

This rule was files as 7 NMAC 36.2.

TITLE 7 HEALTH
CHAPTER 36 DIALYSIS AND KIDNEY FACILITIES AND TRAINING
PART 2 REQUIREMENTS FOR END STAGE RENAL DISEASE FACILITIES

7.36.2.1 ISSUING AGENCY: New Mexico Department of Health, Public Health Division, Health Facility Licensing and Certification Bureau.
[10/31/96; Recompiled 10/31/01]

7.36.2.2 SCOPE: These regulations apply to:
A. public, profit or nonprofit facilities or entities providing dialysis services as outlined by these regulations;
B. any facility providing services as outlined by these regulations which by federal regulation must be licensed by the state of New Mexico to obtain or maintain full or partial, permanent or temporary federal funding.
[1/27/84, 5/7/91; Recompiled 10/31/01]

7.36.2.3 STATUTORY AUTHORITY: The regulations set forth herein are promulgated by the secretary of the New Mexico department of health, pursuant to the general authority granted under Section 9-7-6(E) of the Department of Health Act, NMSA 1978, as amended; and the authority granted under Sections 24-1-2(D), 24-1-3(I) and 24-1-5 of the Public Health Act, NMSA 1978, as amended.
[1/27/84, 5/7/91, 10/31/96; Recompiled 10/31/01]

7.36.2.4 DURATION: Permanent.
[10/31/96; Recompiled 10/31/01]

7.36.2.5 EFFECTIVE DATE: October 31, 1996, unless a different date is cited at the end of a Section or Paragraph.
[10/31/96; Recompiled 10/31/01]
[Compiler's note: The words *or paragraph*, above, are no longer applicable. Later dates are now cited only at the end of sections, in the history notes appearing in brackets.]

7.36.2.6 OBJECTIVE:
A. Establish minimum standards for end stage renal disease facilities in the state of New Mexico.
B. Monitor end stage renal disease facilities with these regulations through surveys to identify any areas which could be dangerous or harmful to the patients or staff.
C. Encourage the maintenance of end stage renal disease facilities that will provide quality services which maintain or improve the health and quality of life for the patients.
[1/27/84, 5/7/91; Recompiled 10/31/01]

7.36.2.7 DEFINITIONS: For purposes of these regulations the following shall apply:
A. **“Applicant”** means the individual who, or organization which, applies for a license. If the applicant is an organization, then the individual signing the application on behalf of the organization must have authority from the organization. The applicant must be the owner.
B. **“Deficiency”** means a violation of or failure to comply with a provision(s) of these regulations.
C. **“License”** means the document issued by the licensing authority pursuant to these regulations granting the legal right to operate for a specified period of time, not to exceed one (1) year.
D. **“Licensee”** means the person(s) who, or organization which, has an ownership, leasehold or similar interest in the end stage renal disease facility and in whose name a license has been issued and who is legally responsible for compliance with these regulations.
E. **“Licensing authority”** means the New Mexico department of health.
F. **“NMSA”** means the New Mexico Statutes Annotated, 1978 compilation, and all the revisions and compilations thereof.

G. “Plan of correction” means the plan submitted by the licensee or representative of the licensee addressing how and when deficiencies identified at time of a survey will be corrected.

H. “Policy” means a statement of principal that guides and determines present and future decisions and actions.

I. “Procedure” means the action(s) that must be taken in order to implement a policy.

J. “Variance” means an act on the part of the licensing authority to refrain from pressing or enforcing compliance with a portion or portions of these regulations for an unspecified period of time where the granting of a variance will not create a danger to the health, safety, or welfare of patients or staff of a facility, and is at the sole discretion of the licensing authority.

K. “Waive/waiver” means to refrain from pressing or enforcing compliance with a portion or portions of these regulations for a limited period of time provided the health, safety or welfare of the patients and staff are not in danger. Waivers are issued at the sole discretion of the licensing authority.

[5/7/91, 10/31/96; Recompiled 10/31/01]

7.36.2.8 STANDARD OF COMPLIANCE: The degree of compliance required throughout these regulations is designated by the use of the words “shall” or “must” or “may.” “Shall” or “must” means mandatory. “May” means permissive. The use of the words “adequate”, “proper”, and other similar words means the degree of compliance that is generally accepted throughout the professional field by those who provide dialysis services as outlined in these regulations.

[5/7/91; Recompiled 10/31/01]

7.36.2.9 TYPES OF END STAGE RENAL DISEASE (ESRD) FACILITIES AND SCOPE OF SERVICES:

A. Renal transplantation center: A hospital unit which is approved to furnish directly, transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A renal transplantation center may also be a renal dialysis center.

