



SOUTH CAROLINA
DEPARTMENT OF
PUBLIC HEALTH

Regulation 61-97 Standards for Licensing Renal Dialysis Facilities

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Table of Contents

SECTION 100 – DEFINITIONS AND LICENSURE..... 1

 101. Definitions. 1

 102. Licensure. (II) 5

SECTION 200 – ENFORCEMENT OF REGULATIONS..... 7

 201. General..... 7

 202. Inspections and Investigations. 7

 203. Consultations. 8

SECTION 300 – ENFORCEMENT ACTIONS 9

 301. General..... 9

 302. Violation Classifications. 9

SECTION 400 – POLICIES AND PROCEDURES..... 10

SECTION 500 – STAFF AND TRAINING 11

 501. General..... 11

 502. Administrator. (II)..... 11

 503. Director of Nursing..... 11

 504. Staffing. (I)..... 12

 505. Medical Staff..... 12

 506. Job Descriptions. 12

 507. Orientation. (II)..... 13

 508. Training. (I)..... 13

 509. Health Assessment..... 14

SECTION 600 – REPORTING 14

 601. Incidents..... 14

602. Reportable Diseases and Infections. (II)	15
603. Closure and Zero Census.....	16
SECTION 700 – PATIENT RECORDS	16
701. Content.	16
702. Authentication. (II)	17
703. Individual Plan of Care.	17
704. Record Maintenance.	18
705. Record Retention.	18
SECTION 800 – [RESERVED].....	19
SECTION 900 – PATIENT CARE AND SERVICES.....	19
901. Dietary Services.	19
902. Laboratory Services. (II)	19
903. Social Services.	19
904. Home Dialysis.....	20
905. Transfer Agreement.	20
SECTION 1000 – PATIENT’S RIGHTS AND ASSURANCES.....	21
SECTION 1100 – PATIENT PHYSICAL EXAMINATIONS	21
SECTION 1200 – MEDICATION MANAGEMENT	21
1201. General.	21
1202. Medication Orders.	22
1203. Medicine Storage.....	22
SECTION 1300 – [RESERVED].....	23
SECTION 1400 – EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS.....	23
1401. Disaster Preparedness. (II)	23
1402. Continuity of Essential Services. (II).....	23
SECTION 1500 – FIRE PREVENTION	23
1501. Arrangements for Fire Department Response and Protection. (I).....	23
1502. Tests and Inspections. (I)	23
1503. Fire Response Training. (I).....	24
1504. Fire Drills.....	24
1505. Fire Extinguishers, Standpipes, and Automatic Sprinklers.	24
SECTION 1600 – MAINTENANCE.....	25
1601. General Maintenance.....	25

1602. Equipment Maintenance.	25
SECTION 1700 – INFECTION CONTROL.....	25
1701. Staff Practices.....	25
1702. Committee.....	25
1703. Tuberculosis Risk Assessment and Screening. (I).....	26
1704. Staff Hepatitis Screening.	27
1705. Patient Hepatitis Screening.....	27
1706. Isolation Room.....	28
1707. Housekeeping. (II).....	28
1708. Linen.....	28
1709. Refuse and Waste Disposal. (II)	29
1710. Outside Areas.....	29
1711. Toxic and Hazardous Substances.	29
SECTION 1800 – QUALITY IMPROVEMENT PROGRAM.....	30
SECTION 1900 – DESIGN AND CONSTRUCTION	30
1901. General.	30
1902. Codes and Standards.....	30
1903. Submission of Plans and Specifications.	31
1904. Code and Standards Compliance and Inspections.	32
SECTION 2000 – FIRE PROTECTION, PREVENTION, AND LIFE SAFETY	32
SECTION 2100 – GENERAL CONSTRUCTION	32
SECTION 2200 – [RESERVED]	32
SECTION 2300 – WATER SUPPLY	32
SECTION 2400 – ELECTRICAL	33
2401. General. (I)	33
2402. Lighting and Electrical Services.....	34
SECTION 2500 – HEATING, VENTILATION, AND AIR CONDITIONING (HVAC).....	34
SECTION 2600 – PHYSICAL PLANT	35
2601. General.	35
2602. Ground Fault Protection.....	36
SECTION 2700 – SEVERABILITY	36

SECTION 100 – DEFINITIONS AND LICENSURE

101. Definitions.

For the purpose of these standards, the following definitions shall apply:

A. Abuse. Physical abuse or psychological abuse.

1. Physical Abuse. The act of intentionally inflicting or allowing infliction of physical injury on a patient by an act or failure to act. Physical abuse includes, but is not limited to, slapping, hitting, kicking, biting, choking, pinching, burning, actual or attempted sexual battery, use of medication outside the standards of reasonable medical practice for the purpose of controlling behavior, and unreasonable confinement. Physical abuse also includes the use of a restrictive or physically intrusive procedure to control behavior for the purpose of punishment except that of a therapeutic procedure prescribed by a licensed physician or other legally authorized healthcare professional. Physical abuse does not include altercations or acts of assault between patients.

2. Psychological Abuse. The deliberate use of any oral, written, or gestured language or depiction that includes disparaging or derogatory terms to a patient or within the patient's hearing distance, regardless of the patient's age, ability to comprehend, or disability, including threats or harassment or other forms of intimidating behavior causing fear, humiliation, degradation, agitation, confusion, or other forms of serious emotional distress.

B. Administering Medication. The acts of preparing and giving a single dose of a medication to the body of a Patient by injection, ingestion, or any other means in accordance with the orders of a physician or other Authorized Healthcare Provider.

C. Administrator. The staff member designated by the Licensee to have the authority and responsibility to manage the Facility and oversees all functions and activities of the Facility.

D. Annual. A time period that requires an activity to be performed at least every twelve (12) months.

E. Assessment. A procedure for determining the nature and extent of the problems and needs of a Patient, or potential Patient, to ascertain if the Facility can adequately address those problems and needs, and to secure information for use in the development of the Individual Plan of Care.

F. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina as a physician, advanced practice registered nurse, or physician assistant to provide specific treatments, care, or services to Patients.

G. Consultation. A meeting with a licensed Facility and individuals authorized by the Department to provide information to Facilities to enable/encourage Facilities to better comply with the regulations.

H. Continuous Ambulatory Peritoneal Dialysis. A continuous manual exchange of dialysate into and from the peritoneal cavity (usually every four to six hours).

I. Continuous Cycling Peritoneal Dialysis. The use of a machine to warm and cycle the dialysate in and out of the peritoneal cavity (usually every four hours).

J. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act or the South Carolina Controlled Substances Act.

K. Department. The South Carolina Department of Health and Environmental Control. L. Designee. A staff member designated by the Administrator to act on his or her behalf.

M. Dialysis. A process by which dissolved substances are removed from a Patient's body by diffusion from one fluid compartment to another across a semipermeable membrane.

N. Dietitian. An individual currently licensed as a Dietitian by the South Carolina Department of Labor, Licensing and Regulation.

O. Direct Care Staff. Those individuals who are employees (full- and part-time) of the Facility providing direct treatment, care, and services to Patients, and those individuals contracted to provide treatment, care, and services to Patients.

P. Discharge. The point at which treatment, care, and services in a Facility are terminated and the Facility no longer maintains active responsibility for the treatment, care, and services of the Patient.

Q. End-Stage Renal Disease . That stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.

R. End-Stage Renal Disease Service. The type of care or services furnished to an End-Stage Renal Disease Patient. Such types of care are: transplantation service; Dialysis service and Home Dialysis training.

S. Exploitation. 1) Causing or requiring a Patient to engage in an activity or labor that is improper, unlawful, or against the reasonable and rational wishes of a patient. Exploitation does not include requiring a patient to participate in an activity or labor that is a part of a written Individual Plan of Care or prescribed or authorized by the patient's attending physician; 2) an improper, unlawful, or unauthorized use of the funds, assets, property, power of attorney, guardianship, or conservatorship of a patient by an individual for the profit or advantage of that individual or another individual; or 3) causing a patient to purchase goods or services for the profit or advantage of the seller or another individual through undue influence, harassment, duress, force, coercion, or swindling by overreaching, cheating, or defrauding the patient through cunning arts or devices that delude the patient and cause him or her to lose money or other property.

T. Health Assessment. An evaluation of the health status of a staff member or volunteer by a Physician, other Authorized Healthcare Provider, or a registered nurse, A registered nurse may complete the Health Assessment pursuant to standing orders approved by a Physician as evidenced by the Physician's signature. The standing orders shall be reviewed annually by the physician, with a copy of the review maintained at the Facility.

U. Home Dialysis. Dialysis performed by a Patient and/or individuals who assist Patients at home. The Patient and individuals who assist patients are trained and supervised by licensed nurses to do dialysis treatments on their own.

