

BUREAU OF MEDICAL SERVICES

Chapter 126: REGULATIONS GOVERNING THE LICENSING AND FUNCTIONING OF END STAGE RENAL DISEASE UNITS/FACILITIES

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CHAPTER 1: GENERAL DEFINITIONS

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings:

1. **Agreement:** means a written document executed between an ESRD Facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.
2. **Arrangement:** means a written document executed between an ESRD Facility and another facility in which the other facility agrees to furnish specified services to patients, but the ESRD Facility retains responsibility for those services and for obtaining reimbursement for them.
3. **Deeming:** means a Medicare certified End Stage Renal Disease Unit/Facility is deemed to meet the State licensure requirements, if it meets all Federal certification requirements.
4. **Department:** means the Maine Department of Human Services.
5. **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. The two (2) types of dialysis that are in common use are hemodialysis and peritoneal dialysis.
6. **End-Stage Renal Disease or ESRD:** means that stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.
7. **ESRD Facility:** includes a renal transplantation center, a renal dialysis center or a renal dialysis facility.
8. **Renal Transplantation Center:** means a hospital unit that is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A renal transplantation center may also be a renal dialysis center.
9. **Renal Dialysis Center:** means a hospital unit that is approved to furnish the full spectrum of diagnostic, therapeutic and rehabilitative services required for the care of ESRD dialysis patients, including inpatient dialysis furnished directly or under arrangement. A hospital need not provide renal transplantation to qualify as a renal dialysis center.
10. **Renal Dialysis Facility:** means a unit that is approved to furnish dialysis services directly to ESRD patients. "Renal Dialysis Facility" includes a self-dialysis unit or a special-purpose renal dialysis facility.
11. **Self-Dialysis Unit:** means a unit that is part of an approved renal transplantation center, renal dialysis center or renal dialysis facility and furnishes self-dialysis services.
12. **Special-Purpose Renal Dialysis Facility:** means a renal dialysis facility that is approved to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must

be either special rehabilitative locations, including vacation locations, serving ESRD patients temporarily residing at those locations or locations in need of ESRD facilities under emergency circumstances

CHAPTER 2: LICENSING APPLICATION PROCEDURES

2.A. Requirements

- 2.A.1. No ESRD Facility may provide ESRD services without receiving a license from the Department, authorizing such services or operation.
- 2.A.2. No ESRD Facility shall accept any remuneration for delivering ESRD services without having first secured a license authorizing its operation in accordance with these regulations.

2.B. Application Procedure

2.B.1. Filing of Application

Any person, partnership, association or corporation desiring a license to engage in ESRD services shall, prior to the commencement of such operation, file an application with the Department. Applications submitted on behalf of a corporation or association shall be made by any two (2) officers thereof or by its administrator. All applicants shall comply with the rules and regulations adopted pursuant to Title 22 M.R.S.A., c. 412., §2041 and §2042. The applicant shall comply with all other applicable Maine Statutes and rules and regulations.

2.B.2. Contents of Application

Each application shall contain:

- a. The name by which the ESRD Facility is to be legally known and the name under which it shall be doing business;
- b. A description of all facilities utilized by the ESRD Facility. This will include the address(es), telephone number(s) and name of owner(s) of all buildings utilized by the ESRD Facility;
- c. A listing of ESRD services provided by the ESRD Facility;
- d. For proprietary corporations: the full name and address of each person, firm or corporation having (directly or indirectly) an ownership interest of 5% or more in the facility;
- e. For business entities with one owner or business partnerships: the full name and address of the owner or each partner;
- f. For not-for-profit organizations: the full name and address of the President of the Board of Directors or appropriate municipal government representative;
- g. The name, home address, home telephone number and office telephone numbers of the individual designated by the applicant as the administrator of the ESRD Facility;

- h. The name of the Director of Nursing;
- i. The number of full-time equivalent staff.

