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TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 10 – FACILITY REGULATION

PART 12 – Rules and Regulations for the Licensing of Kidney Disease Treatment Centers

12.1 Authority

These amended Rules and Regulations for Licensing of Kidney Disease Treatment Centers are promulgated under the authority conferred under R.I. Gen. Laws § 23-17-10, and are established for the purpose of adopting minimum standards for licensed kidney disease treatment centers in this state.

12.2 Definitions

A. Whenever used in these rules and regulations, the following terms shall be construed as follows:

1. "Acute dialysis" means short term intensive dialysis requiring hospitalization.

2. "Change in operator" means a transfer by the governing body or operator of a kidney disease treatment center 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 kidney disease treatment center;

    b. Maintain and control the books and records of the kidney disease treatment center;

    c. Dispose of assets and incur liabilities on behalf of the kidney disease treatment center; or

    d. Adopt and enforce policies regarding operation of the kidney disease treatment center.

    e. This definition is not applicable to circumstances wherein the governing body of a kidney disease treatment center retains the immediate authority and jurisdiction over the activities enumerated in §§ 12.2(A)(2)(a) through (d) of this Part herein.

3. "Change in owner" means:

a. In the case of a kidney disease treatment center 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 a kidney disease treatment center which is an unincorporated sole proprietorship, the transfer of the title and property to another person;

c. In the case of a kidney disease treatment center which is a corporation;

(1) A sale, lease, exchange or 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 a kidney disease treatment center 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 a kidney disease treatment center which is a non-business corporation, any change in membership which results in a new person acquiring controlling vote in such corporation.

4. "Dialysis" means a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane either by the use of hemodialysis or peritoneal dialysis.

5. "Director" means the Director of the Rhode Island Department of Health.

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 a kidney disease treatment center which funds are free and clear of any repayment or liens against the assets of the proposed owner and/or licensee and that result in a like reduction in the portion of the capital cost that is required to be financed or mortgaged.

7. "Health Services Council" means the advisory body to the Rhode Island Department of Health established in accordance with R.I. Gen. Laws Chapter 23-17, appointed and empowered in accordance with R.I. Gen. Laws Chapter 23-15, as amended, to serve as the advisory body to the state agency in its review functions.

8. "Home dialysis" means carrying out the therapeutic process of dialysis in the patient's place of residence by a properly trained patient or `helper.'

9. "Hospital affiliation" means a contractual arrangement with a licensed hospital for the provision of services for patients with medical problems in need of hospital services, equipment and personnel for in-patient care.

10. "Kidney disease treatment center" means a "free-standing (non-hospital) dialysis facility for renal disease" which may be a public or private organization or sub-unit of such an agency or organization providing chronic maintenance dialysis to ambulatory patients on the premises of the facility or in the patient's place of residence.

11. "Licensing agency" or "state agency" means the Rhode Island Department of Health.

12. "The licensed capacity" (of a kidney disease treatment center) means the number of dialysis stations that the center is licensed to operate.

13. "Person" means any individual, trust or estate, partnership, corporation (including associations, joint stock companies) state, or political subdivision or instrumentality of a state.

14. "Self-care dialysis" means dialysis performed with nominal professional supervision by a patient who has completed an appropriate course of training.

15. "Sub-unit" means a satellite of a licensed kidney disease treatment center which serves patients in a geographic area different from its parent agency and which can share administration, supervision and services on a daily basis with its parent agency.

16. "Technical advisory committee" means a multidisciplinary body of persons with professional training in renal disease and other related professional fields, acceptable to the affiliated hospital, to serve as an advisory body on matters pertaining to standards, policies, staffing, program and services of the free-standing facility.

12.3 Licensing Procedures

12.3.1 General Requirements for Licensure

No person acting severally or jointly with any other person, shall establish, conduct or maintain a kidney disease treatment center in this state without a license in accordance with the requirements of R.I. Gen. Laws § 23-17-4.

12.3.2 Application for License or for Changes in the Owner, Operator, or Lessee

A. Application for a license to conduct, maintain or operate a kidney disease treatment center shall be made to the licensing agency upon forms provided by it one month prior to the expiration date of the license and shall contain such information as the licensing agency reasonably requires which may include affirmative evidence of ability to comply with the provisions of R.I. Gen. Laws § 23-17-4 and the rules and regulations herein.

1. Each application shall be accompanied by an application fee as set forth in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.