V. Home Dialysis Training. A program that trains and provides support services to End-Stage Renal Disease Patients and individuals who assist them in performing Home Dialysis with little or no professional assistance.

W. Individual Plan of Care. A documented regimen of appropriate care and services or written action plan prepared by the Facility for each Patient, based on the Patient's needs and preferences, and which is to be implemented for the benefit of the Patient.

X. Interdisciplinary Team. A group designated by the Facility to provide or supervise care and services provided by the facility. The group may include the following persons: physician or other Authorized Healthcare Provider, licensed nurse, dietary, social services, and direct care staff members.

Y. Inspection. A visit by Department representatives for the purpose of determining compliance with current statutes and regulations.

Z. Investigation. A visit by Department representatives to a licensed Facility or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to statutory and regulatory compliance.

AA. Legend Drug.

1. A drug when, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements:

a. “Caution: Federal law prohibits dispensing without prescription”;

b. “Rx only”;

2. A drug which is required by any applicable federal or state law to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only;

3. Any drug products considered to be a public health threat, after notice and public hearing as designated by the S.C. Board of Pharmacy; or

4. Any prescribed compounded prescription drug within the meaning of the S.C. Pharmacy Practice Act.

BB. License. The authorization to operate a Facility as defined in this regulation and as evidenced by a current certificate issued by the Department to a Facility.

CC. Licensed Capacity. The number of dialysis stations that the Facility is authorized to operate to include chronic hemodialysis and home hemodialysis training stations.

DD. Licensed Nurse. A person to whom the South Carolina Board of Nursing has issued a license as a registered nurse or licensed practical nurse, or a person granted multi-state licensing privileges by the South Carolina Board of Nursing and who may practice nursing in any Facility or activity licensed by the Department subject to the provisions and conditions as indicated in the Nurse Licensure Compact Act.

EE. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care and services at the Facility and with whom rests the ultimate responsibility for compliance with the current regulation.

FF. Medical Director. A physician currently licensed in South Carolina who is responsible for the medical direction of the End-Stage Renal Disease Services.

GG. Medication. A substance that has therapeutic effects including, but not limited to, Legend, Non-Legend, herbal products, over-the counter, nonprescription, vitamins, and nutritional supplements.

HH. Neglect. The failure or omission of a direct care staff member to provide the care, goods, or services necessary to maintain the health or safety of a Patient including, but not limited to, food, clothing, medicine, shelter, supervision, and medical services. Failure to provide adequate supervision resulting in harm to patients, including altercations or acts of assault between patients, may constitute neglect. Neglect may be repeated conduct or a single incident that has produced or could result in physical or psychological harm or substantial risk of death. Noncompliance with regulatory standards alone does not constitute neglect.

II. Non-Legend Drug. A drug that may be sold without a prescription and that is labeled for use by the consumer in accordance with state and federal law.

JJ. Patient. A person who receives care, treatment, or services from a Facility licensed by the Department.

KK. Physical Examination. An examination of a Patient that meets the requirements set forth in Section 1100 of this regulation by an Authorized Healthcare Provider.

LL. Quality Improvement Program. The process used by a Facility to examine its methods and practices of providing care and services, identify the ways to improve its performance, and take actions that result in higher quality of care and services for the Facility's Patients.

MM. Quarterly. A time period that requires an activity to be performed every three (3) months.

NN. Registered Health Information Administrator. An individual who holds a professional certification as a Registered Health Information Administrator from the American Health Information Management Association.

OO. Registered Health Information Technician. An individual who holds a professional certification as a Registered Health Information Technician from the American Health Information Management Association in the United States.

PP. Renal Dialysis Equipment Technician. An individual who cleans, sterilizes, sets up, monitors, adjusts, and tests dialysis machines and accessory equipment used in the treatment of Patients with End- Stage Renal Disease.

QQ. Renal Dialysis Facility (Facility). An outpatient Facility which offers staff-assisted Dialysis or Home Dialysis Training and support services to -End-Stage Renal Disease Patients. A Facility may be composed of one or more fixed buildings, mobile units, or a combination.

RR. Revocation of License. An action by the Department to cancel or annul a Facility License by recalling, withdrawing, or rescinding the Facility's authorization to operate.

SS. Social Worker. A person licensed as a social worker by the South Carolina Board of Social Work Examiners.

TT. Station. An individual Patient treatment area that provides sufficient space to accommodate the dialysis equipment and supplies needed for Dialysis. Includes Stations specifically for chronic Hemodialysis, Home Hemodialysis Training, and Peritoneal Dialysis.

UU. Suspension of License. An action by the Department requiring a Facility to cease operations for a period of time or to require a Facility to cease admitting Patients, until such time as the Department rescinds that restriction.

VV. Tuberculosis Risk Assessment. An initial and ongoing evaluation of the risk for transmission of Mycobacterium tuberculosis in a particular healthcare setting.

102. Licensure. (II)

A. No person, partnership, corporation, private or public organization, political subdivision or other governmental agency shall establish, operate, maintain, or represent itself (advertise or market) as a Renal Dialysis Facility in South Carolina without first obtaining a License from the Department. The Facility shall not admit Patients prior to the effective date of the License. When it has been determined by the Department that treatment, care, or services are being provided at a location, and the owner has not been issued a license from the Department to provide such treatment, care and services the owner shall cease operation immediately and ensure the safety, health, and well-being of the Patients. Current or previous violations of South Carolina Code or Department regulations may jeopardize the issuance of a License for the Facility or the licensing of any other Facility, or addition to an existing Facility that is owned and/or operated by the Licensee. The Facility shall provide only the treatment, care, and services it is licensed to provide pursuant to the definition in Section 101.QQ. (I)

B. A Renal Dialysis Facility License shall not be required for, nor shall such a License be issued to:

1. Facilities operated by the federal government.

2. Renal dialysis services provided in licensed hospitals (such services remain within the purview of R.61-16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries).

C. Compliance. An initial License shall not be issued to a proposed Facility until the Licensee applicant has demonstrated to the Department that the proposed Facility is in substantial compliance with this regulation. In the event a Licensee who already has a Facility or activity licensed by the Department makes application for another Facility or an increase in Licensed Capacity, the currently licensed Facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a License to the proposed Facility or an amended License to the existing Facility. A copy of licensing standards shall be maintained at the Facility and accessible to all staff members and volunteers. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

D. Licensed Dialysis Stations. No Facility that has been authorized to provide a set number of licensed stations, as identified on the face of the License, shall exceed the Licensed Capacity. No Facility shall establish new care or services or occupy additional Stations or renovated space without first obtaining authorization from the Department.

E. Issuance and Terms of License.

1. The License issued by the Department shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, services, personal safety, fire safety, or the well-being of any patient or occupant of a facility.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this state.

4. A license shall be effective for a specified facility, at a specific location, for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

5. Facilities owned by the same entity but which are not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, shall not be considered as dividing otherwise adjoining or contiguous property. For facilities owned by the same entity, separate licenses are not required for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

6. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

F. Facility Name. No proposed Facility shall be named, nor shall any existing facility have its name changed to, the same or similar name as any other facility licensed in South Carolina.

G. Application. Applicants for a License shall submit to the Department a complete and accurate application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application shall be signed by the owner(s) if an individual or partnership; by two (2) officers if a corporation; or by the head of the governmental department having jurisdiction if a governmental unit. Corporations or limited partnerships, limited liability companies or any other organized business entity shall be registered with the S.C. Secretary of State's Office if required to do so by state law. (II)

H. The application for initial licensure shall include:

1. The application shall set forth the full name and address of the Facility for which the License is sought and of the owner in the event his or her address is different from that of the Facility, and the names of the persons in control of the Facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with this regulation;

2. The applicant's oaths assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation;

3. Proof of ownership of real property in which the Facility is located, or lease agreement allowing the Licensee to occupy the real property in which the Facility is located;

4. Verification of Administrator's qualifications;

5. Name of director of nursing services; and

6. Number of renal dialysis Stations.

I. Licensing Fees. Each applicant shall pay an Annual License fee prior to issuance of a License. The Annual fee shall be two hundred dollars (\$200.00) for the first ten (10) Stations and twenty dollars (\$20.00) for each additional Station. Annual licensing fees shall also include any outstanding inspection fees. All fees are non-refundable, shall be made payable by check or credit card to the Department or online, and shall be submitted with the application. (II)

J. Licensing Late Fee. Failure to submit a renewal application and fee to the Department by the license expiration date shall result in a late fee of seventy-five dollars (\$75.00) or twenty-five percent (25%) of the

licensing fee amount, whichever is greater, in addition to the licensing fee. Failure to submit the licensing fee and licensing late fee to the Department within thirty (30) days of the license expiration date shall render the Facility unlicensed. (II)

K. License Renewal. For a License to be renewed, applicants shall submit a complete and accurate application on a form prescribed and furnished by the Department, shall pay the License fee, and shall not have pending enforcement actions by the Department. If the License renewal is delayed due to enforcement actions, the renewal License shall be issued only when the matter has been resolved by the Department, or when the adjudicatory process is completed, whichever is applicable.

