

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF HEALTH CARE QUALITY

Statutory Authority: 16 Delaware Code, Section 122(3)aa. (16 **Del.C.** §122(3)aa.)

FINAL

ORDER

3330 Regulations Governing Dialysis Centers

Nature of The Proceedings

Delaware Health and Social Services (“DHSS”) initiated proceedings to adopt the State of Delaware Regulations Governing Dialysis Centers. The DHSS proceedings to adopt regulations were initiated pursuant to 29 Delaware Code Chapter 101 and authority as prescribed by 16 Delaware Code, Section 122 (3)aa.

On January 1, 2019 (Volume 22, Issue 7), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 **Del.C.** §10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by January 31, 2019, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying “Summary of Evidence.”

Summary of Proposal

Effective April 1, 2019, DHSS/Division of Health Care Quality (DHCQ) is publishing the final regulations governing Dialysis Centers.

Background

On September 2, 2014, House Bill (HB) 360 with House Amendment 2 became law. HB 360 amended 16 **Del.C.** §122 to require the DHSS to establish and enforce dialysis center quality assurance standards, which includes a standard requirement for an appropriate emergency energy source capable of use for at least 48 hours and at least a monthly test of those emergency sources.

Subsequently, Senate Bill (SB) 131 with Senate Amendment 1 (signed into law June 30, 2015) amended 16 **Del.C.** §122 to define a dialysis center as an independent or hospital-based unit approved to furnish outpatient dialysis services (maintenance dialysis services or home dialysis training and support, or both) directly to end stage renal disease patients. In addition, SB 131 includes 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 four (4) hours following a power shutdown or outage. 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.

Statutory Authority

16 **Del.C.** §122(3)(aa)

Purpose

The Division of Health Care Quality published “proposed” regulations governing Dialysis Centers and held them out for public comment per Delaware law. These regulations 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, including maintenance dialysis services, or home dialysis training and support services, or both to end stage renal disease patients.

Fiscal Impact

16 **Del.C.** §122(3)(aa) gives the DHSS authority to impose licensure fees. The amount charged for each fee imposed shall approximate and reasonably reflect all costs necessary to defray the expenses incurred by the DHSS. There shall be a separate fee charged for each service or activity.

Proposed Initial Fee	Proposed Renewal Fee
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\$1000 + \$500 for each additional service above 1	\$600 + \$300 for each additional service above 1
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SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Dialysis Centers were published in the Delaware *Register of Regulations*. Written comments were received on the proposed regulations during the public comment period (January 1, 2019 through January 31, 2019).

Public comments and the DHSS (Department) responses are as follows:

Ann C. Fisher, Chairperson Governor's Advisory Council for Exceptional Citizens

Comment: The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed the Delaware Health and Social Services (DHSS)/Division of Health Care Quality (DHCQ) proposal to establish quality assurance standards for dialysis centers thus implementing the 2014 and 2015 changes to 16 Del.C. §122(3)(aa). The proposed regulation also gives DHSS the authority to charge licensing fees to offset the costs of performing their responsibilities under the statute and regulation. Dialysis is a medical service that is necessary for individuals with kidney disease. Council endorses the proposed regulation as it is a comprehensive regulation that aims to protect the public in obtaining dialysis services from an independent or hospital based center. However, we would like to share one observation with you.

Section 10.4.14 under Patient Rights notes that the dialysis center must provide written notice to the patient on his/her right to "Be informed of the dialysis centers policies for transfer, routine or involuntary discharge and discontinuation of services." Council queries who discharge information is reported to and what happens to the patient if they are involuntarily discharged. We would suggest a transparent discharge policy be shared with all patients and some type of follow up when patients are involuntarily discharged.

Please feel free to contact me or Wendy Strauss at the GACEC office if you have questions on our endorsement. Thank you for the opportunity to share our comments with you.

Response: Thank you for your comments. Involuntary discharges should be a rare occurrence and preceded by demonstrated efforts on the part of the dialysis center to address issues in a mutually beneficial manner. All involuntary discharges are to be reported to the Department as required by regulations 17.10 and 17.10.2.5. The dialysis center regulations adopt the provisions of 42 CFR Ch. IV, Part 494, Subparts A, B, C and D, which are the federal Conditions for Coverage (CfCs) for End-Stage Renal Disease Facilities (dialysis centers). The federal CfCs contain more specific requirements related to involuntary discharges.

J. Todd Webb, Chairperson, State Council for Persons with Disabilities (SCPD)

Comment: 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 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.

Response: Thank you for your comments. Involuntary discharges should be a rare occurrence and preceded by demonstrated efforts on the part of the dialysis center to address issues in a mutually beneficial manner. The dialysis center regulations adopt the provisions of 42 CFR Ch. IV, Part 494, Subparts A, B, C and D, which are the federal Conditions for Coverage (CfCs) for End-Stage Renal Disease Facilities (dialysis centers). The federal CfCs contain more specific requirements related to involuntary discharges.

Carole Finamore RN, BSN, Field Vice President Regulatory Affairs, Fresenius Kidney Care

Comment: Fresenius Medical Care North America (FMCNA) is submitting comments in response to the "Regulations Governing Dialysis Centers" that was published in the DE Federal Register on December 31, 2018. Thank you for providing us the opportunity to comment on these regulations.

As background, FMCNA is the largest supplier of dialysis products and services in the country. We operate over 2,200 outpatient dialysis clinics and care for over 190,000 patients in the United States each year. In Delaware, FMCNA is currently the predominant dialysis provider to nearly 1500 Delawareans with kidney failure in 25 programs that provide outpatient hemodialysis, inpatient acute hemodialysis, and home dialysis training and support across the state.

As previously stated, Delaware has not been a licensing state for dialysis facilities and FMCNA is concerned that these new regulations will create more stress on an already fragile delivery system. While we have provided comments to individual regulations below, we initially wish to highlight some overarching concerns.

First; the regulations do not consider the impact of the additional financial burden being placed on dialysis providers. The cost of the license will be \$1000 per facility and an additional \$500 per service and the renewal will be \$600 and \$300 per service. Considering that DE Medicaid reimbursement is below the cost of providing the dialysis treatment any additional financial burdens to dialysis providers further highlights how this industry continues to be over-regulated and underfunded. There are no safeguards in place to protect providers from increased licensing fees if the State has not budgeted accordingly.

Response: Thank you for your comment. The 148th General Assembly passed legislation, which was signed by the Governor, to regulate dialysis centers to ensure safe, quality healthcare. This legislation also gave the Department the authority to collect fees which shall approximate and reasonably reflect all costs necessary to defray the expenses incurred by the Department. The fees published in the proposed regulations approximate all costs related to the dialysis center licensure program.

Second; dialysis providers are already following the CMS Conditions for Coverage (CfC) and some of the new DE regulations that do not follow the "CfC" create additional burdens on providers who are already following the proven regulations that industry professionals helped develop. It would benefit the State to closely follow the "CfC" to eliminate any unintended consequences of these new DE licensing regulations.

Response: Thank you for your comment. The regulations published as proposed on January 1, 2019 closely reflect the "CMS Conditions for Coverage". The regulations that contain more stringent requirements were added to protect this vulnerable patient population and ensure the provision of safe and quality care.

FMCNA has reviewed the regulations and offers the following comments for your consideration:

Comment:

3.3 Issuance of Licenses

3.1.5 Separate licenses are required for dialysis centers maintained in separate locations, even though operated under the same management

FMCNA requests clarity on whether this would impact home programs located in separate space from in-center, where Home programs may be located on a second floor or different suite from the in-center unit. The State responded that if a home program was located in the same building it would not need a separate license. FMCNA would like to see this language in the regulations.

Response: Thank you for your comment. Per Department policy, a provider which has a home therapies program located in the same building, which is considered the same location even though in a separate suite/floor, would fall under the same license.

Comment:

3.1.6 Any dialysis center that undergoes a modification of ownership and control is required to re-apply as a new dialysis center and must meet the current design and construction standards recognized by the Department.

If a change in clinic ownership, or converting to a Joint Venture, will require reapplication as a new dialysis center,

certain older locations could have some major challenges having been constructed under different, older code requirements. Bringing an existing and operating clinic up to the very latest code requirements would overly burden that clinic financially and be very disruptive to the patient care in that clinic. Oftentimes a relocation is the best option, which can also be challenging if the clinic is in a long-term lease situation that they cannot be released from. With proper guidance, planning and training, an existing older clinic can implement an evacuation plan that will allow all staff and patients to leave the building quickly in the case of a fire. We continue to see this as a concern and believe a clinic that undergoes an MOC should be grandfathered in. A clinic that is fully operational and converts from a wholly owned to JV would be affected by this requirement.

Response: Thank you for your comment. If a facility undergoes an MOC, it is in the interest of patient safety that the facility be brought up to current standards. We have other provider regulations that contain this same requirement; therefore, this regulation will stand as written.

Comment:

3.1.8 Patients shall not be admitted to a dialysis center until a license has been issued.

The State indicated that it would work with providers to ensure continuity of care as long as all paperwork and applications have been timely filed. FMCNA would like to see this language added to the above.

Response: Thank you for your comment. The Department routinely works with all of our licensed providers to ensure continuity of care for all patients. The regulation will stand as written.

