PART He-P 827 FREESTANDING MEGAVOLTAGE RADIATION THERAPY FACILITY

REVISION NOTE:

Document #12751, effective 3-26-19, adopted Part He-P 827 titled "Freestanding Megavoltage Radiation Therapy Facility." Part He-P 827 had formerly contained rules titled "Regulations for Special Hospitals-Rehabilitation" which had been adopted by Document #5849, effective 6-22-94, but had expired 6-22-00 and were not adopted again. The rule number He-P 827 therefore became available for future rulemaking until used for the rules in Document #12751.

He-P 827.01 Purpose. The purpose of this part is to set forth the special health care service licensing requirements for freestanding megavoltage radiation therapy facility (FMRTF) services pursuant to RSA 151:2-e, II(c).

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.02 Scope. This part shall apply to any organization, business entity, partnership, corporation, government entity, association or other legal entity operating megavoltage radiation therapy equipment in a free standing facility.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.03 Definitions.

(a) "Abuse" means any one of the following:

(1) "Emotional abuse" which 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 patients;

(2) "Physical abuse" which means the misuse of physical force which results or could result in physical injury to patients; or

(3) "Sexual abuse" which means contact or interaction of a sexual nature involving patients without his or her informed consent.

(b) "Accredited hospital" means a hospital accredited by the organizations deemed by the Centers for Medicare and Medicaid Services (CMS) as accrediting organizations.

(c) "Addition" means an increase in the building area, aggregate floor area, building height, or number of stories of a structure.

(d) "Administer" means an act, by an individual authorized by law, whereby a single dose of a drug is instilled into the body of, applied to the body of, or otherwise given to a person for immediate consumption or use.

(e) "Administrator" means the individual appointed by the licensee to be responsible for all aspects of the daily operation of the FMRTF.

(f) "Admission" means accepted by a licensee for the provision of services to a patient.

(g) "Advance directive" means a legal document allowing a person to give directions about future medical care or to designate another person to make medical decisions if he or she should lose the capacity

to make health care decisions. The term “advance directive” includes living wills and durable powers of attorney for health care, in accordance with RSA 137-J.

(h) “Adverse event” means a negative consequence of care, including any misadministration as defined in He-P 4000, which results in unintended injury which might have been preventable, and which is listed in RSA 151:38.

(i) “Affiliated or related parties” means companies or individuals that serve as operators, landlords, management companies or advisors, real estate or consulting companies, members of limited liability companies, administrative services companies, lenders and companies providing financial guarantees, captive or affiliated insurance companies or other companies as the commissioner shall decide.

(j) “Agent” means an adult to whom authority to make health care decisions is delegated under an activated durable power of attorney for health care executed in accordance with RSA 137-J or a surrogate decision-maker in accordance with RSA 137-J:35.

(k) “Applicant” means an individual, agency, partnership, corporation, government entity, association, or other legal entity seeking a license to operate a FMRTF pursuant to RSA 151:2, I(a) and RSA 151:2-e.

(l) “Area of non-compliance” 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 827, or other federal or state requirements.

(m) “Care plan or treatment plan” means a documented guide developed by the licensee, in consultation with personnel, the patient, and/or the patient’s guardian, agent, surrogate, or personal representative, if any, as a result of the assessment process for the provision of care and services.

(n) “Change of ownership” means a change in the controlling interest of an established FMRTF to an individual or successor business entity.

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

(p) “Core services” means those minimal services to be provided to any patient by the licensee that must be included in the basic rate.

(q) “Critical incident stress management (CISM)” means an adaptive, short-term psychological helping-process that focuses solely on an immediate and identifiable problem. Its purpose is to enable people to return to their daily routine more quickly and with less likelihood of experiencing post-traumatic stress disorder.

(r) “Days” means calendar days unless otherwise specified in the rule.

(s) “Demonstrated competency” means the ability of the employee to demonstrate to an evaluator that he or she is able to complete the required task in a way that reflects the minimum standard such as a certificate of completion of course material or a post-test to the training provided.

(t) “Department” means the New Hampshire department of health and human services.

(u) “Direct care” means hands on care or services to a patient, including but not limited to medical, nursing, psychological or rehabilitative treatments.

(v) “Directed plan of correction” means a plan developed and written by the department that specifies the actions the licensee must take to correct identified areas of non-compliance.

(w) "Do not resuscitate order (DNR order)" means an order, signed by a licensed provider, that in the event of an actual or imminent cardiac or respiratory arrest, chest compression, and ventricular defibrillation will not be performed, the patient will not be intubated or manually ventilated, and there will be no administration of resuscitation drugs. This term also includes "do not attempt resuscitation order (DNAR order)."

(x) "Emergency plan" means a document outlining the responsibilities of personnel in an emergency.

(y) "Employee" means anyone employed by the licensee and for whom the licensee has direct supervisory authority.

(z) "Enforcement action" means the imposition of an administrative fine, the denial of an application for a license, or the revocation of a license in response to non-compliance with RSA 151 or He-P 827.

(aa) "Equipment or fixtures" means any plumbing, heating, electrical, ventilating, air-conditioning, refrigerating, and fire protection equipment, and any elevators, dumbwaiters, escalators, boilers, pressure vessels, or other mechanical facilities or installations related to building services.

(ab) "Exploitation" means the illegal use of a patient'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 patient through the use of undue influence, harassment, duress, deception or fraud.

(ac) "Facility" means any hospital, building, residence, or other place or part thereof, where services are provided under the provisions of RSA 151:2-e.

(ad) "Freestanding megavoltage radiation therapy facility (FMRTF)" means a facility, geographically separate from the parent hospital(s), which is owned or operated, directly or indirectly, by the parent hospital(s) and that performs megavoltage therapy radiation services.

(ae) "Governing body" means a group of individuals who are responsible for policy direction of the licensee.

(af) "Guardian" means a person appointed in accordance with RSA 463, RSA 464-A or the laws of another state, to make informed decisions relative to the patient's health care and other personal needs.

(ag) "Hospital" means "hospital" as licensed under in RSA 151:2, I(a).

(ah) "Incident Command System (ICS)" means a standardized on-scene emergency management system specifically designed to provide for the adoption of an integrated organizational structure that reflects the complexity and demands of single or multiple incidents, without being hindered by jurisdictional boundaries. ICS is the combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure, designed to aid in the management of resources during incidents.

(ai) "Independent contractor" means an individual providing service to the licensee or its clients but employed by an outside agency.

(aj) "Infectious disease" means any disease caused by the growth of microorganisms in the body which might or might not be contagious.

(ak) "Infectious waste" means those items specified by Env-Sw 904.

(al) "Informed consent" means the decision by a person or his/her guardian or agent to agree to a proposed course of treatment, after the person 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.

(am) "In-service" means an educational program which is designed to increase the knowledge, skills, and overall effectiveness of personnel.

(an) "Inspection" means the process followed by the department to determine an applicant's or a licensee's compliance with RSA 151 and He-P 827 or to respond to allegations, pursuant to RSA 151:6, of non-compliance with RSA 151 and He-P 827.

(ao) "License" means the document issued by the department to an applicant at the start of operation as an FMRTF which authorizes operation of an FMRTF in accordance with RSA 151 and He-P 827, and includes the name of the licensee, the name of the business, the physical address, the license classification, the effective date, and license number.

(ap) "License certificate" means the document issued by the department to an applicant or licensee that, in addition to the information contained on a license, includes the name of the administrator, the type(s) of services authorized, and the number of beds for which the FMRTF is licensed.

(aq) "Licensed practitioner" means a:

(1) Medical doctor;

(2) Physician's assistant;

(3) Advanced practice registered nurse (APRN);

(4) Doctor of osteopathy;

(5) Doctor of naturopathic medicine; or

(6) Any other practitioner with diagnostic and prescriptive powers licensed by the appropriate state licensing board.

(ar) "Licensed premises" means the building(s), or portion thereof, that comprise the physical location the department has approved for the licensee to conduct operations in accordance with its license.

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

(at) "Life safety code" means the National Fire Protection Association (NFPA) 101, as adopted by the commissioner of the department of safety in Saf-C 6000 under RSA 153, and as amended pursuant to RSA 153:5, I, by the state fire marshal with the board of fire control.

(au) "Medical director" means a licensed practitioner in New Hampshire in accordance with RSA 329 or 326-B who is responsible for overseeing the quality of medical care and services in a FMRTF.

(av) "Medical staff" means those physicians and other licensed practitioners permitted by law and policies to provide patient care services independently within the scope of their practice acts.

(aw) "Medication" means a substance available with or without a prescription, which is used as a curative or remedial substance.

(ax) “Megavoltage” means energy levels equal to or greater than 1.0 million electron volts or one MeV. MeV stands for megavolts.

(ay) “Megavoltage radiation therapy equipment” means therapeutic equipment having a minimum power rating in excess of one MeV which utilizes directed beams of ionizing radiation to kill cancerous tissues. The term includes but is not limited to Cobalt-60 and linear accelerator machines.

(az) “Modification” means the reconfiguration of any space; the addition, relocation, or elimination of any door or window; the addition or elimination of load-bearing elements; the reconfiguration or extension of any system; or the installation of any additional equipment. The term does not include repair or replacement of interior finishes.

(ba) “Neglect” means an act or omission which results or could result in the deprivation of essential services or supports necessary to maintain the minimum mental, emotional or physical health and safety of any patient.

(bb) “Notice to correct” means a report issued pursuant to RSA 151:6-a, II, following a life safety code inspection when a facility is found to be out of compliance with applicable life safety rules or codes.

(bc) “Nursing care” means the provision or oversight of a physical, mental, or emotional condition or diagnosis by a nurse.

(bd) “Orders” means a document, produced verbally, electronically, or in writing, by a licensed practitioner for medications, treatments, recommendations, and referrals, and signed by the licensed practitioner using terms such as authorized by, authenticated by, approved by, reviewed by, or any other term that denotes approval by the licensed practitioner.

(be) “Over-the-counter medications” means non-prescription medication.

(bf) “Owner” means any person, corporation, association, or any other legal entity, whether organized for profit or not, holding or claiming ownership of, or title to, a license.

