

Proposed changes to 105 CMR 145.000, Licensing of Out-of-Hospital Dialysis Units in
Massachusetts

Bold blue=new language

~~Red-strikethrough~~=deleted language

Regular text=existing language

105 CMR 145.000: LICENSING OF OUT-OF-HOSPITAL DIALYSIS UNITS IN
MASSACHUSETTS

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145.001: Purpose

The purpose of 105 CMR 145.000 is to provide for the protection of the health and safety of individuals receiving dialysis in out-of-hospital dialysis units.

145.002: Authority

105 CMR 145.000 is adopted under authority of M.G.L. c. 111, §§ 3, 51A and 53.

~~145.003: Citation~~

~~105 CMR 145.000 shall be known, and may be cited 105 CMR 145.000: Licensing of Out-of-Hospital Dialysis Units in Massachusetts.~~

145.010: Scope

(A) Procedures Permitted in an Out-of-Hospital Dialysis Unit. The unit shall provide chronic maintenance dialysis **and/or home training** on the premises as set forth in 105 CMR 145.050 through 145.980 and also if permitted under the terms of its license, a home dialysis program as set forth in 105 CMR 145.800 through 145.850.

(B) Procedures Not Permitted in an Out-of-Hospital Dialysis Unit. No unit shall provide acute dialysis or any other service which under 105 CMR 130.000 may be provided only

at a hospital, ~~N~~nor shall any unit engage in any activity ~~which that~~ is permitted only at long-term care facilities or duties under 105 CMR 150.000.

145.020: Definitions

Back-up dialysis means dialysis given to a patient in a situation other than the patient's usual dialysis environment.

Chronic maintenance dialysis means the usual periodic dialysis treatments of a patient who has chronic renal disease ~~in order to sustain life and ameliorate uremic symptoms.~~

Commissioner means the Commissioner of Public Health ~~or his or her designee appointed under M.G.L. c. 17, § 2.~~

Department means the Department of Public Health ~~which, by law (M.G.L. c. 17, § 1), consists of the Commissioner and the Public Health Council appointed under M.G.L. c. 17, § 3.~~

~~Direct Care means initiating and discontinuing dialysis, monitoring patients during treatment, and administering medications.~~

Direct Care Staff means registered nurses, licensed practical nurses, and trained dialysis technicians who provide direct care to patients undergoing dialysis in the unit. Direct care staff may include charge nurses, but shall not include the director of nurses, nurses assigned to dialysis training, or technicians assigned to dialyzer preparation or reuse, equipment maintenance, and water testing and purification.

~~Division of hospital and ambulatory care or Division means the program of the Department with the responsibility for administering the provisions of M.G.L. c. 111, §§51 through 54 and 56, and of related laws.~~

Governing body means, in the case of a corporation, the board of directors, or an executive committee thereof empowered under the by-laws of the corporation to supervise the operation of the unit; or in every other case, the owner and such other individuals as are associated with the owner in the management of the unit.

Healthcare-associated Infection (HAI), means a localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that:

- (1) occurs in a patient in an out-of-hospital dialysis unit; and
- (2) was not present or incubating at the time of the admission during which the reaction occurs;
- (3) meets the criteria for a specific infection as defined by the federal Centers for Disease Control and Prevention and its National Healthcare Safety Network; and

(4) any additional elements as set forth in administrative guidelines of the Department based on the National Healthcare Safety Network.

Home dialysis means chronic maintenance dialysis performed ~~in the patient's~~ at home by a trained patient with the assistance of a trained partner.

Licensed or approved hospital means any hospital licensed under M.G.L. c. 111, § 51, ~~or approved as a public medical institution under M.G.L. c. 118E, § 2.~~

Licensed practical nurse means an individual who is currently licensed pursuant to M.G.L. c. 112, § 74A, to practice practical nursing in Massachusetts.

National Healthcare Safety Network (NHSN) means the HAI tracking system- by the federal Centers for Disease Control and Prevention.

Original license means the first license issued to a person to maintain the premises named therein, whether upon the initial establishment of the unit or subsequently upon the relocation or transfer of ownership of the unit.

Out-of-hospital dialysis unit or Unit means a unit, however named, maintained separate from a licensed or approved hospital or license issued thereto, whether conducted for charity or for profit, for the purpose of providing chronic maintenance dialysis to persons suffering from chronic renal disease. It shall not include a dialysis unit maintained as part of a licensed or approved hospital.

Person means any individual or his estate upon his death; or a partnership, corporation, or trust or other unincorporated association; or any receiver, trustee, or other liquidating agent of any of the foregoing while acting in such capacity.

Physician means an individual who is currently licensed, pursuant to M.G.L. c. 112, § 2, to practice medicine or osteopathy in Massachusetts.