Comment:

3.2 Application Process

3.2.1.3 The names, addresses and types of facilities previously and currently owned or managed by the applicant;

The State has indicated that it needs a list of previous facilities previously or currently owned or managed by the applicant and has indicated that this is not specific to the State of Delaware. FMCNA operates over 2200 facilities and manages numerous dialysis programs which makes this a burdensome proposition, but to also need previously owned business for a company that is decade's old makes FMCNA's ability to grow business in DE extremely burdensome and not business friendly. FMCNA is currently the largest dialysis provider in DE with a footprint in DE for decades. FMCNA requests this section be changed to be specific to DE.

Response: Thank you for your comment. This requirement is the standard operating procedure for healthcare facilities/agencies licensed by the Department. This regulation will stand as written.

Comment:

3.3 Issuance of Licenses

3.3.1 Initial License

3.3.1.3 All dialysis centers shall have an on-site survey, conducted by the Department, during the first three (3) calendar months of operation.

FMCNA would like clarification on whether the clinic can continue to operate with existing patients while applying with MOC. It is also critical that the effective date on the license is consistent with the effective date of MOC and not the date of survey to ensure there is no gap in time that would affect billing for treatments.

Response: Thank you for your comment. A dialysis center that is applying for an MOC can operate with the existing patients to ensure continuity of care. The effective date on the license will be the date the MOC occurred, provided that the provider has submitted all of the required documentation.

Comment:

3.3.1.3.2 Facilities that, at the time of the onsite survey, do not meet the definition of a dialysis center or that are not in substantial compliance with these regulations will not be granted a license.

It is very rare that a state conducts a survey as part of the licensure process when there is a MOC, and we are unaware of a similar requirement in other states. The proposed regulation is unclear as to whether a license will be denied if there is a deficiency in the MOC survey, and whether the license will be granted to the new owner as of the date of the MOC transaction. It is not typical that a deficiency in a survey would negatively affect a dialysis center's license to operate. If facility is found to not be in substantial compliance, and a license is denied, do the facility's current patients have to be moved, or would it just be closed to new admissions until compliance is achieved? How does the state define not being in substantial compliance – is that condition, or IJ, or both? Also: would the facility be allowed an opportunity to write a Plan of Correction? The answer here implies they would not – that the state would just revoke their ability to operate. That seems inconsistent with other regulations & disruptive to patients. It is critical that we ensure the effective date on the license is consistent with the effective date of MOC and not the date of survey to ensure there is no gap in time that would affect billing for treatments. FMCNA is not aware of other states conducting a survey as part of the licensure process when there is a MOC.

Response: Thank you for your comment. In the event of an MOC, an initial license would be issued which would require an unannounced onsite survey during the initial licensure period. This process is routine for all provider types licensed by the Department. Substantial compliance means a level of compliance with the regulations such that any identified deficiencies pose no greater risk to patient health or safety than the potential for causing minimal harm. Substantial compliance constitutes compliance with regulatory requirements. This regulation refers to facilities that are not in substantial compliance with the regulations. If the facility does have deficiencies that are not substantial, they would be

permitted to submit a plan of correction to pursue further licensure.

Comment:

5.9 Supervision of clinical services

5.9.3 The nurse manager shall

5.9.3.1 Be a registered nurse with at least:5.9.3.1.2 Six (6) months of experience providing maintenance dialysis; and

FMCNA recommends changing this requirement to match the CMS requirement that a nurse manager is a registered nurse who has 12 months of nursing experience, including 3 months of experience in maintenance dialysis.

Response: Thank you for your comment. This regulation will not be changed as it is consistent with the CMS regulations which also require the nurse manager to have 6 months of experience in maintenance dialysis.

Comment:

6.0 Infection Prevention and Control

6.2 The dialysis center must designate in writing, a qualified licensed healthcare professional who will lead the facility's infection prevention and control program. The dialysis center must determine that the individual has had training in the principles and methods of infection prevention and control.

6.2.1 The individual designated to lead the dialysis center's infection prevention and control program must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases. The plan of action must include mechanisms that result in immediate action to take preventive or corrective measures that improve the dialysis center's infection control outcomes.

This is not consistent with the Conditions for Coverage. FMCNA would like clarification about what is considered a "Qualified" licensed health care professional to lead the infection control program.

Response: Thank you for your comment. Due to the complexity and nature of the ESRD patients' care, infection prevention is crucial. Based on the past compliance history of existing dialysis centers, the need for improved infection prevention and control is evident. In addition, the requirement for a designated infection preventionist is not new to other healthcare providers; therefore, this regulation will stand as written. The dialysis center must determine that the individual designated to lead the dialysis center's infections prevention and control program has had training in the principals and methods of infection prevention and control. While it would be highly desirable for this individual to be certified in infection control, it is not required as long as there is evidence that the individual has training that qualifies him/her to lead the facility's infection prevention and control program. This individual must also maintain the qualifications through ongoing education and training.

As a Corporate partner in the State of Delaware, FMCNA wants to assure our patients receive only the highest quality of care available through the most efficient means for the State. Thank you again for your consideration and allowing FMCNA to comment on the regulations.

Response: Thank you for your comments.

Findings of Fact:

There were no changes made to the regulations based on the comments received and detailed in the "Summary of Evidence". The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Dialysis Centers is adopted and shall become effective April 11, 2019, after publication of the final regulation in the Delaware *Register of Regulations*.

3/22/19

Date

Kara Odom Walker, MD, MPH, MSHS, Secretary, DHSS

[3330] Regulations Governing Dialysis Centers

1.0 Purpose

Delaware Department of Health and Social Services adopts these regulations pursuant to the authority vested by 16 Del.C. §122(3)(aa). These regulations establish standards with respect to the operation and emergency energy sources of dialysis centers.

2.0 Definitions

The following words and terms, when used in this regulation, shall have the following meaning unless the context clearly indicates otherwise:

"Administrator" means a person who is delegated the responsibility for the implementation and proper application of policies, programs, and services established for the dialysis center.

"Adverse Event" means an unintended consequence or injury to resulting from or contributed to by the care, or lack thereof, that requires additional investigation, monitoring, treatment, hospitalization, or results in death.

“All-Hazards Approach” means an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those in addition to a wide spectrum of emergencies or disasters.

“Department” means the Department of Health and Social Services.

“Dialysis Center” means 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).

“Disaster” means an event that can affect the facility internally as well as the staff, patients, community or geographic area by causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively.

“Dummy Drip Chamber” means a fluid-filled chamber used to bypass the dialysis machines air detectors.

“Emergency” means an event that can affect the facility internally as well as the staff, patients, community or geographic area by causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively.

“Emergency Preparedness Program” means the dialysis center’s comprehensive approach to meeting the health, safety and security needs of the facility, staff, patient population and community prior to, during and after an emergency or disaster. The program encompasses four core elements:

- an Emergency Plan that is based on a Risk Assessment and incorporates an all hazards approach;
- Policies and Procedures;
- Communication Plan; and
- the Training and Testing Program

“ESRD” means end stage renal disease.

“Facility” means the dialysis center.

“Full-time” means the number of hours the dialysis center is open or requires for full-time employment.

“Hazard Vulnerability Assessment” means a comprehensive process the dialysis center uses to assess and document potential hazards that are likely to impact their geographical region, community, facility and patient population and identify gaps and challenges that should be considered and addressed in developing the emergency preparedness program.

“Home Dialysis Service” means dialysis performed at the patient’s residence by an ESRD patient or caregiver who has completed a dialysis center’s required training.

“Incompetence” means the inability to function at a safe level or to provide care that is consistent with standards of practice.

“Interdisciplinary Team” means a team, which at a minimum consists of the patient or patient’s designee (if the patient chooses), a registered nurse, a physician treating the patient for end stage renal disease, a social worker and a dietitian.

“ISO” means International Organization for Standardization.

“Long Term Care Facility” means a facility licensed pursuant to Title 16, Chapter 11 of the Delaware Code.

“Misconduct” means behavior that is professionally unethical, immoral and/or illegal.

“Modality” means the different treatment options and settings for patients with end stage renal disease, for example, in-center dialysis, home hemodialysis, peritoneal dialysis, self-care dialysis, nocturnal dialysis, and transplantation.

“Modification of Ownership and Control” means a change of ownership or transfer of responsibility for the dialysis center’s operation.

“Negligence” means an act or omission of care that deviates from the accepted standard of care and can lead to illness, disability or death.

“Non-physician Provider” means a person currently licensed as an advanced practice nurse pursuant to Title 24, Chapter 17 of the Delaware Code, or a person currently licensed as a physician’s assistant pursuant to Title 24, Chapter 19 of the Delaware Code.

“Patient” means a person who receives health care services from a dialysis center.

“Patient Care Technician” means any person who provides direct care to patients and who is not classified as another professional (i.e. registered nurse, dietitian, social worker, etc.).

“Physician” means a person currently licensed as a physician by Title 24, Chapter 17 of the Delaware Code.

“Plan of Correction” means a written document that includes specific measures to correct identified problems or areas of concern; identifies strategies for implementing system improvements; and includes outcome measures to indicate the effectiveness of system improvements in reducing, controlling or eliminating identified problem areas.

"Quality Assessment and Performance Improvement" (QAPI) means an ongoing program that measures, analyzes, and tracks quality indicators related to improving health outcomes and patient care emphasizing a multidisciplinary approach. The program implements plans and evaluates the implementation until resolution is achieved.

"Registered Nurse" means a person currently licensed as a registered nurse pursuant to Title 24, Chapter 19 of the Delaware Code.

"Reprocessing" means the process of cleaning and the installation of germicide into a dialyzer.

