CHAPTER He-P 800 RESIDENTIAL AND HEALTH CARE FACILITY RULES

Statutory Authority: RSA 151:9

PART He-P 811 END STAGE RENAL DISEASE DIALYSIS CENTERS

He-P 811.01 Purpose. The purpose of this part is to set forth the licensing requirements for all end stage renal disease (ESRD) dialysis centers pursuant to RSA 151:2, I(d).

Source. #5600, eff 3-24-93, EXPIRED: 3-24-99
New. #9963, eff 7-28-11

He-P 811.02 Scope. This part shall apply to any individual, agency, partnership, corporation, government entity, association or other legal entity operating an end stage renal disease dialysis centers, except:

(a) All facilities listed in RSA 151:2, II(a)-(g); and

(b) All entities which are owned or operated by the state of New Hampshire, pursuant to RSA 151:2, II(h).

Source. #9963, eff 7-28-11

He-P 811.03 Definitions.

(a) “Abuse” means any one of the following:

(1) “Emotional abuse” means the misuse of power, authority, or both, verbal harassment, or unreasonable confinement which results or could result in the mental anguish or emotional distress of clients;

(2) “Physical abuse” means the misuse of physical force which results or could result in physical injury to clients; and

(3) “Sexual abuse” means contact or interaction of a sexual nature involving clients without his or her informed consent.

(b) “Administrator” means the licensee or individual appointed by the licensee to be responsible for all aspects of the daily operation of the licensed premise.

(c) “Admitted” means accepted by a licensee for the provision of services to a client.

(d) “Affiliated or related parties” means companies or individuals that serve as operators, management companies or advisors, members of limited liability companies, or companies providing financial guarantees.

(e) “Applicant” means an individual, agency, partnership, corporation, federal, state, county or local government entity, association, or other legal entity seeking a license pursuant to RSA 151.

(f) “Change of ownership” means the transfer of a controlling interest in a sole proprietorship, joint venture, partnership, corporation, limited liability company, or any other kind of entity to another sole proprietor, joint venture, partnership, corporation, limited liability company, or any other kind of entity.

(g) “Client” means any person admitted to or in any way receiving care, services, or both from a health care facility licensed in accordance with RSA 151 and He-P 811.
(h) “Client record” means a separate file maintained for each person receiving care and services, which includes all documentation required by RSA 151 and He-P 811 and all documentation received relative to the client as required by other federal and state requirements.

(i) “Commissioner” means the commissioner of the department of health and human services or his or her designee.

(j) “Deficiency” means any action, failure to act, or other set of circumstances that cause a licensee to be out of compliance with RSA 151, He-P 811, or other federal and state requirements.

(k) “Department” means the New Hampshire department of health and human services at 129 Pleasant Street, Concord, NH, 03301.

(l) “Dialysis” means the passage of a solute through a membrane.

(m) “Direct care personnel” means any person providing hands-on care or services to a client.

(n) “Directed plan of correction” means a plan developed and written by the department that specifies the actions the licensee must take to correct identified deficiencies.

(o) “Emergency” means an unexpected occurrence or set of circumstances, which require immediate, remedial attention.

(p) “Emergency plan” means a document outlining the responsibilities of personnel in an emergency.

(q) “Employee” means anyone employed by the ESRD dialysis center and for whom the facility has direct supervisory authority.

(r) “End stage renal disease dialysis center (ESRDDC)” means a facility which provides hemodialysis or peritoneal dialysis on an outpatient basis and any other acute or chronic dialysis related procedures as approved by their governing body.

(s) “Exploitation” means the illegal use of a client’s person or property for another person’s profit or advantage, or the breach of a fiduciary relationship through the use of a person or person’s property for any purpose not in the proper and lawful execution of a trust, including, but not limited to, situations where a person obtains money, property, or services from a client through the use of undue influence, harassment, duress, deception, or fraud.

(t) “Facility” means the building and other structures, which comprise the place or places where the licensee has applied to or is authorized to operate.

(u) “Guardian” means a person appointed in accordance with RSA 463 for a minor, RSA 464-A for an incapacitated adult, or the laws of another state, to make informed decisions over the individual’s person and/or estate.

(v) “Hemodialysis” means removal of toxic substances from the blood of persons for whom one or both kidneys are defective or absent by passing it through tubes made of semi permeable membranes which are continually bathed by solution which selectively remove unwanted material.

(w) “Infectious waste” means those items specified by Env-Sw 103.28.

(x) “Informed consent” means the decision by a client or his/her guardian or agent to agree to a proposed course of treatment, after the client, guardian, or agent has received full disclosure of the facts, including information about risks and benefits of the treatment and available alternatives, needed to make the decision intelligently.
(y) “Inspection” means the process used by the department to determine a licensee’s compliance with RSA 151, He-P 811, and all other federal and state requirements.

(z) “Investigation” means the process used by the department to respond to allegations of non-compliance with RSA 151 or He-P 811.

(aa) “License” means the document issued by the department to an applicant authorizing operation in accordance with RSA 151 and He-P 811 and includes the name of the licensee, the name of the business, the physical address, the license category, the effective date, and the license number.

(ab) “Licensed practitioner” means:

1. Medical doctor;
2. Physician’s assistant;
3. Advanced practice registered nurse;
4. Doctor of osteopathy;
5. Doctor of naturopathic medicine; or
6. Anyone else with diagnostic and prescriptive powers licensed by the appropriate New Hampshire licensing board.

(ac) “Licensed premises” means the building or portion thereof that comprises the physical location the department has approved for the licensee to conduct operations in accordance with its license.

(ad) “Licensee” means any person or legal entity to which a license has been issued pursuant to RSA 151.

(ae) “Licensing classification” means the specific category of services authorized by a license.

(af) “Medical director” means a board certified physician certified in internal medicine or pediatrics with a board approved training program in nephrology and licensed in New Hampshire in accordance with RSA 329 who is responsible for overseeing the quality of medical care and services in an ESRDDC.

(ag) “Medication” means a substance available with or without a prescription, which is used as a curative or remedial substance.

(ah) “Neglect” means an act or omission, which results or could result in the deprivation of essential services necessary to maintain the mental, emotional, or physical health and safety of a client.

(ai) “Nursing assessment” means obtaining a medical history of the client, obtaining a physical assessment of the client, and determining nursing intervention.

(aj) “Orders” means prescriptions or instructions for administering or discontinuing treatments, special diets, or therapies given by a licensed practitioner.

(ak) “Owner” means any person, corporation, association, or any other legal entity who has controlling interest in the facility.

(al) “Parenteral” means medication or products administered into the body through any route other than through the intestinal tract.
(am) “Patient rights” means the privileges and responsibilities possessed by each client provided by RSA 151:21.

(an) “Peritoneal dialysis” means removal of toxic substances from the body for treating renal failure or in certain poisonings by perfusing specific warm, sterile chemical solutions through the peritoneal cavity.

(ao) “Personnel” means individual(s) who provide direct care or services or both to a client.

(ap) “Physician” means medical doctor or doctor of osteopathy licensed in the state of New Hampshire pursuant to RSA 329.

(aq) “Plan of correction (POC)” means a plan developed and written by the licensee, which specifies the actions that will be taken to correct identified deficiencies.

(ar) “Procedure” means a licensee’s written, standardized method of performing duties and providing services.

(as) “Qualification” means education, experience and skill requirements specified by the federal government, state government, an accredited professional review agency, or by policy of the licensee.

(at) “Service” means a specific activity performed by the licensee, either directly or indirectly, to benefit or assist a client.

(au) “Significant change” means a visible or observable change in physical or functional capacity of the client.

(av) “Unusual incident” means an occurrence of any of the following while the client is either in the ESRDDC or in the care of ESRDDC personnel:

1. The unanticipated death of a client that is not related to their diagnosis or underlying condition;

2. An accident or other circumstance that has resulted in an injury that requires treatment in an emergency room by a licensed practitioner; or

3. A disappearance from the ESRDDC or other circumstances that resulted in the notification and/or involvement of law enforcement or safety officials.

Source. #9963, eff 7-28-11

He-P 811.04 Initial License Application Requirements.

(a) Each applicant for a license shall comply with the requirements of RSA 151:4, I–III-a and submit to the department:

1. A completed application form entitled “Application for Residential or Health Care License,” (February 12, 2010) signed by the applicant or 2 of the corporate officers, affirming to the following:

   “I affirm that I am familiar with the requirements of RSA 151 and the rules adopted thereunder and that the premises are in full compliance. I understand that providing false information shall be grounds for denial, suspension, or revocation of the license and the imposition of a fine.”;

2. A floor plan of the prospective ESRDDC;
(3) Proof of authorization from the New Hampshire secretary of state to do business in the state of New Hampshire in the form of one of the following:

   a. “Certificate of Authority,” if a corporation;

   b. “Certificate of Formation,” if a limited liability corporation; or

   c. “Certificate of Trade Name,” where applicable;

(4) List of affiliated or related parties;

(5) The applicable fee in accordance with RSA 151:5, XIV, payable in cash in the exact amount of the fee or, if paid by check or money order, the exact amount of the fee made payable to the “Treasurer, State of New Hampshire”;

(6) A resume identifying the qualifications of the ESRDDC administrator;

(7) Written local approvals as follows:

   a. For an existing building, the following written local approvals shall be obtained no more than 90 days prior to submission of the application, from the following local officials or if there is no such official(s), from the board of selectmen or mayor:

      1. The health officer verifying that the applicant complies with all applicable local health requirements and drinking water and wastewater requirements;

      2. The building official verifying that the applicant complies with all applicable state building codes and local building ordinances;

      3. The zoning officer verifying that the applicant complies with all applicable local zoning ordinances; and

      4. The fire chief verifying that the applicant complies with the state fire code, including the health care chapter of NFPA 101 as adopted by the department of safety, and local fire ordinances applicable for a health care facility; and

   b. For a building under construction, the written approvals required by a. above shall be submitted at the end of construction based on the local official’s review of the building plans and their final on site inspection of the construction project;

(8) If the ESRDDC uses a private water supply, documentation that the water supply has been tested in accordance with RSA 485 and Env-Dw 700, or, if a public water supply is used, a copy of a water bill; and

(9) The results of a criminal records check from the NH department of safety for the applicant and the administrator, as applicable.

