

Pursuant to the authority vested in the Public Health and Health Planning Council by Section 2803 of the Public Health Law, subject to the approval of the Commissioner of Health, Part 757 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 757 Chronic Renal Dialysis Services is REPEALED in its entirety, and New Part 757 is added as follows:

PART 757 CHRONIC RENAL DIALYSIS SERVICES

(Statutory authority: Public Health Law §2803)

Sec.

§757.1 Codes and standards.

§757.2 Additional requirements for chronic renal dialysis centers.

§757.3 Chronic renal dialysis center staffing.

§757.1 Codes and standards.

Operators of chronic renal dialysis centers shall comply with the codes and standards referred to in this section. Nothing herein shall preclude the operator of a chronic renal dialysis center from exceeding any codes and standards relating to the quality of care set forth in this Part. If a conflict occurs between the codes and standards set forth herein, or

between them and regulations found elsewhere in this Chapter, the operator of a chronic renal dialysis center shall comply with the more restrictive requirement. The following codes and standards are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein. Copies of such codes and standards are available for inspection and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237. Copies are also available from the publisher or issuing organization at the addresses listed below.

(a) Title 42 of the Code of Federal Regulations, Part 494, *Conditions for Coverage for End-Stage Renal Disease Facilities*, 2008 edition, including all standards incorporated therein. These regulations are published by the Office of the Federal Register National Archives and Records Administration. Copies may be obtained from the Superintendent of Documents, United States Government Printing Office, Washington, D. C. 20402.

(b) In the document entitled "Guidelines for the Prevention of Intravascular Catheter Related Infections", the provisions entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children", Parts I -IV; and "Central Venous Catheters, Including PICCs, Hemodialysis and Pulmonary Artery Catheters in Adult and Pediatric Patients", pages 16 through 18, Morbidity and Mortality Weekly Report, volume 51, number RR-10, August 9, 2002. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration, United States Government Printing Office, Washington, D. C. 20402.

(c) "Recommendation for Preventing Transmission of Infections Among Chronic Hemodialysis Patients", developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration, United States Government Printing Office, Washington, D. C. 20402.

§757.2 Additional requirements for chronic renal dialysis centers.

(a) Whenever referred to in this Part, the following definitions shall have the following meanings:

(1) *Dialysis station* means an individual patient treatment area that accommodates the dialysis equipment and the routine and emergency care indicated, and is sufficiently separate from other dialysis stations to afford protection from cross-contamination with blood-borne pathogens. A hemodialysis station shall be equipped with a chair or a bed, a hemodialysis machine, and access to a purified water source and dialysate concentrates.

(2) *End-Stage Renal Disease (ESRD) network* means entities contracted with the federal government that collect and share data and other information with the Centers for Medicare and Medicaid Services

(CMS), New York State and chronic renal dialysis centers within a specific geographic area.

(3) *Chronic renal dialysis center* means an ambulatory care facility approved by CMS to provide chronic renal dialysis services and licensed by the New York State Department of Health to provide such services.

(4) *Home dialysis* means dialysis provided at home by a patient or care partner who is trained by a registered professional nurse to deliver dialysis (peritoneal or hemodialysis) treatments at the patient's place of residence. The nurse responsible for home dialysis training must be a registered professional nurse who meets the licensure and practice requirements of New York State, has 12 months experience providing nursing care and 3 months experience working as a nurse in the specific dialysis modality (peritoneal or hemodialysis).

(5) *Dialysate* means aqueous fluid containing electrolytes and, usually, dextrose, which is intended to exchange solutes with blood during hemodialysis. It is the fluid made from water and concentrates delivered to the dialyzer by the dialysate supply system.

(6) *Product water* means water produced by a water treatment system or by an individual component of a system.

(b) Operators of chronic renal dialysis centers shall comply with Parts 751 and 752 of this Subchapter.

(c) The operator of a chronic renal dialysis center that provides pediatric services on other than an emergency basis, shall obtain pediatric nephrology consultation services with one or more board certified pediatric nephrologists. Such board certified pediatric nephrologist(s) shall follow current evidence based professionally accepted clinical practice standards for evaluating and monitoring the pediatric dialysis patients.