"Reuse" means the clinical use of a reprocessed dialyzer.

"Serious Injury" means physical injury that creates a substantial risk of death, or that causes serious disfigurement, prolonged impairment of health or prolonged loss or impairment of the function of any bodily organ.

3.0 Licensure Requirements and Procedures

3.1 General Requirements

- 3.1.1** No person shall establish, conduct or maintain in this State any dialysis center without first obtaining a license from the Department.
- 3.1.2** A license issued hereunder shall be subject, at any time, to revision or revocation by the State.
- 3.1.3** A license is not transferable from person to person, entity to entity or from one location to another.
- 3.1.4** The license shall be posted in a conspicuous place on the licensed premises, at or near the entrance in a manner which is plainly visible and easily read by the public.
- 3.1.5** Separate licenses are required for dialysis centers maintained in separate locations, even though operated under the same management.
- 3.1.6** Any dialysis center that undergoes a modification of ownership and control is required to re-apply as a new dialysis center and must meet the current design and construction standards recognized by the Department.
- 3.1.7** The submission of an application is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department.
- 3.1.8** Patients shall not be admitted to a dialysis center until a license has been issued.
- 3.1.9** The dialysis center shall advise the Department in writing at least 30 calendar days prior to closure of the dialysis center and voluntary surrender of a license.
- 3.1.10** The dialysis center shall notify the Department in writing at least 30 calendar days prior to adding/removing a service or modifying the station count.

3.2 Application Process

- 3.2.1** All persons or entities wanting to apply to open a dialysis center shall submit to the Department the following information:
 - 3.2.1.1** A Statement of Intent describing the services to be offered at the dialysis center;
 - 3.2.1.2** A completed application for licensure;
 - 3.2.1.3** The names, addresses and types of facilities previously and currently owned or managed by the applicant;
 - 3.2.1.4** Identity of:
 - 3.2.1.4.1** Each officer and director of the corporation, if the entity is organized as a corporation;
 - 3.2.1.4.2** Each general partner or managing member, if the entity is organized as an unincorporated entity;
 - 3.2.1.4.3** The governing body; and
 - 3.2.1.4.4** Any officers/directors, partners, or managing members, or members of a governing body who have a financial interest in a licensee's operation or related business.
 - 3.2.1.5** Proof of not-for-profit status, if claiming tax-exempt status;
 - 3.2.1.6** Disclosure of any officer, director, partner, employee, managing member or member of the governing body with a felony criminal record;
 - 3.2.1.7** Name of the director and the person designated to act in the absence of the director;
 - 3.2.1.8** A list of management personnel, including credentials;
 - 3.2.1.9** A plan for providing orientation, continuing education, and training for personnel or contractors during the first year of operation;
 - 3.2.1.10** Policy and procedure manuals; and

3.2.1.11 Any other information required by the Department.

3.3 Issuance of Licenses

3.3.1 Initial License

3.3.1.1 An initial license shall be issued for a period of three (3) calendar months to those applicants who meet the requirements for licensure.

3.3.1.2 Once an initial license has been issued, the dialysis center may begin to offer services to patients.

3.3.1.3 All dialysis centers shall have an on-site survey, conducted by the Department, during the first three (3) calendar months of operation.

3.3.1.3.1 If the dialysis center meets the licensure requirements, as contained within these regulations, is in operation and caring for patients at the time of the initial on-site survey, an annual license for the remainder of the licensure year will be issued.

3.3.1.3.2 Facilities that, at the time of the on-site survey, do not meet the definition of a dialysis center or that are not in substantial compliance with these regulations will not be granted a license.

3.3.1.4 An initial license may not be renewed.

3.3.2 Provisional License

3.3.2.1 A provisional license shall be granted, for a period of less than one year, to all dialysis centers that:

3.3.2.1.1 Are not in substantial compliance with these rules and regulations; or

3.3.2.1.2 Fail to renew a license within the timeframe prescribed by these regulations.

3.3.2.2 The Department shall designate the conditions and the time period under which a provisional license is issued.

3.3.2.3 A provisional license may not be renewed unless a plan of correction for coming into substantial compliance with these rules and regulations has been approved by the Department and implemented by the dialysis center.

3.3.2.4 A license will not be granted pursuant to subsection 3.3.2 after the provisional licensure period to any dialysis center that is not in substantial compliance with these rules and regulations.

3.3.3 Annual License

3.3.3.1 An annual license shall be granted, for a period of one year (12 months) to all dialysis centers which are and remain in substantial compliance with these rules and regulations.

3.3.3.2 A license shall be effective for a twelve (12) month period following the date of issue and shall expire one year following such date, unless it is:

3.3.3.2.1 Modified to a provisional license;

3.3.3.2.2 Suspended;

3.3.3.2.3 Revoked; or

3.3.3.2.4 Surrendered prior to the expiration date.

3.3.3.3 All applications for renewal of licenses shall be filed with the Department at least thirty (30) days prior to the expiration date of the license.

3.3.3.4 Dialysis centers which have not been inspected/surveyed during a licensure year may apply for, and be issued, a new license until an inspection/survey is completed.

3.3.3.5 A license may not be issued to a dialysis center which is not in substantial compliance with these regulations or whose deficient practices present an immediate threat to the health and safety of its patients.

3.4 Disciplinary Sanctions

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

3.4.1.1 Violated any of these regulations;

3.4.1.2 Failed to submit a reasonable timetable for correction of deficiencies;

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

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

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

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

3.4.1.7 Mistreated or abused patients cared for by the dialysis center;

- 3.4.1.8 Violated any statutes relating to medical assistance or Medicare reimbursement for those facilities who participate in those programs; or
- 3.4.1.9 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.
- 3.4.2 Disciplinary sanctions include any of the following:
 - 3.4.2.1 Permanent revocation of a license which extends to:
 - 3.4.2.1.1 The dialysis center;
 - 3.4.2.1.2 Any owner;
 - 3.4.2.1.3 Officers/directors, partners, managing members or members of a governing body who have financial interest of 5% or more in the dialysis center; or
 - 3.4.2.1.4 Corporation officers.
 - 3.4.2.2 Suspension of a license;
 - 3.4.2.3 A letter of reprimand;
 - 3.4.2.4 Placement on provisional status with the following requirements:
 - 3.4.2.4.1 Report regularly to the Department upon the matters which are the basis of the provisional status;
 - 3.4.2.4.2 Limit practice to those areas prescribed by the Department; and/or
 - 3.4.2.4.3 Suspend operations.
 - 3.4.2.5 Refusal of a license;
 - 3.4.2.6 Refusal to renew a license;
 - 3.4.2.7 Other disciplinary action as appropriate.
- 3.4.3 The Department may request the Superior court 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.
 - 3.4.3.1 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 constitutes a separate violation.
 - 3.4.3.2 In determining the amount of any civil or administrative penalty imposed, the Court or the Department shall consider the following factors:
 - 3.4.3.2.1 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 the patient;
 - 3.4.3.2.2 The history of violations committed by the person or the person's affiliate, agent, employee or controlling person;
 - 3.4.3.2.3 The efforts made by the dialysis center to correct the violation(s);
 - 3.4.3.2.4 Any misrepresentation made to the Department; and
 - 3.4.3.2.5 Any other matter that affects the health, safety or welfare of a patient.
- 3.4.4 Imposition of a disciplinary action
 - 3.4.4.1 Before any disciplinary action is taken the following shall occur:
 - 3.4.4.1.1 The Department shall give 20 calendar days written notice to the holder of the license, setting forth the reasons for the determination;
 - 3.4.4.1.2 The disciplinary action shall become final 20 calendar days after the mailing of the notice unless the licensee, within such 20-calender-day period, shall give written notice of the dialysis centers desire for a hearing;
 - 3.4.4.1.3 If the licensee give such notice, the dialysis center shall be given a hearing before the Secretary of the Department or his/her designee and may present such evidence as may be proper;
 - 3.4.4.1.4 The Secretary of the Department or his/her designee shall make a determination based upon the evidence presented.
 - 3.4.4.1.5 A written copy of the determination and the reasons upon which it is based shall be sent to the dialysis center;
 - 3.4.4.1.6 The decision shall become final 20 calendar days after the mailing of the determination letter unless the licensee, within the 20-calender-day period, appeals the decision to the appropriate court of the State.
- 3.4.5 Order to immediately suspend a license

- 3.4.5.1 In the event the Department identifies activities which the Department determines present an immediate jeopardy or imminent danger to the public health, welfare and 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.
- 3.4.5.2 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.
- 3.4.5.3 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.
- 3.4.5.4 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 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.
- 3.4.5.5 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.

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

- 3.5.1 The application for license after termination of rights to provide services shall follow the procedure for the initial licensure application.
- 3.5.2 In addition to the initial 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 led to the original termination action. Submission of evidence supporting compliance with the plan of correction and cooperation with Department monitoring during initial licensure status is required for reinstatements to full licensure status.
- 3.5.3 Upon successful completion of the initial licensure period, the dialysis center will be granted a provisional license for a period of no more than 1 year. The provisional period will be identified by the Department after having considered the circumstances that created the original action for license revocation.
- 3.5.4 A license will be granted to the dialysis center after the provisional licensure period if:
 - 3.5.4.1 The dialysis center has remained in compliance with these rules and regulations; and
 - 3.5.4.2 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.
- 3.5.5 A license will not be granted after the provisional licensure period to any dialysis center that is not in compliance with these rules and regulations.