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) of any mortgage, deed or trust note or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility. The list shall also include all officers, directors and other persons or any subsidiary corporation owning stock, if the facility is organized as a corporation, and all partners if the facility is organized as a partnership.

C. Application for initial licensure or changes in the owner, operator, or lessee of a kidney disease treatment center 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 R.I. Gen. Laws § 23-17-3 or to the considerations enumerated in § 12.3.3(E) of this Part. Twenty-five (25) copies 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 in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.

12.3.3 Issuance and Renewal of License

A. Upon receipt of an application for a license, the licensing agency shall issue a license or renewal thereof for a period of one (1) year if the applicant meets the requirements of R.I. Gen. Laws Chapter 23-17 and the rules and regulations herein. Said license, unless sooner suspended or revoked, shall expire by limitation on the 31st day of December following its issuance and may be renewed from year to year after inspection and approval by the licensing agency.

1. All renewal applications shall be accompanied by a license renewal fee as set forth in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.

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.

1. Any initial licensure or change in owner, operator, or lessee of a licensed kidney disease treatment center shall require prior review by the Health Services Council and approval of the licensing agency as provided in §§ 12.3.3(E) and (F) of this Part, or for expedited reviews conducted pursuant to § 12.3.3(H) of this Part, as a condition precedent to the transfer, assignment or issuance of a new license.

C. 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.

D. Except for expedited reviews conducted pursuant to § 12.3.3(H) of this Part, reviews of applications for initial licensure or for changes in the owner, operator or lessee of licensed kidney disease treatment center 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 a license in connection with a change in the owner, operator or lessee of an existing kidney disease treatment center, the licensing agency will notify and afford the public thirty (30) days to comment on such application.

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

3. 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.

4. 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.

E. Except as otherwise provided in R.I. Gen. Laws Chapter 23-17, a review by the Health Services Council of an application for initial licensure or for a license in the case of a proposed change in owner, operator, or lessee of a licensed kidney disease treatment center, may not be made subject to any criterion unless the criterion directly relates to the statutory purpose expressed in R.I. Gen. Laws § 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 kidney disease treatment center 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):

(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;

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.

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 facility'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 health care facility;

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

(4) The applicant's demonstrated financial capability;

(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 facility's services and the extent to which the facility will encourage quality improvement in all aspects of the operation of the health care facility as evidenced by:

a. the 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 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 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.

5. In consideration of the proposed continuation or termination of emergency, primary care and/or other core health care services by the facility.

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

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.

F. Subsequent to reviews conducted under §§ 12.3.3(D), (E), (G) and (H) of this Part, 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 R.I. Gen. Laws § 23-17-3, or to the review criteria set forth in § 12.3.3(E) of this Part. This shall not limit the authority of the licensing agency to require correction of conditions or defects which existed prior to the proposed change of owner, operator or lessee and of which notice had been given to the facility by the licensing agency.

G. Applicants for initial licensure may, at the sole discretion of the licensing agency, be reviewed under expedited review procedures established in § 12.3.3(H) of this Part if the licensing agency 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 licensing agency 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 set forth in § 12.3.3(E) of this Part.

H. Expedited reviews of applications for initial licensure of kidney disease treatment centers 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 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 § 12.3.3(E) of this Part 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.

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 licensing agency may propose a preliminary report on such application provided such proposed report incorporates findings relative to the review criteria set forth in § 12.3.3(E) of this Part. 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 processed under the provisions for expedited review as delineated in §§ 12.3.3(G) and (H) 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 § 12.3.3(D) 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.

12.3.4 Capacity and Classification

Each license shall be issued for the licensed dialysis station capacity of the kidney disease treatment center. No kidney disease treatment center shall have more stations or operate more shifts than authorized by the licensing agency.

12.3.5 Change of Ownership, Operation and/or Location

A. When a change of ownership or operation or location of a kidney disease treatment center or when discontinuation of a service is contemplated, the owner and/or operator shall notify the licensing agency in writing no later than six (6) weeks prior to the proposed action.

B. A license shall immediately become void and shall be returned to the licensing agency when operation of a kidney disease treatment center is discontinued or when any changes in ownership occur in accordance with the rules and regulations herein and R.I. Gen. Laws § 23-17-6.

1. When there is change in ownership or in the operation or control of an existing kidney disease treatment center the licensing agency reserves the right to extend the expiration date of such license, allowing the kidney disease treatment center to operate under the same conditions which applied to the prior

licensee for such time as shall be required for the processing of a new application or for transfer of patients, not to exceed six (6) weeks.