(d) Each chronic renal dialysis center certified for home dialysis services must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to patients who receive such services at the chronic renal dialysis center, and meet all applicable requirements contained in Title 42 of the Code of Federal Regulations, Part 494, *Conditions for Coverage for End-Stage Renal Disease Facilities*, 2008 edition.

(e) Each chronic renal dialysis center shall ensure that its water treatment and dialysate supply systems protect hemodialysis patients from adverse effects arising from known chemical and microbial contaminants that may be found in water and improperly prepared dialysate. Each chronic renal dialysis center shall develop, implement and comply with policies and procedures related to water treatment, dialysate, and reuse that are understandable and include the following:

- (1) sample of product water and a sample of dialysate shall have a microbiological examination at least once every month;
 - (2) sample of product water shall have a chemical examination at least once every three months; and
 - (3) water samples shall be examined by a laboratory licensed pursuant to Section 502 of the Public Health Law that is approved by the Department for the analysis of potable water.
- (f) Each chronic renal dialysis center shall ensure that dialysis stations meet the requirements set forth in subdivision (a) (1) of this section.
- (g) Each chronic renal dialysis center shall collaborate with its ESRD network, suppliers, utility service providers and the Department for surveys and for emergency preparedness, and shall also collaborate with other chronic renal dialysis centers to ensure that lifesaving dialysis services are available in the event of an emergency or disaster. The chronic renal dialysis center shall develop written policies and procedures that detail the actions it shall take and plan to be implemented in the event of an emergency or disaster.

§ 757.3 Chronic renal dialysis service staffing.

(a) In addition to other requirements that may be applicable to the operator as set forth in this Chapter, the operator of chronic renal dialysis center shall ensure that the center is adequately staffed with qualified personnel as described in and in accordance with this section.

(1) *Registered Professional Nurses.* All registered professional nurses (RNs) working in a chronic renal dialysis center shall hold an active New York State license to practice in accordance with Article 139 of the Education Law and its implementing regulations. At least one RN shall be present, on duty, and available to provide nursing services including nursing supervisory duties at all times when patients are present at the center.

(2) *Licensed Practical Nurse.* All licensed practical nurses (LPNs) working in a chronic renal dialysis center shall hold an active New York State license to practice in accordance with Article 139 of the Education Law and its implementing regulations. LPN responsibilities shall be consistent with the authorization and training provided by the center. In addition, LPNs practicing in a chronic renal dialysis center who have received training and demonstrated the competencies required by such chronic renal dialysis center may, if authorized by the LPNs' supervising RN, access and provide care to patients with central venous catheters. A supervising RN shall, in his or her sole discretion, determine whether an LPN has received the appropriate training and

demonstrated competencies as required by the center to provide care to patients with central venous catheters. All LPNs who are authorized to perform intravenous therapy procedures shall perform such procedures in accordance with the provisions set forth in Section 400.15 of this Title.

(3) *Qualified Social Worker.* The operator of chronic renal dialysis center shall have on staff, a qualified social worker who is licensed and registered by the New York State Education Department to practice as a licensed master social worker (LMSW) or licensed clinical social worker (LCSW) as defined in and in accordance with Article 154 of the Education Law.

(4) *Patient Care (Dialysis) Technicians.* The operator of a chronic renal dialysis center shall ensure that all unlicensed staff who have responsibility for direct patient care meet or exceed the center's written policies and procedures that define the minimum experience and training qualifications of patient care technicians(PCTs) and perform such patient care only under the direction of an RN. The operator of a chronic renal dialysis center shall ensure that all PCTs that provide patient care at its center are certified by a CMS approved national commercial dialysis technician certification organization within 18 months post hire. Such PCTs must, under the direction of an RN, complete a training program approved by the medical director of the chronic renal dialysis center.