(b) The applicant shall mail or hand-deliver the documents to:

Department of Health and Human Services
Health Facilities Administration
129 Pleasant Street
Concord, NH 03301

Source: #9963, eff 7-28-11
He-P 811.05  Processing of Applications and Issuance of Licenses.

(a) An application for an initial license shall be complete when the department determines that all items required by He-P 811.04(a) have been received.

(b) If an application does not contain all of the items required by He-P 811.04(a), the department shall notify the applicant in writing of the items required before the application can be processed.

(c) Any licensing fee submitted to the department in the form of a check or money order and returned to the state for any reason shall be processed in accordance with RSA 6:11-a.

(d) Licensing fees shall not be transferable to any other application(s).

(e) Following an inspection, a license shall be issued if the department determines that an applicant requesting an initial license is in full compliance with RSA 151 and He-P 811.

(f) The department shall deny a licensing request after reviewing the information required by He-P 811.04(a)(9) above if it determines that the applicant, proposed licensee, or administrator:

   (1) Has been convicted of any felony in this or any other state;

   (2) Has been convicted of a sexual assault, other violent crime, assault, fraud, abuse, neglect, or exploitation;

   (3) Has had a finding by the department or any administrative agency in this or any other state for assault, fraud, abuse, neglect, or exploitation of any person; or

   (4) Otherwise poses a threat to the health, safety, or well-being of clients.

Source. #9963, eff 7-28-11

He-P 811.06  License Expirations and Procedures for Renewals.

(a) A license shall be valid on the date of issuance and expire the following year on the last day of the month it was issued unless a completed application for renewal has been received.

(b) Each licensee shall complete and submit to the department an application form pursuant to He-P 811.04(a)(1) at least 120 days prior to the expiration of the current license.

(c) The licensee shall submit with the renewal application:

   (1) The materials required by He-P 811.04(a)(1) and (5);

   (2) The current license number;

   (3) A request for renewal of any existing waivers previously granted by the department, in accordance with He-P 811.10(f), if applicable;

   (4) A statement identifying any variances applied for or granted by the state fire marshal; and

   (5) A list of current employees who have a permanent waiver granted in accordance with He-P 811.18(d).

(d) In addition to (c) above, if a private water supply is used, the licensee shall provide documentation that every 3 years the water supply has been tested for bacteria and nitrates and determined to be at acceptable levels, in accordance with Env-Dw 702 for bacteria and Env-Dw 704 for nitrates.
(e) Following an inspection as described in He-P 811.09, a license shall be renewed if the department determines that the licensee:

1. Submitted an application containing all the items required by (c) and (d) above as applicable, prior to the expiration of the current license;
2. Has submitted a POC that has been accepted by the department and implemented by the licensee if deficiencies were cited at the last licensing inspection or investigation; and
3. Is found to be in compliance with RSA 151 and He-P 811 at the renewal inspection.

Source. #9963, eff 7-28-11

He-P 811.07 ESRDDC Construction, Modifications, or Structural Alterations.

(a) Sixty days prior to initiating construction, the ESRDDC shall provide to the department notice and written plans drawn to scale for construction, modifications or structural alterations for the following:

1. A new building;
2. Structural alterations to any client area;
3. Modifications that require approval from local or state authorities; and
4. Modifications that might affect compliance with the health and safety, fire or building codes, including but not limited to, fire suppression, detection systems and means of egress.

(b) The department shall review plans for construction, modifications, or structural alterations of a ESRDDC for compliance with all applicable sections of RSA 151 and He-P 811 and notify the applicant or licensee as to whether the proposed changes comply with these requirements.

(c) Department approval shall not be required prior to initiating construction, modifications, or structural alterations, however an applicant or licensee who proceeds prior to receiving approval shall do so at their own risk.

(d) The ESRDDC shall comply with all applicable licensing rules when doing construction, modifications, or structural alterations.

(e) A licensee or applicant constructing, modifying, or structurally altering a building shall comply with the following:

1. The state fire code, Saf-C 6000, including, but not limited to, NFPA 1 and NFPA 101 as adopted by the commissioner of the department of safety under RSA 153; and
2. The state building code as defined in RSA 155-A:1, IV, as amended by the building code review board pursuant to RSA 155-A:10, V.

(f) All ESRDDCs newly constructed after the 2011 effective date of He-P 811 shall comply with the Facility Guidelines Institute “Guidelines for Design and Construction of Health Care Facilities,” “Specific Locations for Renal Dialysis Centers” chapter, 2010 edition, as applicable.

(g) The department’s bureau of health facilities administration shall be the authority having jurisdiction for the requirements in (f) above and shall negotiate compliance and grant waivers in accordance with He-P 811.10 as applicable.
(h) Waivers granted by the department for construction or renovation purposes shall not require annual renewal.

(i) Waivers pertaining to the state fire code referenced in (e)(1) above shall be granted only by the state fire marshal.

(j) The completed building shall be subject to an inspection pursuant to He-P 811.09 prior to its use.

Source. #9963, eff 7-28-11

He-P 811.08 ESRDDC Requirements for Organizational Changes.

(a) The ESRDDC shall provide the department with written notice at least 30 days prior to changes in any of the following:

(1) Ownership;
(2) Physical location;
(3) Address;
(4) Name;
(5) Dialysis stations; or
(6) Affiliated parties or related parties.

(b) When there is a change in the name, the ESRDDC shall submit to the department a copy of the certificate of amendment from the New Hampshire secretary of state, if applicable.

(c) The ESRDDC shall complete and submit a new application and obtain a new or revised license, license certificate, or both, as applicable, prior to operating, for:

(1) A change in ownership;
(2) A change in the physical location; or
(3) An increase in the number of dialysis stations beyond what is authorized under the current license.

(d) When there is a change in address without a change in location, the ESRDDC shall provide the department with a copy of the notification from the local, state, or federal agency that requires the change.

(e) The ESRDDC shall inform the department in writing as soon as possible prior to a change in administrator and provide the department with the following:

(1) The information specified in He-P 811.04(a)(9);
(2) A resume identifying the name and qualifications of the new administrator; and
(3) Copies of applicable licenses for the new administrator.

(f) Upon review of the materials submitted in accordance with (e) above, the department shall make a determination as to whether the new administrator:

(1) Does not have a history of any of the criteria identified in He-P 811.05(f); and
(2) Meets the qualifications for the position as specified in He-P 811.15(a).

(g) If the department determines that the new administrator does not meet the qualifications as specified in He-P 811.15(a), it shall so notify the ESRDDC in writing so that a waiver can be sought or the program can search for a qualified candidate.

(h) When there is to be a change in the services provided, the ESRDDC shall provide the department with a description of the service change and, where applicable, identify what additional personnel will be hired and their qualifications, how the new services will be incorporated into the infection control and quality improvement programs, and describe what changes, if any, in the physical environment will be made.

(i) The department shall review the information submitted under (h) above and determine if the added services can be provided under the ESRDDC’s current license.

(j) An inspection by the department shall be conducted prior to operation when there are changes in the following:

   (1) Ownership, unless the current licensee has no outstanding administrative actions in process and there will be no changes made by the new owner in the scope of services provided;

   (2) The physical location; or

   (3) An increase in the number of dialysis stations beyond what is authorized under the current license.

(k) A new license and license certificate shall be issued for a change in ownership or a change in physical location.

(l) A revised license and license certificate shall be issued for changes in the ESRDDC’s name.

(m) A revised license certificate shall be issued for any of the following:

   (1) A change of administrator;

   (2) A change in the number of dialysis stations from what is authorized under the current license; or

   (3) When a waiver has been granted.

(n) Licenses issued under (j)(1) above shall expire on the date the license issued to the previous owner would have expired.

(o) The licensee shall return the previous license to the division within 10 days of the ESRDDC changing its ownership, physical location, address, or name.

Source: #9963, eff 7-28-11

He-P 811.09 Inspections.

   (a) For the purpose of determining compliance with RSA 151 and He-P 811, as authorized by RSA 151:6 and RSA 151:6-a, the licensee shall admit and allow any department representative at any time to inspect the following:

      (1) The licensed premises;

      (2) All programs and services provided by the ESRDDC; and
(3) Any records required by RSA 151 and He-P 811.

(b) The department shall conduct an inspection to determine full compliance with RSA 151 and He-P 811, to include a clinical and a life safety inspection, prior to:

(1) The issuance of an initial license;
(2) A change in ownership, except as allowed by He-P 811.08(j)(1);
(3) A change in the licensee’s physical location;
(4) A relocation within the facility or an increase in the number of beds beyond what is authorized under the current license;
(5) Occupation of space after construction, renovations, or structural alterations;
(6) The renewal of a license for non-certified ESRDDCs; or
(7) Verification of the implementation of any POC accepted or issued by the department as part of an annual or follow-up inspection.