Primary Care Provider means a health care professional qualified to provide general medical care for common health care problems, who supervises, coordinates, prescribes or otherwise provides or proposes health care services, initiates referrals for specialist care and maintains continuity of care within the scope of practice.

~~Program director means the employee of the Department who, under the general supervision of Commissioner or his designee, administers the Division of Hospitals and Ambulatory Care.~~

~~Program staff means any and all employees of the Department, under the direction of the Program Director, participating in the administration of the Division of Hospitals and Ambulatory Care.~~

Registered nurse means an individual who is currently registered pursuant to M.G.L. c. 112, § 74, to practice professional nursing in Massachusetts.

Renewal license means the first and each subsequent renewal of the original license to maintain premises named therein as an out-of-hospital dialysis unit.

Transfer of ownership includes, in the case of a partnership, any change in partners, and, in the case of a corporation, any transfer of fifty percent or more of the outstanding shares of stock in such corporation.

~~Words and phrases not expressly defined in 105 CMR 145.020 shall be interpreted according to the common and approved usage of the language; but technical words and phrases and such others as may have acquired a peculiar and appropriate meaning in medicine or Department practice shall be interpreted according to such meaning.~~

145.025 Special Projects

The Department will consider proposals for special projects for the innovative delivery of dialysis services. No such proposal shall be implemented without prior written approval of the Department. The Department may impose conditions on special projects as necessary.

145.099: Waivers

The Department may waive the applicability to a particular unit of one or more of the requirements set forth in 105 CMR 145.000 if:

(A) the Department finds that:

- (1) compliance would cause undue hardship to the unit;
- (2) the unit is in substantial compliance with the spirit of the requirement; and
- (3) the unit's non-compliance does not jeopardize the health or safety of its patients and does not limit the unit's capacity to give adequate care; and

(B) the unit provides to the Department written documentation supporting its request for a waiver.

145.100: Governing Body

The unit shall have an effective governing body, ~~which shall adopt by-laws consistent with 105 CMR 145.000 setting forth the purposes and policies of the unit, and which shall ensure that by-laws are followed in the operation of the unit.~~ or designated person or persons with full legal authority and responsibility for the governance and operation of the unit; establishing and implementing policies regarding management and operations; oversight and accountability for the quality assessment and performance improvement program; and the appointment of a

qualified administrator reporting to the governing body who shall be responsible for the day-to-day operations.

145.110: Administrator

There shall be an administrator responsible for the administration of the unit. **The administrator must be physically present in the unit as necessary to perform the duties of his or her position.**

145.120: Medical Director

There shall be a medical director who shall be responsible for planning, organizing, coordinating and directing the unit's professional services and for liaison with the affiliated institutions. The medical director shall **be physically present in the unit as necessary** ~~devote sufficient time~~ to carry out these responsibilities.

145.121: Qualifications of Medical Director

The medical director shall be a physician who is certified, or **is an active candidate** ~~eligible~~ for certification, by the American Board of Internal Medicine, and who has had at least one year of formal training in chronic renal disease patient care or at least two years of experience in such care. In either case, a significant portion of the required time shall have been spent working in a dialysis unit ~~which that provideds~~ maintenance dialysis to patients with chronic renal disease.

145.122: Hours Staffed by Medical Director

The medical director is not required to be a full time employee; provided that he or she devotes sufficient time to ensure the proper provision of professional services in accordance with the unit's by-laws and 105 CMR 145.000.

145.123: Medical Director and Administrator

The position of administrator and medical director may be held by the same person; ~~provided;~~ that such a person is able to carry out both responsibilities.

145.124: Medical Staff

The medical director, with the governing body, shall establish criteria for granting privileges to licensed physicians or other providers. The medical director shall review credentials of candidates for medical staff membership and make recommendations to the governing body on the initial appointment of candidates. The medical director must periodically conduct appraisals of the members and make recommendations to the governing body for reappointment of medical staff.

145.125: Medical Staff By-laws

The medical staff must operate pursuant to by-laws and rules approved by the governing body. The by-laws must describe the organization of the medical staff and set forth rules for its operation. The by-laws must describe the procedure for applying for medical staff privileges, and the qualifications to be met by a candidate in order for the candidate to be appointed and/or reappointed to the medical staff by the governing body.

145.130: On-Call Physician

Whenever patients are undergoing treatment in the unit, a physician shall be available on call to provide medical consultation and treatment of patients as needed. The medical director may serve in this capacity when he is on the premises.

145.140: ~~Director of Nursing~~ Nurse Manager

Each unit shall have a ~~nurse manager~~ ~~director of nursing~~, who shall direct the nursing staff in the provision of nursing services to patients.