(bg) “Parent hospital” means the hospital which owns and operates a FMRTF.

(bh) “Patient” means any person admitted to or in any way receiving care, services or both from a hospital or provider of special health care services licensed in accordance with RSA 151 and He-P 827.

(bi) “Patient record” means documents maintained for each person receiving care and services, which includes all documentation required by RSA 151, He-P 827 and all documentation compiled relative to the patient as required by other federal and state requirements.

(bj) “Patient rights” means the privileges and responsibilities possessed by each patient provided by RSA 151:21.

(bk) “Personal care” means personal care services that are non-medical, hands-on services provided to a patient to assist with activities of daily living such as grooming, toileting, eating, dressing, bathing, getting into or out of a bed or chair, or walking.

(bl) “Personal representative” means a person designated in accordance with RSA 151:19, V, to assist the patient for a specific, limited purpose or for the general purpose of assisting a patient in the exercise of any rights.

(bm) “Personnel” means an individual(s), who is employed by the FMRTF, who is a volunteer, or who is an independent contractor who provides direct care or personal care services to patients.

(bn) "Physician" means medical doctor currently licensed in the state of New Hampshire pursuant to RSA 329.

(bo) "Plan of correction (POC)" means a plan developed and written by the licensee, which specifies the actions that will be taken to correct identified areas of non-compliance at the time of clinical or life safety code inspection conducted pursuant to RSA 151:6-a or during the course of a complaint investigation conducted pursuant to RSA 151:6.

(bp) "Previously operating special health care service" shall mean a special health care service as defined by RSA 151:2-e that was being offered prior to July 1, 2016 and has continued to be offered since July 1, 2016.

(bq) "Pro re nata (PRN) medication" means medication taken as circumstances may require in accordance with licensed practitioner's orders.

(br) "Procedure" means a licensee's written, standardized method of performing duties and providing services.

(bs) "Qualified personnel" means personnel that have been trained to adequately perform the tasks which they perform, such as nursing staff, clinical staff, housekeeping staff trained in infection control, and kitchen staff trained in food safety protocols.

(bt) "Radiographic images" means x-rays or other images which are either on film, discs, paper, or stored electronically.

(bu) "Reconstruction" means the reconfiguration of a space that affects an exit or a corridor shared by more than one occupant space, or the reconfiguration of a space such that the rehabilitation work area is not permitted to be occupied because existing means of egress and fire protection systems, or their equivalent, are not in place or continuously maintained.

(bv) "Renovation" means the replacement in kind, strengthening, or upgrading of building elements, materials, equipment or fixtures, that does not result in a reconfiguration of the building spaces within.

(bw) "Repair" means the patching, restoration, or painting of materials, elements, equipment, or fixtures for the purpose of maintaining such materials, elements, equipment, or fixtures in good or sound condition.

(bx) "Reportable incident" means an occurrence of any of the following while the patient is either in the FMRTF or in the care of personnel:

(1) The unanticipated death of the patient; or

(2) An injury to a patient that is potentially due to abuse or neglect.

(by) "Service" means a specific activity performed by the licensee, either directly or indirectly, to benefit or assist a patient, such as dietary, laboratory, nursing, or surgery.

(bz) "Special health care service" shall mean cardiac catheterization laboratory services, open heart surgery or coronary artery bypass graft surgery, or megavoltage radiation therapy.

(ca) "Staff" means those employees of the licensee who are not subject to the credentialing process.

(cb) "State monitoring" means the placement of individuals by the department at a FMRTF to monitor the operation and conditions of the facility.

(cc) "Volunteer" means an unpaid person who assists with the provision of personal care services, food services, or activities, and who does not provide direct care or assist with direct care. This term does not include visitors or those persons who provide religious services or entertainment.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.04 License Application Submission.

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

(1) A completed application form entitled "Application for Residential or Health Care License" (March 2019) signed by the applicant or 2 of the corporate officers, affirming and certifying the following:

a. "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.";

b. For any FMRTF to be newly licensed :

"I certify that I have notified the public of the intent to file this application with a description of the facility to be licensed by publishing a notice in a newspaper of general circulation covering the area where the facility is to be located in at least 2 separate issues of the newspaper no less than 10 business days prior to the filing of this application."; and

c. For any FMRTF to be newly licensed and to be located within a radius of 15 miles of a hospital certified as a critical access hospital, pursuant to 42 C.F.R. 485.610 (b) and (c):

"I certify that the facility is to be located within a radius of 15 miles of a hospital certified as a critical access hospital, pursuant to 42 C.F.R. 485.610 (b) and (c), and that I have given written notice of the intent to file this application with a description of the facility to be licensed to the chief executive officer of the hospital by registered mail no less than 10 business days prior to the filing of this application.";

(2) A floor plan of the prospective FMRTF;

(3) If applicable, 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) A $500 fee, in accordance with RSA 151:2-e, payable in cash or, if paid by check or money order, in the exact amount of the fee made payable to the "Treasurer, State of New Hampshire";

(5) A resume identifying the qualifications of the FMRTF administrator;

(6) Copies of applicable licenses for the FMRTF 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, Saf-C 6000, as amended pursuant to RSA 153:5, I, by the state fire marshal with the board of fire control, as adopted by the commissioner of the department of safety, and local fire ordinances applicable for a business; and

b. For a building under construction, the written approvals required by a. above shall be submitted at the time of the application based on the local official's review of the building plans and upon completion of the construction project;

(8) If the FMRTF uses a private water supply, documentation that the water supply has been tested in accordance with RSA 485 and Env-Dw 702.02 and Env-Dw 704.02, or if a public water supply, a copy of a water bill;

(9) The results of a criminal records check from the NH department of safety for the applicant(s), licensee if different than the applicant, medical director, and administrator for which the application is submitted; and

(10) A copy of the signed and dated FMRTF's criminal statement form for the administrator and medical director as described in He-P 827.18(t).

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

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

(c) A previously operating special health care service shall not be required to apply for a licensed pursuant to RSA 151:2-e.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.05 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 827.04(a) have been received.

(b) If an application does not contain all of the items required by He-P 827.04(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) Unless a waiver has been granted, the department shall deny a licensing request in accordance with He-P 827.13(b) if it determines that the applicant, licensee, medical director, or administrator:

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

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

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

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

(f) At the time of initial onsite inspection, the applicant shall have the following on hand and available for inspection:

(1) A copy of the personnel records; and

(2) A copy of the FMRTF standard disclosure form.

(g) Following both clinical and life safety code inspections, 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 827.

(h) All licenses issued in accordance with RSA 151 shall be non-transferable by person, location, or agency affiliation.

(i) A written notification of denial, pursuant to He-P 827.13(b)(10), shall be sent to an applicant applying for an initial license if it has been determined by the inspection in (g) above and a maximum of 2 follow-up inspections that the prospective premises are not in full compliance with RSA 151 and He-P 827.

(j) A written notification of denial, pursuant to He-P 827.13(b)(4), shall be sent to an applicant applying for an initial license if the department has received no communication from the applicant within 3 months of sending written notification to the applicant that their application is complete and an inspection needs to be scheduled.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.06 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 prior to the month in which it was issued unless a completed application for renewal has been received.

(b) Each licensee seeking renewal shall complete and submit to the department an application form pursuant to He-P 827.04(a)(1) at least 120 days prior to the expiration of the current license and include with the application:

(1) The current license number;

(2) A request for renewal of any existing non-permanent waivers previously granted by the department, in accordance with He-P 827.10(f), if applicable. If such a request is not received, the rule(s) for which the waiver was previously requested shall not continue to be waived beyond the expiration of the current license;

(3) A list of any current employees who have a permanent waiver granted in accordance with He-P 827.18(e)(2); and

(4) A copy of any non-permanent or new variances applied for and granted by the state fire marshal, in accordance with Saf-C 6005.03 - 6005.04, as amended pursuant to RSA 153:5, I by the state fire marshal, with the board of fire control.

(c) In addition to (b) 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 702.02 for bacteria and Env-Dw 704.02 for nitrates.

(d) Following an inspection as described in He-P 827.09, a license shall be renewed if the department determines that the licensee:

(1) Submitted an application containing all the items required by (b) and (c) above, as applicable, prior to the expiration of the current license; and

(2) Is found to be in compliance with RSA 151 and He-P 827 at the renewal inspection, or submitted an acceptable plan of correction if areas of non-compliance were cited.

(e) Any licensee who does not submit a complete application for renewal prior to the expiration of an existing license and does not intend to cease operation shall be required to submit an application for an initial license pursuant to He-P 827.04.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.07 FMRTF New Construction and Existing Rehabilitation.

(a) For new construction and for rehabilitation, renovation, modification, reconstruction, or addition of an existing building, all construction documents, shop drawings, and architectural, sprinkler, and fire alarm plans shall be submitted to the department 60 days prior to the start of such work.

(b) The architectural, sprinkler, and fire alarm plans in (a) above shall accurately show the room designation(s) and exact measurements of each area to be licensed, including but not limited to windows and door sizes and each room's use.

(c) Architectural, sprinkler, and fire alarm plans shall be submitted to the state fire marshal's office as required by RSA 153:10-b, V.

(d) Any licensee or applicant who wants to use performance-based design to meet the fire safety requirements shall provide the department with documentation of fire marshal approval for such methods.

(e) The department shall review construction documents, drawings, and plans of a newly proposed or existing facility for compliance with all applicable sections of RSA 151 and He-P 827 and shall notify the applicant or licensee as to whether the proposal complies with these requirements.

(f) Construction and building rehabilitation initiated prior to receiving department approval shall be done at the applicant or licensee's own risk.

(g) The FMRTF shall comply with all applicable state laws, rules, and local ordinances when undertaking construction or rehabilitation.

(h) A licensee or applicant undertaking construction or rehabilitation of a building shall comply with the following:

(1) The state fire code, Saf-C-6000, as amended pursuant to RSA 153:5, I by the state fire marshal with the board of fire control; 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;

(i) All FMRTF newly constructed or rehabilitated after the 2019 effective date of these rules shall comply with the Facility Guidelines Institutes (FGI) "Guidelines for Design and Construction of Hospitals" (2018 Edition) or the Facility Guidelines Institutes (FGI) "Guidelines for Design and Construction of Outpatient Facilities," (2018 Edition), as applicable, available as noted in Appendix A.