Source. #9963, eff 7-28-11

He-P 811.10 Waivers.

(a) Applicants or licensees seeking waivers of specific rules in He-P 811, except for waivers referenced in He-P 811.07(i), shall submit a written request for a waiver to the commissioner that includes:

(1) The specific reference to the rule for which a waiver is being sought;
(2) A full explanation of why a waiver is necessary;
(3) A full explanation of alternatives proposed by the applicant or license holder, which shall be equally as protective of public health and clients as the rule from which a waiver is sought; and
(4) The period of time for which the waiver is sought.

(b) Waivers shall not exceed 12 months, or the current license expiration date, except as allowed by He-P 811.18(d).

(c) A request for waiver shall be granted if the commissioner determines that the alternative proposed by the applicant or licensee:

(1) Meets the objective or intent of the rule;
(2) Does not have the potential to negatively impact the health or safety of the clients; and
(3) Does not negatively affect the quality of client services.

(d) The licensee’s subsequent compliance with the alternatives approved in the waiver shall be considered equivalent to complying with the rule from which waiver was sought.

(e) Waivers shall not be transferable.

(f) When a licensee wishes to renew the waiver beyond the approved period of time, the licensee shall apply for a new waiver by submitting the information required by (a) above:
(1) When the licensee submits its application for license renewal pursuant to He-P 811.06(c); or

(2) At least 15 days prior to the expiration of the waiver if the waiver expires on a date other than the expiration date of the licensing certificate.

(g) The request to renew a waiver shall be subject to (b) through (f) above.

Source. #9963, eff 7-28-11

He-P 811.11 Complaints.

(a) The department shall investigate complaints that allege:

(1) A violation of RSA 151 or He-P 811;

(2) That an individual or entity is operating as a ESRDDC without being licensed; or

(3) That an individual or entity is advertising or otherwise representing the ESRDDC as having or performing services for which they are not licensed to provide, pursuant to RSA 151:2, III.

(b) When practicable, the complaint shall be in writing and contain the following information:

(1) The name and address of the ESRDDC, or the alleged unlicensed individual or entity;

(2) The name, address, and telephone number of the complainant; and

(3) A description of the situation that supports the complaint and the alleged violation(s) of RSA 151 or He-P 811.

(c) For the ESRDDC, the department shall:

(1) Provide written notification of the results of the investigation to the licensee along with an inspection report if deficiencies were found as a result of the investigation; and

(2) Notify any other federal, state, or local agencies of alleged violations of their statutes or rules based on the results of the investigation, as appropriate.

(d) If the department determines that the complaint is unfounded or that the alleged act does not violate any statutes or rules, the department shall so notify the unlicensed individual or licensee and take no further action.

(e) If the investigation results in deficiencies being cited, the licensee shall be required to submit a POC in accordance with He-P 811.12(c).

(f) For the unlicensed individual or entity, the department shall provide written notification to the owner or person responsible that includes:

(1) The date of inspection;

(2) The reasons for the inspection; and

(3) Whether or not the inspection resulted in a determination that the services being provided require licensing under RSA 151:2, I(d).

(g) The owner or person responsible shall be allowed 7 days from the date of receipt of the notice required by (f) above to respond to a finding that they are operating without a license or submit a completed application for a license in accordance with RSA 151:7-a, II.
(h) If the owner of an unlicensed ESRDDC does not comply with (g) above, or if the department does not agree with the owner’s response, the department shall:

1. Issue a written warning to immediately comply with RSA 151 and He-P 811; and
2. Provide notice stating that the individual has the right to appeal the warning in accordance with RSA 151:7-a, III.

(i) Any person or entity who fails to comply after receiving a warning, as described in (h) above, shall be subject to an action by the department for injunctive relief under RSA 151:17.

(j) The fact that the department takes action for injunctive relief under RSA 151:17 shall not preclude the department from taking other action under RSA 151, He-P 811, or other applicable laws.

(k) Complaint investigation files shall be confidential in accordance with RSA 151:13, and shall not be disclosed publicly but shall be released by the department on written request only:

1. To the department of justice when relevant to a specific investigation;
2. To law enforcement when relevant to a specific criminal investigation;
3. When a court of competent jurisdiction orders the department to release such information; or
4. In connection with any adjudicative proceedings relative to the licensee.

Source. #9963, eff 7-28-11

He-P 811.12 Administrative Remedies.

(a) The department shall impose administrative remedies for violations of RSA 151, He-P 811, or other applicable licensing rules, including:

1. Requiring a licensee to submit a POC;
2. Imposing a directed POC upon a licensee;
3. Imposing fines upon an unlicensed individual, applicant, or licensee;
4. Suspension of a license; or
5. Revocation of a license.

(b) When fines are imposed, the department shall provide a written notice, as applicable, which:

1. Identifies each deficiency;
2. Identifies the specific remedy(s) that has been proposed; and
3. Provides the licensee with the following information:
   a. The right to a hearing in accordance with RSA 541-A and He-C 200 prior to the fine becoming final; and
   b. The automatic reduction of a fine by 25% if the licensee waives the right to a hearing, the fine is paid within 10 days of the date on the written notice from the department and the deficiency has been corrected, or a POC has been accepted and approved by the department.
(c) A POC shall be developed and enforced in the following manner:

(1) Upon receipt of a notice of deficiencies, the licensee shall submit a POC detailing:
   a. How the licensee intends to correct each deficiency;
   b. What measures will be put in place, or what system changes will be made to ensure that the deficiency does not recur; and
   c. The date by which each deficiency shall be corrected;

(2) The licensee shall submit a POC to the department within 21 days of the date on the letter that transmitted the inspection report unless the licensee requests, either verbally or in writing, and the department agrees, to extend that deadline, based on the following criteria:
   a. The licensee demonstrates that he or she has made a good faith effort to develop and submit the POC within the 21 day period but has been unable to do so; and
   b. The department determines that the health, safety or well-being of a patient will not be jeopardized as a result of granting the extension;

(3) The department shall review and accept each POC that:
   a. Achieves compliance with RSA 151 and He-P 811;
   b. Addresses all deficiencies and deficient practices as cited in the inspection report;
   c. Prevents a new violation of RSA 151 or He-P 811 as a result of the implementation of the POC; and
   d. Specifies the date upon which the deficiencies will be corrected;

(4) If the POC is acceptable, the department shall issue a license certificate or provide written notification of acceptance of the POC, whichever is applicable;

(5) If the POC is not acceptable:
   a. The department shall notify the licensee in writing of the reason for rejecting the POC;
   b. The licensee shall develop and submit a revised POC within 14 days of the date of the written notification from the department that states the original POC was rejected unless, within the 14 day period, the licensee requests an extension, either via telephone or in writing, and the department grants the extension, based on the following criteria:
      1. The licensee demonstrates that he or she has made a good faith effort to develop and submit the POC within the 14 day period but has been unable to do so; and
      2. The department determines that the health, safety or well being of a patient will not be jeopardized as a result of granting the waiver;
   c. The revised POC shall comply with (1) above and be reviewed in accordance with (3) above; and
   d. If the revised POC is not acceptable to the department, or is not submitted within 14 days of the date of the written notification from the department that states the original POC was
rejected, the licensee shall be subject to a directed POC in accordance with (d) below and a fine in accordance with (f)(11) below;

(6) The department shall verify the implementation of any POC that has been submitted and accepted by:
   a. Reviewing materials submitted by the licensee;
   b. Conducting a follow-up inspection; or
   c. Reviewing compliance during the next annual inspection;

(7) Verification of the implementation of any POC shall only occur after the date of completion specified by the licensee in the plan; and

(8) If the POC or revised POC has not been implemented by the completion date at the time of the next inspection the licensee shall be:
   a. Notified by the department in accordance with He-P 811.12(b); and
   b. Issued a directed POC in accordance with (d) below and shall be subject to a fine in accordance with (f)(12) below.

(d) The department shall develop and impose a directed POC that specifies corrective actions for the licensee to implement when:

   (1) As a result of an inspection, deficiencies were identified that require immediate corrective action to protect the health and safety of the clients and personnel;
   (2) A revised POC is not submitted within 14 days of the written notification from the department; or
   (3) A revised POC submitted by the licensee or administrator has not been accepted.

(e) If at the time of the next inspection the directed POC in (d) above has not been implemented by the completion date stated in the directed POC, the department shall, as appropriate:

   (1) Issue a warning that enforcement action will be taken if the POC is not implemented;
   (2) Impose a fine;
   (3) Deny the application for a renewal of a license; or
   (4) Revoke or suspend the license in accordance with He-P 811.13.