L. Amended License. A Facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

1. Addition of Renal Dialysis Station or any part thereof; including:
 - a. Chronic Hemodialysis Stations;
 - b. Home Hemodialysis Training Stations; or
 - c. Peritoneal Stations;
2. Change of Facility location from one geographic site to another;
3. Change in Facility name or address (if notified by post office the address has changed)

M. Change of Licensee. A Facility shall request issuance of a new License by application to the Department prior to a change of the legal entity, for example, sole proprietorship to or from a corporation, or partnership to or from a corporation, even if the controlling interest does not change.

N. The licensee shall notify the Department, in a means as determined by the Department, of a change in controlling interest even if, in the case of a corporation or partnership, the legal entity retains its identity and name.

O. Variance. A variance is an alternative method that ensures the equivalent level of compliance with the standards in this regulation. The Facility may request a variance to this regulation in a format as determined by the Department. Variances shall be considered on a case by case basis by the Department. The Department may revoke issued variances as determined to be appropriate by the Department.

SECTION 200 – ENFORCEMENT OF REGULATIONS

201. General.

The Department shall utilize Inspections, Investigations, Consultations, and other pertinent documentation regarding a proposed or licensed Facility in order to enforce this regulation.

202. Inspections and Investigations.

A. A Facility shall undergo Inspection by the Department prior to initial licensing and is subject to subsequent Inspections as deemed appropriate by the Department. (I)

B. The Facility shall allow all individuals authorized by South Carolina law to enter the Facility for the purpose of Inspection and/or Investigation and granted access to all properties and areas, objects, requested records, and documentation at the time of the Inspection or Investigation. The Department shall have the authority to require the Facility to make photocopies of those documents required in the course of Inspections or Investigations. Photocopies shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. The physical areas of Inspections and Investigations shall be determined by the Department based on the potential impact or effect upon Patients. (I)

C. When there is noncompliance with the licensing standards, the Facility shall submit an acceptable plan of correction in a format determined by the Department. The plan of correction shall be signed by the Administrator and returned by the date specified on the report of Inspection or Investigation. The plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar); and
3. The actual or expected completion dates of those actions.

D. The Facility shall make available to the public copies of reports of Inspections or Investigations conducted by the Department, including the Facility response, upon written request with redactions of names of individuals in the report as provided by S.C. Code Sections 44-7-310 and 44-7-315.

E. The Facility shall pay a fee of three hundred fifty dollars (\$350.00) plus twelve dollars (\$12.00) per licensed Station for initial and routine Inspections. The fee for Station increase Inspections and follow-up inspections is two hundred dollars (\$200.00) plus twelve dollars (\$12.00) per licensed Station.

F. The Licensee shall pay the following inspection fees during the construction phase of the project. The plan inspection fee is based on the total estimated cost of the project whether new construction, an addition, or a renovation. The fees are detailed in the table below.

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	Fee
< \$10,001	\$750
\$10,001 - \$100,000	\$1,500
\$100,001 - \$500,000	\$2,000
> \$500,000	\$2,500 plus \$100 for each additional \$100,000 in project cost
Site Inspection	
50% Inspection	\$500
80% Inspection	\$500
100% Inspection	\$500

203. Consultations.

Consultations may be provided by the Department as requested by the Facility or as deemed appropriate by the Department.

SECTION 300 – ENFORCEMENT ACTIONS

301. General.

When the Department determines that a Facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such Facility, the Department, upon proper notice to the Licensee, may deny, suspend, or revoke Licenses, or assess a monetary penalty, or both.

302. Violation Classifications.

Violation of standards in this regulation are classified as follows:

A. Class I violations are those that present an imminent danger to the health, safety, or well-being of the persons in the Facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a Facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that have a negative impact on the health, safety or well-being of persons in the Facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in this regulation or those that are against the best practices. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

D. The notations “(I)” or “(II),” placed within sections of this regulation, indicate those standards are considered Class I or II violations if they are not met, respectively. Failure to meet standards not so annotated are considered Class III violations.

E. In determining an enforcement action the Department shall consider the following factors:

1. Specific conditions and their impacts or potential impacts on health, safety, or well-being of the Patients including, but not limited to: deficiencies in medication management; critical waste water problems; housekeeping, maintenance, or fire and life safety-related problems that pose a health threat to the Patients; power, water, gas, or other utility and/or service outages; Patients exposed to air temperature extremes that jeopardize their health; unsafe condition of the building or structure; indictment of an administrator for malfeasance or a felony, which by its nature indicates a threat to the Patients; direct evidence of abuse, neglect, or exploitation; no staff available at the Facility with Patients present; unsafe procedures and/or treatment being practiced by staff; (I)

2. Repeated failure of the Licensee or Facility to pay assessed charges for utilities and/or services resulting in repeated or ongoing threats to terminate the contracted utilities and/or services; (II)

3. Efforts by the Facility to correct cited violations;

4. Overall conditions of the Facility;
5. History of compliance; and
6. Any other pertinent conditions that may be applicable to current statutes and regulations.

F. When imposing a monetary penalty, the Department may invoke S.C. Code Section 44-7-320(C) to determine the dollar amount or may utilize the following schedule:

FREQUENCY OF CLASS I VIOLATION	CLASS I	CLASS II	CLASS III
1 st	\$500-1,500	\$300-800	\$100-300
2 nd	1,000-3,000	500-1,500	300-800
3 rd	2,000-5,000	1,000-3,000	500-1,500
4 th	5,000	2,000-5,000	1,000-3,000
5 th	5,000	5,000	2,000-5,000
6 th	5,000	5,000	5,000

SECTION 400 – POLICIES AND PROCEDURES

A. The Facility shall maintain and adhere to written policies and procedures addressing the manner in which the requirements of this regulation shall be met. The Facility shall be in full compliance with the policies and procedures. (II)

B. The written policies and procedures shall include the following: (II)

1. Staffing and training
2. Reporting incidents, accidents, reportable diseases, closure and zero census
3. Patient records
4. Patient care and services
5. Patient rights and assurances
6. Medication management
7. Admissions and discharge
8. Fire prevention

9. Maintenance including doors, windows, HVAC, fire alarm, electrical, mechanical, plumbing, and for all equipment

10. Infection control and housekeeping

11. Water supply

12. Quality Improvement Program

C. The Facility shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented and signed by the Administrator. All policies and procedures shall be accessible to Facility staff, printed or electronically, at all times.

SECTION 500 – STAFF AND TRAINING

501. General.

A. The Facility shall maintain accurate and current information regarding all staff members of the Facility, to include at least address, phone number, date of hire, date of initial Patient contact, and personal, work, and training background.

B. The Facility shall assign all staff members duties and responsibilities in writing and in accordance with the individual's capability. The Facility shall maintain a personnel file for each staff member. The file shall contain a health assessment, laboratory test results, resumés of training and experience, and current job description that reflects the staff member's responsibilities and work assignments, orientation, and periodic evaluations. (II)

502. Administrator. (II)

A. The Facility shall employ a full-time Administrator who shall be responsible for the management and administration of the Facility. The Administrator shall hold at least a bachelor's degree or have a minimum of an associate degree in a health-related field with at least two (2) years of experience in End-Stage Renal Disease within the past five (5) years. The Director of Nursing may serve as the Administrator.

B. Designee. A staff member shall be designated in writing to act in the absence of the Administrator.

C. The Facility shall notify the Department in writing within seventy-two (72) hours of any change in Administrator status and shall provide the Department the name of the newly-appointed Administrator and the effective date of the appointment.

503. Director of Nursing.

The Facility shall have a licensed registered nurse to act as Director of Nursing. The Director of Nursing shall have the following:

A. At least twelve (12) months of experience in clinical nursing, and an additional six (6) months of experience in nursing care for patients with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the Dialysis process; or

B. Eighteen (18) months of experience in nursing care of a patient on dialysis, or in nursing care of a patient with a kidney transplant, including training in and experience with the dialysis process.

C. If responsible for Home Dialysis Training, at least three (3) months of the total required End-Stage Renal Disease experience shall be in training patients in Home Dialysis.

504. Staffing. (I)

A. Each Facility shall have the following minimum staffing to provide services:

1. A registered nurse who shall serve as charge nurse (the Director of Nursing may act in this role);
2. At least one (1) registered nurse shall be on duty during hours of operation for every ten (10) Patients or fraction thereof. The charge nurse may serve in this capacity; and
3. If the Facility provides Home Dialysis training, such training shall be provided by a registered nurse who has had at least twelve (12) months experience in dialysis. At least three (3) months of the total required End-Stage Renal Disease experience shall be in training patients in Home Dialysis.

