RULES AND REGULATIONS

FOR THE LICENSING OF

ORGANIZED AMBULATORY CARE FACILITIES

(R23-17-OACF)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH
December 1981

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INTRODUCTION

These *Rules and Regulations for Licensing Organized Ambulatory Care Facilities* (R23-17-OACF) 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 minimum standards for licensed organized ambulatory 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: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) significant economic impact placed on facilities through these amended regulations. No alternative approach was identified. The protection of the health, safety and welfare of the public necessitates the adoption of these amended regulations despite the economic impact which may be incurred as a result of the regulations.

These rules and regulations shall supersede any previous rules and regulations related to the licensure of organized ambulatory care facilities 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 ***"Ambulatory and urgent health care"*** shall mean 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 this state pursuant to Chapters 5-37 and 5-31, respectively, of the General Laws of Rhode Island, as amended.

1.2 ***"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.

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 subsections (a) through (d) herein.

1.3 ***"Change in owner"*** means:

(1) 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;

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

(3) in the case of an OACF which is a corporation:

(a) a sale, lease, exchange 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 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

(e) 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.

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

1.5 ***"Emergency medical care"*** shall mean 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.

1.6 ***"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 organized ambulatory 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.

1.7 ***"Initial licensure"*** means a review conducted pursuant to the provisions contained in section 6.0 herein.

1.8 ***"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.

1.9 ***"Licensing agency"*** shall mean the Rhode Island Department of Health.

1.10 ***"Organized Ambulatory Care Facility"*** hereinafter referred to as *OACF* shall mean 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 in section 1.1 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, organized ambulatory care facilities owned and operated by professional service corporations as defined in Chapter 7-5.1 of the General Laws of Rhode Island, as amended, (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.

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

1.12 ***"Premises"*** means a tract of land and the buildings thereon where direct patient care services are provided.

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

2.1 No person acting severally or jointly with any other person shall establish, conduct or maintain an OACF in this state without a license in accordance with the requirements of section 23-17-4 of reference 1, and shall meet the requirements of the rules and regulations herein.

2.2 No facility providing ambulatory health care as defined herein shall represent itself as an Organized Ambulatory Care Facility unless licensed as an Organized Ambulatory Care Facility pursuant to the provisions herein.

2.3 Each premise of a licensed OACF shall comply with all pertinent provisions herein consistent with the scope of services provided at such premise.

2.4 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 licensing agency as provided in sections 6.1 and 6.2 herein, or for expedited reviews conducted pursuant to sections 6.5 and 6.6 herein, as a condition precedent to the transfer, assignment or issuance of a new license.

Section 3.0 ***Application for License***

3.1 Application for a license to conduct, maintain or operate an OACF 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) 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.

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 of renewal thereof for a period of no more than one (1) year if the applicant meets the requirements of reference 1 of the rules and regulations herein. Said license, unless sooner suspended or revoked, shall expire by limitation on the 31st day of December following its issuance and may be renewed from year to year after inspection, approval and payment of all fees.

4.1.1 All applications for licenses shall be accompanied by a fee of five hundred ($500) dollars 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.

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.

4.3 Thirty (30) days prior to voluntary cessation of any facility license, the Department of Health shall be notified and provided with a plan for orderly closure, notification and transfer of patients, transfer and storage of medical records, and notification of the public.

Section 5.0 *Application for Initial Licensure or Changes in Owner, Operator, or Lessee*

5.1 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 licensing agency and shall contain but not be limited to information pertinent to the statutory purpose expressed in section 23-17-3 of Chapter 23-17 or to the considerations enumerated in section 6.2 herein. Twenty-five (25) copies of such applications are required to be provided.

5.1.1 Each application filed pursuant the provisions of this section shall be accompanied by an application fee, made payable to the Rhode Island General Treasurer, as follows: applicants shall submit a fee equal to one tenth of one percent (0.1%) of the projected annual facility net operating revenue contained in the application; provided, however, that the minimum fee shall be five hundred dollars ($500) and the maximum fee shall not exceed ten thousand dollars ($10,000).