3.6 Modification of Ownership and Control (MOC)

- 3.6.1 Any proposed MOC must be reported to the Department in writing a minimum of 30 calendar days prior to the change.
- 3.6.2 A MOC occurs whenever the ultimate legal authority for the responsibility of the dialysis center's operation is transferred.
- 3.6.3 A MOC voids the current license in possession of the dialysis center.
- 3.6.4 A MOC will be treated as an initial license and the dialysis center must meet the current design and construction standards recognized by the Department.
- 3.6.5 A MOC may include but is not limited to:
 - 3.6.5.1 Transfer of the dialysis center's legal title;

- 3.6.5.2 Transfer of the full ownership rights;
- 3.6.5.3 Transfer of the majority interest;
- 3.6.5.4 Transfer of ownership interest that results in the owner with the majority interest becoming a minority interest owner;
- 3.6.5.5 Transfer or re-organization that results in an additional majority interest that is equal in ownership rights;
- 3.6.5.6 Transfer resulting in a measurable impact upon the operational control of the dialysis center;
- 3.6.5.7 Dissolution of any partnership that owns a controlling interest in the dialysis center;
- 3.6.5.8 Merger of a dialysis center owner (a corporation) into another corporation where, after the merger, the owner's shares of capitol stock are cancelled; or
- 3.6.5.9 The consolidation of a corporate dialysis center owner with one or more corporations.
- 3.6.6 Transactions which do not constitute an MOC include, but are not limited to the following:
 - 3.6.6.1 Changes in the membership of a corporate board of directors or board of trustees;
 - 3.6.6.2 Two or more corporations merge and the originally licensed corporation survives;
 - 3.6.6.3 Changes in the membership of a non-profit corporation; or
 - 3.6.6.4 Corporate stock transfers or sales that do not result in a transfer of interest or ownership.
- 3.6.7 Applications for licensure, as a result of an MOC must include a description of:
 - 3.6.7.1 Any actual or anticipated change in the health care services provided before the MOC;
 - 3.6.7.2 Any actual or anticipated change in staff, including the composition of staff;
 - 3.6.7.3 Any actual or anticipated change in the policies and procedures; and
 - 3.6.7.4 Any change in the manner of delivery of health care services.
- 3.7 Fees. Fees shall be in accordance with 16 Del.C. §122(3)aa.
- 3.8 Inspection. A representative of the Department shall periodically inspect every dialysis center for which a license has been issued under this chapter. Inspections by authorized representatives of the Department may occur at any time and may be scheduled or unannounced.

4.0 Governing Body

- 4.1 Each dialysis center shall have an identified, organized governing body (governing authority, owner or person(s) designated by the owner) fully responsible for the organization, management, control, and operation of the facility.
- 4.2 The governing body responsibilities include, but are not limited to:
 - 4.2.1 Appointing an administrator in writing:
 - 4.2.1.1 The administrator exercises the responsibility for the management of the dialysis center and the provision of dialysis services, including but not limited to:
 - 4.2.1.1.1 Maintenance of sound fiscal operations;
 - 4.2.1.1.2 The relationship with the ESRD Network 4; and
 - 4.2.1.1.3 Allocation of necessary staff and resources for the dialysis center's quality assessment and performance improvement program.
 - 4.2.2 Appointing a qualified medical director (refer to subsection 5.2) in writing;
 - 4.2.3 Appointing members of the medical and clinical staff, ensuring their competence and delineating their job responsibilities;
 - 4.2.4 Ensuring all staff, including the medical director and medical staff, have appropriate orientation to the dialysis center and their work responsibilities;
 - 4.2.5 Ensuring an adequate number of qualified personnel are present in the dialysis center whenever patients are undergoing dialysis;
 - 4.2.6 Ensuring the registered nurse, social worker and dietitian of the interdisciplinary team are available to meet the patients' clinical needs;
 - 4.2.7 Offering opportunities for continuing education and related development activities for all employees;
 - 4.2.8 Establishing, adopting, implementing, and enforcing written policies and procedures for the total operation of and all services provided by the dialysis center;
 - 4.2.9 Documentation of annual review and evaluation of the dialysis center policies and services;
 - 4.2.10 Ensuring that all services, whether furnished directly or under contract, are provided in a safe and effective manner that permits the facility to comply with all applicable rules and standards;

- 4.2.11 Conducting meetings, when the governing body is more than one person, at least annually and maintaining written minutes of the meetings;
- 4.2.12 Adopting governing body and medical staff bylaws for the orderly development and management of the dialysis center:
 - 4.2.12.1 Bylaws shall be reviewed annually by the governing body and so dated. Revisions shall be completed as necessary.
- 4.2.13 Ensuring a physical environment that protects the health and safety of patients, personnel, and the public;
- 4.2.14 Ensuring that all equipment utilized by dialysis center staff or by patients is properly used and maintained per manufacturer's recommendations;
- 4.2.15 Adopting, implementing and enforcing policies and procedures related to emergency planning and disaster preparedness. The governing body shall review the dialysis center's emergency preparedness plan, and associated policies and procedures at least annually;
- 4.2.16 Ensuring there is a quality assessment and performance improvement (QAPI) program to evaluate the provision of patient care. The governing body shall review and monitor QAPI activities quarterly;
- 4.2.17 Implementing an internal grievance process for patients to file an oral or written grievance with the dialysis center.
 - 4.2.17.1 The dialysis center must ensure that there will be no reprisal or denial of services for any patient or patient representative that files a grievance.
 - 4.2.17.2 The grievance process must include:
 - 4.2.17.2.1 The procedure to submit a grievance;
 - 4.2.17.2.2 Timeframes for the review of the grievance; and
 - 4.2.17.2.3 An explanation of how the patient or patient representative will be informed of the steps taken to resolve the grievance.
- 4.2.18 Ensuring that all staff follow the dialysis center's involuntary discharge and transfer policies.
- 4.2.19 Ensuring emergency coverage:
 - 4.2.19.1 The dialysis center must:
 - 4.2.19.1.1 Provide patients and staff with written instructions for obtaining emergency medical care;
 - 4.2.19.1.2 Have a written plan for physician coverage and contact numbers to be called for emergencies;
 - 4.2.19.1.3 Have an agreement with a hospital that can promptly provide inpatient care, routine and emergency services which is available 24 hours a day, 7 days a week.
- 4.3 The governing body shall provide for full disclosure of ownership to the Department.

5.0 Administration/Personnel

- 5.1 All dialysis center staff (whether employees or contractors) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients.
- 5.2 The medical director must:
 - 5.2.1 Be a physician;
 - 5.2.2 Be board-certified in internal medicine, pediatrics, nephrology or pediatric nephrology by a professional board;
 - 5.2.3 Have completed a board-approved training program in nephrology; and
 - 5.2.4 Have at least 12-months of experience providing care to patients receiving dialysis.
- 5.3 The medical director shall have the overall authority and responsibility for the daily operation and management of the dialysis center.
- 5.4 The medical director shall be accountable to the governing body for the quality of medical care provided to patients.
- 5.5 The medical director shall be responsible for the direction, provision and quality of medical care.
- 5.6 The authority, duties and responsibilities of the medical director shall be defined in writing and shall include but not be limited to:
 - 5.6.1 Program planning, budgeting, management and program evaluation;
 - 5.6.2 Development and approval of the policies and procedures manual;
 - 5.6.3 Reviewing policies and procedures at least annually, and reporting, in writing, to the governing body on the review;
 - 5.6.4 Staff education, training and performance;

- 5.6.5 Ensuring all individuals, including attending physicians and non-physician providers, providing patient care adhere to all policies and procedures pertaining to patient admissions/discharge/transfers, patient care, infection control and safety;
- 5.6.6 Maintenance of the dialysis center's compliance with federal and state licensure regulations and standards;
- 5.6.7 An ongoing QAPI program;
- 5.6.8 Documentation of complaints relating to the conduct or actions by employees/contractors/medical staff and action taken secondary to the complaints; and
- 5.6.9 Conducting or supervising the resolution of complaints received from patients/patient representatives regarding the delivery of care or services.
- 5.7 The medical director shall designate, in writing, a person who meets the medical director qualifications to act in the absence of the medical director.
- 5.8 The dialysis center shall advise the Department in writing within 15 calendar days following any change in the designation of the medical director.
- 5.9 Supervision of clinical services
 - 5.9.1 The governing body shall appoint, in writing, a full-time employee of the facility as the nurse manager.
 - 5.9.2 The nurse manager shall be responsible for implementing, coordinating and assuring quality of patient care services at only one (1) dialysis center.
 - 5.9.3 The nurse manager shall:
 - 5.9.3.1 Be a registered nurse with at least:
 - 5.9.3.1.1 One (1) year of full-time experience in clinical nursing;
 - 5.9.3.1.2 Six (6) months of experience providing maintenance dialysis; and
 - 5.9.3.1.3 Six (6) months experience in maintenance dialysis supervision/administration.
 - 5.9.3.2 Provide general supervision and direction of the services offered by the dialysis center.
 - 5.9.4 The medical director shall designate, in writing, a person who meets the nurse manager qualifications to act in the absence of the nurse manager.
 - 5.9.5 The dialysis center shall advise the Department in writing within 15 calendar days following any change in the designation of the nurse manager.
- 5.10 Contract services
 - 5.10.1 The dialysis center maintains responsibility for all services provided to the patient.
 - 5.10.2 Services provided by the dialysis center through arrangements with a contractor agency or individual shall be set forth in a written contract which clearly specifies:
 - 5.10.2.1 The services to be provided by the contractor;
 - 5.10.2.2 The necessity to conform to all dialysis center policies;
 - 5.10.2.3 The procedure for annual assurance of clinical competence of all individuals utilized under contract;
 - 5.10.2.4 The procedure for supervision of services of the contracted individuals; and
 - 5.10.2.5 The frequency for contract renewal.
 - 5.10.3 The dialysis center must ensure that personnel and services contracted meet the requirements specified in these regulations for dialysis center personnel and services.
- 5.11 Medical Staff
 - 5.11.1 Members of the medical staff may include physicians and non-physician practitioners with training or demonstrated experience in the care of patients with end stage renal disease.
 - 5.11.2 All members of the dialysis center medical staff must be:
 - 5.11.2.1 Individually credentialed to ensure the individual is deemed qualified; and
 - 5.11.2.2 Appointed to their position within the dialysis center by the governing body.
 - 5.11.3 Medical staff privileges must be granted by the governing body, in writing.
 - 5.11.4 Medical staff privileges must be reappraised by the dialysis center at least every 24 months.
 - 5.11.4.1 Reappraisals must include assessment of current competence by the dialysis center medical director.
 - 5.11.5 The medical staff shall adopt, implement and enforce written bylaws to carry out its responsibilities. The bylaws shall:
 - 5.11.5.1 Be approved by the governing body;
 - 5.11.5.2 Include a statement of the duties and privileges of each category of medical staff;