145.141: Qualifications of ~~Nurse Manager~~ ~~Director of Nursing~~

The ~~nurse manager~~ ~~director of nursing~~ shall be a registered nurse ~~with and have had~~ at least ~~12 six~~ months ~~experience as a registered nurse and of formal training, in a teaching institution, in chronic renal disease patient care or~~ at least ~~two-years six months~~ of experience in dialysis treatment ~~and~~ chronic renal disease patient care.

145.142: Hours Staffed by ~~Nurse Manager~~ ~~Director of Nursing~~

The ~~nurse manager~~ ~~director of nursing~~ shall be a full-time employee of the unit.

145.150: Nursing Personnel

The unit shall have on duty sufficient direct care nursing personnel to ensure that all patients undergoing dialysis have nursing care, provided by registered nurses ~~or licensed practical nurses and other staff~~ trained in chronic dialysis, available at all times at a ratio of at least one direct care staff member to every three patients. If dialysis is performed in more than one room of the unit, at least one nursing staff member shall be present at all times in each room in which a patient is undergoing dialysis.

145.151: Nursing Staff On Duty

There shall be at least one registered nurse other than the director of nursing on duty whenever patients are undergoing dialysis in the unit. This nurse may give direct patient care; provided that he ~~or~~ she is also available to all patients for provision of any nursing care ~~which that~~ must by law be provided by a registered nurse.

145.152: Qualifications of Nursing Personnel

Nursing staff shall have training or experience in chronic maintenance dialysis appropriate to their duties.

145.153: ~~Licensed Practical Nurses and Technical Assistants~~ Clinical Hemodialysis Technicians

~~Licensed practical nurses and technical assistants~~ Clinical hemodialysis technicians trained in chronic dialysis may assist the ~~registered nurses~~ nursing staff and be given responsibilities appropriate to their training and experience. Such responsibilities may include starting and ending dialysis, maintenance and use of dialysis equipment, surveillance of the patient's condition during dialysis, and administration of agents prescribed for regulation of blood clotting mechanisms as part of the dialysis process.

145.160: Counseling Services

The unit shall make available to each patient, when needed, either through its own resources or through affiliations ~~under part 7~~ pursuant to 105 CMR 145.300, or through another institution or agency under written agreement, the following professional services: social services, dietary counseling, mental health services and vocational counseling.

145.200: Location of Dialysis Unit

The dialysis area shall be separate from other patient care and administrative activities and shall not be located in an area ~~which~~ that provides access to such other areas.

145.210: Square Footage per Dialysis Station

There shall be space between beds, in addition to that necessary for associated equipment, sufficient to allow access to **provide needed care and services, prevent cross contamination, and to accommodate medical emergency equipment and staff access to** the patient by at least two persons. ~~In any unit constructed or undergoing major renovations after May 1, 1975, there shall be a minimum of 110 square feet of floor space per dialysis station.~~

145.220: Isolation Room

~~An area~~ room shall be provided for isolation of potentially infectious patients, which shall be physically separated from any other dialysis area, and shall be used in accordance with written policies approved by the medical director and director of nursing ~~which~~ that provide for infection control procedures. **The isolation room must be at least 110 square feet and must be equipped with a handwashing sink.**

145.225: Home Training Room

If home training is provided in the dialysis unit, a private treatment area of at least 120 square feet shall be provided for patients who are being trained to use dialysis equipment at home. The home training room must contain a work counter, handwashing facilities and a separate drain for fluid disposal.

145.230: Dialysis Unit Support Spaces ~~Provision of Storage, Handwashing and Toilet Facilities~~

There shall be adequate provision for the following **support spaces in conveniently accessible locations:**

- (A) ~~s~~Space for patient's' belongings;
- (B) ~~t~~Toilet and handwashing facilities for patients;
- (C) ~~t~~Toilet and handwashing facilities for staff;
- (D) Examination room with handwashing facilities;
- (E) Medication station with work counter and handwashing facilities;
- (F) Clean supply storage room;
- (G) Soiled workroom equipped with flushing rim sink, handwashing facilities, work counter, storage cabinets, waste receptacles, and soiled linen receptacle;
- (H) Housekeeping room with floor receptor sink; and
- (I) Reprocessing room. If dialyzers are reused, the unit must contain a reprocessing room sized to perform the required functions. The reprocessing room must provide for one-way flow of materials from soiled to clean. The reprocessing room must have provisions for refrigeration for temporary storage of dialyzers, decontamination/cleaning areas, sinks, a packaging area, and dialyzer storage cabinets.