Section 6.0 *Initial Licensure and Change in Owner, Operator, or Lessee Review*

6.1 Except for expedited reviews conducted pursuant to sections 6.5 and 6.6 herein, 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:

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 OACF, the licensing agency will notify and afford the public thirty days (30) to comment on such application.

b) The decision of the licensing agency will be rendered within ninety (90) days from acceptance of the application.

c) The decision of the licensing agency shall be based upon the findings and recommendations of the Health Services Council unless the licensing agency shall afford written justification for variance therefrom.

d) All applications reviewed by the licensing agency and all written materials pertinent to licensing agency review, including minutes of all Health Services Council meetings, shall be accessible to the public upon request.

6.2 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 organized ambulatory 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:

6.2.1 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 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 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 health care facility;

6.2.2 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 OACF's services as evidenced by:

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

(i) The proposed amount and sources of owner's equity to be provided by the applicant;

(ii) The proposed financial plan for operating and capital expenses and income for the period immediately prior to, during and after the implementation of the change in owner, operator or lessee of the health care facility;

(iii) The relative availability of funds for capital and operating needs;

(iv) The applicant's demonstrated financial capability; and,

(v) Such other financial indicators as may be requested by the state agency;

6.2.3 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 facility will encourage quality improvement in all aspects of the operation of the health care facility as evidenced by:

(A) The applicant's demonstrated record in providing safe and adequate treatment to individuals receiving services at facilities owned, operated, or directed by the applicant; and

(B) The credibility and demonstrated or potential effectiveness of the applicant's proposed quality assurance programs;

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

(A) In cases where the proposed owners, operators, or directors of the health care facility currently own, operate, or direct a health care facility, or in the past five years owned, operated or directed a health care facility, both within and outside of Rhode Island, the demonstrated record of that person(s) with respect to access of traditionally 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 health care facility for traditionally underserved populations, which include but are not limited to Medical Assistance beneficiaries and uninsured and underinsured populations;

6.2.5 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;

6.2.6 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.

6.3 Subsequent to reviews conducted under sections 6.1, 6.2, 6.5 and 6.6 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 6.2 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 in owner, operator, or lessee and of which notice had been given to the OACF by the licensing agency.

6.4 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.

6.5 Applicants for initial licensure may, at the sole discretion of the licensing agency, be reviewed under expedited review procedures established in section 6.6 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 section 6.2 herein.

6.6 Expedited reviews of applications for initial licensure of organized ambulatory 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 6.2 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 6.2. 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 6.5 and 6.6. 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 6.1 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.

Section 7.0 ***Inspections***

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

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

7.3 Written reports and recommendations of inspections and inspection logs or journals shall be maintained on file in each facility for a period of no less than three (3) years.

Section 8.0 ***Denial, Suspension, Revocation of License or Curtailment of Activities***

8.1 The licensing agency 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 the rules and regulations pertaining to the licensing of OACF; and (2) has failed to comply with the provisions of reference 1.

8.1.1 Reports of deficiencies noted in inspections conducted in accordance with section 7.0 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 an OACF.

8.2 Whenever an action shall be proposed to deny, suspend or revoke the license of or to curtail the activities of an OACF, the licensing agency 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 section 23-17-8 of reference 1 and section 42-35-9 of reference 2 and pursuant to the provisions of section 25.0 herein.

8.2.1 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 3 and section 42-35-14(c) of reference 2.

8.3 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 9.0 *Governing Body and Management*

9.1 Each facility shall have an organized governing body or equivalent legal authority, ultimately responsible for: (1) the program and fiscal management and operation of the facility; (2) the assurance of the quality of care and services; and (3) the compliance with all federal, state and local laws and regulations pertaining to fire, safety, sanitation, communicable and reportable diseases, smoking policies and other health and safety requirements relevant to organized ambulatory care facilities and all rules and regulations herein.

9.2 The governing body or equivalent legal authority shall provide appropriate personnel, physical resources, and equipment to facilitate the delivery of ambulatory health care services, during established hours of operation.

9.3 The governing body or equivalent legal authority shall designate: (a) an administrator who shall be operationally responsible for the management and operation of the facility; and (b) a medical or dental director to ensure achievement and maintenance of quality standards of professional practice in accordance with section 11.0 herein.