B. In addition to nursing staff, Direct Care Staff shall be in the building and immediately available to ensure a ratio of one (1) Direct Care Staff to each four (4) Patients or fraction thereof. (I)

C. The Facility shall maintain documentation to ensure the Facility meets Sections 504.A and 504.B.

505. Medical Staff.

A. If more than one (1) physician practices in a Facility, they shall be organized as a medical staff with appropriate bylaws approved by the governing body. The medical staff shall meet at least Quarterly and the Facility shall maintain minutes of such meetings.

B. The Facility shall have a licensed physician to serve as Medical Director of the End-Stage Renal Diseases services.

C. The Medical Director shall be responsible for the execution of Patient care policies and medical staff bylaws and rules and regulations. (II)

D. A licensed physician or nephrologist with demonstrated experience in the care of Patients with End-Stage Renal Disease shall be on-call to respond to Dialysis-related Patient issues during all times of clinical operations.

E. The Facility shall maintain a contact list for all on-call personnel, to include name, telephone number, and dates on-call. The Facility shall update the contact list as changes in personal occur, but not less than annually.

506. Job Descriptions.

A. The Facility shall maintain written job descriptions that describe the duties of every position. Each job description shall include position, title, authority, specific responsibilities, and minimum qualifications.

B. Job descriptions shall be signed by each staff member when assigned to the position and when revised.

507. Orientation. (II)

A. The Facility shall develop and execute a written orientation program to familiarize all new staff members with the Facility, its policies, and the staff members' job responsibilities. Documentation of orientation shall include training source, duration, and shall be signed and dated by the trainer and trainee. All required orientation shall be completed prior to Patient contact.

B. For Direct Care Staff, the orientation program shall contain at least the following subject content:

1. Fluid and electrolyte balance;
2. Kidney disease and treatment;
3. Dietary management;
4. Principles of Dialysis;
5. Dialysis technology;
6. Venipuncture technique;
7. Care of Dialysis Patients; and
8. Prevention of Hepatitis and other infectious diseases.

508. Training. (I)

A. Documentation of all in-service training shall be signed and dated by both the individual providing the training and the individual receiving the training. The following training shall be provided to all Direct Care Staff prior to Patient contact and at a frequency determined by the Facility, but at least annually unless otherwise specified by certificate, e.g., cardiopulmonary resuscitation (CPR):

1. Basic first aid;
2. Confidentiality of Patient information;
3. Patient's rights and assurances;
4. End-Stage Renal Disease care;
5. Cardiopulmonary resuscitation for designated staff members to ensure that there is a certified staff member present whenever residents are in the Facility.

B. Each equipment technician shall have completed a training course. Documentation of the training course shall be maintained in the staff file. The training shall include the following:

1. Prevention of Hepatitis via Dialysis equipment;
2. The safety requirements of dialysate delivery systems;
3. Bacteriologic control;

4. Water quality standards; and
5. Repair and maintenance of Dialysis and other equipment.

C. Facilities may allow Licensed Practical Nurses to perform intravenous (IV) push medication therapy. Prior to any Licensed Practical Nurse performing IV push medication therapy the Facility shall secure and maintain in the individual staff file the following:

1. Documentation of completion of an intravenous (IV) therapy course to include didactic and skill competency verification as required by current state and federal regulations;
2. Documentation of competency of performing IV push medication therapy, and annually thereafter, to include:
 - a. Administration of set prescribed dose routine and chronic medications;
 - b. Lab value parameters;
 - c. Technical administration process monitoring;
 - d. Emergency plan according to Facility policy and procedures; and
 - e. All Medications to be administered, to include appropriate dosage, actions, side effects, and contraindications.

509. Health Assessment.

A. All Direct Care Staff shall have a documented Health Assessment within twelve (12) months prior to initial Patient contact. The Health Assessment shall include tuberculin skin testing as described in Section 1704.

B. For staff members working at multiple Facilities operated by the same Licensee, copies of the documented Health Assessment shall be accessible at each Facility.

SECTION 600 – REPORTING

601. Incidents.

A. The Facility shall document every incident, and include an incident review, investigation, and evaluation as well as corrective action taken, if any. The Facility shall retain all documented incidents reported pursuant to this section for six (6) years after the Patient involved is last discharged. For the first year following discharge, these records shall be kept on site and readily available at that Facility.

B. The Facility shall report following types of incidents to the responsible party or emergency contact for each affected individual at the earliest practicable hour, not exceeding twenty-four (24) hours of the incident. The Facility shall notify the Department immediately, not to exceed twenty-four (24) hours, via the Department's electronic reporting system or as otherwise determined by the Department. Incidents requiring reporting include:

1. Confirmed or suspected crimes against Patients;

2. Confirmed or suspected Abuse, Neglect, or Exploitation;
3. Use of wrong dialyzer on Patient;
4. Blood spills of more than one hundred (100) milliliters;
5. Adverse reactions to Hemolytic transfusion;
6. Adverse reactions to dialyzers;
7. Medication errors with the potential for adverse impact;
8. Hospitalization or death resulting from the incident;
9. Severe hematoma or laceration requiring medical attention or hospitalization;
10. Bone or joint fracture;
11. Severe injury;
12. Fire;
13. Natural disaster

C. The Facility shall submit a separate written investigation report within five (5) days of every incident required to be reported to the Department pursuant to Section 601.B via the Department's electronic reporting system or as otherwise determined by the Department. Reports submitted to the Department shall contain only: Facility name, License number, type of accident and/or incident, the date of accident and/or incident occurred, number of Patients directly injured or affected, Patient medical record identification number, Patient age and sex, number of Staff directly injured or affected, number of visitors directly injured or affected, witness(es) name(s), identified cause of accident/incident, internal investigation results if cause unknown, a brief description of the accident/incident including location where occurred, and treatment of injuries

D. The Facility shall notify the Patient's Physician and responsible party or emergency contact within twenty-four (24) hours of significant changes in a Patient's condition and shall document the significant changes and notification in the Patient's record. (I)

602. Reportable Diseases and Infections. (II)

A. Reportable Diseases. The Facility shall report cases of reportable diseases in accordance with Regulation 61-20, Communicable Diseases, and any occurrences, such as epidemic outbreaks or poisonings or other unusual occurrence, which threaten the welfare, safety or health of Patients or personnel shall be reported immediately to the local health director and to the Bureau of Health Facilities Licensing.

B. Reports of infections such as abscesses, septicemia, hepatitis, or other communicable diseases observed during admission or follow-up (or return) visit of the Patient shall be made and kept as a part of the Patient's medical records. Efforts shall be made to determine the origin of any such infection and if the dialysis procedure was found to be related to acquiring the infection, remedial action shall be taken to prevent recurrence.

603. Closure and Zero Census.

A. The Facility shall notify the Department and Patients, or Patients' representatives when appropriate, in writing prior to permanent closure of the Facility and shall provide the effective closure date. The Facility shall return its License to the Department on the date of closure.

B. The Facility shall notify the Department in writing within fifteen (15) days prior to a temporary closure, or within forty-eight (48) hours if the temporary closure is due to an emergency. The notification shall include the reason for the temporary closure, records maintenance plan, anticipated reopening date, and documentation of Patient notification. Facilities that are temporarily closed longer than one (1) year shall reapply for licensure with the Department and be subject to all applicable licensing and construction requirements for new Facilities.

C. The Facility shall notify the Department in writing if there have been no Patients in the Facility for any reason for ninety (90) days or more no later than one hundred (100) days after the last Patient is discharged. Facilities that are zero census longer than one (1) year shall reapply for licensure with the Department and be subject to all applicable licensing and construction requirements for new Facilities.

D. Prior to the closing of a Facility for any reason, the Licensee shall arrange for preservation of records to ensure compliance with this regulation. The Facility shall notify the Department in writing within ten (10) days of closure of the provisions for records maintenance describing the arrangements and the location of the records.

SECTION 700 – PATIENT RECORDS

701. Content.

A. The Facility shall maintain an organized medical record for each Patient. All entries shall be permanently written, typed, or electronic media, authenticated by the author, and dated.

