

SPONSOR: Rep. Atkins & Sen. Hocker & Sen. Venables
Reps. Briggs King, Heffernan, Keeley, M. Smith; Sens. Ennis, Henry, Poore

HOUSE OF REPRESENTATIVES

147th GENERAL ASSEMBLY

HOUSE BILL NO. 360
AS AMENDED BY
HOUSE AMENDMENT NO. 2

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO THE POWERS, DUTIES, REGULATIONS AND ORDERS OF THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE (Three-fifths of all members elected to each house thereof concurring therein):

Section 1. Amend § 122(3), Title 16 of the Delaware Code by making deletions as shown by strike through and insertions shown by underline as follows and re-letter accordingly:

§ 122 Powers and duties of the Department of Health and Social Services.

The Department shall have the following general powers and duties:

(1) Supervision of all matters relating to the preservation of the life and health of the people of the State.

(2) Supreme authority in matters of quarantine; it may declare and enforce such quarantine, when necessary and where no quarantine exists, and may modify, relax or abolish it, where it has been established.

(3) Adopt, promulgate, amend, and repeal regulations consistent with law, which regulations shall not extend, modify or conflict with any law of this State or the reasonable implications thereof, and which shall be enforced by all state and local public health officials, to:

(aa) Establish standards for public health quality assurance in the operation of dialysis centers and regulate the public health practice of such programs, which shall include but not be limited to a standard requirement for appropriate emergency energy sources capable of use for at least 48 hours and at least a monthly test of those emergency sources. For purposes of this section, a "dialysis center" means a facility approved to furnish outpatient dialysis services directly to end stage renal disease (ESRD) patients. Outpatient dialysis includes

HD : SLT : TEH:1031470308
LC : MJC : RAY:4801470178

staff-assisted dialysis (dialysis performed by the staff of the facility) and self-dialysis (dialysis performed with little or no professional assistance by an ESRD patient who has completed an appropriate course of training). ESRD is that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life. To perform these functions, the Division of Public Health shall have the authority to collect and retain reasonable fees necessary to defray costs of these functions.

1. The amount charged for each fee imposed under this section shall approximate and reasonably reflect all costs necessary to defray the expenses incurred by the Division of Public Health. There shall be a separate fee charged for each service or activity, but no fee shall be charged for a purpose not specified in this chapter. The application fee shall not be combined with any other fee or charge. At the beginning of each calendar year, the Division of Public Health, or any other state agency acting on its behalf, shall compute for each separate service or activity the appropriate fees for the coming year.

2. Upon receipt of an application for licensure and the nonrefundable application fee, the Department shall issue a license if the dialysis center meets the requirements established under this chapter. A license, unless sooner suspended or revoked, shall be renewed annually upon filing by the licensee and payment of an annual licensure fee.

3. A provisional license, as authorized by the Department, shall be issued when health requirements are not met and a licensure fee has been submitted. A dialysis center which has been issued a provisional license shall resubmit the application fee for reinspection prior to the issuance of an annual license.

4. The Department may impose sanctions singly or in combination when it finds a licensee or former licensee has:

A. Violated any of these regulations;

B. Failed to submit a reasonable timetable for correction of deficiencies;

C. Failed to correct deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department;

D. Exhibited a pattern of cyclical deficiencies which extends over a period of 2 or more years;

E. Engaged in any conduct or practices detrimental to the welfare of the patients;

F. Exhibited incompetence, negligence or misconduct in operating the dialysis center or in providing services to patients;

G. Mistreated or abused patients cared for by the dialysis center;

H. Violated any statutes relating to Medical Assistance or Medicare reimbursement for those facilities who participate in those programs; or

I. Refused to allow the Department access to the dialysis center or records for the purpose of conducting inspections/surveys/investigations as deemed necessary by the Department.

5. Disciplinary sanctions include any of the following:

A. Permanent revocation of a license which extends to:

i. The dialysis center;

ii. Any owner;

iii. Officers/directors, partners, managing members or members of a governing body who have a financial interest of five percent (5%) or more in the dialysis center; and

iv. Corporation officers.

B. Suspension of a license;

C. A letter of reprimand;

D. Placement on provisional status with the following requirements:

i. Report regularly to the Department upon the matters which are the basis of the provisional status;

ii. Limit practice to those areas prescribed by the Department;

iii. Suspend operations;

E. Refusal of a license;

F. Refusal to renew a license; and/or

G. Other disciplinary action as appropriate.

6. The Department may request the Superior Court to impose a civil penalty of not more than $10,000 for a violation of these regulations. Each day a violation continues constitutes a separate violation.