9.4 The governing body or equivalent 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:

a) the qualifications and responsibilities of the administrator;

b) the scope of health and medical services to be provided;

c) maintain linkages and referrals with other health care facilities to assure continuity of care;

d) quality assurance for patient care and services;

e) 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

f) such other matters as may be relevant to the organization and operation of the facility.

9.5 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.

Quality Improvement

9.6 The governing body shall ensure that there is an effective, ongoing, facility-wide quality improvement program to evaluate the provision of patient care.

9.7 The organized facility-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:

a) program objectives;

b) organization(s) involved;

c) oversight responsibility (e.g., reports to the governing body);

d) facility-wide scope;

e) program administration and coordination;

f) involvement of all patient care disciplines/services;

g) methodology for monitoring and evaluating quality of care;

h) priority setting and problem resolution;

i) determination of the effectiveness of action(s) taken;

j) documentation of the quality improvement plan review.

9.8 All patient care services, including services rendered by a contractor, shall be evaluated.

9.9 Nosocomial infections and medication therapy shall be evaluated.

9.10 All medical and surgical services performed in the facility shall be evaluated for appropriateness in diagnosis and treatment.

9.11 The facility 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.

9.12 The provisions of sections 9.6--9.11 herein ("Quality Improvement") shall be deemed to have been met if the facility has met similar requirements of a national accrediting body, as approved by the Director.

Pending and Actual Labor Disputes/Actions

9.13 Health care facilities shall provide the licensing agency 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. Health care facilities 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.

Section 10.0 ***Administrator***

10.1 The governing body or equivalent legal authority 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.

Section 11.0 ***Medical or Dental Director***

11.1 Each OACF shall have a physician or dentist, as appropriate, licensed in this state responsible for 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.

Section 12.0 ***Personnel***

12.1 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.

12.2 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.

12.3 The OACF shall have a physician or dentist, as appropriate, licensed in Rhode Island, who is accessible during hours of operation.

12.4 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

12.5 Upon hire and prior to delivering services, an employment health examination shall be required for each individual involved in direct patient care and shall include a physician's certification (i.e., documented evidence) which shall include, but not be limited to, screening for the infectious diseases described below. If documented evidence is provided by the individual that said health examination, including

the required screenings, has been performed during the most recent six (6) months prior to hire, the requirements of this section shall be met.

12.5.1 ***Tuberculosis (TB)****:* Evidence that the individual is free of active tuberculosis based upon the results of a negative two-step tuberculin skin test shall be required.

a) If the Mantoux (PPD/tuberculin) test is positive, or a previous one is know to have been positive, the physician's certification shall be based on documentation of adequate chemotherapy for TB or on a chest x-ray taken not more than six (6) months prior to the physician's certification.

b) Any positive reaction must be recorded in millimeters in the personnel record.

12.5.2 ***Rubella:*** In accordance with the current guidelines of *The Red Book: Report on the Committee for Infectious Diseases* and the *Advisory Council on Immunization Practices (ACIP*), evidence of immunity is required (with the exception of individuals who are not fit subjects for immunization for documented medical reasons) of all health care workers through:

a) Documented record of rubella immunization; or

b) Serologic evidence of naturally acquired immunity.

12.5.3 ***Measles*****:** In accordance with the current guidelines of *The Red Book: Report on the Committee for Infectious Diseases* and the *Advisory Council on Immunization Practices (ACIP*), evidence of immunity is required (with the exception of individuals who are not fit subjects for immunization for documented medical reasons) of all health care workers through:

a) Proof of physician-documented illness; or

b) Positive serologic test for antibody; or

c) Documented receipt of either **one** (1) dose of measles-containing vaccine (for persons born on or before 31 December 1956) or **two** (2) doses of live-virus measles vaccine (for persons born on or after 01 January 1957). All documented receipt of vaccines must have occurred after the first birthday.

12.5.4 ***Influenza:***. Each facility shall offer annual vaccination against influenza to all persons involved in direct patient care, including employees and volunteers. The facility shall be responsible for documenting and reporting to the Department annually (by July 1st of each year): 1) the number of persons who are eligible for said vaccination; and 2) the number of persons who accept said vaccination. Further, the facility shall be responsible for providing, on an annual basis, to those persons having direct patient contact, staff education on the nature of influenza and the role of vaccination in controlling its spread.