(f) The department shall impose fines as follows:

   (1) For a failure to cease providing unlicensed services after being notified by the department of the need for a license, in violation of RSA 151:2, the fine shall be $2000.00 for an applicant or unlicensed provider;
   (2) For a failure to cease operations after a denial of a license or after receipt of an order to cease and desist immediately, in violation of RSA 151:2 and RSA 541-A:30, the fine for an applicant, unlicensed provider, or licensee shall be $2000.00;
(3) For advertising services or otherwise representing themselves as having a license to provide services that they are not licensed to provide, in violation of RSA 151:2, III, the fine for an applicant, licensee, or unlicensed provider shall be $500.00;

(4) For a failure to comply with the directives of a warning issued by the department in violation of RSA 151:7-a and He-P 811.11(h), the fine shall be $500.00;

(5) For a failure to submit a renewal application for a license prior to the expiration date, in violation of He-P 811.06(b), the fine shall be $100.00;

(6) For a failure to notify the department prior to a change of ownership, in violation of He-P 811.08(a)(1), the fine shall be $500.00;

(7) For a failure to notify the department prior to a change in the physical location, in violation of He-P 811.08(a)(2), the fine shall be $500.00;

(8) For a refusal to allow access by the department to the ESRDDC’s premises, programs, services, or records, in violation of He-P 811.09(a), the fine for an applicant, individual, or licensee shall be $2000.00;

(9) For refusal to cooperate with the inspection or investigation conducted by the department, the fine shall be $2000.00;

(10) For a failure to submit a POC or revised POC, within 21 or 14 days, respectively, of the date on the letter that transmits the inspection report, in violation of He-P 811.12(c)(2) or (5)(b), the fine for a licensee shall be $100.00 unless an extension has been granted by the department;

(11) For a failure to implement any POC that has been accepted or issued by the department, in violation of He-P 811.12(c)(8), the fine for a licensee shall be $1000.00;

(12) For a failure to establish, implement, or comply with licensee policies, after being notified in writing by the department of the need to establish, implement, or comply with licensee policies, as required by He-P 811.14(c), the fine for a licensee shall be $500.00;

(13) For a failure to provide services or programs required by the licensing classification and specified by He-P 811.14(b), the fine for a licensee shall be $500.00;

(14) For exceeding the maximum number of dialysis stations, in violation of He-P 811.14(j), the fine for a licensee shall be $500.00;

(15) For falsification of information contained on an application or of any records required to be maintained for licensing, in violation of He-P 811.14(g), the fine shall be $500.00 per offense;

(16) For a failure to meet the needs of the client, in violation of He-P 811.14(l)(1), the fine for a licensee shall be $500.00;

(17) For employing an administrator or other personnel who do not meet the qualifications for the position, in violation of He-P 811.15(a) and 811.18(a)(4)-(5), the fine for a licensee shall be $500.00;

(18) When an inspection determines that a violation of RSA 151 or He-P 811 has the potential to jeopardize the health, safety, or well-being of a client, in addition to any other enforcement actions taken by the department, the fines assessed shall be as follows:
a. If the same deficiency is cited within 2 years of the original deficiency, the fine for a licensee shall be double the initial fine, but not to exceed $2000.00; and

b. If the same deficiency is cited a third time within 2 years of being fined in a. above, the fine for a licensee shall be triple the initial fine, but not to exceed $2000.00;

(19) Each day that the individual or licensee continues to be in violation of the provisions of RSA 151 or He-P 811 shall constitute a separate violation and shall be fined in accordance with He-P 811.12(f); and

(20) If the applicant or licensee is making good faith efforts to comply with (4) or (17) above, the department shall not issue a daily fine.

(g) Payment of any imposed fine to the department shall meet the following requirements:

(1) Payment shall be made in the form of check or money order made payable to the “Treasurer, State of New Hampshire” or cash in the exact amount due; and

(2) Cash, money order, or certified check shall be required when an applicant or licensee has issued payment to the department by check, and such check was returned for insufficient funds.

Source. #9963, eff 7-28-11

He-P 811.13 Enforcement Actions and Hearings.

(a) At the time of imposing a fine, or denying, revoking or suspending a license, the department shall send to the applicant or licensee a written notice that sets forth:

(1) The reasons for the proposed action;

(2) The action to be taken by the department; and

(3) The right of an applicant or licensee to a hearing in accordance with RSA 151:8 or RSA 541-A:30, III, as applicable before the enforcement action becomes final.

(b) The department shall deny an application or revoke a license if:

(1) An applicant or a licensee has violated provisions of RSA 151 or He-P 811, which violations have the potential to harm a client’s health, safety, or well-being;

(2) An applicant or a licensee has failed to pay a fine imposed under administrative remedies;

(3) An applicant or a licensee has had a check returned to the department for insufficient funds and has not re-submitted the outstanding fee in the form of cash, money order or certified check;

(4) After being notified of and given an opportunity to supply missing information, an applicant or licensee fails to submit an application that meets the requirements of He-P 811.04;

(5) An applicant, licensee, or any representative or employee of the applicant or licensee:

   a. Provides false or misleading information to the department;

   b. Prevents or interferes, or fails to cooperate with any inspection or investigation conducted by the department; or

   c. Fails to provide requested files or documents to the department;
(6) The licensee failed to implement or continue to implement a POC that has been accepted or imposed by the department in accordance with He-P 811.12(c), (d) and (e);

(7) The licensee is cited a third time under RSA 151 or He-P 811 for the same violations within the last 5 inspections;

(8) A licensee, including corporation officers or board members, has had a license revoked and submits an application during the 5-year prohibition period specified in (h) below;

(9) Upon inspection, the applicant’s premise is not in compliance with RSA 151 or He-P 811;

(10) The department makes a determination that one or more of the factors in He-P 811.05(f) is true; or

(11) The applicant or licensee fails to employ a qualified administrator or received a waiver allowing the employment of an administrator who does not meet requirements of He-P 811.15(a).

(c) An applicant or licensee shall have 30 days after receipt of the notice of enforcement action to request a hearing to contest the action.

(d) If a written request for a hearing is not made pursuant to (c) above, the action of the department shall become final.

(e) The department shall order the immediate suspension of a license, the cessation of operations, and the transfer of care of clients when it finds that the health, safety or welfare of clients is in jeopardy and requires emergency action in accordance with RSA 541-A:30, III.

(f) If an immediate suspension is upheld, the licensee shall not resume operating until the department determines through inspection that compliance with RSA 151 and He-P 811 is achieved.

(g) Hearings under this section shall be conducted in accordance with RSA 541-A and He-C 200.

(h) When an ESRDDC’s license has been denied or revoked, the applicant, licensee, or administrator shall not be eligible to reapply for a license or be employed as an administrator for 5 years, if the enforcement action pertained to their role in the ESRDDC.

(i) The 5 year period in (h) above shall begin on:

(1) The date of the department’s decision to revoke or deny the license, if no request for an administrative hearing is requested; or

(2) The date a final decision upholding the action of the department is issued, if a request for a hearing is made and a hearing is held.

(j) Notwithstanding (i) above, the department shall consider an application submitted after the decision to revoke or deny becomes final, if the applicant demonstrates that circumstances have changed to the extent that the department now has good cause to believe that the applicant has the requisite degree of knowledge, skills, and resources necessary to maintain compliance with the provisions of RSA 151 and He-P 811.

(k) RSA 541 shall govern further appeals of department decisions under this section.

(l) No ongoing enforcement action shall preclude the imposition of any remedy available to the department under RSA 151, RSA 541-A:30, III, or He-P 811.
(m) The department shall offer an opportunity for informal dispute resolution to any applicant or licensee who disagrees with a deficiency cited by the department on a statement of findings, provided that the applicant or licensee submits a written request for an informal dispute resolution.

(n) The informal dispute resolution shall be requested in writing by the applicant, licensee or program director no later than 14 days from the date the statement of findings was issued by the department.

(o) The department shall review the evidence presented and provide a written notice to the applicant or licensee of its decision.

(p) An informal dispute resolution shall not be available for any applicant or licensee against whom the department has initiated action to suspend, revoke, deny, or refuse to issue or renew a license.

Source. #9963, eff 7-28-11

He-P 811.14 Duties and Responsibilities of All Licensees.

(a) The licensee shall ensure that written policy and procedures setting forth the rights and responsibilities of clients admitted to the ESRDDC are established.

(b) The licensee shall define, in writing, the scope and type of services to be provided by the ESRDDC.

(c) The licensee shall develop and implement written policies and procedures governing the operation and all services provided by the ESRDDC.

(d) All policies and procedures shall be reviewed annually by the medical director and revised as needed.

(e) The licensee shall educate personnel about the needs and services required by the clients under their care.

(f) The licensee shall assess and monitor the quality of care and service provided to clients on an ongoing basis.

(g) The licensee or any employee shall not falsify any documentation or provide false or misleading information to the department.

(h) The licensee shall not advertise or otherwise represent the program as having health care programs or services that they are not licensed to provide.

(i) The licensee shall comply with all conditions of warnings and administrative remedies issued by the department and all court orders.

(j) The licensee shall not exceed the maximum number of stations authorized by the department.

(k) The licensee shall establish and maintain by-laws that:

   (1) Define the operation and performance of the ESRDDC;

   (2) Establish a credentialing process; and

   (3) Maintain documentation of all medical staff privileges.

(l) Licensees shall have responsibility and authority for:
(1) Ensuring that the dialysis needs of the clients are met during those hours that the client is in the care of the ESRDDC;

(2) Establishing, in writing, a chain of command that sets forth the line of authority for the operational responsibilities of the ESRDDC;

(3) Appointing an administrator;

(4) Appointing a medical director;

(5) Initiating action to maintain the ESRDDC in full compliance at all times with all relevant health and safety requirements contained in applicable federal, state, and local laws, rules, regulations, and ordinances;

(6) Providing sufficient numbers of personnel who are present in the ESRDDC and are qualified to meet the needs of clients during all hours of operation;

(7) Providing the ESRDDC with sufficient supplies, equipment, and lighting to ensure that the needs of clients are met;

(8) Implementing any POC that has been accepted or issued by the department; and

(9) Initiating, implementing, and continuing action to correct any issue identified by the quality improvement committee.

