

CHAPTER 412**LICENSING OF END-STAGE RENAL DISEASE FACILITIES****§2041. Definitions**

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings. [PL 1997, c. 658, §1 (NEW).]

1. Agreement. "Agreement" means a written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

[PL 1997, c. 658, §1 (NEW).]

2. Arrangement. "Arrangement" means a written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

[PL 1997, c. 658, §1 (NEW).]

3. Dialysis. "Dialysis" means 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 2 types of dialysis that are in common use are hemodialysis and peritoneal dialysis.

[PL 1997, c. 658, §1 (NEW).]

4. End-stage renal disease or ESRD. "End-stage renal disease" or "ESRD" means that stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.

[PL 1997, c. 658, §1 (NEW).]

5. ESRD facility. "ESRD facility" means a renal dialysis center, a renal dialysis facility, a self-dialysis unit or a special-purpose renal dialysis facility.

[PL 2011, c. 257, §10 (AMD).]

6. Renal transplantation center.

[PL 2011, c. 257, §11 (RP).]

7. Renal dialysis center. "Renal dialysis center" means a hospital unit that is approved 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.

[PL 1997, c. 658, §1 (NEW).]

8. Renal dialysis facility. "Renal dialysis facility" means a unit that is approved to furnish dialysis services directly to ESRD patients. "Renal dialysis facility" includes a self-dialysis unit or a special-purpose renal dialysis facility.

[PL 1997, c. 658, §1 (NEW).]

9. Self-dialysis unit. "Self-dialysis unit" means a unit that is part of an approved renal dialysis center or renal dialysis facility and furnishes self-dialysis services.

[PL 2011, c. 257, §12 (AMD).]

10. Special-purpose renal dialysis facility. "Special-purpose renal dialysis facility" means a renal dialysis facility that is approved to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative locations, including vacation locations, serving ESRD patients

temporarily residing at those locations or locations in need of ESRD facilities under emergency circumstances.

[PL 1997, c. 658, §1 (NEW).]

SECTION HISTORY

PL 1997, c. 658, §1 (NEW). PL 2011, c. 257, §§10-12 (AMD).

§2042. Licensing of facilities

1. Licensing and certification required. The following licensing and certification requirements apply to ESRD facilities.

A. Beginning January 1, 1999, a person, partnership, association or corporation may not represent itself as an ESRD facility, operate as an ESRD facility or otherwise provide ESRD services unless the person, partnership, association or corporation has obtained a license from the department. [PL 1997, c. 658, §1 (NEW).]

B. Beginning January 1, 1999, an ESRD facility, other than an acute care hospital, must be Medicare-certified and meet Medicare requirements to be eligible for licensure as an ESRD facility. [PL 1997, c. 658, §1 (NEW).]

[PL 1997, c. 658, §1 (NEW).]

2. Licenses. If, after receiving an application for a license under this chapter, the department finds that all other conditions of licensure are met, it shall issue a license to the applicant for a period of one year. If the department finds less than full compliance with the conditions of licensure, it may issue a conditional license.

The department may issue a conditional license if the applicant fails to comply with applicable laws and rules but the best interest of the public would be served by issuing a conditional license. The conditional license must specify when and what corrections must be made during the term of the conditional license.

When an applicant fails to comply with applicable laws and rules, the department may refuse to issue or renew a license.

[PL 1997, c. 658, §1 (NEW).]

3. Appeals. An applicant for a license under this chapter who is denied a license or whose application is not acted upon with reasonable promptness has the right of appeal to the commissioner. The commissioner shall provide the appellant with reasonable notice and opportunity for a fair hearing. The commissioner or a member of the department designated and authorized by the commissioner shall hear all evidence pertinent to the matter at issue and render a decision within a reasonable period after the date of hearing. The hearing must conform to the procedures detailed in this subsection. Review of any action or failure to act under this chapter must be pursuant to Title 5, chapter 375, subchapter VII. An action relative to the denial of a license provided under this chapter must be communicated to the applicant in writing and must include the specific reason or reasons for that action and must state that the person affected has a right to a hearing.

[PL 1997, c. 658, §1 (NEW).]

4. Right of entry and inspection. A duly designated employee of the department may enter the premises of any ESRD services provider who has applied for a license or who is licensed pursuant to this chapter or rules adopted pursuant to this chapter. These employees may inspect relevant documents of the ESRD services provider to determine whether the provider is in compliance with this chapter and rules adopted pursuant to this chapter. The right of entry and inspection extends to any premises and documents of a provider the department has reason to believe is providing ESRD services without a license. An entry or inspection must be made with the permission of the owner or person in charge

unless a warrant is first obtained from the District Court authorizing that entry or inspection under section 2148.

[PL 1997, c. 658, §1 (NEW).]

5. Application fee. An application for a license under this chapter must be accompanied by a fee established by the department based on the cost of survey and enforcement. All fees collected under this subsection must be deposited into the General Fund.

[PL 1997, c. 658, §1 (NEW).]

6. Compliance. An ESRD facility must meet all appropriate state rules and federal regulations.

[PL 1997, c. 658, §1 (NEW).]

7. Minimum survey requirement. An ESRD facility is not eligible for licensure or renewal of licensure unless the ESRD facility has had a Medicare survey or a state licensure survey within the previous 36 months.

[PL 2011, c. 257, §13 (AMD).]

8. Rules. The department shall adopt rules governing the specific requirements for licensure under this chapter. These rules are routine technical rules in accordance with Title 5, chapter 375, subchapter II-A. The rules must include at least the following.

A. The ESRD facility must be in compliance with applicable federal, state and local laws and regulations. [PL 1997, c. 658, §1 (NEW).]

B. The ESRD facility must meet all Medicare certification requirements. [PL 1997, c. 658, §1 (NEW).]

C. All ESRD facilities must be required to have a backup emergency generator. The emergency generator must be made operational for a period of at least 1/2 hour each month. [PL 1997, c. 658, §1 (NEW).]

[PL 1997, c. 658, §1 (NEW).]

9. Sanctions. A person who violates this chapter commits a civil violation for which a forfeiture not to exceed \$100 per day of violation may be adjudged.

[PL 1997, c. 658, §1 (NEW).]

SECTION HISTORY

PL 1997, c. 658, §1 (NEW). PL 2011, c. 257, §13 (AMD).

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