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

12.6 ***Blood borne pathogens:***
Facilities must adhere to the OSHA Blood borne Pathogens Standard (29 *CFR* 1910-1030), including the offering of hepatitis B vaccination along with all recommendations for infection control training and provision of protective equipment to those individuals at risk.

An exposure control plan shall be in place in all facilities licensed by the Department of Health, pursuant to the provisions of Chapter 23-17 of the General Laws.

12.7 The facility shall have a policy related to individual health screenings (other than those described above) that may be required to document that individuals are physically able to perform their duties and show no evidence of communicable disease.

Section 13.0 ***Rights of Patients***

13.1 Each OACF shall observe the standards of section 23-17-19.1 of reference 1 with respect to each patient as follows:

a) The patient shall be afforded considerate and respectful care;

b) Upon request, the patient shall be furnished with the name of the physician responsible for coordinating his/her care;

c) Upon request, the patient shall be furnished with the name of the physician or other person responsible for conducting any specific test or other medical procedure performed by the health care facility in connection with the patient's treatment;

d) The patient shall have the right to refuse any treatment by the health care facility to the extent permitted by law;

e) The patient's right to privacy shall be respected to the extent consistent with providing adequate medical care to the patient and with the efficient administration of the health care facility. Nothing in this section shall be construed to preclude discreet discussion of a patient's case or examination by appropriate medical personnel;

f) The patient's right to privacy and confidentiality shall extend to all records pertaining to the patient's treatment except as otherwise provided by law;

g) The health care facility shall respond in a reasonable manner to the request of a patient's physician for medical services to the patient. The health care facility shall also respond in a reasonable manner to the patient's request for other services customarily rendered by the health care facility to the extent the services do not require the approval of the patient's physician or are not inconsistent with the patient's treatment;

h) Upon request, the patient shall be furnished with the identities of all other health care and educational institutions that the health care facility has authorized to participate in the patient's treatment and the nature of the relationship between the institutions and the health care facility;

i) If the health care facility proposes to use the patient in any human experimentation project, it shall first thoroughly inform the patient of the proposal and offer the patient the right to refuse to participate in the project;

j) Upon request, the patient shall be allowed to examine and shall be given an explanation of the bill rendered by the health care facility irrespective of the source of payment of the bill;

k) Upon request, the patient shall be permitted to examine any pertinent health care facility rules and regulations that specifically govern the patient's treatment;

l) The patient shall be offered treatment without discrimination as to race, color, religion, national origin, or source of payment.

13.2 Each OACF shall display in a conspicuous place in the licensed OACF a copy of the "Rights of Patients."

Section 14.0 ***Administrative Records***

14.1 Each OACF 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 visits and number of patients seen;

b) 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

c) a triage plan for the screening and classification of patients to determine priority needs and to utilize staff personnel and equipment efficiently.

Section 15.0 ***Uniform Reporting System***

15.1 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.

15.2 Each OACF shall make available for review upon request of the licensing agency 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.

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

15.4 The directives promulgated by the Director pursuant to these regulations shall be sent to each OACF 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 *HEALTH CARE SERVICES*

Section 16.0 *Management of Services*

16.1 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.

16.2 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:

a) the responsibility of the physician(s) or dentist, as appropriate, for the provision of health care services;

b) the designation of personnel authorized to deliver health care services in accordance with licensure and/or certification requirements and the provisions of section 9.4(e) herein;

c) standards of practice for each health care service provided;

d) procedures that may and may not be performed;

e) procurement and storage of drugs and medications in accordance with references 4 and 5;

f) designation of personnel authorized to prescribe, administer, or dispense drugs;

g) disposal of hypodermic needles, syringes and instruments in accordance with the requirements of reference 6;

h) delineation of clinical privileges of non-physician practitioners;

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

j) such other conditions as may be deemed appropriate.

Financial Interest Disclosure

16.3 Any health care facility licensed pursuant to Chapter 23-17 of the Rhode Island General Laws, as amended, which refers clients to another such licensed health care facility or to a residential care/assisted living facility licensed pursuant to Chapter 23-17.4 of the Rhode Island General Laws, as amended, 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: (1) that the referring entity has a financial interest in the facility or provider to which the referral is being made; (2) 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.