B. Renal dialysis center: A hospital unit which is approved and licensed to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

C. Renal dialysis facility: A unit which is located in a building other than a hospital which is approved and licensed to furnish dialysis services directly to ESRD patients.

D. Self dialysis unit: A unit that is within a licensed renal transplantation center, renal dialysis center, or a renal dialysis facility, which provides self-dialysis service.

E. Special purpose renal dialysis facility: A renal dialysis facility which is approved and licensed pursuant to these regulations to provide dialysis at special locations on a short term basis (not to exceed eight (8) months) to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

F. End stage renal disease (ESRD) services: The types of care or services furnished to an ESRD patient are:

(1) transplantation service which is a process by which:

- (a) a kidney is excised from a live or cadaveric donor;
- (b) that kidney is implanted in an ESRD patient;
- (c) supportive care is furnished to the living donor and to the recipient following implantation;
- (d) this service is only provided at an approved and licensed transplantation center.

(2) inpatient dialysis which because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital. This service may only be provided by a transplantation center or renal dialysis center.

(3) outpatient dialysis is dialysis furnished on an outpatient basis at a licensed transplantation center, renal dialysis center, or renal dialysis facility and includes:

- (a) staff assisted dialysis which is dialysis performed by the staff of the center or facility;
- (b) self dialysis which is performed with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training;

(c) home dialysis performed by an appropriately trained patient at home.

(4) self dialysis and home dialysis training in which the licensed ESRD transplantation center, renal dialysis center, or renal dialysis facility provides a program that trains ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

[5/7/91; Recompiled 10/31/01]

7.36.2.10 INITIAL LICENSURE PROCEDURES: To obtain an initial license for an end stage renal disease facility pursuant to these regulations the following procedures must be followed by the applicant:

A. Initial phase: These regulations should be thoroughly understood by the applicant and used as a reference for design of a new building or renovation or addition to an existing building for licensure as an ESRD facility pursuant to these regulations. Prior to starting construction, renovations or additions to an existing building the applicant of the proposed ESRD facility shall advise the licensing authority of intention to open an ESRD facility pursuant to these regulations and submit the following:

(1) Plans: Submit a complete set of construction documents (blueprints) for the total building. Plans should indicate if new construction, remodeled or alteration, or an addition. If remodeled or an addition the plans must indicate existing and new construction.

(2) Functional program outline: The proposed end stage renal disease facility must also submit to the licensing authority a functional program outline that provides the following information:

- (a) scope of services to be provided by the proposed ESRD facility;
- (b) projected number of patients to be served daily;
- (c) number of staff and duties to be performed;
- (d) services that will be provided under agreement or arrangement with another facility;
- (e) number of dialysis stations, treatment rooms and other rooms for diagnostic use such as X-ray, laboratory, etc.

B. Construction phase: During the construction of a new building or renovations or additions to an existing building the applicant must coordinate with the licensing authority and submit any changes to the blueprints or plans for approval before making such changes.

C. Licensing phase: Prior to completion of construction, renovation or addition to an existing building the applicant will submit to the licensing authority the following:

(1) Application form:

- (a) will be provided by the licensing authority;
- (b) all information requested on the application must be provided;
- (c) will be printed or typed;
- (d) will be dated and signed;
- (e) will be notarized.

(2) Fees: All applications for licensure must be accompanied by the required fee.

(a) Current fee schedules will be provided by the licensing authority.

(b) Fees must be in the form of a certified check, money order, personal, or business check made payable to the state of New Mexico.

(c) Fees are non-refundable.

(3) Zoning and building approval:

(a) All initial applications must be accompanied with written zoning approval from the appropriate authority (city, county or municipality).

(b) All initial applications must be accompanied with written building approval (certificate of occupancy) from the appropriate authority (city, county, or municipality).

(4) Fire authority approval: All initial applications must be accompanied with written approval of the fire authority having jurisdiction.

(5) New Mexico environment department approval: All initial applications must be accompanied by written approval of the environmental department for the following:

- (a) private water supply, if applicable;
- (b) private waste or sewage disposal, if applicable;
- (c) X-ray equipment, if applicable.

(6) Copy of appropriate drug permit issued by the state board of pharmacy, if applicable.

(7) Initial survey: Upon receipt of a properly completed application with all supporting documentation as outlined above an initial survey of the proposed end stage renal disease facility will be scheduled by the licensing authority.