B. The medical record shall be current and contain: (II)

1. Face sheet;

a. identification data (name, date of birth, gender);

b. diagnosis;

c. primary care physician's name and phone number;

d. Responsible person or other individual to be contacted in case of emergency and phone number;

e. Patient's address and phone number; and

f. date of admission;

2. Orders from Physicians and other Authorized Healthcare Providers for at least one (1) year. Standing orders shall be updated on an Annual basis;

3. Documentation of Physician or other Authorized Healthcare Provider visits for at least one (1) year. Physician or other Authorized Healthcare Provider visits shall be made at least monthly, as evidenced by a

monthly progress note placed in the medical record, and periodically while the patient is receiving in-facility dialysis. The Facility shall document each visit missed by the Patient;

4. Physician progress notes for Home Dialysis Patients shall be documented monthly;
5. Lab and x-ray reports;
6. Annual history and physical;
7. Social worker initial assessments, updates, and quarterly progress notes;
8. Dietary initial assessments, updates, and monthly progress notes;
9. Miscellaneous consultations, hospitalizations;
10. Current Individual Plan of Care;
11. Nurses' progress notes each time of dialysis for one (1) month;
12. Nurse's initial admission assessment;
13. Signed consent forms.

702. Authentication. (II)

Facilities employing electronic signatures or computer-generated signature codes shall ensure authentication and confidentiality. If the Facility permits any portion of a Patient's record to be generated by electronic means, there shall be policies and procedures to prohibit the use or authentication by unauthorized users.

703. Individual Plan of Care.

A. The Interdisciplinary Team shall develop an Individual Plan of Care for each Patient to ensure appropriate modality of care. The Interdisciplinary Team shall develop the Individual Plan of Care either within the first thirty (30) calendar days of care or within the first thirteen (13) treatments. Individual Plans of Care shall be based on Patient's needs.

B. The Interdisciplinary Team shall review the Individual Plan of Care at least monthly for unstable Patients, and Annually for stable Patients and as changes in Patient needs occur. The Facility shall document participation of the Interdisciplinary Team, Patient and/or Patient's responsible party as appropriate, as evidenced by their signatures and date. The Individual Plan of Care shall include the following care areas:

1. Medical;
2. Psychological;
3. Social;
4. Dietary needs;
5. Stability of Patients;

6. Diagnosis;
7. Type of dialysis treatment;
8. Determination of stability of Patient (stable or unstable);
9. Indication whether candidate for transplantation or home dialysis;
10. Psychological needs, goals, and interventions; and
11. Dietary needs and interventions.
12. The course of action to be taken, the response and reaction to the care, and results of the treatment, and/or services provided.

704. Record Maintenance.

A. The Licensee shall provide accommodations, space, supplies, and equipment for the protection, storage, and maintenance of Patient records. Patient records shall be stored in an organized manner.

B. The Patient record is confidential and shall be made available only to individuals authorized by the Facility and/or the South Carolina Code of Laws. (II)

C. Copies of records generated by organizations or individuals contracted by the Facility for care or services shall be maintained by the Facility.

D. Upon Discharge of a Patient, the record shall be closed within thirty (30) calendar days and filed in an inactive or closed file maintained by the Licensee.

E. The Facility shall designate a staff member to serve as supervisor of Patient records. The Facility- designated staff member shall be a Registered Health Information Administrator or a Registered Health Information Technician. If the designated staff member is not a Registered Health Information Administrator or a Registered Health Information Technician the staff member shall receive consultation from a Registered Health Information Administrator or a Registered Health Information Technician. (II)

F. The Facility shall safeguard information in the medical record against loss, tampering, or use by unauthorized persons.

G. Records of current Patients shall be the property of the Facility. The records of current Patients shall be maintained at the Facility and shall not be removed without court order.

705. Record Retention.

A. When a Patient is transferred to an emergency Facility, a transfer summary to include, at a minimum, the diagnosis shall accompany the Patient to the receiving Facility at the time of transfer or forwarded immediately after the transfer. Documentation of the information forwarded shall be maintained in the Facility's Patient record. (I)

B. Records generated by organizations or individuals contracted by the Facility for care, treatment, procedures, surgery, and/or services shall be maintained by the Facility that has admitted the Patient. Appropriate information shall be provided to assure continuity of care.

C. The Facility shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by Facility staff, as needed, and for regulatory compliance Inspections.

D. Records of Patients shall be maintained for at least six (6) years following the discharge of the Patient. For the first year following discharge, these records must be kept on site and readily available at that Facility. Other documents required by the regulation, e.g., fire drills, shall be retained at least twelve (12) months or until the next Department Inspection, whichever is longer.

SECTION 800 – [RESERVED]

SECTION 900 – PATIENT CARE AND SERVICES

901. Dietary Services.

Each Facility shall employ or contract with a Dietitian(s) to provide for the dietary needs of each Patient. The Dietitian, in consultation with the physician or other Authorized Healthcare Provide, shall be responsible for assessing the nutritional and dietetic needs of each Patient, recommending therapeutic diets, counseling Patients and their families on prescribed diets, and monitoring adherence and response to diets. Each Patient shall be evaluated as to his or her nutritional needs by the attending physician or other Authorized Healthcare Provider and a Dietitian.

902. Laboratory Services. (II)

A. Laboratory services shall be provided under contract to meet the needs of the Patient. Hematocrits, clotting times, and blood glucoses may be done by the Facility's staff. Such staff shall be qualified by education and experience to perform such duties under the direction of a physician.

B. Controls. There shall be a Quarterly constant packing time performed on all centrifuges used for hematocrits. Records of performed constant packing time shall be maintained.

C. Administration of Blood. A Facility administering blood to Patients shall comply with the following:

1. Blood must be transported from the laboratory processing the blood to the Facility in a container that will ensure maintenance of a temperature of one to ten (1 to 10) degrees centigrade. Temperature must be recorded upon arrival.

2. If blood is not administered immediately upon arrival, it must be stored in a refrigerator at one to six (1 to 6) degrees centigrade. The temperature of the refrigerator must be monitored and recorded.

D. All expired laboratory supplies shall be disposed of in accordance with Facility policy and procedures.

903. Social Services.

Each Facility shall employ or contract with a social worker to meet the social needs of Patients. The Social Worker shall document and conduct psycho-social evaluations, participate in team review of Patient progress, and document recommended changes in treatment based on the Patient's current psycho-social needs. (II)

904. Home Dialysis.

Home Dialysis Services shall include the following: (II)

A. Hemodialysis:

1. Surveillance of the Patient's home adaptation, including provisions for visits to the home or the Facility;
2. Consultation for the Patient with a Social Worker and Dietitian;
3. A record keeping system which ensures continuity of care;
4. Installation and maintenance of equipment;
5. Testing and appropriate treatment of the water; and
6. Ordering of supplies on an ongoing basis.

B. Continuous Ambulatory Peritoneal Dialysis:

1. Consultation for the Patient with a licensed Social Worker and a licensed Dietitian;
2. A record keeping system which ensures continuity of care; and
3. Ordering of supplies on an ongoing basis.

C. Continuous Cycling Peritoneal Dialysis:

1. Surveillance of the Patient's home adaptation, including provisions for visits to the home or the Facility;
2. Consultation for the Patient with a licensed Social Worker and a licensed Dietitian;
3. A record keeping system which ensures continuity of care;
4. Installation and maintenance of equipment; and
5. Ordering of supplies on an ongoing basis.

905. Transfer Agreement.

A. The Facility shall have in effect a written transfer agreement, signed by the Administrator, with one or more hospitals, for the provision of inpatient care and other hospital services.

B. The Dialysis Facility shall transfer a Patient to a hospital whenever a transfer or referral is determined as medically necessary by the attending physician.

C. There shall be an exchange of information, within one (1) business day, of medical and other information necessary or useful in the care and treatment of Patients transferred to a hospital or any other inpatient medical facility, or to another End-Stage Renal Disease Facility.

SECTION 1000 – PATIENT’S RIGHTS AND ASSURANCES

A. The following rights shall be guaranteed to the Patient, and, at a minimum, the Facility shall provide the Patient and any guardians, next of kin, or sponsoring agencies a written and oral explanation of these rights:

1. Fully informed of these rights and responsibilities, and of all rules and regulations governing Patient conduct and responsibilities;

2. Fully informed of services available in the Facility and provided an explanation any out of pocket expenses to the patient within fifteen (15) calendar days of admission and any time there are changes to their insurance coverage;

3. Informed by a Physician of their medical condition as documented in the Patient’s medical record unless the medical record documents a contraindication;

4. Afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

5. Be transferred or discharged only for medical reasons, at the Patient’s request, or for the welfare of the Patient, other Patients, or Facility Staff, or for nonpayment of fees and given notice to ensure orderly transfer or discharge; and

6. Treated with consideration, respect and full recognition of their individuality and personal needs, including the need for privacy in treatment.

B. The Facility shall maintain written documentation evidencing the Patient has had his or her rights explained.

SECTION 1100 – PATIENT PHYSICAL EXAMINATIONS

A. A Physical Examination shall be completed for Patients within thirty (30) calendar days prior to admission and at least Annually thereafter. A Physical Examination included in a discharge summary from a healthcare facility licensed by the Department, completed within thirty (30) calendar days, is acceptable as the admission Physical Examination. The Facility’s physician shall attest to the Physical Examination’s accuracy by countersigning it.