12.3.6 Inspections

A. The licensing agency shall make or cause to be made such inspections and investigations as deemed necessary in accordance with R.I. Gen. Laws § 23-17-10 or Chapter 23-17 and the rules and regulations herein.

B. Every kidney disease treatment center shall be given prompt notice by the licensing agency of all deficiencies reported as a result of an inspection or investigation.

C. Written reports and recommendations of inspections shall be maintained on file in each kidney disease treatment center for a period of no less than three (3) years.

12.3.7 Denial, Suspension, Revocation of License or Curtailment of Activities

A. The licensing agency is authorized to deny, suspend or revoke the license or curtail activities of any kidney disease treatment center which: has failed to comply with the rules and regulations pertaining to licensing of kidney disease treatment centers; and has failed to comply with the provisions of R.I. Gen. Laws Chapter 23-17.

1. Lists of deficiencies noted in inspections conducted in accordance with § 12.4.6 of this Part shall be maintained on file in the licensing agency, and shall be considered by the licensing agency in rendering determinations to deny, suspend or revoke the license or curtail activities of a kidney disease treatment center.

B. Where the licensing agency deems that operation of a kidney disease treatment center results in undue hardship to patients as a result of deficiencies, the licensing agency is authorized to deny licensing to facilities not previously licensed, or to suspend for a stipulated period of time or revoke the license of a kidney disease treatment center already licensed or curtail activities of the kidney disease treatment center.

C. Whenever an action shall be proposed to deny, suspend or revoke a kidney disease treatment center license, or curtail its activities, the licensing agency shall notify the kidney disease treatment center by certified mail, setting forth reasons for the proposed action, and the applicant or licensee shall be given an opportunity for a prompt and fair hearing in accordance with R.I. Gen. Laws §§ 23-17-8 and 42-35-9.

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 R.I. Gen Laws §§ 23-1-21 and 42-35-14(c).

D. The appropriate state and federal placement and reimbursement agencies shall be notified of any action taken by the licensing agency pertaining to either denial, suspension, or revocation of license or curtailment of activities.

12.4 Organization and management

12.4.1 Governing Body and Management

A. Each facility shall have an organized governing body or other legal authority, responsible for:

1. the management and control of the operation;

2. the assurance of quality of care and services;

3. the conformity of the facility with all federal, state and local laws and regulations relating to fire, safety, sanitation, infection control; and

4. other relevant health and safety requirements and with all the rules and regulations herein.

B. The governing body or other legal authority shall provide appropriate physical resources and equipment and personnel required to meet the special needs of patients on chronic dialysis maintenance.

C. The governing body or other legal authority shall designate an administrator who will be responsible for the management and operation of the facility and a medical director to ensure achievement and maintenance of quality standards of professional practice.

D. The governing body shall adopt and maintain by-laws defining responsibilities and identifying purposes and means of fulfilling such, in addition to:

1. A statement relating to development and implementation of long range plans;

2. A statement of qualifications and responsibilities of the medical director and administrator;

3. A statement of the governing body's responsibilities for the quality of care and services;

4. A statement relating to conflict of interest on the part of the governing body, medical staff and employees;

5. A policy statement concerning publication of an annual report including a certified financial statement; and

6. Such other matters as may be relevant to the organization of the facility.

E. Financial Interest Disclosure

1. Any health care facility 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;

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 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

F. Non-compliance with §§ 12.4.1(E)(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.

G. Pending and Actual Labor Disputes/Actions

~~1.~~ 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.

12.4.2 Administrator

A. The governing body shall appoint a qualified administrator who may be the medical director, who shall be responsible for:

1. the management and operation of the facility;

2. the enforcement of policies, rules and regulations and statutory provisions pertaining to the health and safety of patients;

3. serving as liaison between the governing body and the staff; and

4. the planning, organizing and directing of such other activities as may be delegated by the governing body.

12.4.3 Medical Director

A. The clinical services of the facility shall be under the direction of a physician licensed in Rhode Island who shall be trained in dialysis techniques, has an appointment in that specialty service at the affiliated hospital and who shall be responsible for no less than the following:

1. The coordination and supervision of all services;

2. The selection of patients for dialysis (either for chronic maintenance, self-care, or home dialysis) in accordance with criteria established with the technical advisory committee (see § 12.5.4 of this Part);

3. The achievement and maintenance of quality assurance of professional practice;

4. The training of physicians, nurses and paramedical personnel in dialysis techniques; and

5. The establishment of provisions for infection control.

12.4.4 Technical Advisory Committee

A. Each facility shall establish a Technical Advisory Committee with representatives from the affiliated hospital as defined in § 12.1 of this Part to serve as an advisory body to:

1. Determine the appropriateness of renal dialysis care, treatment procedures and policies and services delivered to patients;

2. Review adequacy of patient selection for care;

3. Review appropriateness of medical services provided including ancillary services; and

4. Make necessary recommendations to maintain quality care and services.

12.4.5 Personnel

A. Each facility shall maintain a sufficient number of qualified personnel to provide effective patient care and other related services.