(8) Issuance of license: Upon completion of the initial survey and determination that the end stage renal disease facility is in compliance with these regulations the licensing authority will issue a license.
[1/27/84, 5/7/91, 10/31/96; Recompiled 10/31/01]

7.36.2.11 LICENSES:

A. Annual license: An annual license is issued for a one (1) year period to an end stage renal disease facility which has met all requirements of these regulations.

B. Temporary license: The licensing authority may, at its sole discretion, issue a temporary license prior to the initial survey, or when the licensing authority finds partial compliance with these regulations.

(1) A temporary license shall cover a period of time, not to exceed one hundred-twenty (120) days, during which the facility must correct all specified deficiencies.

(2) In accordance with Section 24-1-5(D) NMSA 1978, no more than two (2) consecutive temporary licenses shall be issued.

C. Amended license: A licensee must apply to the licensing authority for an amended license when there is a change of administrator/director, or when there is a change of name for the facility.

(1) Application must be on a form provided by the licensing authority.

(2) Application must be accompanied by the required fee for an amended license.

(3) Application must be submitted within ten (10) working days of the change.

[1/27/84, 5/7/91, 10/31/96; Recompiled 10/31/01]

7.36.2.12 LICENSE RENEWAL:

A. Licensee must submit a renewal application on forms provided by the licensing authority, along with the required fee at least thirty (30) days prior to expiration of the current license.

B. Upon receipt of renewal application and required fee, the licensing authority will issue a new license effective the day following the date of expiration of the current license, if the facility is in substantial compliance with these regulations.

C. If a licensee fails to submit a renewal application with the required fee and the current license expires, the ESRD facility shall cease operations until it obtains a new license through the initial licensure procedures. Section 24-1-5(A) NMSA 1978, as amended, provides that no health facility shall be operated without a license.

[1/27/84, 5/7/91, 10/31/96; Recompiled 10/31/01]

7.36.2.13 POSTING OF LICENSE: The ESRD facility's license must be posted in a conspicuous place in an area visible to the public.

[5/7/91; Recompiled 10/31/01]

7.36.2.14 NON-TRANSFERABLE RESTRICTION ON LICENSE: A license shall not be transferred by assignment or otherwise to other persons or locations. The license shall be void and must be returned to the licensing authority when any one of the following situations occur:

A. ownership of the facility changes;

B. the facility changes location;

C. licensee of the facility changes;

D. the facility discontinues operation;

E. a facility wishing to continue operation as a licensed end stage renal disease facility under circumstances 14.1 through 14.4 [now Subsections A through D of 7.36.2.14 NMAC] above must submit an application for initial licensure in accordance with Section 10 [now 7.36.2.10 NMAC] of these regulations, at least thirty (30) days prior to the anticipated change.

[5/7/91, 10/31/96; Recompiled 10/31/01]

7.36.2.15 AUTOMATIC EXPIRATION OF LICENSE: A license will automatically expire at midnight on the day indicated on the license as the expiration date, unless sooner renewed, suspended or revoked, or:

A. on the day a facility discontinues operation;

- B. on the day a facility is sold, leased, or otherwise changes ownership and/or licensee;
 - C. on the day a facility changes location.
- [1/27/84, 5/7/91, 10/31/96; Recompiled 10/31/01]

7.36.2.16 SUSPENSION OF LICENSE WITHOUT PRIOR HEARING: In accordance with Section 24-1-5(H) NMSA 1978, if immediate action is required to protect human health and safety, the licensing authority may suspend a license pending a hearing, provided such hearing is held within five (5) working days of the suspension, unless waived by the licensee.
[1/27/84, 5/7/91; Recompiled 10/31/01]

7.36.2.17 GROUNDS FOR REVOCATION OR SUSPENSION OF LICENSE, DENIAL OF INITIAL OR RENEWAL APPLICATION FOR LICENSE, OR IMPOSITION OF INTERMEDIATE SANCTIONS OR CIVIL MONETARY PENALTIES: A license may be revoked or suspended, an initial or renewal application for license may be denied, or intermediate sanctions or civil monetary penalties may be imposed after notice and opportunity for a hearing, for any of the following reasons:

- A. Failure to comply with any provision of these regulations.
 - B. Failure to allow survey by authorized representatives of the licensing authority.
 - C. Any person active in the operation of a facility licensed pursuant to these regulations shall not be under the influence of alcohol or narcotics or convicted of a felony.
 - D. Misrepresentation or falsification of any information on application forms or other documents provided to the licensing authority.
 - E. Discovery of repeat violations of these regulations during surveys.
 - F. Failure to provide the required care and services as outlined by these regulations for the patients receiving care at the facility.
- [1/27/84, 5/7/91, 10/31/96; Recompiled 10/31/01]