B. Physical examinations by physicians licensed in states other than South Carolina are permitted for new admissions under the condition that residents obtain an attending physician licensed in South Carolina and undergo a second (2nd) physical examination by that physician within thirty (30) calendar days of admission to the facility.

SECTION 1200 – MEDICATION MANAGEMENT

1201. General.

A. Medications, including Controlled Substances, medical supplies, and those items necessary for the rendering of first aid, shall be properly managed in accordance with federal, state, and local laws and regulations. Such management shall address the securing, storing, and administering of Medications, medical supplies, first aid supplies, and biologicals, their disposal when discounted or expired, and their disposition at discharge, death, or transfer of a Patient.

B. Applicable reference materials published within the previous three (3) years shall be available at the Facility in order to provide staff members or volunteers with adequate information concerning Medications. (II)

1202. Medication Orders.

A. Medications, to include oxygen, shall be administered in the Facility to Patients only upon orders of a physician or other Authorized Healthcare Provider.

B. All other orders shall be received only by Licensed Nurses or Authorized Healthcare Providers and shall be authenticated and dated by a physician or other Authorized Healthcare Provider pursuant to the Facility's policies and procedures, but no later than fourteen (14) calendar days after the order is given. Verbal orders received shall include the time of receipt of the order, description of the order, and identification of the physician or other Authorized Healthcare Provider and the individual receiving the order.

C. Medications and medical supplies ordered for a specific Patient shall not be provided to or administered to any other Patient.

1203. Medicine Storage.

A. Medication and drugs maintained in the Facility for daily administration shall be properly stored and safeguarded in enclosures of sufficient size and that are not accessible to unauthorized persons. Refrigerators used for storage of Medications shall maintain an appropriate temperature as determined by the requirements established on the label of Medications. A thermometer accurate to plus or minus three (3) degrees shall be maintained in these refrigerators. Only authorized personnel shall have access to storage enclosures. Controlled Substances and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws. Expired or discounted Medications shall not be stored with current Medications. (I)

B. Medicine Preparation Area. Medicines and drugs shall be prepared for administration in an area that contains a counter and a sink. This area shall be located in such a manner to prevent contaminations of medicines being prepared for administration. (II)

C. Stock Medications.

1. Unless the Facility has a permitted pharmacy, stocks of Legend Medications shall not be stored except those specifically prescribed for individual Patients.

2. Non-legend Medications may be retained and labeled as stock in the Facility for administration as ordered by a Physician or other Authorized Healthcare Provider.

3. Stocks of naloxone may be stored for emergency overdose crises, with or without specific prescription for individual Patients.

4. If stock non-Patient specific Controlled Substances are to be used, a Controlled Substances registration from the Department's Bureau of Drug Control and a Controlled Substances registration from the federal Drug Enforcement Administration shall be obtained. The registrations shall be displayed in a conspicuous location within the Facility. Records shall be kept of all stock supplies of Controlled Substances giving an accounting of all items received and/or administered. (I)

D. Poisonous Substances. All poisonous substances shall be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration. (I)

E. Review of Medications. A Physician, pharmacist, or Licensed Nurse shall document review at least monthly all Medications prescribed by the Facility's physician for each Patient, for potential adverse reactions, allergies, interactions, etc. (II)

SECTION 1300 – [RESERVED]

SECTION 1400 – EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

1401. Disaster Preparedness. (II)

A. The Facility shall develop and maintain a written plan for actions to be taken in the event of a disaster or an emergency evacuation. The plan shall be implemented as necessary and at the time of need. The plan shall be evaluated, updated at least Annually, and available upon request by Patients, Patients' families, and the Department.

B. During any emergent event the Facility shall provide data, Facility and evacuation status, and other requested information as determined by the Department, and at a frequency as determined by the Department.

1402. Continuity of Essential Services. (II)

There shall be a plan to be implemented to ensure the continuation of essential Patient services for such reasons as power outage, water shortage, or in the event of the absence from work of any portion of the work force resulting from inclement weather or other causes.

SECTION 1500 – FIRE PREVENTION

1501. Arrangements for Fire Department Response and Protection. (I)

A. Each Facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire, such as fire plan and evacuation plan.

B. Facilities located outside of a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. A copy of the agreement shall be kept on file in the Facility and a copy shall be forwarded to the Department. If the agreement is changed, a copy shall be forwarded to the Department.

1502. Tests and Inspections. (I)

Fire protection and suppression systems shall be maintained and tested in accordance with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility.

1503. Fire Response Training. (I)

All Facility staff shall complete Annual fire response training in accordance with specific duties and responsibilities outlined in their job description. Training shall be documented in a staff record and maintained in the Facility.

A. Fire response training shall address, at a minimum, the following:

1. Reporting a fire;
2. Use of the fire alarm system, if applicable;
3. Location and use of fire-fighting equipment;
4. Methods of fire containment; and
5. Specific responsibilities, tasks, or duties of each individual.

B. A plan for the evacuation of Patients, staff members, and visitors, to include evacuation routes and procedures, in case of fire or other emergencies, shall be established and posted in a conspicuous public area.

C. All Patients capable of self-evacuation shall be trained in the proper actions to take in the event of a fire, for example, actions to take if the primary escape route is blocked.

D. Patients shall be made familiar with the fire plan and evacuation plan upon admission and this plan will be reinforced during subsequent Fire Drills.

1504. Fire Drills.

A. An unannounced fire drill shall be conducted at least Quarterly for all shifts. Each staff member shall participate in a fire drill at least once each year. Records of drills shall be maintained at the Facility, indicating the date, time, shift, description, and evaluation of the drill, and the names of staff members, volunteers, and Patients directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, then the mandated statute or regulation requirements supersede the requirements of this regulation, and the Facility shall comply with the provisions of the statute or regulation.

B. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1503 above.

C. All Patients shall participate in fire drills. In instances when a Patient refuses to participate in a drill, efforts shall be made to encourage participation, for example, counseling, implementation incentives rewarding Patients for participation, specific staff-to-Patient assignments to promote Patient participation. Continued refusal may necessitate implementation of the discharge planning process to place the Patient in a setting more appropriate to his or her needs and abilities.

1505. Fire Extinguishers, Standpipes, and Automatic Sprinklers.

The Facility shall provide fire-fighting equipment such as fire extinguishers, standpipes, and automatic sprinklers as required by the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility. The Facility shall ensure

extinguishers are sized, located, installed, and maintained in accordance with National Fire Protection Association No. 10. The Facility shall install suitable fire extinguishers in all hazardous areas. The Facility shall comply with all state and local fire and safety provisions. (I)

SECTION 1600 – MAINTENANCE

1601. General Maintenance.

The Facility shall keep all equipment and building components including, but not limited to, doors, windows, lighting fixtures, and plumbing fixtures in good repair and operating condition. The Facility shall document preventive maintenance. The Facility shall comply with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility. (II)

1602. Equipment Maintenance.

A written preventive maintenance program for all fire alarm, electrical, mechanical, plumbing, fire protection systems, and for all equipment used in dialysis and related procedures including, but not limited to, all Patient monitoring equipment, isolated electrical systems, conductive flooring, Patient ground systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. (II)

SECTION 1700 – INFECTION CONTROL

1701. Staff Practices.

Staff practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for proper disposal of toxic and hazardous substances. These preventive measures and/or practices shall be in compliance with applicable guidelines of the Blood borne Pathogens Standard of the Occupational Safety and Health Act of 1970; the Centers for Disease Control and Prevention; R.61-105, Infectious Waste Management; and other applicable federal, state, and local laws and regulations.

1702. Committee.

A. The Facility shall have an infection control committee composed of at least the Administrator, a Physician, and a registered nurse that shall be responsible for writing and enforcing policies and procedures for preventing and controlling hepatitis and other infections.

B. The policies and procedures for preventing and controlling hepatitis and other infections shall include, but not be limited to: (II)

1. appropriate procedures for prevention of hepatitis and other infectious diseases, to include the utilization of universal precautions for prevention of transmission of bloodborne pathogens currently recommended by the Centers for Disease Control;

2. appropriate procedures for surveillance and reporting of infections to include infection rates;

3. housekeeping;

4. handling and disposal of waste and contaminants;
5. sterilization and disinfection of equipment;
6. prevention of contamination by blood and other body fluids of units outside of the dialysis and Dialyzer reprocessing areas including toilet facilities, staff lounge, etc.;
7. protection of Patient clothing during the time when blood lines are opened or needles inserted or withdrawn; and
8. investigation of infections.