2.C. Fees

- 2.C.1. Each initial application under this chapter shall be accompanied by a \$450.00 fee. Thereafter an annual fee of \$450.00.
- 2.C.2. No such fee shall be refunded.
- 2.C.3. Change in Ownership of a ESRD Facility
 - a. No license shall be assigned or transferred.
 - b. At least thirty (30) days advance written notice shall be given to the Division of Licensing and Certification, in the Bureau of Medical Services, Department of Human Services, prior to the transfer of ownership of any ESRD Facility.
 - c. Each application for a license from a new owner shall be accompanied by a statement from the previous owner or his duly authorized representative concerning the change of ownership. In lieu of this statement, a copy of the deed or other validating document shall be submitted. In addition, an application fee of \$450.00 shall be submitted to the Department. When the ownership of an ESRD Facility changes, upon receipt of a completed application and fee, the Department may issue a license.

2.D. Compliance with All Local, State and Federal Regulations

- 2.D.1. The applicant shall submit a letter from the appropriate municipal official(s) that demonstrates compliance with all local ordinances relative to zoning and building codes and a certificate of occupancy, if appropriate, which includes electrical and life safety code compliance.
- 2.D.2. The applicant will submit proof of a Clinical Laboratory number, if appropriate, under the Clinical Laboratory Improvement Amendments of 1988.
- 2.D.3. The applicant will submit proof of a Department of Environmental Protection number, if appropriate, regarding disposition of biomedical waste.
- 2.D.4. A person who enters an ESRD program must be given information about their rights to formulate an advance directive.
- 2.D.5. The applicant shall meet all applicable requirements developed by the Association for the Advance of Medical Instrumentation (AAMI).
- 2.D.6. The applicant must be in compliance with all Federal Conditions of Participation listed at 42 Code of Federal Regulations, Section 405.2100 *et seq.*

2.E. Posting of License

The license granted by the Department shall be conspicuously posted in an area where business is conducted/coordinated for ESRD Facilities.

2.F. Changes in Licensed ESRD Services

2.F.1. Each ESRD Facility will notify the Division of Licensing and Certification, in writing, of any changes in:

- a. Ownership;
- b. Scope and nature of services provided;
- c. Relocation or change of business address and telephone;
- d. Administrator; and
- e. Deeming.

2.F.2. Licenses

If, after receiving an application for a license, the Department finds that all the conditions of licensure are met, it shall issue a license to the applicant for a period of one (1) year. If the Department finds less than full compliance with the conditions of licensure, it may issue a conditional license.

The Department may issue a conditional license if the applicant fails to comply with applicable laws and rules, but the best interest of the public would be served by issuing a conditional license. The conditional license must specify when and what corrections must be made during the term of the conditional license.

When an applicant fails to comply with applicable laws and rules, the Department may refuse to issue or renew the license.

Licenses cannot be sold or transferred.

2.G. Types of Licenses Issued

The Department will issue the following types of licenses to ESRD Facilities:

- 2.G.1. Provisional License-The Department will issue a provisional license to all ESRD Facilities who have completed an application and paid the initial annual fee. The Department will, thereafter, issue a full or conditional license upon onsite review of the ESRD Facility.
- 2.G.2. Full License-Effective for the period of twelve (12) months to an applicant who complies with all applicable laws and rules.
- 2.G.3. Conditional License-Effective for a specific period not to exceed one (1) year to an applicant who has not fully complied with all applicable laws and rules, and in

the judgment of the Commissioner, the best interest of the public would be so served by issuing a conditional license.

- a. The decision to grant a conditional license can be made by the Department at the time of application for an initial license, at the expiration of a full license or during the term of a full license.
- b. The conditional license shall specify when and what corrections shall be made during the term of the conditional license.

2.H. Specifications of License

2.H.1. Each license issued by the Department shall identify:

- a. The name of the ESRD Facility;
- b. The name of the Administrator;
- c. The geographical location;
- d. The type of ESRD services provided;
- e. The period of licensure and date of licensure expiration; and
- f. The date issued and the type of license.

CHAPTER 3: LOSS OF, RENEWAL, AND CONDITIONAL LICENSES

3.A. Refusal to Issue a License

- 3.A.1. The Department may refuse to issue a license to the applicant if it finds that any or all of the following conditions exist:
- a. The Department finds that the information submitted in the application is incorrect or incomplete;
 - b. The applicant does not meet all requirements of these laws and regulations;
 - c. The applicant has violated applicable laws and rules and regulations, and the Department finds that these practices of the facility are detrimental to the welfare of persons to whom ESRD services are provided.