~~storage space for clean equipment and all supplies;
area for cleaning and maintenance of dialysis equipment; and
storage and sink facilities for all housekeeping supplies and activities.~~

145.240: Sinks in Treatment Area

The unit shall provide sufficient ~~S~~sinks with warm water and soap available ~~for handwashing shall be provided~~ in the treatment area **to facilitate handwashing.**

145.245: Mechanical Ventilation

The unit shall provide all rooms that do not have direct access to the outside with satisfactory mechanical ventilation. The unit shall provide mechanical exhaust ventilation in the isolation room, toilet rooms, soiled workroom, housekeeping room and reprocessing room.

145.250: Condition of Premises

The premises shall be maintained in good repair and in compliance with the state sanitary code at all times.

145.260: Linen

The unit shall make arrangements for the cleaning of linen unless only disposable linen is used. Space and equipment shall be provided for the handling and separate storage of soiled and clean linen.

145.270: Water System

Water and equipment used for dialysis must meet the water and dialysate quality standards and equipment requirements as issued by the Department in guidelines, based on standards issued by the Association for the Advancement of Medical Instrumentation (AAMI).

(A) Non-Municipal Water System. Where the water supply is not the municipal water system, the unit must obtain written approval of the source of the water supply from the local Board of Health.

(B) Connections to Other Piping. The water system shall have no connection to another piping system or to any fixture ~~which~~**that** presents a foreseeable risk of contamination of the water supply.

145.280: Waste Disposal

The unit shall provide appropriate equipment and employ sanitary procedures for the collection, storage, and disposal of all solid wastes, including garbage, rubbish and other refuse, biological wastes and infectious materials.

(A) Disposal of Infectious and Contaminated Waste. ~~Requirements governing the disposal~~ **The unit shall dispose** of infectious or physically dangerous medical or biological waste **in accordance with** ~~are set forth in~~ 105 CMR 480.000: ~~Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste; State Sanitary Code, Chapter VIII Minimum Requirements for the Management Of Medical Or Biological Waste~~ **are incorporated herein by reference**. **The unit is responsible for the disposal of medical or biological waste generated on its licensed premises and for any such waste generated at any home dialysis program for which the unit provides supplies and services pursuant to 105 CMR 145.825 and 105 CMR 145.830.**

(B) Disposal of Non-Contaminated Solid Wastes. Non-contaminated solid wastes shall be collected, stored, and disposed of in a manner that will prevent the transmission of disease, not to create a nuisance or fire hazard and not to provide a breeding place for insects or rodents. Such solid wastes shall be stored, either indoors or outdoors, in a sanitary rodent-proof, fire-proof, non-absorbent, water-tight container.

(C) Containers for Waste Disposal. Containers used to collect or store solid wastes shall be emptied and cleaned as necessary to maintain a sanitary environment.

145.290: Infection Control

(A) The unit shall have and **must** follow written policies and procedures approved by the medical director and director of nursing for infection control within the unit.

- (B) Such policies and procedures shall include but need not be limited to the following:
- (1) Standards and procedures for housekeeping and sanitation;
 - (2) Standards and procedures for aseptic techniques to be used;
 - (3) Procedures for surveillance, reporting, evaluating, and keeping records of infections among patients and personnel, with particular emphasis on sub-clinical hepatitis;
 - (4) A definition of hepatitis infection for the purpose of such surveillance, and specific indications of the need for and procedures to be used in isolation; and
 - (5) A policy pertaining to eating and drinking in the dialysis area or areas.

145.291: Emergency Electrical Service

(A) An emergency source of electrical power shall be provided on the premises of the dialysis facility.

(B) The source of the emergency electrical service shall be as follows: an emergency electrical generating set, including prime mover and generator, equipped with an automatic transfer switch, which will transfer within ten seconds, and shall be reserved exclusively for supplying the emergency electrical system. The generator set(s) shall have sufficient capacity and proper rating to meet the maximum expected demand of the Essential Electrical System at any one time.

(C) The emergency electrical services shall be provided to circuits as follows:

- (1) Lighting.
 - (a) All task lighting, exitways, exit signs, exit directional signs, exit doorways, stairways, corridors, and lobby.
 - (b) Patient treatment rooms/cubicles, nursing station, medication preparation area, clean workroom, soiled workroom, equipment storage room, mechanical rooms and patient lounge area.
 - (c) Generator set location and switch gear location.
- (2) Equipment.
 - (a) Dialysis distribution systems and related equipment, and, if provided, the water treatment system.
 - (b) A minimum of one duplex receptacle on each side of patient bed or chair.
 - (c) One duplex receptacle in the equipment breakdown room.
 - (d) Corridor receptacles in the patient treatment area.

- (e) Essential refrigerators.
- (f) Telephone equipment, nurses call and intercom systems **which that** depend on electrical power supplied by the facility.
- (g) Central batch delivery equipment and related systems, if provided.
- (h) HVAC systems.
- (i) Fire alarm and extinguishing systems.

(D) The generator must be checked at least quarterly under the operating load to **assure ensure** its proper operation.