B. There shall be written personnel policies and procedures which shall be available to personnel.

C. 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.

D. 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 kidney disease treatment center. Such health screening shall be conducted in

accordance with the rules and regulations pertaining to "Immunization, Testing, and Health Screening for Health Care Workers" promulgated by the Department of Health.

12.4.6 Affiliation and Transfer Agreement

A. There shall be evidence of a current contractual arrangement with a licensed hospital for the provision of services as defined in § 12.1 of this Part. Said contract shall clearly define the mutual responsibilities and relationships of parties involved and shall include reasonable assurance of:

1. Transfer or referral of patients as medically determined with timely acceptance and admission; and

2. Transfer of patient care plans and other necessary medical information.

B. Arrangement with any other agency or facility for the provision of such services, such as laboratory, radiology or other, shall be with a facility which maintains quality standards and is certified or licensed as may be required by statute.

12.4.7 Rights of Patients

Each facility shall observe the standards with respect to each patient admitted to its facility as enumerated in R.I. Gen. Laws § 23-17-19.1.

12.4.8 Disaster Preparedness

A. Each facility shall develop and maintain a written disaster preparedness plan which shall include specific provisions and procedures for the emergency care of patients in the event of fire, natural disaster or functional failures of internal systems and/or equipment.

1. Such a plan shall be developed and coordinated with appropriate state and local agencies and representatives concerned with emergency safety and rescue and with representatives of the affiliate hospital.

2. A copy of such plan shall be submitted to the licensing agency.

3. Each facility 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 must test such plan by October 30, 1999.

    a. 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.

B. Simulated drills testing the effectiveness of the plan shall be conducted at least semi-annually. Written reports and evaluation of all drills shall be maintained by the facility.

C. Fully equipped emergency trays including emergency drugs, and medical supplies sufficient to meet the emergency needs of the facility shall be available at all times on the premises.

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

12.4.9 Uniform Reporting System

A. Each facility shall establish and maintain records and data in such a manner as to make uniform the system of periodic reporting. The manner in which the requirements of this regulation may be met shall be prescribed from time to time in directives promulgated by the Director with the advice of the Health Services Council.

B. Each facility shall report to the licensing agency detailed financial and statistical data pertaining to its operation, services, and facility. Such reports shall be made at such intervals and by such dates as determined by the Director and shall include but not be limited to the following:

1. Utilization of services;

2. Unit of cost of services;

3. Charges for services;

4. Financial condition of the kidney disease treatment center; and

5. Quality of care.

C. The licensing agency is authorized to make the reported data available to any state agency concerned with or exercising jurisdiction over the reimbursement of the facility.

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

12.5 Patient care services

12.5.1 Patient Care Management

A. Each patient shall be under the continuing supervision of a physician and provisions shall be made by the facility to assure the availability of medical care at all times to patients whether on chronic maintenance dialysis, self-care or home dialysis programs.

B. A mechanism shall be established for the development and periodic review and revision of patient care policies and procedures by a professional group including no less than the medical director of the facility, the nursing director and representatives of the Technical Advisory Group.

C. Patient care policies and procedures shall be established for each specific program carried by the facility, (chronic maintenance dialysis, self-care dialysis or home dialysis) and shall pertain to no less than the following:

1. Scope of services provided either directly or per contractual arrangement;

2. Criteria for admission, transfer or discharge from or to chronic maintenance, self-care or home dialysis, or to acute dialysis;

3. Availability and accessibility of services in medical or other emergency;

4. Medical supervision and physician services;

5. Patient care plans and methods of implementation;

6. Pharmaceutical, dietary and social services;

7. Availability of services for working patients;

8. Evaluation of patient care services by the technical advisory committee;

9. Transfer of patient to affiliate hospital; and

10. The self-care and home dialysis programs.

D. There shall be posted at each nursing station a roster with the names and telephone number(s) of physicians to be called in an emergency.