- 5.11.5.3 Describe the organization of the medical staff; and
- 5.11.5.4 Include criteria for privileges to be granted and a procedure for applying the criteria to individuals requesting privileges.

5.12 Nursing services

- 5.12.1 There shall be an organized nursing services which must be under the direction of the nurse manager.
- 5.12.2 There must be sufficient nursing staff with the appropriate qualifications to assure the nursing needs of all dialysis patients are met.
- 5.12.3 Nursing services must be provided in accordance with recognized standards of practice.
- 5.12.4 Charge nurse
 - 5.12.4.1 Each charge nurse must:
 - 5.12.4.1.1 Be a registered nurse; and
 - 5.12.4.1.2 Have at least twelve (12) months full-time nursing experience; and
 - 5.12.4.1.3 Have at least six (6) months full-time experience, within the last twenty-four (24) months, providing nursing care to patients on maintenance dialysis.
 - 5.12.4.2 There must be at least one (1) charge nurse present and designated at all times during the operating hours of the dialysis center.
 - 5.12.4.3 The charge nurse responsibilities include, but are not limited to:
 - 5.12.4.3.1 Making daily patient care assignments based on individual patient needs;
 - 5.12.4.3.2 Providing immediate supervision of direct patient care;
 - 5.12.4.3.3 Patient assessment when indicated; and
 - 5.12.4.3.4 Communicating with other members of the healthcare team.
- 5.12.5 Staff nurse
 - 5.12.5.1 There must be a registered nurse present and immediately available in the facility at all times in-center dialysis patients are being treated.
- 5.12.6 Self-care and home dialysis training and support nurse
 - 5.12.6.1 Each nurse responsible for self-care and/or home training and support must:
 - 5.12.6.1.1 Be a registered nurse; and
 - 5.12.6.1.2 Have at least twelve (12) months full-time nursing experience; and
 - 5.12.6.1.3 Have at least three (3) months full-time experience, within the last twenty-four (24) months, in each specific modality for which the nurse will provide training.

5.13 Dietitian

- 5.13.1 The dialysis center must have a dietitian:
 - 5.13.1.1 Registered with the Commission on Dietetic Registration; and
 - 5.13.1.2 With a minimum of one (1) year professional work experience in clinical nutrition as a registered dietitian.
- 5.13.2 One full-time equivalent of dietitian time shall be available for up to 100 patients, with the maximum patient load per full-time equivalent of dietitian time being 125 patients for all modalities.

5.14 Social Worker

- 5.14.1 The dialysis center must have a social worker with a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education.
- 5.14.2 Each facility shall employ or contract with a social worker(s) to meet the psychosocial needs of the patients.
 - 5.14.2.1 One (1) full-time equivalent qualified social worker time shall be available for up to 100 patients.
 - 5.14.2.2 If the patient load exceeds 100 patients, personnel shall be assigned to assist a social worker(s) with ancillary tasks (e.g., assistance with financial services, transportation, administrative, clerical, etc.). The maximum patient load, including all modalities, per full-time equivalent qualified social worker, with assigned personnel assistance, is 125 patients.

5.15 Patient Care Technicians

- 5.15.1 Patient care technicians must:
 - 5.15.1.1 Have a high school diploma or the equivalent;
 - 5.15.1.2 Complete a training program which includes the following subjects:
 - 5.15.1.2.1 The principles of dialysis;
 - 5.15.1.2.2 Care of patients with end stage renal disease;

5.15.1.2.3 Communication and interpersonal skills with end stage renal disease, including:

5.15.1.2.3.1 Patient sensitivity training; and

5.15.1.2.3.2 Care of difficult patients.

5.15.1.2.4 Dialysis procedures and documentation, including:

5.15.1.2.4.1 Initiation of dialysis;

5.15.1.2.4.2 Proper cannulation techniques;

5.15.1.2.4.3 Monitoring during the dialysis treatment;

5.15.1.2.4.4 Termination of dialysis.

5.15.1.2.5 Possible complications of dialysis;

5.15.1.2.6 Water treatment and dialysate preparation;

5.15.1.2.7 Infection control and prevention; and

5.15.1.2.8 Safety.

5.15.1.3 Demonstrate competency in the knowledge and skills of each component of the training program before independently providing patient care; and

5.15.1.3.1 Until the patient care technician has demonstrated competency in each component of the training program, he/she may only provide patient care as part of the training program under the direct supervision of the assigned preceptor.

5.15.1.4 Be certified by a state or national commercially available certification program within 18 months of the hire.

5.16 Water Treatment System Technicians

5.16.1 Prior to performing water treatment task independently, the staff member must complete a training program approved by the medical director and governing body.

5.17 Personnel records

5.17.1 Records of each dialysis center employee/contractor shall be available upon request by authorized representatives of the Department.

5.17.2 The dialysis center shall maintain current individual personnel records for each employee/contractor on-site which shall at a minimum include:

5.17.2.1 Written verification of compliance with pre-employment requirements;

5.17.2.2 Documentation of clinical competence;

5.17.2.3 Evidence of current professional licensure, registration or certification as appropriate;

5.17.2.4 Educational preparation and work history;

5.17.2.5 Written performance evaluations conducted, at least, annually; and

5.17.2.6 A written and signed job description.

5.18 Staff development

5.18.1 All employees/contractors, including medical staff, are required to complete an orientation program.

5.18.2 An orientation/training program should be based on an instruction plan that includes learning objectives, clinical content and minimum acceptable performance standards, and shall include but not be limited to:

5.18.2.1 Organizational structure of the dialysis center;

5.18.2.2 Patient care policies and procedures;

5.18.2.3 Infection control;

5.18.2.4 Philosophy of patient care;

5.18.2.5 Patient rights;

5.18.2.6 Personnel and administrative policies;

5.18.2.7 Job description;

5.18.2.8 Emergency preparedness; and

5.18.2.9 Applicable state regulations governing the delivery of services.

5.18.3 Documentation of orientation must include the date and hours, content, and name and title of the person providing the orientation.

5.18.4 It is the responsibility of the dialysis center to ensure that employees/contractors are proficient to carry out the assigned care in a safe, effective and efficient manner.

5.18.5 Nothing in these regulations is intended to restrict the practice of licensed independent practitioners practicing in accordance with Delaware law.

5.18.6 All newly hired employees and contractors must have a written validation of competency upon orientation, prior to providing care to patients, and annually thereafter.

5.18.7 Attendance records must be kept for all orientation and continuing education programs.

6.0 Infection Prevention and Control

6.1 The dialysis center shall establish and implement an infection prevention and control program which shall be based upon nationally recognized infection prevention/control guidelines/standards (such as those developed by the Centers for Disease Control and Prevention).

6.1.1 The infection prevention and control program must include all services and each particular area of the dialysis center.

6.2 The dialysis center must designate in writing, a qualified licensed healthcare professional who will lead the facility's infection prevention and control program. The dialysis center must determine that the individual has had training in the principles and methods of infection prevention and control.

6.2.1 The individual designated to lead the dialysis center's infection prevention and control program must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases. The plan of action must include mechanisms that result in immediate action to take preventive or corrective measures that improve the dialysis center's infection control outcomes.

6.3 All dialysis center staff shall receive orientation at the time of employment and annual in-service education regarding the infection prevention and control program.

7.0 Pharmaceutical Services

7.1 Drugs shall be properly secured and accessible only to authorized personnel.

7.2 Drugs must be prepared and administered according to acceptable standards of practice.

7.3 The dialysis center must designate a specific licensed healthcare professional to provide direction to the dialysis center's pharmaceutical service.

7.4 Orders given verbally for drugs and biologicals must be followed by a written order and signed by the prescribing physician.

7.5 The dialysis center must maintain compliance with all federal and state laws, regulations and guidelines governing pharmaceutical services.

8.0 Reprocessing/Reuse of Hemodialyzers and Bloodlines

The reprocessing and reuse of hemodialyzers, bloodlines and transducer filters is prohibited.

