTH**

**CHAPTER 40 - PROFESSIONAL LICENSING AND FACILITY REGULATION**

**SUBCHAPTER 10 - FACILITIES REGULATION**

**PART 3 - Organized Ambulatory Care Facilities (216-RICR-40-10-3)**

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Editorial Note: This Part was filed with the Department of State prior to the launch of the Rhode Island Code of Regulations. As a result, this digital copy is presented solely as a reference tool. To obtain a certified copy of this Part, contact the Administrative Records Office at (401) 222-2473.