3.B. Right of Entry and Inspection

- 3.B.1. Any duly designated employee of the Department shall have the right to enter upon and into the premises of any ESRD Facility who has applied for a license or who is licensed pursuant to these rules and regulations. The Department can inspect relevant Facility documents to determine whether the Facility is in compliance with these rules and regulations. The right of entry and inspection shall extend to any premises and documents of Facilities whom the Department has reason to believe are providing ESRD services without a license. Such entries or inspections shall be made with permission of the owner or person in charge unless a warrant is first obtained from the District Court authorizing that entry or inspection (22 M.R.S.A. §2148). Any duly designated employee of the Department, with the permission of the patient, may also make patient home visits at his/her discretion.
- 3.B.2. Application for licensure, whether initial or renewal, shall constitute permission for entry into, and survey of, an ESRD Facility by authorized licensing authority representatives at reasonable times, during pendency of the application and, if licensed, during the licensure period.
- 3.B.3. Surveys may be unannounced at the sole discretion of the Division of Licensing and Certification. All complaint investigations will be unannounced.
- 3.B.4. Upon receipt of a Statement of Deficiencies from the Division of Licensing and Certification, the licensee or his/her representative will be required to submit a Plan of Correction to the Division of Licensing and Certification within ten (10) working days of receipt stating how the ESRD Facility intends to correct each violation noted and the expected date of completion.
- 3.B.5. The Division of Licensing and Certification may, at its sole discretion, accept the Plan of Correction as written, or request modification of the Plan by the licensee.
- 3.B.6. Regardless of the term of the license, the Department shall monitor for continued compliance with applicable rules and regulations.

3.B.7. Inspections

The Department shall inspect the ESRD Facility for one (1) year, except that State inspections need not be performed during a year when a Medicare certification survey is performed.

3.B.8. An ESRD Facility is not eligible for licensure or renewal of licensure, unless the ESRD Facility has had a Medicare survey or a State licensure survey within the previous year.

3.C. Renewal of License

3.C.1. The Department will send the ESRD Facility a renewal application at least fifty (50) calendar days prior to the expiration of the ESRD license. This application shall be completed and submitted to the Department at least twenty (20) calendar days prior to the expiration of the license. The Department shall review the renewal application to ensure that it is consistent with these rules and regulations.

3.C.2. Based upon its review, Department staff will inform the ESRD Facility of its decision to:

- a. Renew the license for one (1) year;
- b. Issue the ESRD Facility a conditional license; or
- c. Refuse to issue the applicant a new license.

3.D. Suspension or Revocation of License

3.D.1. The Department may recommend suspension or revocation of any license issued, pursuant to 22 M.R.S.A. c. 412, §2041 and §2042, for violation of applicable laws and rules committing, permitting, aiding or abetting any illegal practices in the operation of the provider or conduct or practices detrimental to the welfare of persons to whom ESRD services are provided.

3.D.2. When the Department believes that a license should be suspended or revoked, it shall file a complaint with the Administrative Court in accordance with Title 4 M.R.S.A., §§1151 *et seq.* or the Maine Administrative Procedure Act, Title 5 M.R.S.A. §10051 *et seq.*

3.D.3. Upon suspension or revocation of a license, the license shall be immediately surrendered to the Department.

3.E. Emergency Revocation or Suspension of License

Whenever the Department determines that the health or physical safety of a person is in immediate jeopardy, action in accordance with 5 M.R.S.A., §9051 *et seq.* would fail to respond to a known risk, the Department, in accordance with 4 MRSA, §1153, may file a complaint with the Administrative Court to temporarily revoke or suspend an ESRD Facility license.

3.E.1. Receivership

Pursuant to 22 M.R.S.A., Section 7931, the Department may petition the Superior Court to appoint a receiver to operate an End Stage Renal Disease Unit/Facility in the following circumstances:

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- a. When the End Stage Renal Disease Unit/Facility intends to close, but has not arranged at least thirty (30) days prior to closure for the orderly transfer of its patient/clients;
- b. When an emergency exists in an End Stage Renal Disease Unit/Facility which threatens the health, security or welfare of patient/clients;
- c. When the End Stage Renal Disease Unit/Facility is in substantial or habitual violation of the standards of health, safety or patient/client care established under State or Federal regulations to the detriment of the welfare of the patient/client.