(j) Where rehabilitation is done within an existing facility, all such work shall comply, insofar as practicable, with applicable sections of the FGI "Guidelines for Design and Construction of Hospitals" (2018 Edition) or the FGI "Guidelines for Design and Construction of Outpatient Facilities," (2018 Edition), available as noted in Appendix A.

(k) Per the FGI "Guidelines for Design and Construction of Hospitals" (2018 Edition) or the FGI "Guidelines for Design and Construction of Outpatient Facilities," (2018 Edition) available as noted in Appendix A, and notwithstanding (j) above, where it is evident that a reasonable degree of safety is provided, the requirements for existing buildings shall be permitted to be modified if their application would be impractical in the judgment of the authority having jurisdiction.

(l) The department shall be the authority having jurisdiction for the requirements in (i)-(k) above and shall negotiate compliance and grant waivers in accordance with He-P 827.10 as appropriate.

(m) Penetrations, holes, or other openings in fire walls, fire partitions, smoke barriers, floors, and ceilings that allow the transfer of fire, heat, or smoke shall be closed and sealed using a listed or approved sealant that provides an equivalent rating as provided by the original surface.

(n) Waivers granted by the department for construction or rehabilitation under the FGI guidelines above shall not require annual renewal unless the underlying reason or circumstances for the waivers change.

(o) Exceptions or variances pertaining to the state fire code referenced in (h)(1) above shall be granted only by the state fire marshal.

(p) The building, including all construction and rehabilitated spaces shall be subject to an inspection pursuant to He-P 827.09 prior to its use.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.08 FMRTF Requirements for Organizational or Service Changes.

(a) The FMRTF 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; or

(4) Name;

(b) The FMRTF 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 number of patients or services beyond what is authorized under the current license.

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

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

(e) When there is to be a change in the services provided, the FMRTF 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.

(f) The department shall review the information submitted under (e) above and determine if the added services can be provided under the FMRTF's current license.

(g) An inspection by the department shall be conducted prior to operation for changes in the following:

(1) Ownership, unless the current licensee is in full compliance, then an inspection will be conducted as soon as practicable by the department;

(2) The physical location;

(3) A change in licensing classification; or

(4) A change that places the facility under a different life safety code occupancy chapter.

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

(i) A revised license and license certificate shall be issued for a change in the FMRTF name.

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

(1) A change of administrator;

(2) A change in address without a change in physical location;

(3) A change in the number of patients from what is authorized under the current license, if applicable; or

(4) When a waiver has been granted.

(k) The FMRTF shall inform the department in writing no later than 5 days prior to a change in administrator or medical director or as soon as practicable in the event of a death or other extenuating circumstances requiring an administrator change or medical director change and provide the department with the following:

(1) A resume identifying the name and qualifications of the new administrator or medical director;

(2) Copies of applicable licenses for the new administrator or medical director;

(3) The results of a criminal records check conducted under He-P 827.18(b)(1); and

(4) A copy of the dated and signed criminal statement as described He-P 827.18(t).

(l) Upon review of the materials submitted in accordance with (k) above, the department shall make a determination as to whether the new administrator meets the qualifications for the position as specified in He-P 827.18(h).

(m) If the department determines that the new administrator does not meet the qualifications, it shall so notify the licensee in writing so that a waiver can be sought or the licensee can search for a qualified candidate.

(n) The FMRTF shall inform the department in writing via e-mail, fax, or mail of any change in the e-mail address as soon as practicable and in no case later than 10 days of the change as this is the primary method used for all emergency notifications to the facility.

(o) An organizational restructuring of an established FMRTF that does not result in a transfer of the controlling interest of the facility, but which might result in a change in the name of the facility or corporation, shall not constitute a change in ownership and a new license shall not be required.

(p) If a licensee chooses to cease operation of a FMRTF, the licensee shall submit written notification to the department at least 60 days in advance, which shall include a written closure plan that ensures adequate care of patients until they are transferred or discharged to an appropriate alternate setting.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.09 Inspections.

(a) For the purpose of determining compliance with RSA 151 and He-P 827 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 FMRTF; and

(3) Any records required by RSA 151 and He-P 827.

(b) The department shall conduct a clinical and life safety code inspection as necessary, to determine full compliance with RSA 151 and He-P 827 prior to:

(1) The issuance of an initial license;

(2) A change in ownership, except as allowed by He-P 827.08(g)(1);

(3) A change in the physical location of the FMRTF;

(4) A change in the licensing classification;

(5) Occupation of space after construction, modifications, or structural alterations; or

(6) The renewal of a license.

(c) In addition to (b) above, the department shall conduct an inspection, as necessary, to verify the implementation of any POC accepted or issued by the department.

(d) A statement of findings for clinical inspections or a notice to correct for life safety code inspections shall be issued when, as a result of any inspection, the department determines that the FMRTF is in violation of any of the provisions of He-P 827, RSA 151, or other federal or state requirement.

(e) If areas of non-compliance were cited in either a notice to correct or a statement of findings, the licensee shall submit a POC, in accordance with He-P 827.12(c), within 21 days of the date on the letter that transmits the inspection report.

(f) A written notification of denial will be sent to an applicant applying for an initial license if it has been determined by the inspection mentioned in (b) above, that the prospective premises is not in full compliance with RSA 151 and He-P 827.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.10 Waivers.

(a) Applicants or licensees seeking waivers of specific rules in He-P 827 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; and

(3) A full explanation of alternatives proposed by the applicant or license holder, which shall be equally as protective of public health and patients as the rule from which a waiver is sought or provide a reasonable explanation why the applicable rule should be waived.

(b) A waiver shall be permanent unless the department specifically places a time limit on the waiver.

(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 negatively impact the health, safety, or well-being of the patients; and

(3) Does not negatively affect the quality of patient 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 a non-permanent waiver beyond the approved period of time, the licensee shall apply for a new waiver with the renewal application or at least 60 days prior to the expiration of the existing waiver, as appropriate, by submitting the information required by (a) above.

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

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.11 Complaints.

(a) The department shall investigate any complaint that meets the following conditions:

(1) The alleged violation(s) occurred since the last onsite clinical or life safety inspection;

(2) The complaint is based upon the complainant's first-hand knowledge regarding the allegation(s) or on information reported directly to the complainant by a person who has first-hand knowledge regarding the allegation(s); and

(3) There is sufficient specific information for the department to determine that the allegation(s), if proven to be true, would constitute a violation of any of the provisions of RSA 151 or He-P 827.

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

(1) The name and address of the FMRTF, 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 827.

(c) Investigations shall include all techniques and methods for gathering information which are appropriate to the circumstances of the complaint, including, but not limited to:

(1) Requests for additional information from the complainant or the facility;

(2) A physical inspection of the premises;

(3) Review of relevant records that have probative value; and

(4) Interviews with individuals who might have information that is relevant to the investigation and might have probative value.

(d) For a licensed FMRTF, the department shall:

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

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

(3) Notify the licensee in writing and take no further action if the department determines that the complaint is unfounded, under (a) above, or does not violate any statutes or rules; and

(4) Require the licensee to submit a POC in accordance with He-P 827.12(c) if the inspection results in areas of non-compliance being cited.

(e) The following shall apply to an unlicensed individual or entity:

(1) The department shall provide written notification to the owner or person responsible that includes:

a. The date of investigation;

b. The reasons for the investigation; and

c. Whether or not the investigation resulted in a determination that the services being provided require licensing under RSA 151:2;

(2) In accordance with RSA 151:7-a, II, the owner or person responsible shall be allowed 7 business days from the date of the notice required by (1) above to submit a completed application for a license;

(3) If the owner of an unlicensed facility does not comply with (2) above, the department shall issue a written warning to immediately comply with RSA 151 and He-P 827; and

(4) Any person or entity who fails to comply after receiving a warning as described in (3) above, shall be subject to an action by the department for injunctive relief under RSA 151:17 and an administrative fine pursuant to He-P 827.13(c)(6).

(f) 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 an adjudicative proceeding relative to the licensee.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.12 Administrative Remedies.

(a) The department shall impose administrative remedies for violations of RSA 151, He-P 827, or other applicable licensing rules, including:

(1) Requiring a licensee to submit a POC in accordance with (c) below;

(2) Imposing a directed POC upon a licensee in accordance with (d) below;

(3) Imposing conditions upon a licensee; or

(4) Monitoring of a licensee.

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

(1) Identifies each area in which the licensee is not in compliance with RSA 151 or a provision of these rules; and

(2) Identifies the specific remedy(s) that has been imposed.

(c) A POC shall be developed and enforced in the following manner:

(1) Upon receipt of a statement of findings or a notice to correct, the licensee shall submit a written POC for each item, written in the appropriate place on the statement or notice and containing:

a. How the licensee intends to correct each area of non-compliance;

b. What measures will be put in place, or what system changes will be made to ensure that the area of non-compliance does not recur, to include how the measures will be evaluated for effectiveness;

c. The date by which each area of non-compliance shall be corrected; and

d. The position of the employee responsible for the corrective action;

(2) The licensee shall submit a written POC to the department within 21 days of the date on the letter that transmitted the statement of findings or notice to correct 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 calendar day period but has been unable to do so; and

b. The department determines that the health, safety, or well-being of patients will not be jeopardized as a result of granting the extension;

(3) The department shall review each POC and accept each plan that:

a. Achieves compliance with RSA 151 and He-P 827;

b. Addresses all areas of non-compliance as cited in the statement of findings or notice to correct;

c. Prevents a new violation of RSA 151 or He-P 827 as a result of the implementation of the POC; and

d. Specifies the date upon which the areas of non-compliance 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, 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 (c)(1) above and be reviewed in accordance with (c)(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, unless the department has granted an extension, the licensee shall be subject to a directed POC in accordance with (d) below and a fine in accordance with He- P 827.13(c)(12) 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 an onsite 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 (b) above; and

b. Issued a directed POC in accordance with (d) below and shall be subject to a fine, as appropriate, in accordance with He-P 827.13(c)(13) below.