(E) Records of routine tests as well as periodic maintenance checks must be maintained in the facility's files and be available for review.

~~(F) For facilities in operation at the time of promulgation of 105 CMR 145.291, the emergency electrical power system must be installed at the time of any renovation or expansion, when there is a change in ownership, or within three years from the effective date of 105 CMR 145.291, whichever comes first.~~

145.300: Affiliation Agreements Required

The unit shall affiliate with licensed or approved hospitals, other institutions, and agencies in such a manner as to **offer ensure that** its patients, whether dialyzed at the unit or at home, **can receive inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care 24 hours a day, seven days a week. The agreement must ensure that hospital services are available promptly to the unit's patients when needed and include reasonable assurances that patients from the unit are accepted and treated in emergencies.** ~~the full range of renal and ancillary services, both out-patient and inpatient, which may be reasonably expected as being necessary for the care of a person suffering from chronic renal disease.~~

~~145.310: Affiliation Agreements for Emergency Services~~

~~An affiliation agreement with a licensed or approved hospital which has an emergency service for treatment of any emergency which may occur while a patient is in the unit.~~

~~145.320: Affiliation Agreement for Chronic Maintenance Dialysis~~

~~An affiliation agreement with at least one licensed or approved hospital having for chronic maintenance dialysis and related services, as set forth in 105 CMR 145.35025.~~

145.330: Affiliation Agreement for Kidney Transplantation Service

The unit shall have an~~An~~ affiliation agreement with at least one hospital for kidney transplantation services, including:

- (A)** Tissue typing and matching, surgical transplant capability, kidney perfusion or

other storage devices, immunology services directly or by affiliation;

(B) Availability of surgeons qualified by skill or training in the transplantation of kidneys;

(C) Availability of physicians qualified by skill or training in the management of post transplant patients.

145.340: Affiliation Agreement for Home Dialysis

The unit shall have an affiliation agreement with at least one hospital or out-of-hospital dialysis unit for provision of home dialysis training program conforming to 105 CMR 145.800 through 145.850 if such a program is not provided by the unit.

~~145.350: Provision of Affiliation Agreement~~

~~—Every affiliation agreement with a licensed or approved hospital having dialysis service shall include provision for the following services:~~

~~(A) Back-up dialysis services;~~

~~(B) Medical services, including:~~

~~(C) Medical consultation including at least regular participation by one or more physicians of the hospital dialysis service medical staff in evaluating the quality and appropriateness of services provided by the out-of-hospital unit, in general and for individual patients, and in consideration and recommendation of alternative modes of treatment including but not limited to at least home dialysis, self-dialysis with supervision, and transplantation;~~

~~(D) A physician or physicians available in case of need who has or have demonstrated capability of shunt and fistula insertion and long-term maintenance;~~

~~(E) Treatment of complications and renal disease related conditions on an inpatient or out-patient basis as appropriate;~~

~~(F) Laboratory services from the clinical laboratory of the hospital;~~

~~(G) blood bank services;~~

145.360: Form of Affiliation Agreement

Every affiliation agreement shall be in writing and shall set forth the policies and procedures **which that** will govern the referral and transfer of patients between the unit and the licensed or approved hospital affiliated institution or agency, **including patient care referral information.**

145.370: Affiliation Agreements with Out-of-State Hospitals

Units near to or accessible to hospitals in other states may maintain affiliation with those hospitals for purposes of 105 CMR 145.310, ~~and 145.320 and 145.330~~ **15** provided, that those hospitals have been approved to provide chronic maintenance dialysis ~~or~~ **f** transplantation services by the respective state's designated authority or the ~~F~~ **f**ederal ~~G~~ **g**overnment.

145.400: Admission Policies and Procedures

~~(A) A patient beginning chronic maintenance dialysis~~ **or transferring from another dialysis unit** shall be admitted to the unit only after **completion of a written** ~~a period of prior~~ evaluation **by a physician on staff at the out-of-hospital dialysis unit.** **Written admission criteria must be developed to identify patients who require initiation of dialysis in a hospital, prior to transfer to an out-of-hospital dialysis unit.** ~~and initiation of dialysis in an affiliated hospital which has a chronic dialysis service, or an acute service capable of performing diagnostic studies and completing stabilization of the patient for chronic dialysis, and which agrees to accept the patient for in-patient care and other services as needed. The period of evaluation shall include consideration of what is the most appropriate mode of treatment for the patient and whether the patient can be maintained on self-dialysis or home dialysis.~~

~~(B) A patient already undergoing chronic maintenance dialysis may be admitted directly to the unit but must be evaluated prior to such admission by the medical staff of the chronic dialysis service of an affiliated hospital which agrees to accept the patient for in-patient care and other services as needed, regardless of whether the patient has previously been admitted to that hospital.~~

145.410: Patient's **Primary Care Provider** ~~Attending Physieian~~

The care of each patient at the unit shall be under the supervision of a physician **or primary care provider** of the patient's choice or acceptable to the patient. This physician **or other provider, hereinafter called the "attending physieian", must beneed not be a physieian on the staff of the unit or of an affiliated hospital; provided, that he and must** meets such requirements for practice at the unit as the governing body may set forth in the unit by-laws.