9.0 Physical Environment

9.1 The dialysis center must be designed, constructed, equipped and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

9.1.1 The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, staff and the public.

9.1.2 The dialysis center must implement and maintain a program to ensure that all equipment used at the dialysis center and by home dialysis patients is maintained and operated in accordance with the manufacturer's recommendations.

9.1.2.1 The use of "dummy" drip chambers is acceptable only for machine maintenance purposes and shall not be present in the patient treatment areas.

9.1.2.2 The dialysis center shall have a plan of operation and routine maintenance that, at a minimum, includes:

9.1.2.2.1 Hemodialysis delivery system;

9.1.2.2.2 Water treatment system;

9.1.2.2.3 Ancillary equipment;

9.1.2.2.4 Emergency equipment; and

9.1.2.2.5 Furniture.

9.1.3 The area for treating each patient must be sufficient to provide needed care and services, prevent contamination, and to accommodate medical emergency equipment and staff.

9.1.4 The dialysis center must make accommodations to provide for patient privacy any time body exposure is required during treatment or examination.

9.1.5 Each patient, including the face, vascular access site and bloodline connections, must be in view of staff at all times during hemodialysis treatment.

9.1.5.1 Video surveillance does not meet this requirement.

9.1.6 Emergency equipment, including but not limited to, oxygen, airways, suction, defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available for use.

9.2 Fire Safety

9.2.1 The dialysis center shall comply with the rules and regulations of the State Fire Prevention Commission.

9.2.2 The dialysis center must be inspected annually by the fire marshal having jurisdiction, and all applications for license (new and renewal) must include documentation, dated within the past 12 months, indicating compliance to all applicable fire code regulations.

9.2.2.1 Failure to provide documentation from the fire marshal having jurisdiction, dated within the past 12 months, indicating compliance with all applicable fire code regulations shall be grounds for licensure discipline.

9.2.3 An evacuation floor plan shall be prominently and conspicuously posted for display throughout the facility in areas that are readily visible to patients, staff, and visitors.

9.2.4 The dialysis center shall conduct one (1) fire drill per shift per quarter.

9.2.4.1 Fire drills shall include the transmission of the fire alarm signal and simulation of the emergency fire condition, simulation of evacuation of patients and other occupants, and use of fire-fighting equipment.

9.2.4.2 Written reports shall be maintained to include evidence of patient and staff participation.

9.3 Construction

9.3.1 The provisions of the *Facility Guidelines Institute's Guidelines for Design and Construction of Health Care Facilities, 2018 edition*, are hereby adopted as the regulatory requirements for dialysis centers in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.

9.3.1.1 When a dialysis center is classified under this law or regulation and plans to construct, extensively remodel or convert any buildings, two (2) copies of the properly prepared plans and specifications for the entire dialysis center shall be submitted to the Department.

9.3.1.2 An approval, in writing shall be obtained from the Department before construction/renovation/remodeling work is begun.

9.3.1.3 Upon completion of construction/renovation/remodeling, in accordance with the plans and specifications, the Department will inspect and approve the site prior to occupancy/use by the dialysis center.

9.3.1.4 All facilities shall either be at grade level or shall be equipped with ramps and elevators to allow easy access for persons with disabilities.

9.3.1.5 The dialysis center shall comply with all local and state building codes and ordinances as pertains to this occupancy.

9.3.1.6 Waiver of a standard requires Department approval. Waiver requests must be made in writing, include the full justification behind the request and address issues of safety and infection control. Waivers are an exception to established standards and will only be approved for compelling reasons.

9.3.1.7 Dialysis centers existing prior to the implementation of this regulation shall continue, at a minimum, to meet the building requirements specified in the original approval.

10.0 Patient Rights

10.1 The dialysis center must inform the patient, or patient's representative of the patient's rights and responsibilities:

10.1.1 In a language and manner that the patient or patient representative understands; and

10.1.2 Within the first six (6) hemodialysis treatments after admission.

10.2 Documentation must confirm that the dialysis center informed the patient, or patient's representative of the patient's rights and responsibilities.

10.3 The patient's rights shall be posted in a conspicuous place in the facility's waiting room and must include the address and telephone number of the Department and Quality Insights Renal Network 4 to which patients may report complaints.

10.4 Written notice to the patient shall include the patient's right to:

- 10.4.1 Be treated with respect, dignity, and recognition of his/her individuality and personal needs;
- 10.4.2 Receive care in a safe and sanitary environment;
- 10.4.3 Receive all information in a language and manner that he/she can understand;
- 10.4.4 Privacy and confidentiality in all aspects of treatment and personal medical records;
- 10.4.5 Be free from abuse, neglect, and exploitation;
- 10.4.6 Be informed about and participate, if desired, in all aspects of his/her care, including the right to refuse or discontinue treatment, and the consequences of such decisions;
- 10.4.7 Be informed about his/her right to execute an advance directive and the dialysis center's policy regarding advance directives;
- 10.4.8 Be informed about all dialysis treatment modalities and options (i.e. alternative scheduling options) including those dialysis modalities and options not offered by the dialysis center;
- 10.4.9 Be informed of the dialysis center's policies regarding patient care, including but not limited to the isolation of patients;
- 10.4.10 Be informed by the physician or non-physician practitioner treating the patient for ESRD of his/her own medical status, unless the medical record contains a documented contraindication;
- 10.4.11 Be informed of the services available in the facility and charges for such services;
- 10.4.12 Be informed of the dialysis center's internal grievance process and external grievance mechanisms;
- 10.4.13 File grievances regarding treatment or care that is (or fails to be) furnished; and
- 10.4.14 Be informed of the dialysis centers policies for transfer, routine or involuntary discharge, and discontinuation of services.

11.0 Patient Assessment

- 11.1 The dialysis center interdisciplinary team:
 - 11.1.1 Must consist of at a minimum:
 - 11.1.1.1 The patient or patient representative;
 - 11.1.1.2 A registered nurse;
 - 11.1.1.3 A social worker;
 - 11.1.1.4 A dietitian; and
 - 11.1.1.5 A physician treating the patient for ESRD.
 - 11.1.2 Is responsible to conduct an individualized and comprehensive assessment of each patient, which is used to develop the patient's treatment plan and expectations of care.
- 11.2 Each comprehensive assessment must include, but is not limited to evaluation and documentation of the following:
 - 11.2.1 The current health status and medical conditions;
 - 11.2.2 The appropriateness of the dialysis prescription;
 - 11.2.3 Blood pressure and fluid management needs, including:
 - 11.2.3.1 Pre/intra/post and interdialytic blood pressures;
 - 11.2.3.2 Interdialytic weight gains;
 - 11.2.3.3 Target weights; and
 - 11.2.3.4 Intradialytic symptoms.
 - 11.2.4 Laboratory profile;
 - 11.2.5 Immunization history, including but not limited to:
 - 11.2.5.1 Pneumococcal immunization;
 - 11.2.5.2 Hepatitis immunization;
 - 11.2.5.3 Influenza immunization; and
 - 11.2.5.4 Tuberculosis screening.
 - 11.2.6 Medication history, including allergies and all medications (prescription and over the counter) and supplements;
 - 11.2.7 Factors associated with anemia;
 - 11.2.8 Factors associated with renal bone disease;
 - 11.2.9 Nutritional status by the dietitian;
 - 11.2.10 Psychosocial needs by the social worker;
 - 11.2.11 Dialysis access type and maintenance;

- 11.2.12 The patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process;
- 11.2.13 The preferred modality (hemodialysis or peritoneal dialysis) and setting (in-center or home);
- 11.2.14 The patient's expectations for care outcomes;
- 11.2.15 The suitability, or reason for non-referral, of a transplant referral;
- 11.2.16 Family and/or other support systems;
- 11.2.17 Current physical activity level to determine if the patient is a candidate for referral to vocational and/or physical rehabilitation services;
- 11.3 Frequency of comprehensive assessments for patients new to dialysis
 - 11.3.1 Patients changing dialysis modalities or returning to dialysis from a failed transplant are considered new patients.
 - 11.3.2 An initial comprehensive assessment must be completed on each new patient within the latter of 30 calendar days, or 13 hemodialysis treatments, of admission.
 - 11.3.3 A follow up comprehensive assessment must be completed three (3) months after the completion of the initial comprehensive assessment.
- 11.4 Comprehensive reassessments must be completed as follows:
 - 11.4.1 Annually for stable patients; and
 - 11.4.2 At least monthly for patients with the following:
 - 11.4.2.1 More than three (3) hospitalizations in one (1) month;
 - 11.4.2.2 Marked deteriorations;
 - 11.4.2.3 Any event that interferes with the patient's ability to follow the treatment plan; or
 - 11.4.2.4 Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.
- 11.5 Adequacy of the dialysis prescription must be assessed as follows:
 - 11.5.1 Hemodialysis patients
 - 11.5.1.1 At least monthly calculations of the Kt/V or an equivalent measurement.
 - 11.5.2 Peritoneal dialysis patients
 - 11.5.2.1 At least every four (4) months by calculations of delivered weekly Kt/V or an equivalent measurement.