(m) The licensee shall provide housekeeping and maintenance adequate to protect clients, personnel, and the public.

(n) The licensee shall consider all clients to be competent and capable of making health care decisions unless the client:

   (1) Has a guardian or conservator appointed by a court of competent jurisdiction;

   (2) Has durable power of attorney for health care that has been activated; or

   (3) Is an un-emancipated minor.

(o) The licensee shall only accept a client whose needs can be met under the current licensing classification and through the programs and services offered.

(p) The licensee shall have a written affiliation agreement with at least one acute care hospital for the provision of inpatient care and other acute care hospital services.

(q) In addition to the posting requirements specified in RSA 151:29, the licensee shall post the following documents in a public area:

   (1) The current license certificate issued in accordance with RSA 151:2;

   (2) The most recent inspection report as specified in RSA 151:6-a;

   (3) A copy of the patient’s bill of rights specified by RSA 151:21;

   (4) A copy of the licensee’s policies and procedures relative to the implementation of client’s rights and responsibilities as required by RSA 151:20;
(5) A copy of the licensee’s complaint procedure, including the address and phone number of the department to which complaints may also be made, which shall also be posted on the nursing home website if available; and

(6) The licensee’s evacuation floor plan identifying the location of, and access to all fire exits.

(r) The licensee shall develop policies and procedures regarding the release of information contained in client records.

(s) The licensee shall ensure that all personnel required to be licensed in the state of New Hampshire practice in accordance with the appropriate practice act and the rules adopted there under.

(t) The licensee shall report all positive tuberculosis test results for personnel to the office of disease control in accordance with RSA 141-C:7, He-P 301.02, and He-P 301.03.

(u) The licensee shall ensure that all records required for licensing:

(1) Shall be available to the department during an inspection or investigation conducted in accordance with RSA 151:6 and RSA 151:6-a; and

(2) Shall be legible, current, and accurate.

(v) Smoking shall be prohibited in an ESRDDC.

(w) The water used in the ESRDDC shall be suitable for human consumption.

(x) Licensees shall:

(1) Contact the department within one business day by telephone, fax, or e-mail, and in writing within 72 hours if the initial notice was made by telephone or if additional information is available, to report an unusual incident and provide the following information:

   a. The ESRDDC name;
   b. A description of the incident, including identification of injuries, if applicable;
   c. The name of the licensee(s) or personnel involved in, witnessing, or responding to the unusual incident;
   d. The name of client(s) involved in or witnessing the unusual incident;
   e. The date and time of the unusual incident;
   f. The action taken in direct response to the unusual incident, including any follow-up;
   g. If medical intervention was required, by whom and the date and time;
   h. Whether the client’s guardian or agent, if any, or personal representative was notified;
   i. The signature of the person reporting the unusual incident; and
   j. The date and time the client’s licensed practitioner was notified;

(2) Immediately notify the local police department, the department, guardian, agent, or personal representative, if any, when a client, who has been assessed or is known as being a danger to self or others, has an unexplained disappearance after the licensee has searched the building and the grounds of the ESRDDC; and
(3) Submit additional information if required by the department.

Source. #9963, eff 7-28-11

He-P 811.15 Required Services.

(a) The licensee shall provide administrative services that include the appointment of a full time administrator who:

(1) Meets one of the following requirements:
   a. Has a bachelor’s degree in business administration or a health related field; or
   b. Is a registered nurse currently licensed in the state of New Hampshire with at least 12 months experience in clinical nursing with 6 months of the experience being in the care of clients with nephrology disorders;

(2) Is responsible for the day-to-day operations of the ESRDDC;

(3) Designates, in writing, an alternate administrator who shall assume the responsibilities of the administrator in his or her absence; and

(4) May hold more than one position within the facility if qualified.

(b) The licensee shall credential licensed practitioners involved in the direct care of clients as follows:

(1) The licensee shall establish a credentialing committee composed of, at a minimum, the medical director, the administrator, and the director of nursing; and

(2) The credentialing committee shall be responsible for:
   a. Establishing the education and experience requirements of each direct-care position;
   b. Establishing a system for determining that the person being credentialled is:
      1. Licensed or certified to practice health care in New Hampshire; and
      2. Qualified by education and experience to meet the requirements of the position in a. above;
   c. Approving, and documenting the approval of, the duties that may be performed by the person being credentialled;
   d. Establishing a procedure for updating the approvals in b. above as necessary; and
   e. The annual review of all credentialled personnel.

(c) The licensee shall provide medical services that meet the guidelines in the Association for the Advancement of Medical Instrumentation (AMMI)’s “American National Standard for Dialysate for Hemodialysis” (RD 52:2004 edition) for:

(1) Water quality requirements and testing; and

(2) The reuse of hemodialyzers and other dialysis supplies.
(d) The licensee shall provide instructions and education to clients, including but not limited to medical needs, nutrition, hygiene, medical emergencies, community support and resources.

(e) The licensee shall appoint a medical director who:

1. Is a physician licensed in the state of New Hampshire;
2. Is board certified in internal medicine or pediatrics;
3. Has completed a board-approved training program in nephrology;
4. Has at least 12 months experience providing care to patients receiving dialysis; and
5. Shall perform the following duties:
   a. Participate in the ESRDDC’s quality assurance program;
   b. Participate in the implementation of corrective action plans in affected problem areas;
   c. Participate in the credentialing process for all licensed health care practitioners;
   d. Act as a liaison between the licensed practitioners and the client;
   e. Be available to consult with the client’s licensed practitioner, as needed;
   f. Participate in the development of medical emergency procedures and all standing orders; and
   g. Be available to respond to the center by phone or in person in the case of an emergency or shall ensure that a physician meeting the qualifications of the medical director is available.

(f) The licensee shall provide nursing services that include:

1. A department of nursing that is under the supervision of a director of nursing;
2. The appointment of a full time director of nursing who:
   a. Is a registered nurse currently licensed in the state of New Hampshire;
   b. Has at least one year of experience as a registered nurse with 6 months of the experience being in the care of clients with nephrology disorders; and
   c. Shall perform the following duties:
      1. Provide nursing direction, supervision, and staff evaluations to promote quality nursing care;
      2. Be a member of the ESRDDC’s quality improvement committee; and
      3. Participate in the development nursing protocols and procedures; and
3. Sufficient staff to meet the dialysis needs of clients at all times while in the care of the facility.
(g) The licensee shall provide dialysis technician services that include the employment of dialysis technicians who are qualified through education and technical training as required by the center’s policies and procedures.

(h) The licensee shall not be required to have a separate collection station license to collect patient samples for laboratory testing from clients of its dialysis services.

(i) The licensee shall not be required to have a separate home health license, pursuant to He-P 809, to provide staff-assisted home dialysis in a client’s place of residence.

(j) The licensee shall provide social work services, including the employment of a sufficient number of social workers to meet the needs of their clients and who:

1. Have at least a master’s degree in social work; or
2. Have a bachelor’s degree in a health or human services field, plus:
   a. Two years experience as a social worker; and
   b. Have established a consultative relationship with a person holding a master’s degree in social work.

(k) The licensee shall provide dietary services, including the employment of a sufficient number of dietitians to meet the needs of clients and who:

1. Are registered by the American Dietetic Association and have one year of experience in clinical nutrition; or
2. Have a baccalaureate or advanced degree with major studies in food and nutrition or dietitian and one year of experience in clinical nutrition.

Source. #9963, eff 7-28-11

He-P 811.16 Client Management.

(a) At the time of admission, personnel of the ESRDDC shall:

1. Have a written order from a licensed practitioner for the client’s treatment at the ESRDDC;
2. Provide, both orally and in writing, to the client or the client’s legal representative and obtain written confirmation acknowledging receipt and understanding of the following policies:
   a. The facility’s policy on client rights and responsibilities which, at a minimum, shall contain the patient’s bill of rights under RSA 151:21;
   b. The facility’s policies and procedures on the reuse of dialysis supplies, including hemodialyzers;
   c. The facility’s complaint procedure; and
   d. Information about advanced directives such as:
      1. Living wills, pursuant to RSA 137-H; and
      2. Durable powers of attorney for healthcare, pursuant to RSA 137-J;
3. Collect and record identification data that includes:
a. Client’s name, home address, and home telephone number;
b. Client’s date of birth;
c. Name, address, and telephone number of an emergency contact;
d. Name, address, and telephone number of the client’s primary care provider;
e. Client’s insurance information; and
f. Copies of all executed legal directives such as durable power of attorney, legal guardian, or living will;

(4) Obtain documentation of informed consent for:
   a. All treatments prescribed by the licensed practitioner; and
   b. The reuse of dialysis supplies, including hemodialyzers, if applicable;

(5) Obtain consent for release of information as applicable;

(6) Obtain a medical history and physical examination that has been completed by a licensed practitioner; and

(7) Conduct a nursing assessment completed by:
   a. A registered nurse; or
   b. An LPN, but a review and signature by a registered nurse shall be required in accordance with the nurse practice act RSA 326-B.