145.420: Annual Patient Evaluation

Each patient shall be evaluated at least annually by **an interdisciplinary team Review Committee** composed of a physician, nurse, social worker, **dietician** or others involved in the care of the patient as to the appropriateness and effectiveness of the treatment received and the need for continuation of or change in treatment. Such consideration shall include evaluation of the appropriateness of at least home dialysis, self-dialysis and transplantation. A record of each evaluation is to be made part of the ~~patients'~~ **patient's** clinical record.

145.430: Availability of Alternative Modes of Treatment

All patients shall have access to alternative methods of treatment of chronic renal disease such as home dialysis or transplantation. Evidence of such access shall be available in the contents of the written agreements with hospitals and the unit's own policies, including written criteria for selection of patients for home dialysis.

145.440: Healthcare-associated Infection Data Collection, Submission and Reporting

(A) Each free-standing dialysis unit shall:

- (1) register with the NHSN; and**
- (2) grant access to the Department, in accordance with guidelines of the Department, to healthcare associated infection data elements reportable to the NHSN.**

(B) Each free-standing dialysis unit shall collect and submit to the NHSN, and then grant access, as provided under 105 CMR 145.440(A), to the Department, to healthcare-associated infection data elements.

(C) Each free-standing dialysis unit shall collect and submit to the Department other data related to infection control, including process measures, in accordance with guidelines of the Department.

145.450: Serious Complaint Procedure

Each unit shall develop a written procedure that ensures prompt and complete investigations of all serious complaints that are filed against the unit, employees of the unit or members of its professional staff. The procedure shall include, at a minimum, the following provisions:

(A) Designation of a senior member of the unit administration as the person responsible for overseeing the investigation of serious complaints lodged against the unit, an employee, or a member of the professional staff;

(B) Establishment of a reporting procedure that ensures that the designated administrator will receive reports of serious complaints within one day from unit staff, in writing;

(C) Development by the designated administrator of a written process for investigation, which must include the following:

- (1) A process of fact-gathering that he or she will utilize, including provision for interviewing of the complainant, patient, and relevant witnesses;**
- (2) Creation of a complaint file that includes the original report of**

complaint, progress reports as investigation is carried out and outcome of investigation including action taken, if any; and

(3) Notification of the complainant of the outcome of the investigation.

(D) The complaint files shall be available for inspection by agents of the Department.

145.455: Serious Incident Reports

(A) A unit shall immediately report to the Department, pursuant to Department guidelines, any of the following that occurs on premises covered by its license:

- (1) death that is unanticipated, not related to the natural course of the patient's illness or underlying condition, or that is the result of an error or other incident as specified in guidelines of the Department;
- (2) full or partial evacuation of the facility for any reason;
- (3) fire;
- (4) suicide;
- (5) serious criminal acts;
- (6) pending or actual strike action by its employees, and contingency plans for operation of the unit; or
- (7) any other serious incident or accident as specified in guidelines of the Department.

(B) A unit shall immediately report to the Department, for any patient treated at the unit, any suspected instance(s) of abuse, neglect, mistreatment of that patient, or misappropriation of that patient's property, at or by a nursing home, rest home, home health, home maker or hospice facility.

145.460: Evaluation of Quality

(A) Each unit shall establish an organized, comprehensive program that is adequate to regularly review and evaluate the quality of care provided. The program shall:

- (1) be defined in writing and approved by the governing body;
- (2) identify an individual to be responsible for the implementation and continuity of the program;
- (3) be re-evaluated at least monthly; and
- (4) describe the mechanisms in effect to identify and resolve problems.

(B) The findings of the program shall, as appropriate, be utilized in the revision of facility policies and procedures.

145.470: Pharmaceutical Services

If controlled substances are stored and administered at the facility directly to patients, the facility shall register with the Department pursuant to M.G.L. c. 94C, §7 and must comply with the provisions for storage and administration of controlled

substances pursuant to the Federal Food, Drug and Cosmetics Act, M.G.L. c. 94C, and 105 CMR 700.000.

145.500: Medical Records Required for Each Patient

The unit must maintain a ~~A-current~~ medical record ~~shall be maintained~~ for every patient admitted to the out-of-hospital dialysis unit from the time of admission to the time of discharge. **The unit must maintain a current medical record for every patient whose home dialysis is under the supervision of the unit.**

145.505: Record-Keeping Facilities and Equipment

The unit shall maintain facilities and equipment, appropriately located and adequate to ensure the accurate processing, checking, indexing, filing and prompt retrieval of all medical records and their safe storage.