A. In lieu of seeking a civil penalty, the Department, in its discretion, may impose an administrative penalty of not more than $10,000 for a violation of these regulations. Each day a violation continues constitutes a separate violation.

B. In determining the amount of any civil or administrative penalty imposed, the Court or the Department shall consider the following factors:

i. The seriousness of the violation, including the nature, circumstances, extent and gravity of the violation and the threat or potential threat to the health or safety of a patient;

ii. The history of violations committed by the person or the person's affiliate, agent, employee or controlling person;

iii. The efforts made by the dialysis center to correct the violation(s);

iv. Any misrepresentation made to the Department; and

v. Any other matter that affects the health, safety or welfare of a patient.

7. Imposition of disciplinary action

A. Before any disciplinary action is taken the following shall occur:

i. The Department shall give 20 calendar days written notice to the holder of the license, setting forth the reasons for the determination.

ii. The disciplinary action shall become final 20 calendar days after the mailing of the notice unless the licensee, within such 20 calendar day period, shall give written notice of the dialysis center's desire for a hearing.

iii. If the licensee gives such notice, the dialysis center shall be given a hearing before the Secretary of the Department or her or his designee and may present such evidence as may be proper.

iv. The Secretary of the Department or her or his designee shall make a determination based upon the evidence presented.

v. A written copy of the determination and the reasons upon which it is based shall be sent to the dialysis center.

vi. The decision shall become final 20 calendar days after the mailing of the determination letter unless the licensee, within the 20 calendar day period, appeals the decision to the appropriate court of the State.

8. Order to immediately suspend a license

A. In the event the Department identifies activities which the Department determines present an immediate jeopardy or imminent danger to the public health, welfare or safety requiring emergency action, the Department may issue an order temporarily suspending the licensee's license, pending a final hearing on the complaint. No order temporarily suspending a license shall be issued by the Department, with less than 24 hours prior written or oral notice to the licensee or the licensee's attorney so that the

licensee may be heard in opposition to the proposed suspension. An order of temporary suspension under this section shall remain in effect for a period not longer than 60 calendar days from the date of the issuance of said order, unless the suspended licensee requests a continuance of the date for the final hearing before the Department. If a continuance is requested, the order of temporary suspension shall remain in effect until the Department has rendered a decision after the final hearing.

B. The licensee, whose license has been temporarily suspended, shall be notified forthwith in writing. Notification shall consist of a copy of the deficiency report and the order of temporary suspension pending a hearing and shall be personally served upon the licensee or sent by mail, return receipt requested, to the licensee's last known address.

C. A licensee whose license has been temporarily suspended pursuant to this section may request an expedited hearing. The Department shall schedule the hearing on an expedited basis provided that the Department receives the licensee's written request for an expedited hearing within 5 calendar days from the date on which the licensee received notification of the Department's decision to temporarily suspend the licensee's license.

D. As soon as possible, but in no event later than 60 calendar days after the issuance of the order of temporary suspension, the Department shall convene for a hearing on the reasons for suspension. In the event that a licensee, in a timely manner, requests an expedited hearing, the Department shall convene within 15 calendar days of the receipt by the Department of such a request and shall render a decision within 30 calendar days.

E. In no event shall an order of temporary suspension remain in effect for longer than 60 calendar days unless the suspended licensee requests an extension of the order of temporary suspension pending a final decision of the Department. Upon a final decision of the Department, the order of temporary suspension may be vacated in favor of the disciplinary action ordered by the Department.

9. Application for licensure after revocation or voluntary surrender of a license in avoidance of revocation action.

A. The application for license after termination of rights to provide services shall follow the procedure for initial licensure application.

B. In addition to the licensure application, the dialysis center must also submit and obtain approval of a detailed plan of correction regarding how the dialysis center intends to correct the deficient

practices that lead to the original termination action. Submission of evidence supporting compliance with the plan and cooperation with Department monitoring during probationary and provisional licensure status is required for reinstatement to full licensure status.

C. Upon successful completion of the probationary period, the dialysis center will be granted a provisional license for a period no less than 1 year but no greater than 2 years. The provisional period will be identified by the Department after having considered the circumstances that created the original action for license revocation.

D. A license will be granted to the dialysis center after the provisional licensure period if:

i. The dialysis center has remained in substantial compliance with these rules and regulations; and

ii. The dialysis center fulfilled the expectations of the detailed plan of correction that was created to address the deficient practices that gave rise to the license termination action.

E. A license will not be granted after the probationary or provisional licensure period to any dialysis center that is not in substantial compliance with these rules and regulations.

Section 2: This Act shall become effective 6 months after the date of its enactment.