16.4 The referring entity shall also offer the client a written list prepared by the Department of Health of all such alternative licensed and/or certified facilities or providers. Said written list may be obtained by contacting:

Rhode Island Department of Health, Division of Facilities Regulation
3 Capitol Hill, Room 306
Providence, RI 02908
401.222.2566

16.5 Non-compliance with sections 16.3 and 16.4 (above) 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 Chapter 23-17.10 of the Rhode Island General Laws, as amended.

Section 17.0 ***Radiology and Laboratory Services***

17.1 Any OACF providing diagnostic radiology services must meet the requirements of reference 7.

17.1.1 ***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.

17.2 Clinical laboratory services may be provided on the premises of the OACF subject to the provisions of section 23-16.2-3 of the General Laws of Rhode Island, as amended.

Section 18.0 ***Infection Control***

18.1 Policies and procedures governing infection control and reporting techniques shall be established in accordance with this section.

18.2 The medical/dental director in cooperation with other disciplines shall establish a team which shall be responsible for no less than the following:

a) establishing and maintaining a facility-wide infection surveillance program which shall include an infection surveillance officer to conduct all infection surveillance activities;

b) developing and implementing written policies and procedures for the surveillance, prevention, and control of infections;

c) developing, evaluating and revising on a continuing basis infection control policies, procedures and techniques for all appropriate phases of facility operation and services.

18.3 Infection control provisions shall be established for the mutual protection of patients, employees and the public.

18.4 A continuing education program on infection control shall be conducted periodically for all staff.

18.5 ***Reporting of Communicable Diseases:***

a) The facility shall promptly report to the Rhode Island Department of Health cases of communicable diseases designated as "reportable diseases" by the Director of Health, when such cases are diagnosed in the facility in accordance with the most current rules and regulations pertaining to the reporting of communicable diseases (reference 14).

b) When infectious diseases present a potential hazard to patients or personnel, these shall be reported to the Rhode Island Department of Health, even if not designated as "reportable diseases."

c) ***Reporting by Laboratories:***

Whenever a laboratory performs tests or has the sample(s) tested out of state for diseases in the listing in reference 15, the laboratory shall submit to the Division of Disease Control all positive findings. The report shall consist of a copy of the laboratory findings submitted to the physician who ordered the test.

All laboratories must send an isolate, culture, slide or other appropriate specimen to the State Laboratory for typing (in the case of Salmonella, *H. Influenzae*, and Meningococcus), or sensitivity testing (in the case of Pneumococcus), if such testing has not already been performed by the reporting laboratory. An appropriate specimen must be submitted to the State Laboratory for confirmation in the case of all other diseases marked with a "#" in the listing in reference 15.

d) All laboratories must report zone size by oxacillin disk testing in millimeters or Minimum Inhibitory Concentration (MIC) to Penicillin in micrograms/ml in the case of invasive Pneumococcal disease.

e) 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 reference 15.

Section 19.0 ***Health Care Records***

19.1 Each OACF shall maintain a health care record on every patient seeking health care services.

19.2 For each visit to the OACF the health care record shall contain documentation relating to the following:

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

b) pertinent health history and physical findings;

c) diagnostic and therapeutic orders;

d) reports of procedures, tests and findings of each visit;

e) diagnostic impressions; and

f) such other pertinent data as may be necessary to insure continuity of patient care.

19.3 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.

19.4 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 18 years.

Section 20.0 ***Medical and/or Dental Equipment***

20.1 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.

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

Section 21.0 ***Physical Facility***

21.1 All construction shall be subject to the laws, rules, regulations and codes of references 1, 8, 9, 10 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.

21.2 Any plans for alterations, extensions, modification, renovation or conversion of an existing facility that may affect compliance with references 1 and 8 shall be submitted to the Department of Health for review and approval prior to construction.

21.3 All plans for new facility construction shall be submitted to the Department for review for compliance with references 1 and 8 and approved prior to construction.

Section 22.0 ***Environmental Maintenance***

22.1 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.

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

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

22.4 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.

22.5 Smoking shall be permitted only in designated areas.

22.6 ***Waste Disposal***

22.6.1 ***Medical Waste:***

Medical 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), of reference 11 shall be managed in accordance with the provisions of the aforementioned regulations.