12.5.2 Patient Care Plans

A. There shall be a patient care plan for each patient, developed by the professional team to ensure appropriate modality of care.

1. Such a plan shall be based on the nature of the patient's illness, treatment prescribed and assessment of patient's needs based on prior medical work up.

2. The patient care plan shall furthermore reflect medical, psychological and social needs of patients.

3. The plan shall be reviewed at least monthly until the patient is stable and thereafter every six (6) months and revised as necessary to meet ongoing needs of the patient.

4. The patient, parent, or legal guardian shall be involved in the development of the care plan with the professional team and due consideration shall be given to the patient's preferences when not medically contraindicated.

5. The frequency of home visits, if applicable, will be noted in the patient's care plan and based on each individual patient's needs.

12.5.3 Nursing Services

A. The nursing service shall be under the supervision of a full time licensed registered nurse who has clinical nursing experience and training in dialysis techniques.

B. There shall be a sufficient number of registered nurses to plan, assign supervise and evaluate nursing care as well as a sufficient number of ancillary nursing personnel to meet patient care needs based on the types of programs (e.g., chronic maintenance, self-care or home dialysis) and staff capabilities.

C. A registered nurse with the experience in dialysis techniques shall be on the premises of the dialysis facility at all times whenever a patient is undergoing renal dialysis treatment.

12.5.4 Medical Records

A. A member of the professional staff shall be designated to supervise the medical records and to ensure proper documentation, completion, indexing, filing, retrieval and safe storage.

B. A medical record shall be established and maintained for every patient treated on the premises or at his place of residence.

C. Each medical record shall contain sufficient information and data to support the diagnosis, plan of treatment to define treatment modalities, responses to treatment and on-going progress reports of patient care.

D. Each medical record shall contain no less than the following:

1. Documented evidence of assessment of the needs of the patient an of establishment of an appropriate plan of treatment;

2. Identification and social data;

3. Referral information with authentication of diagnosis;

4. Medical and nursing history of patient;

5. Report(s) of physician examination(s);

6. Observation and progress notes;

7. Reports of treatments and clinical findings;

8. Laboratory reports; and

9. Other related reports.

E. All medical records either original or accurate reproductions shall be retained for a minimum of five (5) years following discharge of the patient. Records of minors shall be kept for at least five (5) years after such minor shall have reached the age of eighteen (18) years.

12.5.5 Laboratory Services

Each facility shall make provisions for laboratory services.

12.5.6 Related Services

A. Social services and dietetic services shall be provided either directly or per contractual arrangements with qualified professional personnel, on either a full or part time basis, depending on the scope of the program and patient care needs.

B. The social worker and dietitian shall have clearly delineated responsibilities which shall include their participation with the professional team to plan and evaluate the psychosocial and nutritional needs of patients.

C. Accurate notations shall be made in the patient's medical record of all services rendered.

12.5.7 Infection Control

A. A mechanism shall be established with appropriate professional staff to establish infection control policies and procedures for the mutual protection of patients, personnel and the public. Such policies and procedures shall pertain to:

1. Infection surveillance activities including a plan for systematic monitoring of hepatitis in patients and personnel.

2. Sanitation and asepsis;

3. Isolation of patients with known or suspected infectious disease;

4. Handling and disposal of waste and contaminants;

5. Sterilization, disinfection and laundry;

6. Reporting, recording and evaluation of occurrences of infections; and

7. Documentation of infection rate.

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

12.5.8 Home Dialysis

A. The therapeutic regimen for any patient to be cared for at home shall be arranged after a sufficient period of initial study, dialysis, planning and self-care dialysis on the premises of the facility and with the responsible person(s) who will assist the patient.

B. Facilities providing home dialysis shall make available either directly or per contractual arrangements with a community agency(ies) the following services:

1. Home visits for supervision of care;

2. Consultation with qualified social worker and dietitian;

3. Installation and maintenance of equipment;

4. Testing appropriateness of water;

5. A record-keeping system to assure continuity of care;

6. Assurance of emergency coverage on a twenty-four (24) hours basis with affiliate hospital;

7. Arrangements for emergency transportation to affiliate hospital in the event of emergency; and

8. Ordering of supplies.

C. Patients on a home dialysis program shall be visited ~~no less than every three (3) months~~ by facility professional staff ~~of the facility~~ to assess and review a patient's care plan and to observe a patient and "helper" ~~carry out~~perform dialysis. The frequency of such visits shall be determined by facility professional staff, applying clinical judgment to the specifics of a patient's case.