3.F. Appeals

Any person aggrieved by the Department's decision to take any of the following actions may request an administrative hearing as provided by the Maine Administrative Procedure Act, Title 5 M.R.S.A., §9051, *et seq.*:

- 3.F.1. Issue a conditional license;
- 3.F.2. Amend or modify a license; or
- 3.F.3. Refuse to issue or renew a full license.

3.G. Public Notice

If a license is revoked, suspended or not renewed, the Department will advise the public of such action. This public notice will be in the form of a paid legal notice in the local newspaper(s), published within fifteen (15) days following the suspension or revocation of the license.

CHAPTER 4: ADMINISTRATION

4.A. Organizational Structure and Lines of Authority

4.A.1. All ESRD Facilities will identify, in writing, the services provided, administrative control, and lines of authority for the delegation of responsibility down to the patient/client care level. A policy and procedure manual(s), including patient care protocols, for the organization and operation of the facility shall be established, implemented, and reviewed at least annually. Each review of the manual(s) shall be documented. This written material shall be maintained at the ESRD Facility's office so that Department staff can examine it during licensing survey visits. This material will include:

- a. A statement describing the organizational goal(s) of the ESRD Facility, its philosophy and objectives, and the services provided by the facility;
- b. An organizational diagram delineating the lines of responsibility and accountability so as to ensure continuity of care down to the patients;
- c. Job descriptions of employees. The job descriptions shall include the qualifications necessary for the position, an outline of the scope of duties, competencies, responsibilities and accountability required of employees in that position;
- d. A description of the orientation programs provided for employees directly employed by the ESRD Facility;
- e. If the organization has an advisory or governing body, a set of bylaws specifying the following will be required:
 1. Membership;
 2. Authority;
 3. Administration's role;
 4. Frequency of meetings; and
 5. Recorded minutes.

The bylaws shall be adopted and updated as deemed necessary by the advisory or governing body.

4.B. Business Records

4.B.1. Business records of the ESRD Facility shall be kept and retained in a manner consistent with all applicable State and Federal laws, ordinances and regulations with proper audit trails available. Business records and contracts will be retained for a minimum of seven (7) years.

4.B.2. Copies of the current licenses of all licensed health professionals employed directly or through a contractual relationship with the ESRD Facility shall be maintained by the ESRD Facility.

4.B.3. The ESRD Facility shall keep a personnel file for each health care professional and paraprofessional employed or contracted, which shall include:

- a. An application;
- b. Evidence of current qualifications;
- c. Periodic evaluation;
- d. Educational program for training;
- e. Evidence of orientation and inservice training; and

4.C. Qualifications of Professional/Other Personnel

4.C.1. The following health care professionals, employed directly or through a contractual relationship with an ESRD Facility, may provide ESRD services by virtue of possession of a current license to practice their discipline in the State of Maine:

- a. Physicians;
- b. Registered Professional Nurses;
- c. Licensed Practical Nurses;
- d. Social Workers; and
- e. Dietitians.

4.C.2. Dialysis technicians employed by an ESRD Facility may provide services in accordance with applicable job descriptions as noted at Chapter 4.A.1.c. of this regulation, or, if applicable, Chapter 6, Rules and Regulations of the Maine State Board of Nursing concerning coordination and oversight.

4.C.3. Identification Badges

All health care provider employees providing direct patient care must wear an identification badge that includes at least the following information:

- a. Name of the health care provider;
- b. Employee's first name and the first initial of the employee's last name;
- c. Initials identifying the employee's registration/ licensure/certification;

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- d. Employee's job title.

4.D. Quality Improvement

The ESRD Facility shall establish a Quality Improvement Program. The program will be an ongoing objective assessment of important aspects of patient care and the correction of identified problems. It will consist of a clinical record review at least quarterly, and an overall ESRD Facility review that will occur annually. The results of the review/evaluation are reported to, and acted upon by those responsible for the operation of the ESRD.

Components of the Quality Improvement Program will include, but are not limited to:

- a. Continual monitoring and evaluation of the care provided;
- b. An identification of issues and potential issues;
- c. An implementation of improvement activities; and
- d. Re-evaluate to determine if further improvement is possible or needed.