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

(1) As a result of an inspection, areas of non-compliance were identified that require immediate corrective action to protect the health and safety of the patients and personnel;

(2) A revised POC is not submitted within 14 days of the written notification from the department or such other date as applicable if an extension was granted by the department; or

(3) A revised POC submitted by the licensee has not been accepted.

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

(1) Impose a fine;

(2) Deny the application for a renewal of a license in accordance with He-P 827.13(b); or

(3) Revoke the license in accordance with He-P 827.13(b).

(f) The department shall offer an opportunity for informal dispute resolution to any applicant or licensee who disagrees with an area or areas of non-compliance cited by the department on a statement of findings or a notice to correct, provided that the applicant or licensee submits a written request for an informal dispute resolution to the department.

(g) The informal dispute resolution shall be requested in writing by the applicant, licensee, or administrator no later than 14 days from the date the statement of findings or notice to correct was issued by the department.

(h) The department shall change the statement of findings or notice to correct if, based on the evidence presented, the statement of findings is determined to be incorrect. The department shall provide a written notice to the applicant or licensee of the determination.

(i) The deadline to submit a POC in accordance with He-P 827.12(c) shall not apply until the notice of the determination in (h) above has been provided to the applicant or licensee.

(j) Any violations cited for the state fire code may be appealed to the New Hampshire state fire marshal and shall not be the subject of informal dispute resolution as describe in this section.

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

(l) The department shall impose state monitoring under the following conditions:

(1) Repeated non-compliance on the part of the facility in areas that impact the health, safety, or well-being of patients; or

(2) The presence of conditions in the FMRTF that negatively impact the health, safety, or well-being of patients.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.13 Enforcement Actions and Hearings.

(a) Prior to taking enforcement action against an applicant or licensee, 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;

(3) If a fine is imposed, the automatic reduction of the fine by 25% if the fine is paid within 10 days of the date on the written notice from the department and the area of non-compliance has been corrected, or a POC has been accepted and approved by the department; and

(4) The right of an applicant or licensee to an administrative 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 violated a provision of RSA 151 or He-P 827 which poses a risk of harm to the health, safety, or well-being of a patient;

(2) An applicant or licensee has failed to pay an administrative fine imposed by the department;

(3) An applicant or licensee 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 or schedule an initial inspection, the applicant or licensee fails to submit an application that meets the requirements of He-P 827.04 or fails to schedule an inspection;

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

a. Provides false or misleading information to the department;

b. Prevents, 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 827.12(c), (d), and (e);

(7) The licensee has submitted a POC that has not been accepted by the department in accordance with He-P 827.12(c)(5) and has not submitted a revised POC in accordance with He-P 827.12(c)(5)b.;

(8) The licensee is cited a third time under RSA 151 or He-P 827 for the same violation within the last 5 inspections;

(9) A licensee, or its corporate officers, has had a license revoked and submits an application during the 5 year prohibition period specified in (k) below;

(10) Unless a waiver has been granted, upon inspection, the applicant is not in compliance with RSA 151 or He-P 827;

(11) Unless a waiver has been granted, the department makes a determination that the applicant, administrator, or licensee has been found guilty of or plead guilty to a felony assault, fraud, theft, abuse, neglect, or exploitation of any person, in this or any other state, or had an investigation for abuse, neglect, or exploitation adjudicated and founded by the department or any administrative agency in this or any other state;

(12) The applicant or licensee fails to employ a qualified administrator; or

(13) The applicant has had a license revoked or denied by another division or unit of the department within a 5 year period of the application.

(c) 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 entity;

(2) For a failure to cease operations after a denial of a license, after receipt of an order to cease and desist operations, in violation of RSA 151:2 and RSA 541-A:30, or continuing to operate after a failure to renew the license by the expiration date, the fine for an applicant, unlicensed entity, or a 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, and He-P 827.14(h), the fine for an applicant, licensee, or unlicensed entity shall be $500.00;

(4) For a failure to transfer a patient whose needs exceed the services or programs provided by the FMRTF, in violation of RSA 151:5-a, the fine for a licensee shall be $500.00;

(5) For admission of a patient whose needs at the time of admission exceed the services or programs authorized by the FMRTF licensing classification, in violation of RSA 151:5-a, II, and He-P 827.16(a), the fine for a licensee shall be $1000.00;

(6) 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 827.11(e), the fine for an unlicensed provider or a licensee shall be $500.00;

(7) For a failure to submit a renewal application for a license at least 120 days prior to the expiration date, in violation of He-P 827.06(b), the fine for a licensee shall be $100.00;

(8) For a failure to notify the department prior to a change of ownership, in violation of He-P 827.08(a)(1), the fine for a licensee shall be $500.00;

(9) For a failure to notify the department prior to a change in the physical location, in violation of He P 827.08(a)(2), the fine for a licensee shall be $1000.00;

(10) For a failure to notify the department of a change in e-mail address as required by He-P 827.08(n), the fine for a licensee shall be $100.00;

(11) For a failure to allow access by the department to the FMRTF's premises, programs, services, or records, in violation of He-P 827.09(a), the fine for an applicant, unlicensed entity, or licensee shall be $2000.00;

(12) For a failure to submit a timely POC in violation of He-P 827.12(c)(2), or a timely or acceptable revised POC in violation of He-P 827.12(c)(5), the fine for a licensee shall be $500.00;

(13) For a failure to implement or maintain the corrective action set forth in any POC that has been accepted or issued by the department, in violation of He-P 827.12(c)(8), the fine for a licensee shall be $1000.00;

(14) For a failure to establish, implement, or comply with licensee policies, as required by He-P 827.14(d) and (s), 827.16(c), 827.17(c), (r), and (v), 827.18(H)(2)g. and (x), 827.19(d) and (h), and 827.20(c), (l), and (n), the fine for a licensee shall be $500.00;

(15) For a failure to provide services or programs required by the licensing classification and specified by He-P 827.14(c), the fine for a licensee shall be $500.00;

(16) For providing false or misleading information or documentation, in violation of He-P 827.14(g), the fine for an applicant or licensee shall be $1000.00 per offense;

(17) For a failure to meet the needs of a patient, as described in He-P 827.14(j), the fine for a licensee shall be $1000.00 per patient;

(18) For employing an administrator or other personnel who do not meet the qualifications for the position, without having a waiver granted by the department in accordance with He-P 827.10, in violation of He-P 827.18(h), the fine for a licensee shall be $500.00;

(19) For failure to submit architectural plans or drawings, when applicable, prior to undertaking construction or renovation of the licensed facility in violation of He-P 827.07(a), the fine for a licensed facility shall be $500.00;

(20) For occupying a renovated area of a licensed facility or new construction prior to approval by local and state authorities, as required by He-P 827.09(b)(5), the fine shall be $500 which shall be assessed daily if the facility fails to vacate the renovated area immediately upon receiving notice from the department;

(21) When an inspection determines that there is a violation of RSA 151 or He-P 827 for which a fine was previously imposed, in addition to any other enforcement actions taken by the department, the fines assessed shall be as follows:

a. If the same area of non-compliance is cited within 2 years of the original area of non-compliance, the fine for a licensee shall be $1000.00; or

b. If the same area of non-compliance is cited a third time within 2 years of being fined in a. above, the fine for a licensee shall be $2000.00;

(22) Each day that the individual or licensee continues to be in violation of the provisions of RSA 151 or He-P 827 shall constitute a separate violation and shall be subject to fines in accordance with He-P 827.13(c); and

(23) If the applicant or licensee is making good faith efforts to comply with (4),(6), and (15) above, as verified by documentation or other means, the department shall not issue a daily fine.

(d) 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.

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

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

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

(h) 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 827 is achieved.

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

(j) When a FMRTF's license has been denied or revoked, the applicant, licensee, or administrator shall not be eligible to apply for a license or be employed as an administrator for 5 years if the denial or revocation specifically pertained to their role in the program.

(k) The 5-year period referenced in (j) above shall begin on:

(1) The date of the department's decision to revoke or deny the license, if no appeal is filed; 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.

(l) Notwithstanding (k) 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 827.

(m) If the department has reasonable information or evidence that a licensee, applicant, administrator, or others are circumventing (j) above by applying for a license through an agent or other individual and will retain ownership, management authority, or both, the department shall deny the application.

(n) 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 827.

(o) Any violations cited for fire code shall be appealed to the New Hampshire state fire marshal.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.14 Duties and Responsibilities of the Licensee.

(a) The licensee shall comply with all relevant federal, state, and local laws, rules, codes, and ordinances, as applicable, including RSA 161-F:49 and rules promulgated under CMS regulation at 42 CFR Part 482;

(b) The licensee shall comply with the patients' bill of rights as set forth in RSA 151:19-21.

(c) The licensee shall define, in writing, the scope and type of services to be provided by the FMRTF, which shall include, at a minimum, the required services listed in He-P 827.16.

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

(e) All policies and procedures shall be reviewed per licensee policy.

(f) The licensee shall assess and monitor the quality of care and service provided to patients 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) Except for the requirements of RSA 151:4, III(a)(5), the licensee shall not:

(1) Advertise or otherwise represent itself as operating as a special health care service provider, unless it is licensed; and

(2) Advertise that it provides services that it is not authorized to provide.

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

(j) Licensees shall:

(1) Meet the needs of the patients during those hours that the patients are in the care of the special health care service provider;

(2) Initiate action to maintain the FMRFT 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;

(3) Establish, in writing, a chain of command that sets forth the line of authority for the provision of FMRTF;

(4) Appoint an administrator;

(5) Appoint a medical director;

(6) Appoint a chief of radiation therapy who shall be a medical radiation oncologist or a consulting medical radiation oncologist that meets the qualifications according to He-P 4000;

(7) Appoint a radiation therapy physicist who shall be a qualified medical physicist that meets the qualifications of He-P 4000;

(8) Verify the qualifications of all personnel;

(9) Provide sufficient numbers of qualified personnel who are present in the facility and are qualified to meet the needs of patients during all hours of operation;

(10) Provide the facility with sufficient supplies, equipment, and lighting to meet the needs of the patients; and

(11) Implement any POC that has been accepted by the department.