(b) The licensee shall ensure that medical care and services are provided as follows:

(1) Each client shall be under the care of a licensed practitioner at all times;

(2) Each ESRDDC shall have at least one dialysis station in which a person with an infectious disease may be dialyzed and universal precautions can be instituted;

(3) The reuse of dialysis supplies, including hemodialyzers, shall be permitted only when the client has:
   a. Been informed of the center’s policies and procedures regarding the reuse of dialysis supplies; and
   b. Provided written consent for the staff use of reused dialysis supplies;

(4) An individualized care plan shall be developed by an interdisciplinary team, composed of the client, the licensed practitioner, a registered nurse, a social worker, and a dietician, and based on the results of:
   a. The client’s medical history and physical examination; and
   b. The interdisciplinary assessment as determined by the client’s needs;

(5) The individualized care plan shall:
   a. Identify the treatment, including modality and dialysis settings, for the client;
b. Be reviewed and updated as indicated by the client’s response to treatment; and
c. Contain documentation that the client or their legal representative participated in the development of the care plan;

(6) The client shall be provided education in the following areas:
   a. Purpose and procedures for the different types of dialysis treatments;
   b. Outcomes associated with end stage renal disease, or chronic kidney disease; and
   c. The center’s emergency procedures, including both medical and non-medical procedures;

(7) Each client shall receive a rehabilitative assessment, as applicable;

(8) The center’s staff shall notify the department within one business day of any unusual incidents or a significant change of status and document such notification;

(9) The personnel of the ESRDDC shall follow the orders of the licensed practitioner;

(10) Written notes shall be documented in the client’s record for:
   a. All care and services provided at the ESRDDC that shall include the:
      1. Date and time of the care or service;
      2. Description of the care or service;
      3. Progress notes; and
      4. Signature and title of the person providing the care or service;
   b. Notification of the licensed practitioner of:
      1. Any significant change in the status of the client; or
      2. Any side effects, adverse reactions, or ineffective results of any medications prescribed for the client; and
   c. Any significant changes or unusual incidents involving the client, which shall include the:
      1. Date and time of the incident or occurrence;
      2. Description of the incident or occurrence, including identification of injuries, if applicable;
      3. If medical intervention was required:
         (i) Date and time the emergency contact person or guardian was notified; and
         (ii) Date and time the licensed practitioner was notified;
      4. Action taken including follow-up; and
      5. Signature and title of the person reporting the incident or occurrence;
(11) The use of chemical or physical restraints shall be prohibited except as allowed by RSA 151:21, IX;

(12) If the ESRDDC offers a home dialysis program, it shall:
   a. Have written policies and procedures for training clients and their caregivers;
   b. Provide oversight and monitoring of the home dialysis procedure;
   c. Provide consultations with a social worker, registered dietitian, or other professionals, as necessary;
   d. Ensure either directly or indirectly that adequate supplies and equipment are available;
   e. Provide annual testing of home water supplies for dialysis use as required by the AMMI’s “American National Standard for Dialysate for Hemodialysis” (RD 52:2004 edition);
   f. Maintain written documentation of all care and services provided by the staff of the ESRDDC; and
   g. Not be required to have a separate home health care provider license, pursuant to He-P 809; and

(13) ESRDDC trained caregivers operating under the direction of the ESRDDC who assist with home dialysis shall not be required to hold a separate home health care provider license, pursuant to He-P 809.

(c) The licensee shall transfer a client whose needs exceed those authorized by the current licensing classification or cannot be met by the programs and services offered at or arranged by the ESRDDC.

(d) If unforeseen complications arise that cannot be stabilized at the ESRDDC, the facility shall:
   (1) Transfer the client to an acute care hospital;
   (1) Call 911 for transport; and
   (2) Have copies of medical information regarding the treatment received at the center transferred with the client.

(e) Documentation for any client discharged or transferred from the facility shall include:
   (1) The date and time of discharge or transfer;
   (2) The physical, mental, and medical condition of the client;
   (3) Destination of client;
   (4) Name of responsible person accompanying the client;
   (5) Discharge planning and referrals;
   (6) Discharge summary;
   (7) Physician signed order for discharge or transfer; and
   (8) In the event of death, the funeral director’s receipt.
(f) Transfers and discharges shall be done in accordance with RSA 151:21 and RSA 151:26.

Source. #9963, eff 7-28-11

He-P 811.17 Medication.

(a) All medications and treatments shall be administered in accordance with the orders of the licensed practitioner.

(b) The licensee shall have a written policy and system in place instructing how to:
   
   (1) Obtain any medication ordered for immediate use at the ESRDDC;
   
   (2) Reorder medications for use at the ESRDDC; and
   
   (3) Receive and record new medication orders.

(c) For each prescription medication being taken by a client at the ESRDDC, the licensee shall maintain, in the client’s record, either the original written order signed by a licensed practitioner, or a copy.

(d) Each medication order shall legibly display the following information:

   (1) The client’s name;
   
   (2) The medication name, strength, prescribed dose, and route, if different then by mouth;
   
   (3) The frequency of administration;
   
   (4) The indications for usage for all medications that are used PRN;
   
   (5) The dated signature of the licensed practitioner; and
   
   (6) For pro re nata (PRN) medications the licensed practitioner shall indicate, in writing, the indications for use and any special precautions or limitations for use of the medication, including the maximum allowed dose in a 24-hour period.

(e) Medications shall be kept in locked storage.

(f) Except as allowed by (d)(6) above, each prescription medication shall legibly display the following information:

   (1) The client’s name;
   
   (2) The medication name, strength, the prescribed dose, and route of administration;
   
   (3) The frequency of administration;
   
   (4) The indications for usage of all PRN medications;
   
   (5) The date ordered;
   
   (6) The name of the prescribing licensed practitioner; and
   
   (7) The expiration date of the medication(s).

(g) Any change or discontinuation of medications taken at the ESRDDC shall be pursuant to a written order from a licensed practitioner.
(h) Telephone orders for medications shall only be taken by a licensed person such as a nurse and shall be counter-signed by the authorized prescriber within 30 days.

(i) There shall be a medication storage area for all medications kept at the ESRDDC, which shall be:

1. Locked and accessible only to authorized personnel;
2. Clean, organized in a fashion to ensure correct identification of each client’s medication(s), and have lighting adequate to read all medication labels; and
3. Equipped to maintain medication at the proper temperature.

(j) Except as allowed by (q) below, all medication at the ESRDDC shall be kept in the original containers as dispensed by the pharmacy and properly closed after each use.

(k) Controlled drugs, as defined by RSA 318-B:1, shall be kept in a separately locked compartment within the locked medication storage area and accessible only to authorized personnel.

(l) The licensee shall develop and implement written policies and procedures regarding a system for maintaining counts of controlled drugs.

(m) Topical liquids, ointments, patches, creams, or powder forms of products shall be stored in such a manner that cross contamination with oral, optic, ophthalmic, and parenteral products shall not occur.

(n) Except as allowed by (o) below, any contaminated, expired, or discontinued medication shall be destroyed within 30 days of the expiration date, the end date of a licensed practitioner’s orders, or the medication becoming contaminated, whichever occurs first.

(o) Controlled drugs shall be destroyed only in accordance with state law and as follows:

1. Be accomplished in the presence of at least 2 registered nurses; and
2. Be documented in the record of the client for whom the drug was prescribed.

(p) If medication is to be returned to pharmacies, it shall be returned to pharmacies for credit only as allowed by the law.

(q) Medication administered by individuals authorized by law to administer medications shall be prepared, identified, and administered by the same person in compliance with RSA 318-B and RSA 326-B.

(r) Personnel shall remain with the client until the client has taken the medication.

(s) If a nurse delegates the task of medication administration to a patient care technician, the nurse shall follow the requirements of the nurse practice act.

(t) The licensee shall maintain a written record for each medication taken by the client at the ESRDDC which contains the following information:

1. Any allergies or allergic reactions to medications;
2. The medication name, strength, dose, frequency, and route of administration;
3. The date and the time the medication was taken;
4. The signature, identifiable initials, and job title of the person who administers, supervises or assists the client taking medication;
(5) For PRN medications, the reason the client required the medication and the effect of the PRN medication; and

(6) Documented reason for any medication refusal or omission.

(u) Each ESRDDC which permits patient care technicians to administer heparin or its derivatives shall:

(1) Require patient care technicians to be under the direction of a registered nurse as required by the nurse practice act for nurse delegation of medications;

(2) Require the delegating licensed nurse to document that patient care technicians have received the required initial competency verification and annual competency evaluations as required by the nurse practice act; and

(3) Have a copy of the client assessment documented in the client record, verifying the client is stable and is an acceptable candidate to receive heparin via nurse delegation, as required by the nurse practice act.

(v) The licensee shall develop and implement a system for reporting any observed adverse reactions to medication and side effects, or medication errors, such as incorrect medications of the adverse reaction or medication error.

(w) The written documentation of any reports in (v) above shall be maintained in the client’s record.

Source. #9963, eff 7-28-11

He-P 811.18 Personnel.

(a) For all new hires the licensee shall:

(1) Obtain and review a criminal records check from the New Hampshire department of safety in accordance with RSA 151:2-d;

(2) Review the results of the criminal records check in accordance with (b) below;

(3) Verify that the potential employee is not listed on the state registry maintained by the department’s bureau of elderly and adult services in accordance with RSA 161-F:49;

(4) Verify that the applicant meets the educational and physical qualifications of the position; and

(5) Verify that the applicant is licensed, registered, or certified if required by state statute.

(b) Unless a waiver is granted in accordance with (c) below, the licensee shall not offer employment for any position if the individual:

(1) Has been convicted for sexual assault, other violent crime, assault, fraud, abuse, neglect, or exploitation;

(2) Has had a finding by the department or any administrative agency in this or any other state for assault, fraud, abuse, neglect, or exploitation of any person; or

(3) Otherwise poses a threat to the health, safety, or well-being of the clients.
(c) The department shall grant a waiver of (b) above if, after reviewing the underlying circumstances, it determines that the person does not pose a threat to the health, safety, or well-being of clients.

