



**STATE OF DELAWARE  
STATE COUNCIL FOR PERSONS WITH DISABILITIES**

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The Honorable John Carney  
Governor

John A. McNeal  
Director

**MEMORANDUM**

DATE: January 30, 2019

TO: Ms. Corinna Getchell, DHHS/DHCQ  
Planning & Policy Development Unit

FROM: J. Todd Webb - Chairperson  
State Council for Persons with Disabilities

RE: 22 DE Reg. 565 [DHSS/DHCQ Proposed Regulation Governing Dialysis Centers  
(1/1/19)]

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health & Social Services/Division of Health Care Quality's (DHSS/DHCQs) proposed regulations governing dialysis centers. This proposed regulation was published as 22 DE Reg. 565 in the January 1, 2019 issue of the Register of Regulations.

The purpose of this regulation is to establish quality assurance standards for dialysis centers to implement the 2014 and 2015 changes in the law [16 *Del. C.* §122(3)(aa)]. It also gives DHSS authority to charge licensing fees to offset the costs of performing their responsibilities under the statute and regulation. This is a comprehensive regulation that aims to protect the public in obtaining dialysis services from an independent or hospital based center.

The regulation applies to dialysis centers and they are defined in both the statute and regulation as "an independent or hospital-based unit approved and licensed to furnish outpatient dialysis services (maintenance dialysis services, home dialysis training and support services or both) directly to end stage renal disease (ESRD) patient(s)."

In summary, this regulation is comprehensive and deals with all aspects of dialysis, including independent and hospital based centers, as well as home dialysis services offered by those centers. It mandates licensing requirements and gives the Department authority to impose a variety of sanctions for non-compliance with the regulation. It requires a center to have a governing body and imposes numerous duties and responsibilities on that body. Each center is

required to have medical staff which includes a medical director, nurse manager, charge and staff nurses, a dietitian, social worker, patient care technicians, and water treatment system technicians. Patients or their representatives must be informed of the patient's rights and responsibilities. An interdisciplinary team consisting of the patient or patient's representative, nurse, social worker, dietitian, and doctor must prepare a comprehensive assessment of the patient which is then used to formulate a treatment plan. If home dialysis is provided by the center, it must be approved by the Department to provide this service and the interdisciplinary team must oversee the training to the patient and patient caregivers. The center must also provide support services to home dialysis patients. Detailed medical records of all patients must be kept and be accessible for review by the Department. There are several patient rights measures, including a provision that requires the center to report the involuntary discharge or transfer of a patient to DHSS. This is an important safety measure. Lastly, the center must have emergency preparedness in that the dialysis machines must operate for at least four (4) hours on an alternative power source if there is a power outage.

SCPD endorses the regulation as it comprehensively addresses this crucial outpatient service. The regulation deals with a medical service that is necessary for those individuals with kidney disease. This regulation should meet its intended goal of protecting dialysis patients by establishing standards and guidelines so that they receive competent medical care for a life-saving procedure. However, SCPD has the following recommendation which would strengthen the regulation:

Currently, the proposed regulation requires dialysis centers to have a discharge policy and share it with the patient. However, it does not include language regarding what is required to be in the involuntary discharge/release policy. The regulation could be strengthened by including language which provides more specifics about what is included in the discharge policy such as procedures, alternative treatment options, and a requirement to follow-up with the patient who is involuntarily discharged.

Thank you for your consideration and please contact SCPD if you have any questions regarding our position or recommendations on the proposed regulation.

cc: Ms. Mary Peterson, DHCQ  
Ms. Laura Waterland, Esq.  
Governor's Advisory Council for Exceptional Citizens  
Developmental Disability Council

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