(k) The licensee shall consider all patients to be competent and capable of making health care decisions unless the patient:

(1) Has a guardian appointed by a court;

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

(3) Is an un-emancipated minor.

(l) The licensee shall not exceed the number of occupants authorized by NFPA 101 as adopted by the commissioner of the department of safety under Saf-C 6000 under RSA 153, and as amended pursuant to RSA 153:5, I, by the state fire marshal with the board of fire control, and identified on the licensing certificate.

(m) If the licensee accepts a patient who is known to have a disease reportable under He-P 301 or an infectious disease, the licensee shall follow the required procedures for the care of the patients, as specified by the Centers for Disease Control and Prevention 2007 “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings,” (June 2007 edition), available as noted in Appendix A.

(n) 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.

(o) The licensee shall implement measures to ensure the safety of patients who are assessed as a danger to self or others.

(p) 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-e;

(2) All inspection reports issued in accordance with He-P 827.09(b), for the previous 12 months;

(3) A copy of the patients' bill of rights;

(4) A copy of the licensee's policies and procedures relative to the implementation of patient rights and responsibilities as required by RSA 151:20;

(5) A copy of the licensee's complaint procedure, including a statement that complaints may be submitted, in writing, to the Department of Health and Human Services, Health Facilities Administration, 129 Pleasant Street, Concord, NH 03301 or by calling 1-800-852-3345, the address and phone number of the department to which complaints may also be made, which shall also be posted on the hospital website if available; and

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

(q) The licensee shall admit and allow any department representative to inspect the premises and all programs and services that are being provided by the licensee at any time for the purpose of determining compliance with RSA 151 and He-P 827 as authorized by RSA 151:6 and RSA 151:6-a.

(r) Licensees shall, in accordance with He-P 827.15:

(1) Report all adverse events to the department as required by He-P 827.15(a)-(c);

(2) Submit additional information if required by the department; and

(3) Report the event to other agencies as required by law.

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

(t) The licensee shall provide cleaning and maintenance services, as needed to protect patients, personnel, and the public.

(u) The building housing the licensee shall comply with all state and local:

(1) Health requirements;

(2) Building ordinances;

(3) Fire ordinances; and

(4) Zoning ordinances.

(v) Smoking shall be prohibited in the facility as required by RSA 155:66, I(b).

(w) If the licensee is not on a public water supply, the water used by the licensee shall be suitable for human consumption, pursuant to Env-DW 702.02 and Env-DW 704.02.

(x) If the licensee holds or manages a patient's funds or possessions, it shall first receive written authorization in accordance with RSA 151:24 and RSA 151:21, VII, and such funds shall not be used for the benefit of the licensee or other patients.

(y) At the time of admission, the licensee shall give a patient and the patient's guardian, agent, or personal representative, a listing of all known applicable charges and identify what care and services are included in the charge.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.15 Adverse Event Reporting.

(a) Pursuant to RSA 151:37, the FMRTF administrator or designee, as a part of the parent hospital, shall report to the department the following adverse events:

(1) Serious reportable events and specifications published in the National Quality Forum's "Serious Reportable Events in Healthcare- 2011 Update" http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69573, available as noted in Appendix A.

(2) Any misadministration as defined in He-P 4047.03(f); and

(3) The exposure of a patient to a non-aerosolized blood borne pathogen by a health care worker's intentional, unsafe act. An act by FMRTF staff resulting in an infection or disease shall be considered to be purposefully unsafe if it meets the following criteria:

a. There was an intentional act or reckless behavior;

b. No reasonable person with similar qualifications, training, and experience would have acted the same way under similar circumstances; and

c. There were no extenuating circumstances that could justify the act.

(b) If the licensee suspects an adverse event occurred, the administrator or designee shall send a report to the department in electronic or paper format, within working 15 days after discovery of event, including:

(1) Provider information;

(2) Patient information;

(3) Event information; and

(4) Type of occurrence as listed in (a) above.

(c) For events reported in (b) above the FMRTF shall within 60 days provide the department:

(1) An analysis that includes the type of harm and contributing factors; and

(2) A corrective action plan that includes what corrective actions are planned, who is responsible for implementation, when the action will be implemented, and what measurements

will be used to evaluate the corrective action plan or the justification for not implementing a corrective action plan if the FMRTF determines that one is not required.

(d) Upon receipt of a report of an adverse event, the department shall:

(1) Acknowledge receipt of event and review information for completeness;

(2) Review corrective action plan for system changes that reduce the risk repeat of similar adverse events;

(3) Communicate specific concerns to the FMRTF if the department does not find the corrective action plan credible;

(4) Track and analyze adverse events for trends, underlying system problems; and

(5) Provide information and make referrals to other state agencies as appropriate.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.16 Required Services.

(a) The licensee shall only provide the services that have been disclosed on its application and have been approved by the department.

(b) If the licensee wishes to provide services other than the ones it is already licensed to provide, the licensee shall submit a letter of intent to provide the additional services, prior to providing the new service(s), to the department which shall include:

(1) A listing of the additional services to be provided;

(2) The physical resources and staffing necessary to provide the additional services;

(3) Floor plans describing change(s) or architectural plans if structural changes are involved;

(4) The date the licensee wishes to start such services; and

(5) Documentation of compliance with the requirements of He-P 827 applicable to the service.

(c) The licensee shall have a policy governing CPR.

(d) The licensee shall establish health and safety services to minimize the likelihood of accident or injury, with protective care and oversight while the patient is at the FMRTF that includes:

(1) Monitoring the patients' functioning, safety, and whereabouts; and

(2) Emergency response and crisis intervention.

(e) All FMRTF laboratories, if applicable, shall comply with He-P 808, He-P 817, and CMS 42 CFR Part 493 – Laboratory Requirements.

(f) There shall be adequate toilet and dressing rooms for patients;

(g) Radiation therapy equipment shall be registered and radioactive material shall be licensed, in accordance with RSA 125-F and shall meet all applicable requirements of He-P 4000;

(h) The technical staff employed by the FMRTF shall perform the service as assigned by the radiation oncologist for the therapeutic uses of radiation, and in accordance with He-P 4000;

(i) The licensee must appoint a chief of radiation oncology who shall be certified in radiation oncology and responsible for:

(1) Overseeing the services provided to ensure safe and quality care;

(2) Ensuring personnel are qualified to perform megavoltage radiation therapy services in accordance with He-P 4000; and

(3) Establishing procedures necessary to ensure the safe and proper use of all therapeutic radiation machines and therapeutic uses of radioactive material in accordance with He-P 4000, including that technologists be trained and licensed commensurate to their duties in the operation and use of x-ray or radiation therapy equipment;

(j) A radiation oncologist shall supervise the therapeutic uses of radiation, including the use of radiation therapy machines, in accordance with He-P 4000;

(k) A licensee providing treatment on megavoltage radiation therapy equipment shall ensure the provision of a comprehensive coordinated care plan which may include:

(1) Clinical oncology services, including chemotherapy and surgical treatment of tumors and follow-up capabilities;

(2) Services of a tumor registry;

(3) Services of a simulation capability and dose computation equipment;

(4) Services of a pathology laboratory;

(5) Services of a physics laboratory or equivalent;

(6) Computerized tomography, magnetic resonance imaging, and position emission tomography capability;

(7) Social work and counseling;

(8) Brachytherapy or a referral arrangement for provision of the service;

(9) Nutrition and dietary consultation; and

(10) In-house capabilities encompassing the full range of radiation therapy modalities, including megavoltage equipment and superficial treatment equipment and systemic therapy or referral arrangements for the provision of these services.

(l) All licensees providing megavoltage radiation therapy shall have sufficient personnel to meet the needs of the patients.

(m) No licensee shall provide megavoltage radiation therapy services unless the program will treat a minimum of 200 patients on an annual basis by the end of the third year of operation. This may be demonstrated by the number of claims the licensee files in any twelve-month period for cognitive planning process codes;

(n) Any licensee holding a special health care service license to provide megavoltage radiation therapy services outside of a hospital shall adopt protocols for the transportation of patients for the provision

of necessary support and emergency services, which shall include a written agreement for the acceptance and transfer of patients needing such emergency care, with the nearest acute care hospital or any acute care hospital within 30 minutes travel time.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.17 Medication Services.

(a) All medications shall be made available to the patient in accordance with the written and signed orders of the licensed practitioner or other professional with prescriptive powers.

(b) All medications and treatments shall be reviewed and signed by a licensed practitioner at each visit or when indicated by a change in the patient's condition.

(c) The licensee shall have a written policy and system in place instructing how to:

(1) Obtain and store any medication ordered for use at the FMRTF;

(2) Reorder medications for use at the FMRTF; and

(3) Receive and record new medication orders.

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

(1) The patient's name;

(2) The medication name, strength, prescribed dose, and route, if different than by mouth;

(3) The frequency of administration;

(4) The indications for usage, to include the maximum allowed dose in a 24-hour period, for all medications that are used PRN; and

(5) The dated signature of the ordering practitioner as allowed by He-P 827.03(bd).

(e) Except for pharmaceutical samples, each prescription medication container and medication record together shall collectively legibly display the following information in such a way so as to clearly identify the intended recipient:

(1) The patient'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 practitioner; and

(7) The expiration date of the medication(s).

(f) Pharmaceutical samples shall be used in accordance with the licensed practitioner's written order and labeled by the licensed practitioner, the administrator, licensee, or their designee, with the patient's name, and shall be exempt from (e)(2)-(6) above.

(g) The dosage, frequency, and route of administration on the labels of all prescription medications for each patient shall be identical to the dosage, frequency, and route of administration on the facility medication record except as allowed by (i) or (j) below.

(h) The change in the dose of a medication, or the discontinuation of a medication, shall be authorized in writing by a licensed practitioner and the FMRTF shall indicate in writing, in the medication record, the date the change in dose or the discontinuance occurred.

(i) Only a pharmacist shall make changes to prescription medication container labels except as allowed by (j) below.

(j) When the licensed practitioner or other professional with prescriptive powers changes the dose and personnel are unable to obtain a new prescription label, the original container shall be clearly marked without obstructing the pharmacy label to indicate a change in the medication order.

