

# MAINE STATE LEGISLATURE

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# 118th MAINE LEGISLATURE

## SECOND REGULAR SESSION-1998

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Legislative Document

No. 2151

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H.P. 1529

House of Representatives, January 21, 1998

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**An Act to Regulate the Functioning of End-stage Renal Disease Facilities.**

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Submitted by the Department of Human Services pursuant to Joint Rule 204.  
Reference to the Committee on Health and Human Services suggested and ordered printed.

A handwritten signature in cursive script that reads "Joseph W. Mayo".

JOSEPH W. MAYO, Clerk

Presented by Representative FULLER of Manchester.

2 Be it enacted by the People of the State of Maine as follows:

4 Sec. 1. 22 MRSA c. 412 is enacted to read:

6 CHAPTER 412

8 LICENSING OF END-STAGE RENAL  
DISEASE FACILITIES

10 §2041. Definitions

12 As used in this chapter, unless the context otherwise  
indicates, the following terms have the following meanings.

14 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.

20 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.

26 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.

32 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.

38 5. ESRD facility. "ESRD facility" includes a renal  
transplantation center, a renal dialysis center or a renal  
dialysis facility.

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

2 7. Renal dialysis center. "Renal dialysis center" means a  
3 hospital unit that is approved to furnish the full spectrum of  
4 diagnostic, therapeutic and rehabilitative services required for  
5 the care of ESRD dialysis patients, including inpatient dialysis  
6 furnished directly or under arrangement. A hospital need not  
7 provide renal transplantation to qualify as a renal dialysis  
8 center.

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

13 9. Self-dialysis unit. "Self-dialysis unit" means a unit  
14 that is part of an approved renal transplantation center, renal  
15 dialysis center or renal dialysis facility and furnishes  
16 self-dialysis services.

17 10. Special-purpose renal dialysis facility.  
18 "Special-purpose renal dialysis facility" means a renal dialysis  
19 facility that is approved to furnish dialysis at special  
20 locations on a short-term basis to a group of dialysis patients  
21 otherwise unable to obtain treatment in the geographical area.  
22 The special locations must be either special rehabilitative  
23 locations, including vacation locations, serving ESRD patients  
24 temporarily residing at those locations or locations in need of  
25 ESRD facilities under emergency circumstances.

26 **§2042. Licensing of facilities**

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

29 A. Beginning January 1, 1999, a person, partnership,  
30 association or corporation may not represent itself as an  
31 ESRD facility, operate as an ESRD facility or otherwise  
32 provide ESRD services unless the person, partnership,  
33 association or corporation has obtained a license from the  
34 department.

35 B. Beginning January 1, 1999, an ESRD facility, other than  
36 an acute care hospital, must be Medicare-certified and meet  
37 Medicare requirements to be eligible for licensure as an  
38 ESRD facility.

39 2. Licenses. If, after receiving an application for a  
40 license under this chapter, the department finds that all other  
41 conditions of licensure are met, it shall issue a license to the  
42 applicant for a period of one year. If the department finds less  
43 than the minimum number of beds, the department may  
44 issue a license for a shorter period.

2 than full compliance with the conditions of licensure, it may  
3 issue a conditional license.

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

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

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13  
14 3. Appeals. An applicant for a license under this chapter  
15 who is denied a license or whose application is not acted upon  
16 with reasonable promptness has the right of appeal to the  
17 commissioner. The commissioner shall provide the appellant with  
18 reasonable notice and opportunity for a fair hearing. The  
19 commissioner or a member of the department designated and  
20 authorized by the commissioner shall hear all evidence pertinent  
21 to the matter at issue and render a decision within a reasonable  
22 period after the date of hearing. The hearing must conform to  
23 the procedures detailed in this subsection. Review of any action  
24 or failure to act under this chapter must be pursuant to Title 5,  
25 chapter 375, subchapter VII. An action relative to the denial of  
26 a license provided under this chapter must be communicated to the  
27 applicant in writing and must include the specific reason or  
28 reasons for that action and must state that the person affected  
29 has a right to a hearing.

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32 4. Right of entry and inspection. A duly designated  
33 employee of the department may enter the premises of any ESRD  
34 services provider who has applied for a license or who is  
35 licensed pursuant to this chapter or rules adopted pursuant to  
36 this chapter. These employees may inspect relevant documents of  
37 the ESRD services provider to determine whether the provider is  
38 in compliance with this chapter and rules adopted pursuant to  
39 this chapter. The right of entry and inspection extends to any  
40 premises and documents of a provider the department has reason to  
41 believe is providing ESRD services without a license. An entry  
42 or inspection must be made with the permission of the owner or  
43 person in charge unless a warrant is first obtained from the  
44 District Court authorizing that entry or inspection under section  
45 2148.

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

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

4  
6           7. Minimum survey requirement. An ESRD facility is not  
eligible for licensure or renewal of licensure unless the ESRD  
8 facility has had a Medicare survey or a state licensure survey  
within the previous year.

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

16           A. The ESRD facility must be in compliance with applicable  
federal, state and local laws and regulations.

18           B. The ESRD facility must meet all Medicare certification  
20 requirements.

22           C. All ESRD facilities must be required to have a backup  
emergency generator. The emergency generator must be made  
24 operational for a period of at least 1/2 hour each month.

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

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32                                   **SUMMARY**

34           This bill provides state licensing regulations for end-stage  
renal disease facilities to be surveyed annually to ensure the  
36 public health, safety and welfare of dialysis patients in the  
State. Presently there is no regular oversight for this critical  
38 lifesaving treatment other than the initial Medicare  
certification and random Medicare surveys, which may occur at any  
40 time from 3 to 5 years. This bill would allow the Medicare  
survey to be deemed to meet state rules, thereby avoiding  
42 duplication of the survey process. The licensing requirements  
will mirror the Medicare requirements. The national trend of  
44 unfavorable outcomes has prompted the Department of Human  
Services, Division of Licensing and Certification to propose this  
46 legislation in a proactive manner to protect the citizens of  
Maine.