22.6.2 ***Other Waste:***

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

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

b) Load packers must conform to the same restrictions required for dumpsters and, in addition, load packers shall be:

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

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

Section 23.0 ***Disaster Preparedness***

23.1 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.

23.2 The plan and procedures shall be developed with the assistance of qualified safety, emergency management, and/or other appropriate experts.

23.3 The plan shall include procedures to be followed pertaining to no less than the following:

(a) Fire, explosion, hurricane, loss of power and/or water, flooding, failure of internal systems or equipment, and other calamities;

(b) Transfer of casualties;

(c) Location and use of alarm systems, signals and fire fighting equipment;

(d) Containment of fire;

(e) Notification of appropriate persons;

(f) Relocation of patients and evacuation routes;

(g) Handling of drugs and biologicals; and

(h) Any other essentials as may be warranted.

23.4 A copy of the plan shall be available to all personnel.

23.5 Emergency steps of action shall be clearly outlined and posted in conspicuous locations throughout the facility.

23.6 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.

23.7 All personnel shall receive training in disaster preparedness as part of their employment orientation.

23.8 All facilities shall develop a plan, approved and adopted by the governing board and consistent with the requirements of this section, to address the year 2000 computer/chip problem ("Y2K") by September 30, 1999 and shall test such plan by October 30, 1999. The plan shall include, at a minimum, facility identification of potential problem areas, remediation of identified problems, and testing for functionality, and shall also include consideration of vendor and supplier compliance.

Section 24.0 ***Fire Safety***

24.1 Each facility shall meet the requirements of reference 9 pertaining to fire and safety.

24.2 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.

PART V *PRACTICES AND PROCEDURES, CONFIDENTIALITY AND SEVERABILITY*

Section 25.0 *Variance Procedures*

25.1 The licensing agency 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.

25.2 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.

25.2.1 Upon the filing of each request for variance with the licensing agency, and within a reasonable time thereafter, the licensing agency shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the facility appeals the denial and in accordance with the provisions of section 26.0 herein.

Section 26.0 *Deficiencies and Plans of Correction*

26.1 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.

26.2 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.

26.3 The licensing agency will be required to approve or reject the plan of correction submitted by a facility in accordance with section 26.2 above within fifteen (15) days of receipt of the plan of correction.

26.4 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 stipulated in section 26.3 above, 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 8.0 herein. If the facility is aggrieved by the action of the licensing agency, the facility may appeal the decision and request a hearing in accordance with Chapter 42-35 of the General Laws.

26.5 The notice of the hearing to be given by the Department of Health shall comply in all respects with the provisions of Chapter 42-35. The hearing shall in all respects comply with the provisions therein.

Section 27.0 *Rules Governing Practices and Procedures*

27.1 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 12.

Section 28.0 ***Confidentiality***

28.1 Disclosure of any health care information relating to individuals shall be subject to the provisions of the Confidentiality Act of reference 13 and other relevant statutory and federal requirements.

Section 29.0 ***Severability***

29.1 If any provision of the rules and regulations herein or the application thereof 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.

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October 17, 2001

PART VI ***REFERENCES***

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

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

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

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

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

6. *Rules and Regulations Governing Hypodermic Needles, Syringes and Other Such Instruments (R21-28-CS-4),* as amended, Rhode Island Department of Health.

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

8. *Guidelines for Construction and Equipment of Hospital and Medical Facilities*, The American Institute of Architects Committee on Architecture for Health with Assistance from the U.S. Department of Health & Human Services. Washington, D.C.: The American Institute of Architects Press, 1993.

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

10. Rhode Island State Building Code, Chapter 23-27-3 of the Rhode Island General Laws, as amended.

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

12. *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),* as amended, Rhode Island Department of Health.

13. "Confidentiality of Health Care Information Act," Chapter 5-37.3 of the General Laws of Rhode Island, as amended.

14. *Rules and Regulations Pertaining to the Reporting of Communicable, Environmental and Occupational Diseases (R23-5-6, 10, 11, 23-24.6-CD/ERD and R23-24.5 ASB*), as amended, Rhode Island Department of Health.