12.5.9 Continuity of Care for Traveling Patients

A. Facilities shall be responsible to make temporary arrangements with dialysis facilities or centers throughout the country or outside the United States for patients who will be traveling and may be confronted with medical problems requiring acute care.

1. Patients shall be given the name and address of facilities in those states or countries in which the patient will be traveling. In addition instructions will be given to the patient in emergency measures to be taken in the event medical problems should arise.

12.6 Environmental Maintenance

12.6.1 Environment

A. The facility shall be maintained and equipped to provide a functional sanitary, safe and comfortable environment with an adequate amount of well lighted space for the services provided.

B. The areas used by patients shall be maintained in good repair and kept free of hazards.

C. Equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe, sanitary condition.

D. Hazardous cleaning solutions, compounds, and substances shall be labeled, stored in a safe place and kept in an enclosed section separate from other cleaning materials.

E. Cleaning shall be performed in a manner which will minimize the spread of pathogenic organisms in the atmosphere.

12.7 Physical Plant and Equipment

12.7.1 General Maintenance Provisions

A. A qualified technically trained and competent person shall be designated to oversee the general maintenance and functional operation of all the mechanical equipment relative to dialysis treatment in a safe and properly functioning order.

B. Each facility utilizing a central-batch delivery system shall provide either on the premises or through contractual arrangement with a supplier, sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.

C. Records of calibration and testing of equipment shall be maintained for at least three (3) years.

12.7.2 Physical Facility

A. The dialysis unit(s) shall be separate from other activities and shall be located in an area free of traffic by non-unit staff or patients.

B. The nursing station shall be located in an area which provides adequate surveillance of patients on dialysis machines.

C. Treatment areas shall be designed and equipped to provide adequate and safe treatment, as well as privacy and comfort for patients. Sufficient space shall be provided to accommodate emergency equipment and staff to move freely to reach patients in emergencies.

D. Heating and ventilation systems shall be capable of maintaining adequate and comfortable temperatures.

E. Each facility shall met the fire and safety provisions of R.I. Gen. Laws Chapter 23-28.1, and shall conform with all state and local building codes.

12.7.3 Emergency Power

A. The facility shall be equipped with an emergency power source.

B. The emergency electrical power system shall be adequate to supply power to maintain the operation of the dialysis machines and other life-support systems, and lighting for egress, fire detection equipment, alarm and extinguishing systems.

12.7.4 Lighting and Electrical Services

All electrical and other equipment used in the facility shall be maintained free of defects which could be a potential hazard to patients or personnel. A planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility shall be established.

12.7.5 New Construction

A. All new construction shall be subject to the provisions of R.I. Gen. Laws Chapters 23-28.1, 23-27.3, and 23-1.

B. All new construction shall also be subject to the provisions of "Specifications for Making Buildings and Facilities Accessible to and Usable by the Physically Handicapped", American National Standards Institute (1980), not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these Regulations.

C. In addition, any other applicable state and local laws, codes and rules and regulations shall apply. Where there is a difference between codes, the code having the higher standard shall apply.

12.7.6 Plumbing

A. All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of R.I. Gen. Laws Chapter 23-27.3.

B. All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections between potable and non-potable water supplies.

12.7.7 Water Supply

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

B. Water used for dialysis purposes shall be analyzed periodically and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques.

12.7.8 Waste Disposal

A. Medical Waste:

1. Medical waste as defined in the Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste of the Rhode Island Department of Environmental Management, shall be managed in accordance with the provisions of the aforementioned regulations.

B. Other Waste:

1. 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:

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

(2) the loading section should be constructed and maintained to prevent rubbish from blowing from said area site.

12.7.9 Waste Water Disposal

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

12.7.10 Deficiencies and Plans of Correction

A. 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 R.I. Gen. Laws § 23-1-21.

B. 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.

C. The licensing agency will be required to approve or reject the plan of correction submitted by a facility in accordance with § 12.7.10(B) of this Part within fifteen (15) days of receipt of the plan of correction.

D. 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 § 12.7.10(B) of this Part, 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 § 12.4.7 of this Part. If the facility is aggrieved by the sanctions of the licensing agency, the facility 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 of Health shall comply in all respects with the provisions of R.I. Gen. Laws Chapter 42-35. The hearing shall in all respects comply with all provisions therein.

12.8 Exception and Severability

12.8.1 Exception

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

12.8.2 Severability

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