

Health, Department of

Health Quality

Chapter 18: Licensure of Renal Dialysis Centers

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**RULES AND REGULATIONS
FOR LICENSURE OF RENAL DIALYSIS CENTERS**

CHAPTER 18

Section 1. Authority. **These rules are promulgated by the Department of Health pursuant to the Health Facilities Licensure Act at W. S. 35-2-901 *et seq.* and the Wyoming Administrative Procedures Act at W. S. 16-3-101 *et seq.***

Section 2. Purpose. These rules have been adopted for the licensure of renal dialysis centers. The purpose of these standards is to provide minimum requirements for services, structure, operation and personnel practices designed to protect the health and safety of patients and employees.

Section 3. Severability. If any portion of this rule is found invalid or unenforceable, the remainder shall continue in effect.

Section 4. Definitions.

(a) "Acceptable plan of correction" means an Office of Health Quality, Planning and Program Evaluation (Office of Health Quality) approved plan to correct the deficiencies identified through a survey. The plan of correction shall be a written document and must contain who is responsible for correction, what was done to correct the problem, who will monitor to ensure that the situation does not develop again, and must contain a timely date for completion of the correction.

(b) "Administrator" is the person in charge of the operation of the facility twenty-four hours per day and is:

(i) A physician,

(ii) A dialysis nurse, or

(iii) An individual with a bachelors degree and one year experience in health service administration, preferably in a renal dialysis center.

(c) "Central Registry" means the registry operated by the Wyoming Department of Family Services pursuant to W.S. §14-3-213, which indexes perpetrators of child abuse or neglect and abuse, neglect, exploitation or abandonment of disabled adults.

(d) "Clinical Laboratory Improvement Act (CLIA)" means the clinical laboratories approved by the U.S. Department of Health and Human Services, Health Care Financing Administration as required by 42 CFR Part 493, Section 1861 (e) and (j), the sentence following Section 1861 (s)(13), and 1902(a)(9) of the Social Security Act and Section 353 of the Public Health Service Act.

(e) "Dialysis" is a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

(f) “Dialysis nurse” is a Registered Nurse who has had at least six (6) months of experience working in a renal dialysis center.

(g) “Dialysis technician” is a person who has successfully completed a core curriculum consisting of didactic and clinical classes in:

- (i) Understanding the person with renal failure,
- (ii) Principles of dialysis,
- (iii) Hemodialysis devices,
- (iv) Hemodialysis procedures,
- (v) Dialyzer reprocessing,
- (vi) Water treatment, and
- (vii) Infection Control

(h) “Dietitian” means a person who is registered by the American Dietetic Association and provides nutritional and dietary consultation services.

(i) “Fidelity bond” means a contract of fidelity insurance. One agrees to insure another against loss arising from the want of honesty, integrity or fidelity of an employee of the renal dialysis center.

(j) “Licensed Practical Nurse” is a graduate of an approved school of practical or vocational nursing who is currently licensed to practice as a licensed practical nurse by the Wyoming Board of Nursing.

(k) “Physician” means a person licensed to practice medicine in Wyoming by the Wyoming Board of Medicine.

(l) “Renal Dialysis Center” means a freestanding facility for the treatment of kidney diseases.

(m) “Registered Nurse” is a graduate of an approved school of professional nursing, who is currently licensed to practice as a registered nurse by the Wyoming Board of Nursing.

(n) “Social Worker” is a person who has graduated with a masters degree from a graduate school of social work accredited by the Council on Social Work Education.

Section 5. Licensing.

(a) Licensing requirements. The Office of Health Quality has been duly authorized to issue licenses to renal dialysis centers. The Office of Health Quality has established a system of licensure to comply with minimum requirements for protecting the health, welfare and safety of patients receiving this

type of service.

(b) Licensing procedure.

(i) For an initial license to be issued the facility shall submit:

(A) A completed application form as supplied by the Office of Health Quality.

(B) The required licensure fee outlined in Chapter 1 Rules and Regulations for Health Care Facilities Licensure Fees. The check or money order shall be made payable to the Treasurer, State of Wyoming.

(C) Demonstrated compliance with the requirements for licensure as required in paragraph (c) of this section. This documentation shall be available through the Office of Health Quality following the on site survey.

(D) The effective date of the initial license shall be:

(I) The date of the survey, if there are no deficiencies, or

(II) If deficiencies exist, the date that an acceptable plan of correction is developed.

(E) The length of the license shall be from the effective date of the license until the next June 30th.