145.510: Medical Record Identification Number

Each medical record shall carry a unique identifying number from the time of the patient's initial admission.

145.515: Responsibility for Completing Medical Record

The completion of a medical record shall be the responsibility of a physician **or other appropriate primary care provider.**

145.520: Physician's Orders

Physician **or primary care provider** orders shall be legibly entered into the medical record and shall be dated and signed by the physician or **other appropriate provider** making the order.

145.525: Telephone Orders

Telephone orders shall be signed and dated by the physician **or other appropriate provider** within ~~24~~ **72** hours.

145.530: Responsibility for Keeping Medical Records

The unit shall designate a person to be in charge of keeping medical records in the manner prescribed in 105 CMR 145.000.

145.535: Medical Record System

Each unit shall develop a workable system for identifying, filing, indexing, and retrieving medical records.

145.540: Content of Medical Record

(A) General Requirement. **Medical records shall be retained for six years after the unit's last treatment of a patient.** The medical record shall be sufficiently detailed to enable a physician or primary care provider to give effective continuing care to the patient, as well as to enable him the physician or primary care provider to determine, at a future date, what the patient's condition was at a specific time and what procedures were performed; a consulting physician or primary care provider to obtain information necessary to form an opinion after his examination of the patient; another physician or primary care provider to assume the care of the patient at any time; and communication among the physicians, primary care providers and trained personnel contributing to the patient's care.

(B) Specific Provisions. Each medical record shall include at least the following:

- (1) Identification data including the patient's name, address, age and next of kin, and guardian, if any;
- (2) The name, address, and telephone number of the patient's attending physician or primary care provider;
- (3) History of present illness, past medical history, and family medical history;
- (4) Records of initial and periodic physical examinations at intervals to be stated in written policies, approved by the medical director including all findings resulting from an assessment of all systems of the body;
- (5) Reports of all diagnostic procedures, tests, evaluations and examinations;
- (6) Records of treatment including order sheets, transfusion records, and record and date of each dialysis treatment;
- (7) Records of complications of treatment, accidents or untoward incidents regarding patients;
- (8) Progress notes, which shall be recorded in sufficient detail to delineate the course and results of treatment;
- (9) Information pertaining to hospital admissions during the patient's course of treatment, including a discharge summary from the hospital whenever possible;
- (10) A record of the patient's evaluations by an interdisciplinary team Review Committee as set forth in 105 CMR 145.325420;. **Records of annual evaluations shall list other methods of treatment considered and the indications for continued chronic maintenance dialysis, home dialysis, self-dialysis, transplantation or other methods of treatment.**
- (11) Discharge summary or clinical resume, which shall briefly recapitulate the significant findings and events of the patient's dialysis treatments and arrangements made for future care; and
- (12) Date of admission and discharge.

~~Records of annual evaluations which shall list other methods of treatment considered and the indications for continued chronic maintenance dialysis, home dialysis, self-dialysis, transplantation or other methods of treatment.~~

145.545: Safeguards Against Loss and Use of Medical Records by Unauthorized Persons

The unit shall ~~consistent with 105 CMR 145.545 and such policies as it shall establish under 105 CMR 145.550;~~ **develop policies to** safeguard its medical records and the information therein against loss and use by unauthorized persons.

145.550: Removal of Medical Record

No medical records shall be removed from the unit except as required by legal action. In the event removal is required by legal action, a duplicate shall be made and kept at the unit until such time as the original is returned from the court.

145.555: Release of Medical Record

Prior to release of any information from a medical record to any person not authorized by law to receive such information, the unit shall have, and place in the record, the written consent of the patient, or, ~~if the patient is not competent, the written consent of his guardian, or, if the patient is deceased, of the patient's estate, or of the designated attorney or other representative of said patient, guardian, or estate~~ **the patient's appropriate legal representative.**

145.560: Medical Record Policies

The unit shall have written policies, either in the unit's by-laws or established by the administrator pursuant to such by-laws, with respect to at least the following:

(A) Use of Records by Authorized Personnel. Use of records by authorized personnel on the staff of the unit, and by authorized personnel from affiliated staffs and attending ~~physicians~~ **care providers** while visiting the unit;

(B) Transmittal Outside the Unit of Information from Medical Record. Transmittal outside the unit of information from a record, either to an authorized person on the staff of an affiliated institution or agency or to ~~an attending physician~~ **primary care provider** at his ~~or her~~ office or institution;

(C) Designation of Persons Authorized to Receive Medical Record. Designation of persons authorized under 105 CMR 145.560(A) and (B) to receive information from a record by either name of person or class of personnel or duty assignment, or any combination of such means; and

(D) Release of Information from Medical Records Outside the Unit. Release of information from a record outside the unit to any other person, including a list, supported by advice of counsel to the unit, of such classes of persons who, by law, are entitled to access to such information without the consent provided for under 105 CMR 145.555.