12.0 Patient Plan of Care

- 12.1 The interdisciplinary team must develop and implement a written, comprehensive, individualized plan of care for each patient based on the comprehensive assessment which:
 - 12.1.1 Specifies the services necessary to address the patient's needs; and
 - 12.1.2 Includes measureable and expected outcomes and estimated timetables to achieve these outcomes.
 - 12.1.2.1 Outcomes must be consistent with current evidence-based professionally-accepted clinical standards of practice.
- 12.2 The plan of care must address:
 - 12.2.1 Dose of dialysis;
 - 12.2.2 Dialysis adequacy;
 - 12.2.3 Nutritional status;
 - 12.2.4 Mineral metabolism;
 - 12.2.5 Anemia;
 - 12.2.6 Vascular access;
 - 12.2.7 Psychosocial status;
 - 12.2.8 Modality;
 - 12.2.9 Transplantation status;
 - 12.2.10 Rehabilitation status; and
 - 12.2.11 Patient education and training.
- 12.3 The plan of care shall include evidence of coordination with other providers (i.e. hospitals, long term care facilities, home and community support services, transportation services, etc.) as needed to assure the provision of safe care.
- 12.4 Implementation of the plan of care
 - 12.4.1 The plan of care must be signed and dated by all members of the interdisciplinary team.

- 12.4.1.1 If the patient chooses not to sign the plan of care, this choice must be documented along with the rationale the signature was not provided.
- 12.4.2 The initial plan of care must be implemented within the latter of 30 calendar days after admission to the dialysis center or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.
- 12.4.3 Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the comprehensive assessment as required by subsection 12.4.
- 12.4.4 If the expected outcome is not achieved, the interdisciplinary team must:
 - 12.4.4.1 Revise the plan of care to reflect the patient's current condition;
 - 12.4.4.2 Document the reason(s) why the patient was unable to achieve the goal; and
 - 12.4.4.3 Implement the revisions to the plan of care.
- 12.5 The dialysis center must ensure that all dialysis patients are seen and evaluated by a physician or non-physician provider providing ESRD care at least monthly and at least quarterly while the patient is receiving in-center hemodialysis, as evidenced by documentation in the medical record.

13.0 Home Dialysis Service

- 13.1 A dialysis center that provides home dialysis training and support must be approved to provide home dialysis services, and ensure through its interdisciplinary team that home dialysis services are at least equivalent to those services provided to in-center patients.
- 13.2 The interdisciplinary team must oversee the training of the home dialysis patient, the designated caregiver(s), or self-dialysis patient before the initiation of home dialysis or self-dialysis and when the home dialysis caregiver(s) or modality changes.
- 13.3 The home dialysis training program must:
 - 13.3.1 Be provided by a dialysis center that is licensed to provide home dialysis services;
 - 13.3.2 Be approved by the medical director;
 - 13.3.3 Be conducted by a registered nurse who meets the requirements set forth in subsection 5.11.6.1;
 - 13.3.4 Be conducted for each home dialysis patient and at a minimum address the specific needs of the patient in the following areas:
 - 13.3.4.1 The nature and management of ESRD;
 - 13.3.4.2 The full range of techniques associated with the treatment modality selected, including:
 - 13.3.4.2.1 Effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription; and
 - 13.3.4.2.2 Safe storage and administration of erythropoiesis-stimulating agent(s) (if applicable) to achieve and maintain the target level hemoglobin and/or hematocrit as written in the patient's plan of care.
 - 13.3.4.3 How to detect, report, and manage potential dialysis complications, including water treatment problems;
 - 13.3.4.4 Availability of support resources and how to access and use those resources;
 - 13.3.4.5 How to self-monitor health status and document and report health status information;
 - 13.3.4.6 How to handle medical and non-medical emergencies;
 - 13.3.4.7 Infection control and prevention precautions; and
 - 13.3.4.8 Proper waste storage and disposal.
- 13.4 Home dialysis monitoring
 - 13.4.1 The dialysis center must:
 - 13.4.1.1 Document in the medical record that the patient, patient's caregiver(s) or both received and demonstrated adequate comprehension of the training;
 - 13.4.1.2 Retrieve and review complete self-monitoring data from home dialysis patients, or their designated caregiver(s) at least every two (2) months;
 - 13.4.1.3 Maintain documentation and self-monitoring data in the patient's medical record; and
 - 13.4.1.4 If the patient or designated caregiver has not provided appropriate self-monitoring data at least every two (2) months, dialysis center staff must make and document all reasonable efforts to obtain these records (if applicable).
- 13.5 A dialysis center that provides home dialysis training and support must furnish home dialysis support services regardless of whether dialysis supplies are provided by the dialysis center or a durable medical equipment company.

13.5.1 Support services must include, but are not limited to:

13.5.1.1 Periodic monitoring of the patient's home adaptation, including visits to the patient's home in accordance with the plan of care:

13.5.1.1.1 A home visit must be conducted at the initiation of home dialysis, annually and whenever a health or treatment problem is identified that could be related to the home dialysis.

13.5.1.2 Coordination of the home dialysis patient's care by a designated member of the interdisciplinary team:

13.5.1.3 Patient consultation with members of the interdisciplinary team as needed:

13.5.1.4 Monitoring of the home hemodialysis patient's water quality and dialysate, including:

13.5.1.4.1 Conducting an onsite evaluation; and

13.5.1.4.2 Testing the water and dialysate:

13.5.1.4.2.1 Prior to the initiation of home dialysis:

13.5.1.4.2.2 In accordance with the manufacturer's instructions; and

13.5.1.4.3 Correcting any water and/or dialysate quality issues, and if necessary, arrange for backup dialysis until the issues are resolved if:

13.5.1.4.3.1 Analysis of water and/or dialysate indicates contamination; or

13.5.1.4.3.2 The home dialysis patient demonstrates clinical symptoms associated with contaminated water and dialysate.

13.5.1.5 Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment:

13.5.1.6 Identifying a plan and arranging for emergency back-up dialysis when necessary.

13.6 Coordination of Services when providing home dialysis in a long term care facility:

13.6.1 Prior to providing home dialysis in a long term care facility, the dialysis center and long term care facility must have a written coordination agreement that outlines clear lines of responsibility and accountability.

13.6.1.1 There must be a written coordination agreement with each long term care facility in which home dialysis patients reside.

13.6.1.2 Each written coordination agreement shall be reviewed and updated at least annually.

13.6.2 The dialysis center is primarily responsible for the quality and safety of the dialysis treatments, including:

13.6.2.1 Training of the patient and each long term care facility staff member that provides home dialysis services:

13.6.2.2 Monitoring of the patient and the home dialysis environment;

13.6.2.3 Availability of social work and nutritional consultation;

13.6.2.4 Assuring continuity of care;

13.6.2.5 Installing and maintaining home dialysis equipment:

13.6.2.5.1 There must be one machine used exclusively for each individual patient's home dialysis treatments. The same dialysis machine must not be used for multiple home dialysis patients.

13.6.2.6 Testing and treating of water; and

13.6.2.7 Ordering dialysis-related supplies.

13.6.3 The dialysis center must maintain documentation that each long term care facility staff member has received, and demonstrated adequate comprehension, of the training specific to each patient that he/she will be providing home dialysis services.

14.0 Medical Records

14.1 The dialysis center shall develop and maintain a system for the collection, processing, maintenance, storage, retrieval, authentication and distribution of patient medical records. Records may exist in hard copy, electronic format, or a combination of the two media.

14.1.1 There shall be an identified locked area for medical record storage at the dialysis center.

14.2 A complete, accurate, legible and accessible medical record must be maintained on every individual receiving care in the dialysis center.

14.2.1 Each medical record shall include, but is not limited to the following:

14.2.1.1 Identifying information;

14.2.1.2 Consents;

14.2.1.3 Medical and surgical history;

- 14.2.1.4 Record of the creation and revision of the dialysis access;
- 14.2.1.5 A comprehensive history and physical examination completed within thirty (30) days of the patient's admission to the dialysis center, and no less than annually thereafter:
 - 14.2.1.5.1 For a patient new to dialysis, the physician is responsible to complete the comprehensive history and physical examination.
 - 14.2.1.5.1.1 Prior to the first treatment in the dialysis center, the physician shall inform the registered nurse functioning in the charge role of at least the patient's diagnoses, medications, hepatitis status, allergies, and dialysis treatment prescription.
 - 14.2.1.5.2 For established dialysis patients, the physician or non-physician practitioners may complete the comprehensive history and physical examination.
- 14.2.1.6 Physician orders, including dialysis treatment orders;
- 14.2.1.7 Progress notes regarding the condition and care of the patient;
- 14.2.1.8 Medication administration records (this can be documented on the treatment sheets);
- 14.2.1.9 A list of medications, including those the patient takes at home, and allergies;
- 14.2.1.10 Transfusion records;
- 14.2.1.11 Laboratory and diagnostic study reports;
- 14.2.1.12 Evidence of patient education;
- 14.2.1.13 Dialysis treatment records;
- 14.2.1.14 Patient assessments;
- 14.2.1.15 Patient plans of care;
- 14.2.1.16 Documentation regarding the patient's advance directive status;
- 14.2.1.17 Hospitalization reports; and
- 14.2.1.18 A discharge summary (if applicable).
- 14.2.2 Home dialysis patient medical records must include:
 - 14.2.2.1 Treatment records maintained by the patient, retrieved and reviewed for adherence to the treatment prescription every two (2) months:
 - 14.2.2.1.1 If the home dialysis patient is a resident of a long term care facility, the treatment records must indicate the name of the long term care facility staff member that provided home dialysis services.
 - 14.2.2.2 Documentation of home dialysis training and adequate comprehension of the training;
 - 14.2.2.3 The provision of home dialysis support services (i.e. dialysis supplies and durable medical equipment); and
 - 14.2.2.4 Periodic home visits and monitoring of the patient's home adaptation.
- 14.2.3 All entries in the medical record shall be dated, timed and authenticated by the responsible person in accordance with the dialysis center's policies and procedures.
- 14.2.4 Signature stamps may not be used to authenticate medical record entries.
- 14.3 Medical records shall be protected from loss, tampering, alteration, improper destruction, and unauthorized or inadvertent use.
 - 14.3.1 The dialysis center must:
 - 14.3.1.1 Maintain compliance with all federal and state laws, regulations and guidelines governing patient privacy and medical records;
 - 14.3.1.2 Ensure that each medical record is treated with confidentiality and is maintained according to professional standards of practice; and
 - 14.3.1.3 Obtain written permission from the patient or the patient's legal representative before releasing information that is not authorized by law.
 - 14.3.2 Medical records shall be retained in a retrievable form until destroyed.
 - 14.3.2.1 Medical records of adults (18 years of age and older) shall be retained for a minimum of six (6) years after the patient's discharge, transfer or death before being destroyed.
 - 14.3.2.2 Records of minors (less than 18 years of age) shall be retained for a minimum of six (6) years after the patient reached 18 years of age.
 - 14.3.2.3 The dialysis center shall not destroy medical records that relate to any matter that is involved in litigation if the facility knows the litigation has not been fully resolved.
 - 14.3.2.4 All records must be disposed of by shredding, burning or other similar protective measure in order to preserve the patient's right to confidentiality.