(b) The operator of chronic renal dialysis center shall comply with the following

requirements and shall annually review, approve and implement policies and procedures that include or address the following:

- (1) Non-catheter patient assessment and documentation must be completed by the RN within sixty (60) minutes of initiation of dialysis.
- (2) Catheter patient assessment and documentation must be completed by the RN within forty-five (45) minutes of initiation of dialysis;
- (3) All supervising RNs must be thoroughly familiar with and clearly understand the training and qualifications of LPNs under their supervision as well as the types of tasks that may be delegated to such LPNs at the chronic renal dialysis center. Supervising RNs shall determine, at their discretion, whether to delegate such tasks to the LPNs.
- (4) All unlicensed staff that has patient care responsibilities must be supervised by RNs.
- (5) Training, qualifications, practice, supervision and other requirements for all LPNs that may access central venous catheters. LPNs that may access central venous catheters must successfully complete an initial and thereafter an annual training program for central venous access which includes successful completion of a written examination and competency demonstration. This training must be approved by the operator's governing body and the medical director. Documentation of such training must be maintained by the chronic renal dialysis center and made available to the Department upon request.

LPNs who access central venous catheters must provide such care under the direction of an RN.

(6) The chronic renal dialysis center shall clearly define the minimum experience and training qualifications of all patient care technicians (PCTs) who provide services in such center and services that PCTs are authorized to perform. The operator of a chronic renal dialysis center shall maintain documentation that demonstrates that PCTs in its center have, within 18 months post hire, and maintain certification by a CMS approved national commercial dialysis technician certification organization.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the promulgation of this regulation is contained in Public Health Law (PHL) section 2803. Section 2803 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection and promotion of the health of the residents of New York State by requiring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost, including chronic renal dialysis services.

Needs and Benefits:

Part 757 of Title 10 of the New York Codes Rules and Regulations (NYCRR) outlines the chronic renal dialysis requirements for services provided in New York State chronic renal dialysis centers. This regulation currently specifies that these centers must comply with the regulations contained in Title 42 of the Code for Federal Regulations (CFR), Public Health, Part 405, Subpart U – Conditions for Coverage of Suppliers of End State Renal Disease (ESRD) Service, (42 CFR Part 405), 1988 edition. In 2008, 42 CFR Part 405 was amended and renumbered as Part 494.

The amendments to 42 CFR Part 494 [formerly Part 405] establish new conditions for coverage that chronic renal dialysis centers must meet to be approved by the Centers for Medicare and Medicaid Services. It establishes performance expectations for centers and encourages patients to participate in their plan of care and treatment. It also reflects advances in dialysis technology and standard care practices.

10 NYCRR Part 757 must be updated to be in compliance with the revised federal Conditions for Coverage for ESRD Facilities. The proposed regulation also requires chronic renal dialysis centers to comply with certain standards that reflect current technology and practice in the field of ESRD care.

The proposed regulations clarify terms specific to dialysis treatment and requirements related thereto. The proposed regulations clarify that the operator of a chronic renal dialysis center that provides pediatric services must obtain pediatric nephrology consultation services with a board certified pediatric nephrologist. The proposed regulations also clarify standards for the frequency and analysis of product water samples, and ensures that the chronic renal dialysis center is adequately staffed by qualified personnel. The proposed regulations clearly define the scopes of practice, and the roles and responsibilities of the chronic renal dialysis staff.

Additionally, the proposed regulations require chronic renal dialysis centers to comply with certain requirements for ESRD care. In particular, for patients receiving dialysis at

the chronic renal dialysis center, time frames for patient assessment and documentation to be completed by an RN would be required no later than 60 minutes of initiation of dialysis for non-catheter patients and no later than 45 minutes of initiation of dialysis for catheter patients. The purpose of this patient assessment is to evaluate the current health status of the patient, the appropriateness of the dialysis prescription and the tolerance of the procedure by the patient. Furthermore provisions were added to require each chronic renal dialysis center to collaborate with its ESRD network, suppliers, utility service providers and the Department for survey and for emergency preparedness, as well as with other chronic renal dialysis centers to ensure that life saving dialysis services are available in the event of an emergency or disaster.

Costs:

Operators of chronic renal dialysis centers are already required to meet the requirements set forth in 42 CFR Part 494 Conditions for Coverage for End-Stage Renal Disease (ESRD) Facilities which have been incorporated into the proposed regulation. The standards that chronic renal dialysis centers must adhere to under the proposed regulation reflect current technology and practice in the field of ESRD care. The proposed regulation will not impose any additional costs.