7.36.2.18 HEARING PROCEDURES:

- A. Hearing procedures for an administrative appeal of an adverse action taken by the licensing authority against an ESRD facility license as outlined in Section 16 and 17 [now Sections 16 and 17 of 7.36.2 NMAC] above will be held in accordance with Adjudicatory Hearings, New Mexico department of health, 7 NMAC 1.2 (2-1-96) [now 7.1.2 NMAC].
 - B. A copy of the adjudicatory hearing procedures will be furnished to an ESRD facility at the time an adverse action is taken against its license by the licensing authority. A copy may be requested at any time by contacting the licensing authority.
- [1/27/84, 5/7/91, 10/31/96; Recompiled 10/31/01]

7.36.2.19 CURRENTLY LICENSED FACILITIES: Any ESRD facility currently licensed on the date these regulations are promulgated and which provides the services prescribed under these regulations, but which fails to meet all building requirements, may continue to be licensed if:

- A. variance may be granted for those building requirements the ESRD facility cannot meet provided the variances granted will not create a hazard to the health, safety and welfare of the patients and staff, and are not in violation of current fire and building codes;
 - B. the building requirements for which variances are granted cannot be corrected without an unreasonable expense to the ESRD facility; and
 - C. variances granted will be recorded and made a permanent part of the end stage renal disease facility file.
- [5/7/91; Recompiled 10/31/01]

7.36.2.20 NEW FACILITY: A new ESRD facility may be opened in an existing building or a newly constructed building.

- A. If opened in an existing building a variance may be granted for those building requirements the ESRD facility cannot meet under the same criteria outlined in Section 19.1, 19.2 and 19.3 [now Subsections A, B and C of 7.36.2.19 NMAC], if not in conflict with existing building and fire codes. This is at the sole discretion of the licensing authority.

B. A new ESRD facility opened in a newly constructed building must meet all requirements of these regulations.
[5/7/91; Recompiled 10/31/01]

7.36.2.21 FACILITY SURVEYS:

A. Application for licensure, whether initial or renewal shall constitute permission for entry into and survey of a ESRD facility by authorized licensing authority representatives at reasonable times during the pendency of the application and, if licensed, during the licensure period.

B. The licensing authority shall perform, as it deems necessary, unannounced on-site surveys to determine compliance with these regulations, to investigate complaints, or to investigate the appropriateness of licensure for any alleged unlicensed facility.

C. Upon receipt of a notice of deficiency from the licensing authority the licensee or his/her representative will be required to submit a plan of correction to the licensing authority within ten (10) working days, stating how the facility intends to correct each violation noted and the expected date of completion.

D. The licensing authority may, at its sole discretion, accept the plan of correction as written or require modifications of the plan by the licensee.
[5/7/91, 10/31/96; Recompiled 10/31/01]

7.36.2.22 ADOPTION OF FEDERAL STANDARDS: The licensing authority hereby adopts the federal standards for certification of end stage renal disease (ESRD) services, as set out in 42 C.F.R. Sections 405.2100 through 405.2171, as amended from time to time, as the standards for licensure of end stage renal disease services in the state of New Mexico.
[5/7/91; Recompiled 10/31/01]

7.36.2.23 RELATED REGULATIONS AND CODES: End stage renal disease facilities subject to these regulations are also subject to other regulations, codes and standards as the same may, from time to time, be amended as follows:

A. Health Facility Licensure Fees and Procedures, New Mexico department of health, 7 NMAC 1.7 (10-31-96) [now 7.1.7 NMAC];

B. Health Facility Sanctions and Civil Monetary Penalties, New Mexico department of health 7 NMAC 1.8 (10-31-96)[now 7.1.8 NMAC];

C. Adjudicatory Hearings, New Mexico department of health, 7 NMAC 1.2 (2-1-96) [now 7.1.2 NMAC].
[1/27/84, 5/7/91, 10/31/96; Recompiled 10/31/01]

HISTORY OF 7.36.2 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed with the State Records Center: HED-84-1 (HSD), Regulations Governing Renal Dialysis Outpatient Facility Licensing, 1/27/84. DOH-91-1 (PHD), New Mexico Regulations Governing Facilities Providing Services For End Stage Renal Disease (ESRD), 5/7/91.

History of Repealed Material: [RESERVED]