(k) Only a licensed nurse shall accept telephone orders for medications, treatments, and therapeutic diets, and the licensed nurse shall immediately transcribe and sign the order.

(l) The transcribed order in (k) above shall be counter-signed by the authorized prescriber within 30 days of receipt.

(m) No medications shall be given to or taken by a patient until a written order is received, except as allowed by (k) and (l) above.

(n) The medication storage area for medications shall be:

(1) Locked and accessible only to authorized personnel;

(2) Clean and organized with adequate lighting to ensure correct identification of each patient's medication(s); and

(3) Equipped to maintain medication at the proper temperature.

(o) All medication at the FMRTF shall be kept in the original containers as dispensed by the pharmacy and properly closed after each use.

(p) 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.

(q) If controlled substances, as defined by RSA 318-B, are stored in a central storage area in the FMRTF, they shall be kept in a separately locked compartment within the locked medication storage area accessible only to authorized personnel.

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

(s) Except as required by (t) below, any contaminated, expired, or discontinued medication shall be destroyed within 30 days following the expiration date, the date a licensed practitioner discontinued the order, or the medication becomes contaminated, whichever occurs first.

(t) Destruction of contaminated, expired, or discontinued controlled drugs shall:

(1) Be in accordance with all applicable standards of practice;

(2) Be accomplished in the presence of at least 2 people who shall sign, date, and record the amount destroyed; and

(3) Be documented in the record of the patient for whom the drug was prescribed.

(u) The licensee shall maintain a written record for each medication taken by a patient at the FMTRF that contains the following information:

(1) Any allergies or adverse 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 patient taking medication;

(5) For PRN medications, the reason the patient required the medication, and the effect of the PRN medication; and

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

(v) The facility shall have a written policy that incorporates the requirements listed in (t) through (v) for use in training and for reference by employees supervising medication administration.

(w) The licensee shall report any adverse reactions and side effects to medications or treatments, or any medication or treatment errors, to the patient's licensed practitioner immediately but not to exceed 24 hours depending on the severity of the reaction or error, and shall document in the patient's record the reaction, the error, and date, time, and person notified.

(x) An FMRTF shall have written orders from the licensed practitioner for all medications being taken by patients while under the care of the FMRTF.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.18 Personnel.

(a) The licensee shall ensure that sufficient numbers of qualified personnel are present at the FMTRF to meet the needs of patients.

(b) For all applicants for employment, for all volunteers, and for all independent contractors who will provide direct care to patients or who will be unaccompanied by an employee while performing non-direct care within the facility, the licensee shall:

(1) Obtain and review a criminal records check from the New Hampshire department of safety, except, pursuant to RSA 151:2-d, VI, for those licensed by the New Hampshire board of nursing;

(2) Review the results of the criminal records check in (1) above in accordance with (e) below; and

(3) Verify the qualifications of all applicants prior to employment; and

(4) Check the names of the persons in (b) above against the bureau of elderly and adult services (BEAS) state registry maintained pursuant to RSA 161-F:49 and He-E 720 and the NH board

of nursing, nursing assistant registry, maintained pursuant to RSA 326-B:26 and 42 CFR 483.156.

(c) Unless a waiver is granted in accordance with (e)(2) below, the licensee shall not offer employment, contract with, or engage a person in (b) above if the person:

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

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

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

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

(d) If the information identified in (c) above regarding any person in (b) above is learned after the person is hired, contracted with, or engaged, the licensee shall immediately notify the department and either:

(1) Cease employing, contracting with, or engaging the person; or

(2) Request a waiver of (c) above.

(e) If a waiver of (c) above is requested, the department shall review all relevant information and the underlying circumstances and either:

(1) Notify the licensee that the person cannot or can no longer be employed, contracted with, or engaged by the licensee if, after investigation, it determines that the person poses a threat to the health, safety, or well-being of patients; or

(2) Grant a waiver of (c) above if, after investigation, it determines that the person does not pose a current threat to the health, safety, or well-being of patients.

(f) The licensee shall:

(1) Not employ, contract with, or engage, any person in (b) above who is listed on the BEAS state registry unless a waiver is granted by BEAS; and

(2) Only employ, contract with, or engage board of nursing licensees who are listed on the licensing site with the New Hampshire board of nursing or with a compact state.

(g) In lieu of (b) above, the licensee may accept from independent agencies contracted by the licensee a signed statement that the agency's employees have complied with (b) and do not meet the criteria in (c) and (f)(1) above.

(h) Each FMRTF shall have a full time administrator who:

(1) Has a master's degree from an accredited institution and at least 4 years of experience working in a health related field or has a bachelor's degree from an accredited institution and at least 8 years of experience working in a health related field; and

(2) Shall be responsible to the governing body for the daily management and operation of the FMRTF including:

a. Management and fiscal matters;

b. The employment and termination of managers and staff necessary for the efficient operation of the FMRTF;

c. The designation of an alternate, in writing, who shall be responsible for the daily management and operation of the FMRTF in the absence of the administrator;

d. To serve as a liaison to the parent hospital;

e. The planning, organizing, and directing of such other activities as may be delegated by the parent hospital;

f. The delegation of responsibility to subordinates as appropriate;

g. Ensuring development and implementation of hospital policies and procedures on:

1. Patient's rights as required by RSA 151:20;

2. Advanced directives as required by RSA 137-J;

3. Discharge planning as required by RSA 151:26;

5. Withholding of resuscitative services from patients pursuant to RSA 137-H and RSA 137-J;

6. Adverse event reporting; and

7. Any other policies and procedures required by law or rule; and

h. Notifying the department, directly or through delegation, as specified in He-P 827.15 of any adverse event involving a patient.

(i) All administrators shall obtain and document 12 hours of continuing education related to the operation and services of the FMRTF each annual licensing period, in accordance with (p) and (q) below.

(j) All direct care personnel shall be at least 18 years of age unless they are:

(1) A licensed nursing assistant working under the supervision of a nurse in accordance with Nur 700; or

(2) Involved in an established educational program working under the supervision of a nurse or radiation therapist.

(k) The licensee shall inform personnel of the line of authority at the FMRTF.

(l) The licensee shall educate personnel about the needs and services required by the patients under its care.

(m) Prior to having contact with patients, personnel shall:

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

(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 and Prevention "Guidelines for Preventing the Transmission of M. tuberculosis in Health-Care Settings" (2005 edition), available as noted in Appendix A, 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.

(n) In lieu of (m)(1) and (3) above, independent agencies contracted by the facility to provide direct care may provide the licensee with a signed statement that its employees have complied with (m)(1) and (3) above before working at the FMRTF.

(o) Prior to having contact with patients, personnel shall receive a tour of and orientation to the FMRTF that includes the following:

(1) The patient's rights in accordance with RSA 151:20;

(2) The FMRTF patient complaint procedures;

(3) The duties and responsibilities of the position;

(4) The emergency medical procedures;

(5) The emergency and evacuation procedures;

(6) The infection control procedures as required by He-P 827.20;

(7) The facility confidentiality requirements;

(8) The grievance procedures for both staff and patients; and

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

(p) 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 patients' rights and complaint procedures required under RSA 151;

(2) The licensee's infection control program;

(3) The licensee's written emergency plan;

(4) The licensee's policies and procedures; and

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

(q) The FMRTF or parent hospital shall maintain a separate employee file for each employee, which shall include the following:

(1) A completed application for employment or a resume;

(2) Proof that the individual meets the minimum age requirements;

(3) A statement signed by each individual that he or she has received a copy of and received training on the implementation of the licensee's policy setting forth the patient's rights and responsibilities as required by RSA 151:21;

(4) A copy of the results of the criminal record check as described in (b) above;

(5) A job description signed by the individual that identifies the:

a. Position title;

b. Qualifications and experience; and

c. Duties required by the position;

(6) Record of satisfactory completion of the orientation program required by (p) above;

(7) Information as to the general content and length of all in-service or educational programs attended;

(8) Record of satisfactory completion of all required education programs and demonstrated competencies that are signed and dated by the employee;

(9) A copy of each current driver's license, including proof of insurance, if the employee transports patients using their own vehicle;

(10) Documentation that the required physical examinations or health screenings, TB test results, and radiology reports of chest x-rays, if required, have been completed by the appropriate health professionals;

(11) The statement required by (w) below; and

(12) The results of the registry checks in (h) above.

(r) Personnel records may be stored at a parent hospital provided that:

(1) The personnel record is available to the department at the licensed premises within 2 hours of being requested; and

(2) The records are maintained in accordance with (q) above.

(s) The FMRTF shall maintain the records for all volunteers, and for all independent contractors who provide direct care to patients or who will be unaccompanied by an employee while performing non-direct care services within the facility, as follows:

(1) For volunteers, the information in (q)(1), (3), (4), (6), and (8)-(12) above; and

(2) For independent contractors, the information in (q)(3), (4), (6), and (8)-(12) above, except that the letter in (g) and (n) above may be substituted for (q)(4), (10), and (12) above, if applicable.

(t) All personnel shall sign a statement at the time the initial offer of employment, contract, or engagement 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, theft, fraud, abuse, neglect, or exploitation or pose a threat to the health, safety, or well-being of a patient; and

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

(u) An individual shall not have to re-disclose any of the matters in (t) above if the documentation is available and the department has previously reviewed the material and determined that the individual can continue employment, contract, or engagement.

(v) The licensee shall protect and store in a secure and confidential manner all records described in (q) and (r) above.

(w) Personnel shall not be impaired while on the job by any substances including, but not limited to, legally prescribed medication, therapeutic cannabis, or alcohol.

(x) The FMRTF shall have a written policy, as described in RSA 151:41, establishing procedures for the prevention, detection, and resolution of controlled substance abuse, misuse, and diversion, which shall apply to all personnel, and which shall be the responsibility of a designated employee or interdisciplinary team.

(y) The policy in (x) above shall include:

(1) Education;

(2) Procedures for monitoring the distribution and storage of controlled substances;

(3) Voluntary self-referral by employees who are addicted;

(4) Co-worker reporting procedures;

(5) Drug testing procedures to include at a minimum, testing where reasonable suspicion exists;

(6) Employee assistance procedures;

(7) Confidentiality;

(8) Investigation, reporting, and resolution of controlled drug misuse or diversion; and

(9) The consequences for violation of the controlled substance abuse, misuse, and diversion prevention policy.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.19 Patient Records.