15. (See table below).

REPORTABLE BY FACILITY AUTHORITIES **IMMEDIATELY** BY TELEPHONE ON THE DAY OF RECOGNITION OR STRONG SUSPICION OF DISEASE.

Animal bites (involving human exposure)
Anthrax#
Botulism#
Cholera#
Diphtheria#**
Foodborne Outbreaks (involving > 2 persons)
Hantavirus#
Institutional Outbreaks
Measles+**
Meningococcal disease; invasive* #
Mumps**
Pertussis**
Plague#
Poliomyelitis#**
Rabies (human)#
Rubella (including congenital rubella)**
Viral hemorrhagic fevers, Ebola, Lassa, Marburg#
Yellow Fever#

REPORTABLE BY FACILITY AUTHORITIES VIA MAIL/TELEPHONE/ELECTRONICALLY **AS SOON AS POSSIBLE BUT NO LATER THAN FOUR (4) DAYS AFTER RECOGNITION** OR STRONG SUSPICION OF DISEASE.

Acquired Immunodeficiency Syndrome (AIDS)
Amebiasis
Babesiosis#
Brucellosis#
Campylobacteriosis
Chlamydia *Trachomatis* (genital & ophthalmic)
Cryptosporidiosis
Cysticercosis
Dengue Fever
E.coli 0157:H7 gastroenteritis#
Ehrlichiosis#
Encephalitis (primary or parainfectious)
Enterococcal infection/colonization# (vancomycin resistant) (VRE)
Group A Streptococcal Disease, invasive (including necrotizing fasciitis)*#
Group B Streptococcal Disease, invasive*
Giardiasis
H. influenzae disease, invasive, all serotypes*#
Hansen's disease (Leprosy)
Hemolytic Uremic Syndrome (HUS)
Hepatitis A,B,C,Delta, unspecified viral^**
Hepatitis B Chronic Carriers**
Histoplasmosis
HIV-1 infection or HIV-2 infection (identity of patient must not be provided)
Creutzfeldt-Jakob Disease
Kawasaki Syndrome
Lead poisoning (blood lead >15 ug/dl)** Age < 18 years only
Legionnellosis
Leptospirosis
Listeriosis#
Lyme Disease
Malaria#
Meningitis (all types)
Ornithosis (psittacosis)
Pneumococcal disease, invasive and non-invasive*@
Rheumatic Fever (acute)
Rocky Mountain Spotted Fever
Salmonellosis#
Sexually Transmitted Diseases:
- Chancroid
- Chlamydia (C.*trachomatis*)
- Gonorrhea
- Lymphogranuloma Venereum
- Syphilis
- Granuloma Inguinale

Shigellosis
Staphylococcus aureus, vancomycin resistant (VRSA) infection/colonization
Toxic Shock Syndrome
Tetanus
Trichinosis
Tuberculosis (all sites) PPD (+) < 6 years age
Tularemia
Typhoid Fever
Typhus

Special Notes:

* Invasive disease: confirmed by isolation from blood, CSF, pericardial fluid, pleural fluid, peritoneal fluid, joint fluid, or normally sterile site.
^ Acute cases only.
\# All laboratories must send isolate, culture, slide or other specimen to the State Laboratory for confirmation or typing, if not performed already.
@ Laboratories must report zone size by oxacillin disk testing in mm or MIC to Penicillin in ug/ml. If zone size < 20 mm and MIC not performed, isolate must be sent to State Laboratory.
\+ Diagnostic specimens for IgM serology for measles and rubella shall be sent to the Rhode Island Department of Health Laboratory for analysis. Call the Immunization Program for pre-authorization (277-2312) or after hours: 272-5952.
** Childhood lead poisoning shall be reported to the Division of Family Health (277-2312). Reportable within ten (10) working days of diagnosis.
Diphtheria, measles, mumps, pertussis, rubella and poliomyelitis reportable immediately to the Division of Family Health (277-2312) or after hours: 272-5952.
HBsAg positive pregnant women shall be reported to the Division of Family Health (277-2312).

16. *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors (R5-19-PHAR),* as amended, Rhode Island Department of Health.

17. "Pharmacy", Chapter 5-19 of the General Laws of Rhode Island, as amended.