1703. Tuberculosis Risk Assessment and Screening. (I)

A. Tuberculosis Testing. The Facility may utilize either Tuberculin skin testing or Blood Assay for Mycobacterium tuberculosis (“BAMT”) for detecting Mycobacterium tuberculosis infection:

1. Tuberculin skin testing (“TST”). A small dose (0.1 mil) of purified protein derivative (“PPD”) tuberculin is injected just beneath the surface of the skin (by the intradermal Mantoux method), and the area is examined for induration (hard, dense, raised area at the site of the TST administration) forty-eight to seventy-two (48 to 72) hours after the injection (but positive reactions can still be measurable up to a week after administering the TST). The size of the indurated area is measured with a millimeter ruler and the reading is recorded in millimeters, including zero (0) mm to represent no induration. Redness and/or erythema is insignificant and is not measured or recorded. Authorized Healthcare Providers are permitted to perform tuberculin skin testing and symptom screening.

2. Blood Assay for Mycobacterium tuberculosis (“BAMT”). A general term to refer to in vitro diagnostic tests that assess for the presence of tuberculosis (“TB”) infection with Mycobacterium tuberculosis. This term includes, but is not limited to, IFN- γ release assays (“IGRA”).

B. The Facility shall conduct an Annual tuberculosis risk assessment in accordance with the Centers for Disease Control guidelines to guide the Facility’s infection control policies and procedures related to the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

C. Baseline Status.

1. The Facility shall determine the baseline status of all staff according to the Centers for Disease Control and the Department’s most current tuberculosis guidelines.

2. Tuberculosis Screening. All staff within three (3) months prior to Patient contact shall have a baseline two-step Tuberculin Skin Test (“TST”) or a single Blood Assay for Mycobacterium tuberculosis (“BAMT”). If a newly employed staff or volunteer has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered and read to serve as the baseline prior to Patient contact.

D. Post Exposure. After known exposure to a person with potentially infectious tuberculosis disease without use of adequate personal protection, the tuberculosis status of all staff shall be determined in a manner prescribed in the Centers for Disease Control and Department’s most current tuberculosis guidelines.

E. Annual Tuberculosis Training. All Direct Care staff shall receive Annual training regarding tuberculosis to include risk factors and signs and symptoms of tuberculosis disease. The Annual tuberculosis training shall be documented in a staff record and maintained at the Facility.

F. Serial Screening. The Facility shall follow the Centers for Disease Control and Department's most current tuberculosis guidelines related to serial screening.

1704. Staff Hepatitis Screening.

A. All Direct Care Staff shall have been vaccinated or have evidence of immunity for hepatitis B prior to Patient contact, unless contraindicated or offered and declined. The Facility shall maintain records of all Direct Care Staff hepatitis B vaccinations in each individual staff file. The HBsAg status of all Direct Care Staff shall be known to identify those individuals who are (1) HBsAg-positive and therefore potential sources of infection to others; (2) anti-HBs-positive and therefore, immune; and (3) HBV-seronegative and therefore susceptible to hepatitis B virus.

B. The Facility shall offer hepatitis B vaccinations to unvaccinated or partially vaccinated new direct care staff members (who do not already exhibit immunity) prior to patient contact. The decision to receive or decline a vaccination shall be documented in the individual staff file.

1. Each Direct Care Staff member who elects vaccination shall start the initial dose of the hepatitis B series within ten (10) days of Patient contact and complete the series within six (6) months. The Facility shall conduct and document routine post-vaccination testing according to the Centers for Disease Control guidelines for response to the vaccination.

2. The Facility shall consider the individuals declining vaccinations as hepatitis B virus susceptible, and follow the Centers for Disease Control guidelines in the event of a reported blood or bodily fluid exposure.

C. For staff members whose status has been determined to be HBsAg-positive, the Facility shall refer to current Centers for Disease Control guidelines and Facility policies and procedures.

1705. Patient Hepatitis Screening.

A. All Patients shall be screened within thirty (30) calendar days prior to admission to the Facility to determine the hepatitis B virus serological status (HBsAg, anti-HBc, and anti-HBs). The HBsAg status of all Patients shall be known to identify those individuals who are (1) HBsAg-positive and therefore potential sources of infection to others; (2) anti-HBs-positive and therefore immune; and (3) HBV-seronegative and therefore susceptible to hepatitis B virus. A status result from hepatitis B testing shall be maintained in the Patient's record.

B. The Facility shall make available to Patients literature describing the risks and benefits of the hepatitis B vaccination. The Facility shall offer hepatitis B vaccinations to unvaccinated and/or susceptible Patients. The Facility shall maintain all Patient vaccination records in each Patient record.

1. Each Patient who elects vaccination shall start the initial dose of the hepatitis B vaccine series within ten (10) days of admission and complete the series within six (6) months according to Centers for Disease Control guidelines for pre-exposure vaccination. The Facility shall conduct and document routine post-vaccination testing according to the Centers for Disease Control guidelines for response to the vaccination.

2. The Facility shall consider the individuals declining vaccinations as hepatitis B virus seronegative, and follow the Centers for Disease Control guidelines for routine testing.

C. For Patients whose status has been determined to be HBsAg positive, the Facility shall refer to current Center for Disease Control guidelines and Facility policies and procedures.

D. The Facility shall conduct routine hepatitis B testing per current Centers for Disease Control guidelines.

1706. Isolation Room.

All Facilities accepting hepatitis B surface antigen positive Patients shall provide a separate isolation Dialysis room. (II)

1707. Housekeeping. (II)

A. The Facility and its grounds shall be clean, and free of vermin and offensive odors.

B. Interior housekeeping shall, at a minimum, include:

1. Cleaning each specific area of the Facility;

2. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area appropriate to the area and the equipment's purpose or use;

3. For chemicals indicated as harmful on the product label, cleaning materials and supplies shall be in locked storage areas and inaccessible to Patients; and

4. During use of chemicals indicated as harmful on the product label, cleaning materials and supplies shall be in direct possession of the staff member and monitored at all times.

C. Exterior housekeeping shall, at a minimum, include:

1. Cleaning of all exterior areas, such as, porches and ramps, and removal of safety impediments such as snow and ice;

2. Keeping the Facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin; and

3. Safe storage of chemicals indicated as harmful on the product label, equipment, and supplies inaccessible to Patients.

D. Paper towels or air hand dryers and soap dispensers with soap must be provided at all lavatories in the Facility. (II)

1708. Linen.

A. All reusable linens, including those used as sterilizing wrappers, must be laundered before re-use.

B. Clean linens shall be handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

C. The Facility shall have available at all times a quantity of linen essential for proper care and comfort of Patients.

D. Used linens shall be kept in closed and covered containers while being stored or transported.

1709. Refuse and Waste Disposal. (II)

A. All garbage and waste shall be collected, stored, and disposed of in a manner to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable-type containers shall not be reused.

B. Containers for garbage and refuse shall be covered and stored outside in durable, rust-resistant, non-absorbent, watertight, rodent-proof, easily cleanable containers placed on an approved platform to prevent overturning by animals, the entrance of flies or the creation of a nuisance. All solid waste shall be disposed of at frequencies in a manner so as not to create a rodent, insect, or other vermin problem.

C. Containers for garbage shall be cleaned and free of debris.

D. All sewage and liquid waste shall be disposed of in a manner not to create a public health hazard and by a sanitary method approved by the Department.

E. A Sharps disposal system shall be utilized and appropriately covered. (II)

1710. Outside Areas.

All outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for vermin. Outside stairs, walkways, ramps, and porches shall be maintained free from accumulations of water, ice, snow, and other impediments.

1711. Toxic and Hazardous Substances.

The Facility shall have policies and procedures for dealing with toxic and hazardous substances. Such policies and procedures shall conform to current Occupational Safety and Health Administration standards regarding formaldehyde, renalin, or any other sterilizing agents. (II)

A. The Facility shall develop procedures to cover at a minimum:

1. Formaldehyde vapor concentration;
2. Fire prevention;
3. Solution exposure;
4. Leaks from machines;
5. Large and small spills; and

6. Solution contact with eyes, skin and/or clothing (appropriate eyewash stations shall be provided in all Facilities).

B. The Facility shall conduct and document routine monitoring of vapor concentration in accordance with current Occupational Safety and Health Administration guidelines.

SECTION 1800 – QUALITY IMPROVEMENT PROGRAM

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care and services provided by the Facility.

B. The quality improvement program, at a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is regularly, systematically, and objectively accomplished;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Analyze the appropriateness of Individual Plans of Care and the necessity of care and services rendered;

5. Analyze all incidents and accidents, to include all medication errors and Patient deaths;

6. Analyze any infection, epidemic outbreaks, or other unusual occurrences which threaten the health, safety, or well-being of the Patients; and

7. Establish a systematic method of obtaining feedback from Patients and other interested persons, as expressed by the level of satisfaction with care and services received.

SECTION 1900 – DESIGN AND CONSTRUCTION

1901. General.

A Facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each Patient. Facility design shall be such that all Patients have access to required services.