(a) The licensee shall maintain a legible, current, and accurate record for each patient receiving the services provided at the FMRTF.

(b) At a minimum, patient records shall contain the following:

(1) Identification data, including:

a. The patient's name, date of birth, and marital status;

b. Home address and telephone number;

c. Name, address, and telephone number for an emergency contact person;

d. Patient's veteran status, if known; and

e. Guardian or agent, if applicable;

(2) The name and telephone number of the patient's licensed practitioner(s);

(3) A signed acknowledgment of receipt of patient bill of rights by the patient, guardian, or agent;

(4) If services are provided at the FMRTF by individuals not employed by the licensee, documentation that includes the name of the agency or individual providing the services, the date services were provided, a brief summary of the services provided, and the business address and telephone number;

(5) Patient's health insurance information;

(6) A written or electronic record of a health examination by a licensed practitioner;

(7) Copies of any executed legal orders and directives, such as guardianship orders issued under RSA 464-A, a durable power of attorney for healthcare, or a living will;

(8) Written, dated, and signed orders for the all medications, treatments, and therapeutic diets ordered at the FMRTF;

(9) Copies of the patient's consent for treatment and DNR;

(10) Results of any laboratory tests, X-rays, or consultations performed at FMRTF;

(11) All assessments and care plans, and documentation that the patient and the guardian or agent, if any, has participated in the development of the care plan;

(12) The consent for release of information signed by the patient, guardian, or agent, if any;

(13) All consult and progress notes;

(14) Documentation of medical, nursing, or other specialized care, as applicable;

(15) Documentation of reportable incidents;

(16) The consent for release of information signed by the patient, guardian, or agent, if any;

(17) Discharge planning and referrals;

(18) The medication record as required by He-P 827.17(u);

(19) Documentation of any accident or injuries occurring while in the care of the facility and requiring medical attention by a practitioner; and

(20) Documentation of a patient's refusal of any care or services.

(c) Patient records and information shall be kept confidential and only provided in accordance with all applicable federal and state law.

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

(e) When not being used by authorized personnel, patient records shall be safeguarded against loss or unauthorized use or access.

(f) A licensee shall, upon request, provide a patient or the patient's guardian or agent, if any, with a copy of his or her patient record pursuant to the provisions of RSA 151:21.

(g) All personnel records required for licensing shall be legible, current, accurate, and available to the department during an inspection or investigation conducted in accordance with RSA 151:6 and RSA 151:6-a.

(h) Any licensee that maintains electronic records shall develop written policies and procedures designed to protect the privacy of patients 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 patients and staff; and

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

(i) Patient records shall be retained 7 years after discharge of a patient, and in the case of minors, patient records shall be retained until at least one year after reaching age 18, but in no case shall they be retained for less than 7 years after discharge.

(j) The licensee shall arrange for storage of, and access to, patient records in the event the FMRTF ceases operation.

(k) Electronic records shall be maintained according to current HIPAA regulations to ensure confidentiality and adequate security.

(l) If the facility uses an electronic record storage system, it shall provide computer access to all patient records for the purpose of verifying compliance with all provisions of RSA 151 and He-P 827 for the onsite inspection. Access shall include assistance navigating the database and printing portions of the record, if needed.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.20 Infection Control.

(a) The licensee 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 FMRTF shall appoint an individual who will oversee the development and implementation of the infection control program.

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

(1) Proper hand washing techniques;

(2) The utilization of universal precautions;

(3) The management of patients with infectious or communicable diseases or illnesses;

(4) The handling, storage, transportation, and disposal of those items identified as infectious waste in Env-Wm 2604;

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

(6) Evaluating and revising the infection control program in accordance with current CDC recommended actions;

(7) Maintenance of a sanitary physical environment; and

(8) Infection control policies specific to each department.

(d) The infection control education program shall be completed by all new employees, all current employees, and all contracted employees on an annual basis and 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.

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

(f) Personnel infected with scabies or lice shall not provide direct care to patients until such time as they are no longer infected as determined by a licensed practitioner.

(g) Pursuant to RSA 141-C:1, personnel with a newly positive TB test or a diagnosis of suspected active pulmonary or laryngeal tuberculosis shall be excluded from the FMRTF 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.

(h) Personnel with an open wound who provide direct care in any capacity shall cover the wound at all times by an impermeable, durable, fitted bandage.

(i) If the FMRTF has an incident of an infectious diseases reported in (c)(5) above, the facility shall contact the public health nurse in the county in which the facility is located and follow the instructions and guidance of the nurse.

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

(k) If a licensee offers influenza or pneumococcal immunizations for patients or staff, the licensee shall document the administration of the immunization as applicable, and such report immunization data to the department’s immunization program.

(l) The FMRTF shall develop and implement a point of care testing policy, if they provide POCT that educates and provides procedures for the proper handling and use of POCT devices, as well as prevention, control, and investigation of infectious and communicable diseases.

(m) The licensee shall have available space, supplies, and equipment for proper handling of suspected or actual infectious conditions.

(n) The licensee shall have a policy requiring employees to make a report to the infection control officer if the employee suspects that they, another employee, or patient has a communicable disease.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.21 Sanitation.

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

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

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

(d) 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 patients.

(e) All patient toileting facilities shall be cleaned and disinfected as often as necessary to prevent illness or contamination.

(f) 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 medications and program supplies.

(g) Toxic materials shall not be used in a way that contaminates equipment or in any way other than in full compliance with the manufacturer's labeling.

(h) Only individuals authorized under RSA 430:33 may apply pesticides, as defined by RSA 430:29, XXVI, for rodent or cockroach control.

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

(j) 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.

(k) Bathrooms shall have non-porous floors.

(l) Sterile or clean supplies shall be stored in dust and moisture-free storage areas or containers.

(m) If equipment or supplies need to be sterilized in order to prevent contamination, the FMRTF shall develop and maintain written procedures for cleaning, packaging, and sterilization that includes:

(1) Testing and documenting sterilization processes used;

(2) Testing and documenting the effectiveness of sterilization equipment for adequate sterilization in accordance with the manufacturer's recommendations or using industry acceptable quality control standards;

(3) Documentation when supplies are outdated; and

(4) Ensuring that all sterile packages are stored separately from non-sterile supplies in an enclosed area.

(n) Any FMRTF that has its own water supply and whose water has been tested and failed to meet the acceptable levels identified in this section, or as required by the department of environmental services, shall notify the department.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.22 Quality Improvement.

(a) The FMRTF shall develop and implement a quality improvement program that reviews policies and services and maximizes quality by preventing or correcting identified problems.

(b) The FMRTF shall determine the size and composition of the quality improvement committee based on the size of the facility and the care and services provided.

(c) The quality improvement committee shall:

(1) Determine the information to be monitored;

(2) Determine the frequency with which information will be reviewed;

(3) Determine the indicators that will apply to the information being monitored;

(4) Evaluate the information that is gathered;

(5) Determine the action that is necessary to correct identified problems;

(6) Recommend corrective actions to the FMRTF;

(7) Evaluate the effectiveness of the corrective actions and determine additional corrective action as applicable;

(8) Meet at least quarterly;

(9) Generate dated, written minutes after each meeting; and

(10) Documentation of all quality improvement activities, including minutes of meetings, shall be maintained on-site for at least 2 years from the date the record was created.

(d) Mandatory monitoring of radiological safety practice standards according to He-P 4000 shall be part of the quality improvement program.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.23 Physical Environment.

(a) The physical environment shall be maintained, inside and outside, so as to provide for the health, safety, well-being, comfort, and privacy of patients and personnel, including reasonable accommodations for patients and personnel with mobility limitations.

(b) The FMRTF shall:

(1) Have all emergency entrances and exits accessible at all times;

(2) Be maintained in good repair and kept free of hazards to personnel and patients, including but not limited to hazards from falls, burns, or electric shocks;

(3) Be free from environmental nuisances, including excessive noise and odors;

(4) Keep all corridors free from obstructions; and

(5) Take reasonable measures to prevent the presence of rodents, insects, and vermin to include but not limited to:

a. Repairing holes and caulking of pipe channels; and

b. Extermination by a pesticide applicator licensed under RSA 430.

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

(1) Maintain a temperature of at least 70 degrees fahrenheit during the day if patients 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.

(d) Electric heating systems shall be exempt from (c)(2) above.

(e) Portable space heating devices shall be prohibited, unless the following conditions 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.

(f) Unvented fuel-fired heaters shall not be used in any FMRTF.

(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 enclosed areas by means of a mechanical ventilation system or one or more screened windows that can be opened.

(i) All hand-washing facilities shall be provided with hot and cold running water.

(j) In accordance with RSA 155:66, I(b), smoking shall be prohibited in the FMRTF.

(k) Each FMRTF shall have a bathroom with a toilet, a hand washing sink, soap dispenser, paper towels or a hand-drying device providing heated air, and hot and cold running water.

(l) Notwithstanding (k) above, if the FMRTF is located within a multi-use business or facility that has a public bathroom with a toilet and the bathroom complies with all applicable sanitation and construction regulations, the facility shall not be required to have its own bathroom but shall have its own hand washing sink with hot and cold running water, soap dispenser, and paper towels or a hand-drying device providing heated air.

(m) There shall be sufficient space and equipment for the services provided at the FMRT facility.

(n) All exam tables shall be changed with clean linens or common paper between use by different patients.

(o) The licensee shall provide patients with continuous access to a device or means that will signal FMRTF personnel when they are in need of assistance.

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

(q) If available, all showers and tubs shall have slip resistant floors and surfaces which are intact, easily cleanable, and impervious to water.

(r) All mattresses and new upholstered furniture or draperies shall comply with the applicable portions of Saf-C 6000, as amended pursuant to RSA 153:5, I, by the state fire marshal with the board of fire control.

(s) A privacy partition, curtain, or screen shall be required between patient care areas.

(t) The FMRTF facility shall keep all entrances and exits to the licensed premises accessible at all times during hours of operation.

