

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 08/14/2020
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 312612	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 07/09/2020
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE LINDEN			STREET ADDRESS, CITY, STATE, ZIP CODE 630 WEST ST GEORGES LINDEN, NJ 07036		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	D PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
V 000	INITIAL COMMENTS This was a Federal COVID-19 Focused Infection Control Survey (NJ00137257) conducted on 7/9/2020. Fresenius Medical Care Linden is not in compliance with 42 CFR, Part 494, Conditions for Coverage (CfC) for End Stage Renal Disease Facilities. A Standard level deficiency was evident.	V 000			
V 113	IC-WEAR GLOVES/HAND HYGIENE CFR(s): 494.30(a)(1) Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. This STANDARD is not met as evidenced by: Based on observation conducted on 7/9/2020 and review of facility policy, it was determined that the facility failed to ensure all staff aseptically connect the patients to the hemodialysis machine in one (1) out of one (1) observations of initiating hemodialysis through an arteriovenous fistula (AVF). Findings include: Reference #1: Facility Policy titled, Hand Hygiene, states, " ... Hands Will Be ... Decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water ... When ... After contact with inanimate objects near the patient ..." Reference #2: Facility policy titled, Initiation of Treatment with a 2008 Series Hemodialysis Machine using an Arteriovenous Graft or Fistula	V 113			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V 113	Continued From page 1 and Optiflux Single Use Ebeam Dialyzer, states, " ... Replacement of Fluid/Connecting Arterial Bloodline ... 2. Connect the arterial bloodline to the arterial fistula needle: [bullet] Ensure the arterial fistula needle is clamped. [bullet] Remove syringe or cap from the arterial fistula needle. [bullet] Connect arterial bloodline to arterial fistula needle using aseptic technique ..."	V 113			
V 117	IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS CFR(s): 494.30(a)(1)(i) Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized)	V 117			

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V 117	<p>Continued From page 2</p> <p>area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>This STANDARD is not met as evidenced by: Based on observation conducted on 7/9/2020, staff interview, and review of facility policy, it was determined that the facility failed to ensure all staff do not wear protective gowns into the medication preparation area in one (1) out of one (1) observations of medication preparation.</p> <p>Findings include:</p> <p>Reference: Facility policy titled, Coronavirus Disease Screening and Infection Control Practices in Fresenius Kidney Care (FKC) Dialysis Clinics, states, " ... Policy ... FKC Staff, Physician and Physician Extender PPE: ... PPE Exception: In the medication preparation area, staff are required to only wear a surgical face mask and will be expected to remove PPE (except face masks) prior to entry to the medication preparation area ..."</p> <p>1. At 10:54 AM, Staff #4 was observed preparing an intravenous medication for patient administration. Staff #4 was wearing a protective gown in the medication preparation area.</p> <p>a. During an interview at 10:55 AM, Staff #4 stated that he/she was wearing the gown because a patient had called him/her over to the chairside just prior to preparing the medication and that he/she should not be wearing the</p>	V 117			

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V 117	Continued From page 3 protective gown inside the medication preparation area. 2. Staff #2 confirmed the above practice was not in accordance with facility policy during an interview at 12:30 PM.	V 117			