

CHAPTER 235
FORMERLY
HOUSE BILL NO. 326

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO 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, Title 16 of the Delaware Code as follows:

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

The Department shall have the following general powers and duties:

(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 all dialysis machines to be connected to an emergency power source so that all dialysis machines will operate for at least 4 hours following a power shutdown or outage. In addition, the emergency power source must be in working condition at all times and the dialysis center must conduct and document at least a monthly test of those emergency power sources. For purposes of this section, a "dialysis center" means an independent or hospital-based unit approved to furnish outpatient dialysis services directly to end stage renal disease (ESRD) patients maintenance dialysis services, or home dialysis training and support services, or both to end stage renal disease patients. To perform these functions, the Department shall have the authority to collect and retain reasonable fees necessary to defray costs of these functions. At all times there must be a facility that meets the requirements of this section in each of the following locations: the City of Wilmington, New Castle County, Kent County, and Sussex County. Dialysis centers operating as of July 1, 2015, are to be compliant with all aspects of this section immediately but may be granted a hardship exemption to immediate compliance but only until at the latest January 1, 2021. Hardship exemptions may be granted for facilities in long term leases, other issues regarding real estate, and any other reason as determined by the Department. Dialysis centers that are newly constructed or relocated after July 1, 2015, must be compliant with all aspects of this section prior to occupancy.

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 Department. 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 Department, 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.

Approved May 19, 2016