(u) The FMRTF facility shall be clean, sanitary, maintained in a safe manner and good repair, and kept free of hazards.

(v) The FMRTF facility shall provide the following:

(1) Reception and waiting areas that include a reception desk or counter, chairs, tables, and lighting adequate to read materials and complete forms as required;

(2) Public access to toilet facilities with non-porous floors;

(3) A number of examination and treatment rooms adequate to provide services to the average number of patients seen daily; and

(4) Hot water available at all times from taps available to patients and not less than 105 degrees Fahrenheit or more than 120 degrees Fahrenheit.

(w) Medical waste shall be disposed of in accordance with the requirements of Env-Sw 904.

(x) Except as described in (b) above, the FMRTF facility shall comply with all federal, state and, local health, building, fire, and zoning laws, rules, and ordinances.

(y) The water used in the FMRTF facility shall be suitable for human consumption, pursuant to Env-Ws 315 and Env-Ws 316.

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

(1) Zoning;

(2) Building;

(3) Health;

(4) Fire;

(5) Waste disposal; and

(6) Water.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.24 Fire Safety.

(a) All FMRTF shall have:

(1) Smoke detectors on every level that are interconnected and either hardwired, powered by the FMRTF's electrical service, or wireless, as approved by the state fire marshal.

(2) At least one UL Listed, ABC type portable fire extinguisher, with a minimum rating of 2A-10BC, installed on every level of the building, and which meets the following requirements:

a. Maximum travel distance to each extinguisher shall not exceed 50 feet;

b. Fire extinguishers shall be inspected either manually or by means of an electronic monitoring device or system at least once per calendar month, at intervals not exceeding 31 days;

c. Records for manual inspection or electronic monitoring shall be kept to demonstrate that at least 12 monthly inspections have been performed for the most recent 12-month period;

d. Annual maintenance shall be performed on each extinguisher by trained personnel, and each extinguisher shall have a tag or label securely attached that indicates that maintenance was performed; and

e. The components of the electronic monitoring device or system shall be tested and maintained annually in accordance with the manufacturer's listed maintenance manual; and

(3) An approved carbon monoxide monitor on every level.

(b) A fire safety program shall be developed and implemented to provide for the safety of patients and personnel.

(c) 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.

(d) The written notification required by (c) 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 patients who were evacuated as a result of the incident, if applicable;

(5) The name of any personnel or patients 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.

(e) The fire safety plan shall be reviewed and approved as follows:

(1) A copy of the fire safety plan shall be made available, annually and whenever changes are made, to the local fire chief for review and approval;

(2) The local fire chief shall give written approval initially to all fire safety plans; and

(3) If changes are made to the plan, they shall be submitted to the local fire chief for review and approval, as appropriate, prior to the change.

(f) Fire drills shall be conducted as follows:

(1) For buildings constructed to the health care occupancy chapter of the life safety code and to the rules and regulations adopted and enforced by the state fire marshal's office and/or the municipality, or which have been physically evaluated, rehabilitated, and approved by a New Hampshire licensed fire protection engineer, the state fire marshal's office, and the department to meet the health care occupancy chapter, the following shall be required:

a. The facility shall develop a fire safety plan, which provides for the following:

1. Use of alarms;

2. Transmission of alarms to fire department;

3. Emergency phone call to fire department;

4. Response to alarms;

5. Isolation of fire;

6. Evacuation of immediate area;

7. Evacuation of smoke compartment;

8. Preparation of floors and building for evacuation;

9. Extinguishment of fire; and

10. Written emergency telephone numbers for key staff, fire and police departments, poison control center, 911, and ambulance service(s);

b. Fire drills shall be conducted quarterly on each shift to familiarize facility personnel including, but not limited to, medical personnel, maintenance engineers, and administrative staff, with the signals and emergency action required under varied conditions;

c. Fire drills shall include the transmission of a fire alarm signal and simulation of emergency fire conditions;

d. Buildings that have a shelter in place, also known as defend in place, shall have this plan approved by the department and their local fire chief and shall be constructed to meet the health care occupancy chapter of the life safety code;

e. Facilities shall complete a written record of fire drills and include the following:

1. The date and time including AM/PM the drill was conducted and if the actual fire alarm system was used;

2. The location of exits used;

3. The number of people, including patients, personnel, and visitors, participating at the time of the drill;

4. The amount of time taken to completely evacuate the facility or to an approved area of refuge or through a horizontal exit;

5. The name and title of the person conducting the drill;

6. A list of problems and issues encountered during the drill;

7. A list of improvements and resolution to the issues encountered during the fire drill; and

8. The names of all staff members participating in the drill; and

f. At no time shall a staff member who has not participated in a fire drill be the only staff member on duty within the facility; and

(2) The facility shall conduct a fire drill in the presence of a representative of the department, state fire marshal's office, or the local fire department upon request.

(g) For the use and storage of oxygen and other related gases, a FMRTF shall comply with NFPA 99 as adopted by the commissioner of the department of safety under Saf-C 6000, as amended pursuant to RSA 153:5, I, by the state fire marshal with the board of fire control, including, but not limited to, the following:

(1) All freestanding compressed gas cylinders shall be firmly secured to the adjacent wall or secured in a stand or rack;

(2) Storage locations shall be outdoors in an enclosure or within an enclosed interior space of noncombustible or limited-combustible construction, with doors, or with gates if outdoors, that can be secured against unauthorized entry;

(3) Oxidizing gases, such as oxygen and nitrous oxide, shall:

a. Not be stored with any flammable gas, liquid, or vapor;

b. Be separated from combustibles or incompatible materials by:

1. A minimum distance of 20 ft. (6.1 m);

2. A minimum distance of 5 ft. (1.5 m) if the entire storage location is protected by an automatic sprinkler system designed in accordance with NFPA 13, Standard for the Installation of Sprinkler Systems; or

3. An enclosed cabinet of noncombustible construction having a minimum fire protection rating of 1/2 hour; and

c. Shall be secured in an upright position, such as with racks or chains;

(4) A precautionary sign, readable from a distance of 5 ft. (1.5 m), shall be conspicuously displayed on each door or gate of the storage room or enclosure, and shall include, at a minimum, the following: "CAUTION, OXIDIZING GAS(ES) STORED WITHIN - NO SMOKING"; and

(5) Precautionary signs, readable from a distance of 5 ft. (1.5 m), and with language such as "OXYGEN IN USE, NO SMOKING", shall be conspicuously displayed wherever supplemental oxygen is in use and in aisles and walkways leading to the area of use, and shall be attached to adjacent doorways or to building walls or be supported by other appropriate means.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19

He-P 827.25 Emergency Preparedness.

(a) Each facility shall have an individual or group, known as an emergency management committee, with the authority for developing, implementing, exercising, and evaluating the emergency management program.

(b) The emergency management committee shall include the facility administrator and others who have knowledge of the facility and the capability to identify resources from key functional areas within the facility and shall solicit applicable external representation, as appropriate.

(c) An emergency management program shall include, at a minimum, the following elements:

(1) The emergency management plan, as described in (d) and (e) below;

(2) The roles and responsibilities of the committee members; and

(3) How the plan is implemented, exercised, and maintained;

(d) The emergency management committee shall develop and institute a written emergency preparedness plan (plan) to respond to a disaster or an emergency.

(e) The plan in (d) above shall:

(1) Include site-specific plans for the protection of all persons on-site in the event of fire, natural disaster, or severe weather and human-caused emergency to include, but not be limited to, bomb threat;

(2) Be approved by the local emergency management director and reviewed and approved, as appropriate, by the local fire department;

(3) Be available to all personnel;

(4) Be based on realistic conceptual events;

(5) Be modeled on the Incident Command System (ICS) in coordination with local emergency response agencies;

(6) Provide that all personnel designated or involved in the emergency operations plan of the facility shall be supplied with a means of identification, such as vests, baseball caps, or hard hats, which shall be worn at all times in a visible location during the emergency;

(7) Develop and implement a strategy to prevent an incident that threatens life, property, and the environment of the facility;

(8) Develop and implement a mitigation strategy that includes measures to be taken to limit or control the consequences, extent, or severity of an incident that cannot be prevented;

(9) Develop and implement a protection strategy to protect life, property, and the environment from human caused incidents and events and from natural disasters;

(10) For (7)-(9) above, incorporate the findings of a hazard vulnerability assessment, the results of an analysis of impact, program constraints, operational experience, and cost-benefit analysis

to provide strategies that can realistically be implemented without requiring undue expenses to the facility;

(11) Conduct a facility-wide inventory and review, to include the property that the facility is located on, to determine the status of hazards that may be incorporated into the prevention, protection, and mitigation strategies and to determine the outcome of prior strategies at least an annually;

(12) Include the facility's response to both short-term and long-term interruptions in the availability of utility service in the disaster or emergency, including establishing contingency plans for continuity of essential building systems or evacuation to include the following, as applicable:

a. Electricity;

b. Potable water;

c. Non-potable water;

d. HVAC;

e. Fire protection systems;

f. Fuel required for building operations to include fuel loss, fuel spill, and fuel exposure that creates a hazardous incident;

g. Fuel for essential transportation to include fuel loss, fuel spill, and fuel exposure that creates a hazardous incident;

h. Medical gas and vacuum systems, if applicable;

i. Communications systems; and

j. Essential services, such as kitchen and laundry services;

(13) Include a plan for alerting and managing staff in a disaster, and accessing Critical Incident Stress Management (CISM), if necessary;

(14) Identify a designated media spokesperson to issue news releases and an area where the media can be assembled, where they will not interfere with the operations of the facility;

(15) Reflect measures needed to restore operational capability with consideration of fiscal aspects because of restoration costs and possible cash flow losses associated with the disruption;

(16) Include an educational, competency-based program for the staff, to provide an overview of the components of the emergency management program and concepts of the ICS and the staff's specific duties and responsibilities; and

(17) If the facility is located within 10 miles of a nuclear power plant and is part of the New Hampshire Radiological Emergency Response Plan (RERP), include the required elements of the RERP.

Source. (See Revision Note at part heading for He-P 827) #12751, eff 3-26-19