Local Government Mandates:

The proposed regulation does not impose any additional mandates on local governments.

Paperwork:

There is no additional paperwork required as a result of the proposed regulation.

Duplication:

The proposed regulation incorporates by reference amended federal regulations, and codes and standards and clarifies requirements for New York State chronic renal dialysis centers to provide a consistent regulatory and enforcement structure and to better meet expectations of the regulated parties and the public and ensure no conflict between federal and State regulations exist.

Alternatives:

There are no viable alternatives. The current regulations in Part 757 are outdated and do not reflect current technology and practice. Federal amendments to 42 CFR Part 494 [formerly Part 405] renders the provisions in Part 757 outdated and obsolete.

Federal Standards:

The proposed regulation incorporates by reference and conforms to the federal standards in 42 CFR Part 494, as well as national standards in end stage renal dialysis treatment. In addition, it clarifies certain definitions, water and dialysate quality provisions and personnel provisions specific to New York State standards.

Compliance Schedule:

This proposed amendment will become effective upon publication of a Notice of Adoption in the *New York State Register*.

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REGULATORY FLEXIBILITY ANALYSIS

Effect of Rule:

There are 246 ESRD sites in New York State and 120 ESRD operators. There are 8 large operators (100 employees or more) and 113 small operators (1 to 99 employees). Of the 246 ESRD sites, 73 are run by large operators and 173 are run by small operators.

Compliance Requirements:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. ESRD facilities are already in compliance with these provisions as this measure incorporates by reference amended federal requirements set forth in 42 CFR Part 494. In addition, the proposed regulation clarifies standards for New York State chronic renal dialysis centers, and standards reflecting current technology and practice in the field of ESRD care. For patients receiving dialysis at the chronic renal dialysis center, time frames for patient assessment and documentation to be completed by an RN would be required no later than 60 minutes of initiation of dialysis for non-catheter patients and no later than 45 minutes of initiation of dialysis for catheter patients. The purpose of this patient assessment and documentation requirement is to ensure that an RN evaluates the current health status of the patient, the appropriateness of the dialysis prescription and the tolerance of the procedure by the patient. Furthermore provisions were added to require each chronic

renal dialysis center to collaborate with its ESRD network, suppliers, utility service providers and the Department for survey and for emergency preparedness, as well as with other chronic renal dialysis centers to ensure that life saving dialysis services are available in the event of an emergency or disaster. Such standards must be immediately complied with in order not to jeopardize health and safety. Therefore, a cure period was not determined necessary and included in the rule.

Professional Services:

No additional professional standards are required as a result of the proposed regulation. This measure incorporates by reference amended federal regulations and standards reflecting current technology and practice in the field of ESRD care, and clarifies such standards for New York State chronic renal dialysis centers.

Compliance Costs:

This measure incorporates by reference amended federal regulations, and standards reflecting current technology and practice in the field of ESRD care, and clarifies requirements for New York State chronic renal dialysis centers.

Economic and Technological Feasibility:

This proposal is economically and technologically feasible.

Minimizing Adverse Impact:

There is no adverse impact.

Small Business and Local Government Participation:

Outreach to the affected parties is being conducted. Organizations who represent the affected parties and the public can also obtain the agenda of the Codes, Regulations and Legislation Committee of the Public Health and Health Planning Council (PHHPC) and the proposed regulation on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

“Dear Chief Executive Officer (CEO)” letters were sent to affected parties outlining the components of 42 CFR Part 494 summarizing the general requirements that apply and linking them to the full text of the federal regulation online. The letter also included a Departmental contact for any questions. Chronic renal dialysis centers should already be in compliance with the federal regulations.

RURAL AREA FLEXIBILITY ANALYSIS

No Rural Area Flexibility Analysis is required pursuant to section 202-bb (4) (a) of the State Administrative Procedure Act (SAPA). It is apparent, from the nature of the proposed regulation that it will not impose any adverse impact on rural areas, and does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a (2) (a) of the State Administrative Procedure Act (SAPA). It is apparent, from the nature of the proposed regulation that it will have no impact on jobs and employment opportunities.