(d) The waiver in (c) above shall be permanent for as long as the individual remains in the same job unless additional convictions or findings under (b) above occur.

(e) If the information identified in (b) above regarding any employee is learned after the person is hired, the licensee shall immediately notify the department.

(f) The department shall review the information in (e) above and notify the licensee that the individual can no longer be employed if, after investigation, it determines that the individual poses a threat to the health, safety, or well-being of a client.

(g) All personnel shall be at least 18 years of age if working as direct care personnel.

(h) The licensee shall inform personnel of the line of authority at the ESRDDC.

(i) Prior to having contact with clients, all personnel shall:

1. Submit to the licensee the results of a physical examination or a health screening and submit results of a 2-step tuberculosis (TB) test, Mantoux method, or other method approved by the Centers for Disease Control, conducted not more than 12 months prior to employment;

2. Be allowed to work while waiting for the results of the second step of the TB test when the results of the first step are negative for TB; and

3. Comply with the requirements of the Centers for Disease Control “Guidelines for Preventing the Transmission of Tuberculosis in Health Facilities/Settings” (2005) if the person has either a positive TB test, or has had direct contact or potential for occupational exposure to M. tuberculosis through shared air space with persons with infectious tuberculosis.

(j) Prior to having contact with clients, all personnel shall receive a tour of the ESRDDC and have an orientation that explains the following:

1. The clients’ rights in accordance with RSA 151:20;

2. The ESRDDC’s complaint procedures;

3. The duties and responsibilities of the position;

4. The medical emergency procedures;

5. The emergency and evacuation procedures;

6. The infection control procedures as required by He-P 811.21; and

7. The mandatory reporting requirements including RSA 161-F:46 and RSA 169-C:29.

(k) The licensee shall provide all personnel with an annual continuing education or in-service education training, which at a minimum contains the following:

1. The licensee’s client rights and complaint procedures required under RSA 151;

2. The licensee’s infection control program; and

3. The licensee’s written emergency plan.
All licensees using the service of independent clinical contractors who have direct contact with clients shall ensure that these personnel have:

1. Been oriented in accordance with (j) above;
2. Submitted results of a physical examination or health screening and 2 step tuberculosis testing, mantoux method, conducted not more than 12 months prior to employment;
3. Provided a copy of any license, registration, or certification as required by (a)(5) above; and
4. Have a written agreement with the licensee that describes the services that will be provided and agrees to comply with (1) through (3) above.

Current and complete personnel files shall be maintained and available to the department for inspection.

The personnel file required by (m) above shall include the following:

1. A completed application for employment or a resume;
2. A statement signed by each employee that he or she has received a copy of the licensee’s policy setting forth the client rights and responsibilities and acknowledging training and implementation of the policy as required by RSA 151:20;
3. A copy of the criminal record check required by (a)(1) above;
4. A job description signed by the individual that identifies the:
   a. Position title;
   b. Qualifications and experience; and
   c. Duties required by the position;
5. Record of satisfactory completion of the orientation program required by (j) above;
6. A copy of each current New Hampshire license, registration, or certification in health care field, if applicable;
7. Documentation that the required physical examination, or health screening, and TB test results or radiology reports of chest x-rays, if required, have been completed by the appropriate health professionals;
8. Documentation of annual in-service education as required by (k) above;
9. For patient care technicians that have been delegated the task of medication administration, the written evaluation by the delegating registered nurse that was used to determine the personnel member is competent to administer medications;
10. A signed statement from the employee required by (o) below; and
11. Documentation to verify compliance with (r), (s) and (t) below, as applicable.

All personnel shall sign a statement at the time the initial offer of employment is made and then annually thereafter stating that they:

1. Do not have a felony conviction in this or any other state;
(2) Have not been convicted of a sexual assault, other violent crime, assault, fraud, abuse, neglect, or exploitation or pose a threat to the health, safety, or well-being of a client; and

(3) Have not had a finding by the department or any administrative agency in this or any other state for assault, fraud, abuse, neglect, or exploitation of any person.

(p) For individuals with the waiver described in (d) above, the statement required by (o) above shall cover the period of time since the waiver was granted.

(q) An individual shall not be required to re-disclose any of the matters in (o) above if the documentation is available and the department has previously reviewed the material and determined that the individual can continue employment.

(r) The license shall ensure that all direct care personnel have current certification in:

   (1) Basic life support (BLS);
   (2) Cardio pulmonary resuscitation (CPR); and
   (3) Automatic electronic defibrillator (AED).

(s) The licensee shall ensure that all personnel are familiar with the location of the equipment required by He-P 811.22(j).

(t) The licensee shall ensure that all personnel, in accordance with their practice act, are familiar with the operation and use of the equipment required by He-P 811.22(j).

Source. #9963, eff 7-28-11

He-P 811.19 Client Records.

(a) The licensee shall maintain a legible, current, and accurate record for each client based on services provided at the ESRDDC which includes, at a minimum:

   (1) The written confirmation required by He-P 811.16(a)(2);
   (2) The identification data required by He-P 811.16(a)(3);
   (3) Consent forms as required by He-P 811.16(a)(4);
   (4) Consent for release of information as applicable required by He-P 811.16(a)(5);
   (5) The record of the medical history and health examination required by He-P 811.16(a)(6);
   (6) All orders from a licensed practitioner, including the date and signature of the licensed practitioner;
   (7) Results of any laboratory tests;
   (8) All consultation reports;
   (9) All assessments for the last 12 months;
   (10) All care plans for the last 12 months;
   (11) All written notes required by He-P 811.16(b)(10);
(12) The medication record required by He-P 811.17(u) and (w);

(13) Discharge or transfer documentation as required by He-P 811.16(e); and

(14) Documentation of nurse delegation of medications as required by the nurse practice act, as applicable.

(b) Client records shall be:

(1) Safeguarded against loss, damage, or unauthorized use; and

(2) Retained for 4 years after discharge, except that when the client is a minor, records shall be retained until the person reaches the age of 19, but no less than 4 years after discharge.

(c) The licensee shall arrange for storage of and access to client records as required by (b)(2) above in the event the ESRDDC ceases operation.

(d) The licensee shall develop and implement a written policy and procedure document that specifies the method by which release of information from a client’s record shall occur.

(e) Any licensee that maintains electronic records shall develop written policies and procedures designed to protect the privacy of clients and personnel that, at a minimum, include:

(1) Procedures for backing up files to prevent loss of data;

(2) Safeguards for maintaining the confidentiality of information pertaining to clients and staff; and

(3) Systems to prevent tampering with information pertaining to clients and staff.

Source. #9963, eff 7-28-11

He-P 811.20 Quality Improvement.

(a) The licensee shall develop and maintain a quality improvement program whose objectives shall be to reveal patterns and initiate action to provide an optimum quality of care for all clients.

(b) The quality improvement program shall include a quality improvement committee, which shall consist of:

(1) The medical director;

(2) The nurse manager;

(3) A social worker;

(4) A dietitian; and

(5) At least one other direct care staff provider.

(c) The quality improvement committee shall:

(1) Review within 24 hours:

a. All client cases where a medical emergency occurs; and

b. Client cases which require unexpected transfer to an acute care facility;
(2) Establish and implement a system for the monthly surveillance of dialysate water and reuse;

(3) Review all reports of unexpected occurrences involving clients, personnel, or visitors;

(4) Ensure that outside services such as laboratory services or water analysis are provided in accordance with federal and state laws, and administrative rules;

(5) Ensure that individuals with appropriate qualifications maintain medical equipment; and

(6) Meet at least quarterly.

(d) Documentation of all quality improvement meetings shall be maintained on-site for at least 2 years.

Source. #9963, eff 7-28-11

He-P 811.21 Infection Control and Sanitation.

(a) The ESRDDC shall develop and implement an infection control program that educates and provides procedures for the prevention, control, and investigation of infectious and communicable diseases.

(b) The infection control program shall include written procedures for:

(1) Proper hand washing techniques;


(3) The care of clients with infectious or contagious diseases or illnesses;

(4) The handling, storage, transportation, and disposal of those items identified as infectious waste in Env-Sw 103.28;

(5) The reporting of infectious and communicable diseases as required by He-P 301; and

(6) Maintenance of a sanitary physical environment.

(c) The infection control education program shall address at a minimum the:

(1) Causes of infection;

(2) Effects of infections;

(3) Transmission of infections; and

(4) Prevention and containment of infections.

(d) Personnel infected with a disease or illness transmissible through food, fomites, or droplets, shall not provide direct care in any capacity without personal protection equipment to prevent disease transmission until they are no longer contagious.

(e) Personnel infected with scabies or lice shall not provide direct care to clients until such time as they are no longer infected.

(f) Pursuant to RSA 141-C, personnel with a newly positive tuberculosis test or a diagnosis of suspected active pulmonary or laryngeal tuberculosis shall be excluded from the ESRDDC until a diagnosis
of tuberculosis is excluded or until the person is receiving tuberculosis treatment and has been determined to be noninfectious by a licensed practitioner.

(g) Personnel with an open wound who provide direct care in any capacity shall cover the wound at all times by an impermeable, durable, and tight-fitting bandage.