(ii) For renewal of a full license for one year beginning July 1st, and unless suspended, or revoked, shall expire on June the of the following year, the Office of Health Quality shall receive:

(A) A completed application form returned by the date indicated in the cover letter.

(I) The application form shall be mailed by the Office of Health Quality to the facility.

(B) License fee. Each application shall be accompanied by the required licensure fee outlined in Chapter 1, Rules and Regulations for Health Care Facilities Licensure Fees. The check shall be made payable to the Treasurer, State of Wyoming.

(C) Must demonstrate full compliance with the requirements for licensure as required in paragraph (c) of this section or an Office of Health Quality accepted plan of correction for deficiencies from the standards. This documentation is maintained on file at the Office of Health Quality following the on site survey.

(c) Requirements for licensure. The Office of Health Quality shall consider:

(i) The renal dialysis center is in conformity with all laws and standards relating to

communicable and reportable diseases as promulgated by the Department of Health, Public Health Division.

(ii) Existing deficiencies shall not create a hazard to the health, safety or welfare of the patients.

(iii) The renal dialysis center is making a positive effort to correct all existing deficiencies.

(iv) Adequate policies and procedures are in place to guide operations.

(v) There is adequate and appropriately trained staff.

(vi) The renal dialysis center shall have an organized and implemented quality improvement plan.

(vii) There is an Office of Health Quality approved plan of correction for all cited deficiencies.

(d) Transfer of, or changes to the license.

(i) No license granted shall be assignable or transferrable. A license shall apply only to the agency location described in the license application.

(A) Whenever ownership of an agency is transferred from the individual or entity named in the license application to any other individual or entity, written notification of change of ownership shall be made to the Office of Health Quality. The buyer shall notify the Office of Health Quality of the impending transfer and apply for a new license.

(I) Any license granted to the buyer shall be subject to the plan of correction submitted by the previous owner as approved by the Office of Health Quality.

(B) The seller shall notify the Office of Health Quality at least thirty (30) days before the actual date of transfer.

(C) Within the week prior to the effective date of the change of ownership a new license will be mailed to the agency provided that the Office of Health Quality is in receipt of the licensure application, and the licensure fee.

(I) The day after the change of ownership the obsolete license must be mailed back to the Office of Health Quality.

(ii) If the renal dialysis center's name is changed, the Office of Health Quality shall be advised in writing and a new license shall be issued upon receipt of the licensure fee and application.

(iii) If the renal dialysis center increases or decreases the number of stations, the Office of Health Quality shall be advised in writing and a new license application requested.

(A) Upon receipt of the licensure application and licensure fee the following actions will be taken:

(I) For additional stations to be added an on site review shall be conducted to determine adequacy of space, equipment, and appropriateness of staff and services. The additional stations will be licensed for service on the day of the on site inspection if all the requirements are met.

(II) If the renal dialysis center is decreasing stations then the new license will be made effective the date the application is received or the date the owner specifies in the licensure application, whichever date is later.

(e) Conditioning or revoking a license.

(i) Denial of application - suspension or revocation of license.

(A) An application for license may be denied or a previously issued license may be suspended or revoked for noncompliance with minimum standards as herein set forth when noncompliance jeopardizes the health, safety or welfare of patients.

(ii) Suspension of admissions.

(A) The Office of Health Quality may suspend new admissions or re-admissions to a renal dialysis center when conditions in the facility are such that patient needs cannot safely be met. Conditions in a renal dialysis center shall not jeopardize the patients' health and safety.

(iii) Hearings.

(A) Any renal dialysis center aggrieved by a decision of the Office of Health Quality may request a hearing by submitting a written request within ten (10) days of the receipt date of the notice of adverse action.

(B) Except in matters concerned with the spread of communicable disease as required in Section 5 (c)(i), the Senior Management Consultant of the Office of Health Quality shall present the preliminary decisions and reasons to the parties concerned and provide an opportunity for a hearing, if a hearing is requested, within ten (10) days.

(C) Hearings requested under the terms of these rules and regulations shall be held by the Office of Health Quality according to the provisions of the Wyoming Administrative Procedures Act at W.S. 16-3-113, and with the contested case rules and regulations of the Wyoming Department of Health.

(f) Posting of license.

(i) The current license issued by the Office of Health Quality shall be displayed in a public area within the renal dialysis center.

(g) Survey of the renal dialysis center.