4.E. Reporting of Abuse, Neglect or Misappropriation of Client and/or Client's Property

- a. The ESRD Facility must ensure that all staff are knowledgeable of the Adult Protective Services Act, 22 M.R.S.A., §3477-3479A, and that all alleged violations involving mistreatment, neglect and abuse, including injuries of unknown source, and/or misappropriation of client property, are reported immediately, through established procedures, to the administrator of the ESRD Facility and to the officials in accordance with the State law.
- b. A procedure must be established by the ESRD Facility for review, within twenty-four (24) hours of each complaint received by the administrator and/or any designated member of the ESRD staff. A report of findings and action taken shall be prepared and submitted to the Quality Assurance Committee or other appropriate committee, and be available for review upon request by the Department.
- c. The ESRD Facility must have evidence that all alleged employee violations are thoroughly investigated in a timely manner. Policies must address administrative procedures to be implemented to prevent further potential violations while the investigation is in progress.
- d. The results of all investigations conducted in-house must be reported to the administrator or his/her designated representative, and to other officials in accordance with State law. If the alleged violation is verified, appropriate corrective action must be taken. All reports must be made available to the Department upon request.

4.F. [RESERVE]

CHAPTER 5: SERVICES

5.A. Mission Statement

An ESRD Facility must have a clear mission statement that is consistent with the standards as established by the ESRD Network.

5.B. Clients

An ESRD Facility may provide services to any person who consents to receive those services.

5.C. Services

All ESRD services delivered must be in compliance with all Federal Conditions of Participation listed at 42 Code of Federal Regulations, Part 405.2100 *et seq.*, and meet the specific requirements of these regulations.

ESRD services must be delivered in accordance with a care plan approved by the interdisciplinary team, regardless of whether the ESRD services are provided by staff or by contractors. The care plan must be based upon treatment prescribed and an assessment of the patient's needs. The care plan must be reviewed periodically by the interdisciplinary team and revised as needed. The interdisciplinary team must consider the need for at least the following services when developing the care plan:

5.C.1. Medical services;

5.C.2. Nursing services;

5.C.3. Dietary services; and

5.C.4. Social services.

5.D. Nursing

Nursing services provided by an ESRD Facility must be provided in accordance with a care plan, and must be under the direction and supervision of a nurse supervisor. The nurse supervisor must:

5.D.1. Develop nursing objectives, policies and procedures;

5.D.2. Develop job descriptions for all personnel;

5.D.3. Establish staffing and on-call schedules for staff; and

5.D.4. Develop and implement orientation and training programs for all staff.

5.E. Orientation

Each ESRD Facility must establish an orientation program specific to their facility and the services provided.

5.F. Continuing Education and Inservice Training

The ESRD Facility must ensure that they employ the number of qualified personnel needed; that all employees have an opportunity for continuing education and related development activities.

5.G. Records

An ESRD Facility shall maintain, at a minimum, the following records:

- a. Individualized patient/client care clinical records;
- b. Personnel files for all staff;
- c. Records of water system maintenance and quality control; and
- d. Records related to reuse procedures.

5.H. Record Retention

All clinical and business records must be retained for a period of time required by State law or seven (7) years from date of discharge.

5.I. Physical Plant

The ESRD Facility must meet all Medicare certification requirements.

All ESRD Facilities are required to have a back-up emergency generator. The emergency generator must be made operational for a period of at least one-half (½) hour each month with documentation of date and time of operation.

5.J. Sanctions

A person who violates 22 M.R.S.A. §1717, Section I, commits a civil violation for which a forfeiture, not to exceed \$100 per day per violation, may be adjudged.

STATUTORY AUTHORITY: 22 MRSA c. 412 §§2041-2042.

EFFECTIVE DATE:

January 1, 1999

NON-SUBSTANTIVE CHANGES:

November 17, 1998 - minor punctuation and formatting.

AMENDED:

April 1, 2000 - Sec. 3.E.1 and 4.C.3 added.

February 11, 2004 - Sec. 4.F, filing 2004-56

AMENDED:

Chapter 4.F Mandatory Reporting of Sentinel Events is repealed and replaced by 10-144 C.M.R. Chapter 114, Rules Governing the Reporting of Sentinel Events.