1902. Codes and Standards.

A. Facility design and construction shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility.

B. Unless specifically required otherwise by the Department, all Facilities shall comply with the adopted construction codes and construction provisions effective at the time its initial License was issued.

1903. Submission of Plans and Specifications.

A. Plans and specifications shall be submitted to the Department for review and approval for new construction, additions or alterations to existing buildings, replacement of major equipment, buildings being licensed for the first time, buildings changing license type, and for Facilities increasing occupant load or Licensed Capacity. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. Unless directed otherwise by the Department, plans shall be submitted at the schematic, design development, and final stages. All plans shall be drawn to scale with the title, stage of submission, and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction, the owner shall employ a registered architect and/or engineer for observation and inspections. Periodic inspections shall be conducted by the Department throughout each phase of a project.

B. Plans and specifications shall be submitted to the Department for review and approval for projects involving Dialysis systems that are periodically replaced, reverse osmosis systems, or that have an effect on:

1. The function of a space;
2. The accessibility to or of an area;
3. The structural integrity of the Facility;
4. The active and/or passive fire safety systems;
5. Doors;
6. Walls;
7. Ceiling system assemblies;
8. Exit corridors;
9. Life safety systems; or
10. That increase the occupant load or Licensed Capacity of the Facility.

C. The Facility shall submit all subsequent addenda, change orders, field orders, and documents altering the Department's review. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.

D. Cosmetic changes utilizing paint, wall covering, floor covering, etc. that are required to have a flame-spread rating or to satisfy other safety criteria shall be documented with copies kept on file at the Facility and made available to the Department.

1904. Code and Standards Compliance and Inspections.

Construction work which violates codes or standards will be required to be brought into compliance. All projects shall obtain all required permits from the locality having jurisdiction. Construction performed without proper permitting shall not be inspected by the Department.

SECTION 2000 – FIRE PROTECTION, PREVENTION, AND LIFE SAFETY

A. Facilities shall have a partial, manual, automatic, supervised fire alarm system. The Facility shall arrange the system to transmit an alarm automatically to a third party. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculation systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. All fire, smoke, heat, sprinkler flow, and manual fire alarming devices shall be connected to and activate the main fire alarm system when activated. (I)

C. Facilities shall not have single and multi-station smoke alarms.

SECTION 2100 – GENERAL CONSTRUCTION

A. Gases, flammable and nonflammable, shall be handled and stored in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

B. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. “No Smoking” signs shall be posted conspicuously, and cylinders shall be properly secured in place. In “Smoke-Free” Facilities, “No Smoking” signs shall not be required provided all four (4) of the following conditions are met:

1. Smoking is prohibited;
2. The Facility nonsmoking policy is strictly enforced;
3. “Smoke-Free” signs are strategically placed at all major entrances; and
4. A facility shall have “No Smoking” signs where oxygen is stored. (I)

SECTION 2200 – [RESERVED]

SECTION 2300 – WATER SUPPLY

A. Water Supply. Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the Facility and shall be adequate in volume and pressure for all purposes. (II)

B. The Facility shall enter into an agreement with the water district or similar authority whereby the Facility is regularly notified of situations occurring outside the Facility that may adversely impact water quality including, but not limited to: (I)

1. changes in treatment methods and source;

2. municipal water treatment equipment failure;
3. damage to the distribution system; and
4. chemical spills.

C. Water used for dialysis purposes shall be analyzed for bacteriological quality at least monthly and chemical quality at least Quarterly and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Water used to prepare a dialysate shall not contain concentrations of elements or organisms in excess of those specified below: (I)

ELEMENTS	LIMIT IN MILLIGRAMS PER LITER
Aluminum	.01
Arsenic	.005
Barium	.100
Cadmium	.001
Calcium	2.0
Chloramines	.001
Chlorine	.500
Chromium	.014
Copper	.100
Fluorides	.200
Lead	.005
Magnesium	4.0
Mercury	.0002
Nitrates (Nitrogen)	2.0
Potassium	8.0
Selenium	.090
Silver	.005
Sodium	70.0
Sulfates	100.0
Zinc	.100
Bacteria	200 colonies per milliliter

SECTION 2400 – ELECTRICAL

2401. General. (I)

A. The Facility shall equip all buildings containing Chronic Hemodialysis Stations with either:

1. An emergency generator with automatic transfer switch(s) that feeds the building and power requirements in Section 2401.B; or

2. An exterior building connection and automatic transfer switch(s) to receive a portable emergency generator that is under contract for delivery and connection. The portable emergency generator shall feed the building and power requirements in Section 2401.B.

B. Facilities subject to Section 2401.A shall meet the following building and power requirements:

1. All power and lighting in the reverse osmosis system, the Chronic Hemodialysis Stations, and the nurse station;
2. Nurse call system supporting the Chronic Hemodialysis Stations;
3. Emergency communication systems;
4. Heating, ventilating, and air conditioning systems for the reverse osmosis system and the Chronic Hemodialysis Stations;
5. Elevator banks serving the Chronic Hemodialysis Stations;
6. All exit lights with backup battery packs;
7. All exit access corridor lighting with backup battery packs;
8. All illumination of means of egress with backup battery packs;
9. All fire detection and alarm systems, if installed;
10. All sprinkler systems, if installed; and
11. Emergency generator run time of at least forty-eight (48) hours.

2402. Lighting and Electrical Services.

A. All electrical and other equipment used in the Facility shall be maintained free of defects that could be a potential hazard to Patients or personnel. The Facility shall provide safe lighting for individual activities as required by applicable codes.

B. The Facility shall maintain all electrical installations and equipment in a safe, operable condition in accordance with the applicable codes.

C. The Facility shall maintain documentation of Annual electrical system inspection by a certified or licensed technician.

SECTION 2500 – HEATING, VENTILATION, AND AIR CONDITIONING (HVAC)

A. The Facility shall maintain documentation of annual Heating, Ventilation, and Air Conditioning system inspection by a certified or licensed technician. (II)

B. The Facility shall maintain a temperature of between seventy-two (72) and seventy-eight (78) degrees Fahrenheit in Patient areas. (II)

C. No Heating, Ventilation, and Air Conditioning supply or return grille shall be installed within three (3) feet of a smoke detector. (I)

D. Heating, Ventilation, and Air Conditioning grilles shall not be installed in floors. (II)

E. Intake air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials. The system shall not discharge in such a manner that would be an irritant to the Patients, staff, or volunteers. (II)

F. Each bathroom and/or restroom shall have either operable windows or have approved mechanical ventilation. (II)

SECTION 2600 – PHYSICAL PLANT

2601. General.

A. The dialysis unit(s) shall be separate from other activities and shall be located in an area free of traffic by non-unit staff or Patients. (II)

B. The nursing station shall be located in an area that provides adequate visual surveillance of Patients on dialysis machines. (I)

C. Treatment areas shall be designed and equipped to provide proper and safe treatment as well as privacy and comfort for Patients. Sufficient space shall be provided to accommodate emergency equipment and staff to move freely to reach Patients in emergencies. (I)

D. At least two (2) acceptable exits shall be provided for each Facility. (II)

E. If the Facility is located on the ground floor there must be one (1) exit to the outside for ambulance and/or handicapped use. (II)

F. If the dialysis units are located above the ground floor, the Facility must have an elevator sized to accommodate a stretcher. (II)

G. Dialysis units shall be at least three (3) feet apart with cubicle curtains or other means to provide complete privacy for each Patient as needed. (II)

H. All rooms shall open onto a corridor leading to an exit and all corridors used by Patients shall be at least four (4) feet wide. (II)

I. A waiting room shall be provided with sufficient seating for Patients and visitors.

J. Storage rooms shall be provided for supplies and equipment. Storage room floor space shall total at least ten (10) square feet per station.

K. A clean work area that contains a work counter, handwashing sink, and storage facilities for the storage of clean and sterile supplies shall be provided. (II)

L. A soiled work area that contains a work counter, handwashing sink, storage cabinets, and waste receptacle shall be provided. (II)

M. Patient toilet facilities shall be provided.

N. A separate staff toilet and personal storage space shall be provided within the unit.

O. Separate storage space shall be provided for oxygen cylinders if a piped system is not provided. (II)

P. A janitor's closet shall be provided adjacent to and for the exclusive use of the dialysis Facility.

2602. Ground Fault Protection.

All electrical and other equipment used in the Facility shall be maintained free of defects that could be a potential hazard to Patients or personnel. There shall be sufficient safe lighting for individual activities, including suitable lighting for corridors and baths. Lighting in work areas shall never be less than fifty (50) foot-candles. (II)

SECTION 2700 – SEVERABILITY

In the event that any portion of this regulation is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of this regulation, and they shall remain in effect as if such invalid portions were not originally a part of this regulation.