(i) The survey of renal dialysis center programs shall be arranged by the Office of Health Quality. The survey shall be made periodically. All records of the facility shall be made available to the surveyor.

(h) Requirements of the Office of Health Quality.

(i) The Office of Health Quality shall provide each renal dialysis center with:

(A) A copy of these standards; and

(B) A copy of any deficiencies found.

(i) Voluntary Closure.

(i) If a renal dialysis center voluntarily ceases to operate, they shall notify the Office of Health Quality in writing at least five working days prior to the closure.

(ii) The first working day after the closure of the renal dialysis center, the license shall be returned to the Office of Health Quality.

Section 6. Organization and Management.

(a) Governing Body. The renal dialysis program shall have a governing body which has the legal authority and responsibility to operate the renal dialysis program. The governing body shall:

(i) Obtain a fidelity bond for client protection arising from the want of honesty, integrity or fidelity of an employee. The bond shall consist of no less than \$2500 and shall be augmented in relation to the number of employees.

(ii) Provide verification of a central registry information check on all employees hired at the time of or after the filing of these rules. The individual agencies or corporations are responsible to initiate and follow this process to completion.

Central registry information can be obtained by contacting The Department of Family Services at 307-777-5366. (This number is subject to change.)

(iii) Adopt, revise, and approve personnel policies; including:

(A) Frequency of evaluations;

(B) Insuring confidentiality of a central registry information checks.

(iv) Prepare an organizational chart that reflects the administrative control and lines of authority for the delegation of responsibility from management down to the client care level.

(v) The governing body shall ensure that all services provided are consistent with accepted standards of practice.

(vi) The governing body shall ensure adequate staffing to provide quality care.

(vii) There shall be policies and procedures for services offered, which shall be reviewed annually by the governing body.

(viii) Ensure in accordance with the State Statute 35-2-910, there is an effective, ongoing, agency wide written quality improvement program which ensures and evaluates quality of care provided to all clients.

(ix) Personnel Records.

(A) There shall be one person designated responsible for maintaining the confidentiality.

(x) Employee Health. The renal dialysis program shall:

(A) Develop policies and procedures for employee health including a policy identifying communicable diseases that could put the client population at risk.

(xi) Advanced Directives.

(A) The renal dialysis program shall adopt policies which assure they provide information on advanced directives to clients. If the client's advanced directives are known they shall be followed by the center.

(xii) Notification. Prior to admission all prospective clients shall be notified if the renal dialysis program is not Medicare/Medicaid certified.

Section 7. Construction.

(a) At the time of initial licensure the renal dialysis center shall meet the most current provisions of NFPA 101 Life Safety Code of the National Fire Protection Association.

(b) ab For new construction or remodeling the following regulations shall apply, but not be limited to:

(i) There shall be a grade level access or ramp, and in multi-story structure where the unit is above grade level, ready access to an elevator.

(ii) Each treatment area shall provide a minimum of 80 square feet with 4 feet between beds and/or lounge chairs for each station.

(iii) Floor space shall be provided for a central nurses' station which has direct visual

observation of all patients.

(iv) Each unit shall be designed to provide visual privacy for patients by the use of cubicle curtains.

(v) Handwashing facilities shall be located in the treatment area. Handwashing sinks shall have faucets that discharge at least five inches above the spill level of the sink. Soap dispensers and hand drying apparatus shall be provided. All sinks must be provided with spray heads or equivalent. Aerators are not allowed.

(vi) Space shall be provided in the work area for an emergency “crash” cart.

(vii) A janitor’s closet shall be provided either within or immediately next to the unit.

(viii) Work areas shall be designed and maintained to separate clean areas from soiled areas.

(ix) A toilet room with a water closet and handwashing lavatory shall be provided for patient use convenient to the unit. The toilet room and lavatory shall be accessible from a wheel chair.

(x) Adequate space shall be provided for instrument maintenance and storage of equipment, and for disassembling, preparation and testing of dialyzers.

(xi) A conference room shall be conveniently located in or near the unit.

(xii) There shall be space for record storage that can be locked.

(xiii) Adequate lighting shall be provided for the unit with a minimum of one hundred (100) footcandles appropriately placed to illuminate the patient’s connection and equipment area.

(xiv) Suction and oxygen equipment shall be available to the unit.

(xv) Mechanical ventilation with air conditioning shall be provided throughout the unit. Mechanical exhaust shall be provided for the reuse equipment area.

(c) Plans must be submitted and approved by the Office of Health Quality.