145.600: Procurement, Use and Storage of Blood

The unit shall obtain blood from a blood bank immediately prior to its administration. All blood so obtained shall be identified, stored, handled and administered in accordance with 105 CMR 135.000: *Use of Blood, Blood Components and Derivatives for the Purpose of Transfusion.*

145.700: ~~Disaster~~ Emergency Preparedness Planning

Each unit shall have and maintain a **comprehensive** written **emergency preparedness plan for staff and patients.** ~~for dealing with fire or other disaster.~~

145.710: Familiarity with **Emergency Preparedness** ~~Disaster~~ Plan

Every staff member shall be familiar with the plan and be able to execute his/her responsibility under the plan. A copy of the plan shall be available to members of the staff, and to any other person on request. **Staff shall ensure that patients have a copy of the plan and are trained in emergency preparedness. Emergency preparedness training shall be documented.**

145.720: Provision of **Emergency Preparedness** ~~Disaster~~ Plan

~~Such a~~ **The emergency preparedness** plan shall specify persons to be notified, location of alarms and fire extinguishers, evacuation routes, procedures for evacuation of ~~handicapped~~ persons **with disabilities**, and assignment of specific responsibilities by name or title of employee. **The plan shall include provisions for direction and control, communication, alerts and warnings, and evacuation and/or closure of the unit.**

145.730: Fire Drills

Fire drills shall be conducted **for all staff** ~~under the plan~~ at least twice a year at varied times, including two drills per work shift per year. **The unit shall maintain records that identify the dates and attendance at such drills.**

145.740: **Emergency Supplies and Equipment**

The unit shall maintain on the premises at all times a fully equipped emergency tray, including emergency, drugs, and medical supplies and equipment, including but not limited to an automated external defibrillator.

145.800: Home Dialysis Program Required

Every unit shall have a home dialysis program or provide its patients access to such a program through affiliation under 105 CMR 145.~~320~~**340.**

145.805: Written Plan for Training of Home Dialysis Patients

There shall be a written plan for the training of patients **and partners** in home dialysis.

145.810: Training Personnel and Equipment

There shall be training personnel and equipment for instructing patients and partners in home dialysis.

145.815: Inspection of Equipment at Home

There shall be policies and procedures for supervision of installation and inspection of equipment in the home. These policies and procedures shall be approved by the medical director and director of nursing.

145.820: Procedures for Supervision of Home Dialysis

There shall be procedures approved by the medical director and director of nursing for supervision of initial dialysis at home.

145.825: Provision of Supplies to Home

There shall be a continuing program for arranging for the provision of supplies to patients at home.

145.830: Provision of Renal and Ancillary Services

Each patient on home dialysis shall have available any renal and ancillary services necessary for his/her care on the same basis as patients being dialyzed in the unit.

145.835: Medical Records on Home Dialysis Patients

Clinical records shall be maintained for patients in a home dialysis program and maintained by the unit in the same manner as set forth in 105 CMR 145.500 through 145.560.

145.840: **Reserved** ~~Agency Responsible for Supervision of Dialysis~~

~~Each patient in the program shall be informed in writing of the institution or agency responsible for the supervision of his or her dialysis and for provision of such renal or ancillary services as the patient needs or may need. This statement may be in the form of a contract between the unit and patient.~~

145.845: Affiliation Agreements for Home Dialysis Patients

Each patient on home dialysis shall, under the affiliation agreement of the unit, have access to the services of affiliate hospitals on the same basis as patients being dialyzed in the unit.

145.850: Description of Home Dialysis Program

The unit shall have and maintain a written description of the nature and the scope of the program, which shall be available upon request to any patient or other person. The responsibilities of each participating institution or agency shall be set forth in this description.

145.900: Licensing and Related Administrative Procedures

Licensing and related administrative procedures for out of hospital dialysis units shall be the same as those ~~in effect for clinics licensed by the Department. See~~ set forth in 105 CMR 140.100~~1~~ through 140.199~~50~~. ~~The Department may at its discretion entertain waivers of the requirements under 105 CMR 145.000 pursuant to the provisions found in the clinic licensure regulations at 105 CMR 140.099.~~

145.910: Severability

The provisions of 105 CMR 145.000 are severable. If any provision herein is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining portions shall not be so affected.

REGULATORY AUTHORITY

105 CMR 145.000: M.G.L. c. 111, § 3, 51A, 53.