(h) Each licensee caring for clients with infectious or contagious diseases shall have available appropriate isolation accommodations, equipment, rooms, and personnel as specified by the United States Centers for Disease Control and Prevention “2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings,” June 2007.

(i) The licensee shall maintain a clean, safe, and sanitary environment, both inside and outside the facility.

(j) The furniture, floors, ceilings, walls, and fixtures shall be clean, sanitary, and in good repair.

(k) A supply of potable water shall be available for human consumption.

(l) A supply of hot and cold running water shall be available at all times and precautions, such as temperature regulation, shall be taken to prevent a scalding injury to the clients.

(m) All client bathing and toileting facilities shall be cleaned and disinfected as often as necessary to prevent illness or contamination.

(n) Cleaning solutions, compounds, and substances considered hazardous or toxic materials, as defined in RSA 147-A:2 VII, shall be distinctly labeled and legibly marked so as to identify the contents and stored in a place, such as a locked box, separate from food, medications and client supplies.

(o) Toxic materials shall not be used in a way that contaminates food, equipment, or utensils or in any way other than in full compliance with the manufacturer’s labeling.

(p) Only individuals authorized under RSA 430:33 shall apply pesticides, as defined by RSA 430:29, XXVI, in food storage, food preparation, or dining areas.

(q) Solid waste, garbage, and trash shall be stored in a manner to make it inaccessible to insects and rodents, outdoor animals, and facility pets.

(r) In-house trash and garbage receptacles shall be emptied in a timely manner and lined, or cleaned and disinfected after emptying or when visibly soiled.

(s) Laundry shall meet the following requirements:

(1) Clean linen shall be stored in a clean area and shall be separated from soiled linens at all times; and

(2) Soiled linens and clothing which are considered contaminated with infectious waste under Env-Sw 103.28 shall be handled as infectious waste.

(t) Laundry rooms and bathrooms shall have non-porous floors.

(u) Sterile or clean supplies shall be stored in dust and moisture-free storage areas.
(v) Any ESRDDC with a non-municipal water supply and whose water has been tested and has failed to meet acceptable levels as required by the department of environmental services shall notify the department.

Source. #9963, eff 7-28-11

He-P 811.22 Physical Environment.

(a) Equipment providing heat within an ESRDDC including, but not limited to, gas furnace or boiler, oil furnace or boiler, wood stove, or pellet stove shall:

(1) Maintain a temperature that is a minimum of 70 degrees Fahrenheit when client(s) are present; and

(2) Be serviced once a year or as recommended by the manufacturer with written documentation of such service retained for at least 4 years.

(b) Electric heating systems shall be exempt from (a)(2) above.

(c) Portable space heating devices shall be prohibited, unless the following are met:

(1) Such devices are used only in employee areas where personnel are present and awake at all times; and

(2) The heating elements of such devices do not exceed 212 degrees Fahrenheit.

(d) Unvented fuel-fired heaters shall not be used in any ESRDDC.

(e) The ESRDDC shall have:

(1) An emergency call system; and

(2) A generator, in working condition at all times.

(f) The generator in (e)(2) above shall be tested regularly in accordance with manufacturer’s recommendations.

(g) Plumbing shall be sized, installed, and maintained in accordance with the state plumbing code as adopted under RSA 329-A:15 and RSA 155-A.

(h) Ventilation shall be provided in all client areas by means of a mechanical ventilation system or one or more screened windows that can be opened.

(i) The ESRDDC shall contain a nursing or monitoring station from which clients receiving dialysis services can be monitored.

(j) Each ESRDDC shall provide the following supplies and equipment, which shall be maintained in an operable condition in accordance with the manufacturer’s recommendations:

(1) Oxygen delivery system;

(2) Emergency ventilating supplies including airways;

(3) AED;

(4) Intravenous fluids and administration devices;

(5) Suction machine capable of battery operation or a secondary power source;
(6) Emergency supplies, under the supervision of a registered nurse or physician, which shall be inventoried and maintained according to ESRDDC policy; and

(7) A stretcher, gurney, or transfer device capable of adjusting to the trendelenberg position.

(k) Restocking of the emergency supplies described in (j) above shall occur immediately after each use.

(l) There shall be at least one toilet and one hand-washing sink for client use, which shall have:

(1) Soap dispensers; and

(2) Paper towels or a hand-drying device providing heated air.

(m) If the ESRDDC has showers and tubs, they shall have:

(1) Slip resistant floors; and

(2) Surfaces which are intact, easily cleanable, and impervious to water.

(n) All bathroom and closet door latches shall be designed for easy opening from the inside of the bathroom or closet. All bathroom door locks or latches shall be designed for easy opening of the locked door from the outside in an emergency.

(o) The ESRDDC shall have a telephone to which the clients have access.

(p) The ESRDDC shall have sufficient space and equipment for the services authorized to be provided at the ESRDDC.

Source. #9963, eff 7-28-11

He-P 811.23 Emergency and Fire Safety.

(a) All ESRDDCs shall, at a minimum, meet the Ambulatory Health Care chapter of NFPA 101 as adopted by the commissioner of the department of safety in Saf-C 6000.

(b) The licensee shall provide and maintain a complete fire alarm system installed and maintained in accordance with Saf-C 6000 regardless of the size of the facility.

(c) The licensee shall comply with all state and local codes and ordinances for:

(1) Building, including the International Building Code as adopted by RSA 155-A: 2;

(2) Health;

(3) Fire, including but not limited to NFPA 101 and Saf-C 6000;

(4) Waste disposal; and

(5) Water, including the requirements of He-P 811.06(d).

(d) The ESRDDC shall:

(1) Have all entrances and exits to the licensed premises accessible at all times;

(2) Be maintained in good repair and kept free of hazards to personnel and clients, including but not limited to hazards from falls, burns, or electrical shocks;
(3) Be free from environmental nuisances, including noise and odors; and

(4) Take measures to prevent the presence of rodents, insects, and vermin including, but not limited to:
   a. Having tightly fitting screens to all doors, windows, or other openings to the outside unless the door is self-closing and remains closed unless in use;
   b. Repairing holes and caulking of pipe channels; and
   c. Extermination by a pesticide applicator licensed under RSA 430.

(e) An emergency and fire safety program shall be developed and implemented to provide for the safety of clients and personnel.

(f) Immediately following any fire or emergency situation, licensees shall notify the department by phone to be followed by written notification within 72 hours, with the exception of:

   (1) A false alarm or emergency medical services (EMS) transport for a non-emergent reason; or
   (2) Emergency EMS transport related to pre-existing conditions.

(g) The written notification required by (f) above shall include:

   (1) The date and time of the incident;
   (2) A description of the location and extent of the incident, including any injury or damage;
   (3) A description of events preceding and following the incident;
   (4) The name of any personnel or clients who were evacuated as a result of the incident, if applicable;
   (5) The name of any personnel or clients who required medical treatment as a result of the incident, if applicable; and
   (6) The name of the individual the licensee wishes the department to contact if additional information is required.

(h) Oxygen shall be stored in the following manner:

   (1) Oxygen tanks shall be separated from combustibles or incompatible materials by either:
      a. A minimum distance of 20 feet; or
      b. A minimum distance of 5 feet if the entire building is equipped with an automatic sprinkler system installed in accordance with SAF-C 6000;
   (2) Oxygen tanks shall be secured in a manner that prevents damage to the valves and cylinder;
   (3) Portable liquid oxygen shall be used and stored in accordance with the Compressed Gas Association’s “Guide for the Safe Storage, Handling, and Use of Small Portable Liquid Oxygen Systems in Health Care Facilities,” CGA P-2.7, edition 3; and
   (4) Any area where oxygen is stored or is in use shall have signage indicating that oxygen is in use or being stored.
(i) Each licensee shall develop a written emergency response plan that covers:

1. Loss of electricity;
2. Loss of water;
3. Loss of heat;
4. Bomb threat;
5. Severe weather;
6. Fire;
7. Gas leaks;
8. Unexplained client disappearances; and
9. Any situation that requires evacuation of the ESRDDC.

(j) Each licensee shall:

1. Annually review and revise, as needed, its emergency plan;
2. Submit its emergency plan to the local emergency management director for review and approval when initially written and whenever the plan is revised; and
3. Maintain documentation on-site which establishes that the emergency plan has been approved as required under (2) above.

(k) Fire and/or evacuation drills shall be conducted quarterly as follows:

1. Each employee shall participate in at least one drill every calendar quarter; and
2. Each drill shall include the transmission of a fire alarm signal and simulation of emergency fire conditions.

(l) For personnel who are unable to participate in the scheduled drill described in (k) above, on the day they return to work the administrator or designee shall, if applicable, instruct them as to any changes in the facility fire and emergency plan and document such instruction in their personnel file.

(m) Personnel who are unable to participate in a drill in accordance with (k) and (l) above shall participate in a drill within the next quarter.

(n) The timing of quarterly drills shall be at varying times to include all shifts and all clients and individuals in the ESRDDC at the time of the drill.

(o) All emergency and evacuation drills shall be documented and include the following information:

1. The names of the participating personnel and clients;
2. The time, date, month, and year the drill was conducted;
3. The exits utilized if the ESRDDC does not comply with the health care chapter of the state fire code;
(4) The total time necessary to evacuate the ESRDDC, when evacuation of the facility is required by the drill;

(5) The time needed to complete the drill; and

(6) Any problems encountered and corrective actions taken to rectify problems.

Source: #9963, eff 7-28-11

APPENDIX

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