- 14.3.2.5 The dialysis center must establish procedures for the notification to patients regarding the pending destruction of the medical records.
 - 14.3.2.6 Documentation of medical record destruction must be maintained by the dialysis center.
 - 14.4 When a dialysis patient is transferred to another dialysis center, the dialysis center releasing the patient must send all medical record information to the receiving facility within one (1) working day of the transfer.
 - 14.5 Prior to providing dialysis treatment to a transient patient, a dialysis center shall obtain:
 - 14.5.1 Orders for dialysis treatment;
 - 14.5.2 A list of medications and allergies;
 - 14.5.3 Reports of laboratory work, including screening for hepatitis B status, that was performed no more than one (1) month prior to treatment at the dialysis center;
 - 14.5.4 The most current plan of care; and
 - 14.5.5 The most current treatment records from the referring facility.
 - 14.6 If the dialysis center plans to close, the facility shall notify the Department in writing at the time of closure of the disposition of the medical records, including where the medical records will be stored, and the name, address, and phone number of the custodian of the records.
 - 14.7 All patient records shall be available for review by authorized representatives of the Department and to legally authorized persons.
 - 14.8 Computerized patient records must be printed by the dialysis center as requested by authorized representatives of the Department.

15.0 Laboratory Services

- 15.1 The dialysis center must provide, or make available, laboratory services (except tissue pathology and histocompatibility) to meet the needs of the ESRD patient.
- 15.2 Any laboratory services must be furnished by, or obtained from, a facility that meets the requirements set forth in 42 CFR Part 493.
- 15.3 Contracts for laboratory services must be in writing and shall specify:
 - 15.3.1 The types of laboratory test to be performed;
 - 15.3.2 Methods for collection and handling of specimens; and
 - 15.3.3 How results are delivered, including a timeline for reporting "panic" values to a responsible person.

16.0 Quality Assessment and Performance Improvement

- 16.1 The dialysis center must develop, implement, maintain, and evaluate an effective, ongoing facility-wide, data driven, interdisciplinary QAPI program.
- 16.2 The QAPI program shall reflect the complexity of the dialysis center's organization and services, including those services furnished under contract or arrangement, and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors.
 - 16.2.1 There must be an operationalized, written plan describing the QAPI program scope, objectives, organizations, responsibilities of all participants, and procedures for overseeing the effectiveness of monitoring, assessing and problem solving activities.
- 16.3 The QAPI program shall include:
 - 16.3.1 An ongoing review of key elements of care using comparative and trend data to include aggregate patient data;
 - 16.3.2 Identification of areas where performance measures or outcomes indicate an opportunity for improvement;
 - 16.3.3 Appointment of an interdisciplinary team to:
 - 16.3.3.1 Identify, measure, analyze and track indicators for variation from desired outcomes;
 - 16.3.3.2 Create and implement improvement plan(s);
 - 16.3.3.3 Evaluate the implementation of the improvement plan(s); and
 - 16.3.3.4 Continuously monitor performance, take actions that result in performance improvements and track performance to ensure that improvements are sustained over time.
 - 16.3.4 Establishment and monitoring of quality indicators related to improved health outcomes and the identification and reduction of medical errors. For each quality assessment indicator, the facility shall establish and monitor a level of performance consistent with current professional knowledge. These performance components shall influence or relate to the desired outcomes themselves. At a minimum, the following indicators shall be measured, analyzed, and tracked on a monthly basis:

- 16.3.4.1 Water and dialysate quality;
 - 16.3.4.2 Dialysis equipment repair and maintenance;
 - 16.3.4.3 Dialysis adequacy;
 - 16.3.4.4 Nutritional status;
 - 16.3.4.5 Mineral metabolism and renal disease bone management;
 - 16.3.4.6 Anemia management;
 - 16.3.4.7 Fluid and blood pressure management;
 - 16.3.4.8 Vascular and/or peritoneal dialysis access;
 - 16.3.4.9 Patient modality choice and transplant referral;
 - 16.3.4.10 Personnel qualifications and issues;
 - 16.3.4.11 Infection prevention and control;
 - 16.3.4.12 Medical errors and medical injuries;
 - 16.3.4.13 Adverse occurrences;
 - 16.3.4.14 Patient satisfaction and grievances;
 - 16.3.4.15 Physical plant safety audits;
 - 16.3.4.16 ESRD Network 4 relationship and communications; and
 - 16.3.4.17 Morbidity and mortality.
- 16.4 The dialysis center must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety.
- 16.5 The dialysis center shall immediately correct any identified problems that threaten the health and safety of patients.
- 16.6 The Department may review the dialysis center's QAPI activities to determine compliance with these requirements.

17.0 General Requirements

- 17.1 The provisions of 42 CFR Ch. IV, Part 494, Subparts A, B, C and D are hereby adopted as the regulatory requirements for dialysis centers in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 17.2 The provisions of the 2012 National Fire Protection Association's Life Safety Code, as adopted and modified by the State Fire Prevention Regulations, are hereby adopted as the regulatory requirements for dialysis centers in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 17.3 The provisions of the Centers for Disease Control and Prevention Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm> are hereby adopted as the regulatory requirements for dialysis centers in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 17.4 The provisions of the State of Delaware, Department of Natural Resources and Environmental Control, Regulations Governing Solid Waste, 7 **DE Admin. Code** 1301 are hereby adopted as the regulatory requirements for dialysis centers in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 17.5 The provisions of the Centers for Disease Control and Prevention recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients, Morbidity and Mortality Weekly Report, available at: <https://www.cdc.gov/mmwr/pdf/rr/rr5005.pdf> are hereby adopted as the regulatory requirements for dialysis centers in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 17.6 No policies shall be adopted by the dialysis center which are in conflict with these regulations.
- 17.7 The dialysis center may contract for services to be provided to its patients. Individuals providing services under contract must meet the same requirements as those persons employed directly by the dialysis center.
- 17.8 All records maintained by the dialysis center shall at all times be open to inspection by authorized representatives of the Department.
- 17.8.1 The dialysis center must permit photocopying of any records or other information by, or on behalf of authorized representatives of the Department, as necessary to determine or verify compliance with these regulations.
- 17.9 Reports of adverse events shall be kept on file at the dialysis center for a minimum of five (5) years.
- 17.10 Report of major adverse events

17.10.1 The dialysis center must report all major adverse events involving a patient to the Department within 48 hours in addition to other reporting requirements required by law.

17.10.2 A major adverse event includes but is not limited to:

17.10.2.1 Suspected abuse, neglect, mistreatment, financial exploitation, solicitation or harassment of patients;

17.10.2.2 Death of a patient during a dialysis treatment;

17.10.2.3 A medication error with the potential to result in adverse health outcomes for the patient;

17.10.2.4 Conversion of staff or a patient to hepatitis B surface antigen positive;

17.10.2.5 Involuntary transfer or discharge of a patient; and

17.10.2.6 A fire in the dialysis center.

17.10.3 Major adverse events must be investigated by the dialysis center.

17.10.4 The dialysis center must submit a complete report to the Department within 30 calendar days of the event.

17.11 Each dialysis center shall designate at least one (1) patient representative for the Quality Insights Renal Network 4 Program.

18.0 Emergency Preparedness

18.1 The provisions of 42 CFR Ch. IV, Part 494.62 are hereby adopted as the regulatory requirements for dialysis centers in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.

18.2 The dialysis center must be connected to an emergency power source to ensure that all dialysis machines will operate for at least four (4) hours following a power shutdown or outage.

18.2.1 The emergency power source must be in working condition at all times.

18.2.2 The dialysis center must conduct and document at least a monthly test of those emergency power sources.

18.3 In the event of inclement weather, or any other interruption of dialysis center's normal business hours, the dialysis center must report the status of the facility's operation by completing and submitting the "Facility Status Reporting Tool" located on the Quality Insights Renal Network 4 website.

19.0 Severability

In the event any particular clause or section of these regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full force and effect.

22 DE Reg. 853 (04/01/19) (Final)