STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	312509	A. BUILDING _____ B. WING _____	C 06/25/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESENIUS MEDICAL CARE JOHN J DEPALMA RENAL CENTER	1 PLAZA DRIVE TOMS RIVER, NJ 08757

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID 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 (NJ00136966) conducted on 6/25/2020. Fresenius Medical Care John J DePalma Renal Center is not in compliance with 42 CFR, Part 494, Conditions for Coverage (CfC) for End Stage Renal Disease Facilities. A Condition level deficiency was evident. The following CfC was found to be out of compliance: CfC: 494.30 Infection Control	V 000		
V 110	CFC-INFECTION CONTROL CFR(s): 494.30 This CONDITION is not met as evidenced by: Based on observation, document review, and staff interview, it was determined that the facility failed to implement and maintain effective infection control practices to prevent transmission of COVID-19. Findings include: 1. The facility failed to ensure that upon entrance into the facility, visitors, patients, and staff are screened to identify and isolate suspected COVID-19 cases. (Cross Refer to Tag V 142) 2. The facility failed to ensure that staff followed proper procedure for Central Venous Catheter (CVC) care. (Cross Refer to Tag V 147)	V 110		
V 142	IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P CFR(s): 494.30(b)(1)	V 142		

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 142	Continued From page 1 The facility must- (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; This STANDARD is not met as evidenced by: Based on observation, staff interview, patient interview, and review of facility documents conducted on [redacted], it was determined that the facility failed to ensure that all visitors, patients, and staff are provided a screening to identify and isolate suspected COVID-19 cases prior to entering the treatment floor on 25 out of 38 logs reviewed. Findings include: Reference: Facility policy titled, Coronavirus Disease Screening and Infection Control Practices in Fresenius Kidney Care (FKC) Dialysis Clinics, states, "... Patient, Visitor, Staff, Physician, and Physician Extender Screening All patients, visitors, staff, physicians, and physician extenders entering an FKC dialysis clinic must be screened for ongoing signs and symptoms of COVID-19 prior to admittance to the dialysis treatment floor or while waiting in the dialysis treatment waiting area. Screening of patients and visitors will take place in the dialysis clinic lobby/waiting room or other designated space, and screening of all FKC staff and physician and physician extender partners in an area removed from the waiting room prior to starting the work shift in the dialysis clinic ... Screening requirements: [bullet] Daily monitoring of patients, visitor, staff, physician and physician extender temperature. Use the attached screening	V 142		

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V 142	Continued From page 2	V 142		

documents to record temperatures and perform screening of all patients, staff, physicians, physician extenders, and other guests of the dialysis clinics without exception ... Inquire whether patients, visitors, staff, or physicians/physician extenders have these symptoms or combinations of symptoms: [bullet] Cough; [bullet] Shortness of Breath; or [bullet] Difficulty breathing [bullet] Fever ([greater than] 100.0 degrees Fahrenheit) [bullet] Chills [bullet] Repeated shaking with chills [bullet] muscle pain [bullet] Headache [bullet] Sore throat [bullet] New loss of taste or smell [bullet] Congestion or runny nose [bullet] Nausea or vomiting [bullet] Diarrhea [bullet] All patients, visitors, staff, or physicians/physician extenders should be asked the following questions: [bullet] To their knowledge, have they been within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period; close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case? [bullet] Have they had direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on by a COVID-19 positive patient) while not wearing PPE [personal protective equipment] (including face mask)? ..."

1. At [redacted] in the waiting room, Staff #9 was observed greeting Patient [redacted] and Patient [redacted]. Staff #9 obtained Patient [redacted] and Patient [redacted] temperatures and then escorted both patients out of the waiting room and into the [redacted] treatment area. Staff #9 did not ask both patients any screening questions prior to escorting them into the [redacted] treatment area.

a. During an interview at [redacted], Staff #9 stated that he/she checks the patient's

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V 142	Continued From page 3 temperature in the waiting room and then, after escorting the patient into the [redacted] treatment area, ask the screening questions while the patient is getting weighed or when the patient is sitting in the reclining chair at his/her station. b. Interviews, starting at [redacted], with Patient [redacted] and Patient [redacted] confirmed that Staff #9 asked the screening questions after entering the [redacted] treatment area. c. During a telephone interview, conducted on [redacted] at [redacted], Administrative Staff #12 stated that screening questions should be asked prior to entering the [redacted] treatment area. 2. This surveyor was greeted by Staff #5 in the waiting room at [redacted] and escorted into the conference room. This surveyor was then escorted to the [redacted] treatment area and greeted by Staff #6, the charge nurse, at [redacted] Staff #6 did not screen this surveyor until [redacted], 40 minutes after first entering the [redacted] treatment area. a. At [redacted] Staff #6 stated that he/she forgot to screen this surveyor for COVID-19 upon entering the [redacted] area. 3. At [redacted] the COVID-19 Patient Screening Log, for the operating days [redacted] were reviewed for completion of responses and the following was revealed: a. On [redacted] 14 out of [redacted] patients/visitors lacked documented evidence of their response to the screening questions indicated on the	V 142		

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V 142	Continued From page 4 COVID-19 Patient Screening Log. b. On [redacted], one (1) out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. c. On [redacted], 47 out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. d. On [redacted] 46 out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. e. On [redacted], four (4) out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. f. On [redacted], 67 out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. g. On [redacted] five (5) out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. h. On [redacted] two (2) out of [redacted] patients/visitors	V 142		

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V 142	Continued From page 5 lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. i. On [redacted], two (2) out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. j. On [redacted], four (4) out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. k. On [redacted], two (2) out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. l. On [redacted] 30 out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. m. On [redacted] one (1) out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient Screening Log. n. On [redacted] two (2) out of [redacted] patients/visitors lacked documented evidence of their response to three (3) out of three (3) of the screening questions indicated on the COVID-19 Patient	V 142		

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V 142	Continued From page 6 Screening Log. 3. At [redacted] the COVID-19 Employee and [redacted] were reviewed for completion of responses and the following was revealed: a. On [redacted] one (1) out of [redacted] employees lacked documented evidence of his/her response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form. b. On [redacted] two (2) out of [redacted] employees lacked documented evidence of their response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form. c. On [redacted] two (2) out of [redacted] employees lacked documented evidence of their response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form. d. On [redacted] two (2) out of [redacted] employees lacked documented evidence of their response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form. e. On [redacted] five (5) out of [redacted] employees lacked documented evidence of their response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form.	V 142		

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V 142	Continued From page 7 f. On [redacted] one (1) out of [redacted] employees lacked documented evidence of his/her response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form. g. On [redacted], three (3) out of [redacted] employees lacked documented evidence of their response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form. h. On [redacted] ten (10) out of [redacted] employees lacked documented evidence of their response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form. i. On [redacted] three (3) out of [redacted] employees lacked documented evidence of their response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form. j. On [redacted], two (2) out of [redacted] employees lacked documented evidence of their response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form. k. On [redacted] four (4) out of [redacted] employees lacked documented evidence of their response to three (3) out of three (3) screening questions indicated on the COVID-19 Employee and Physician Screening Form. 4. At [redacted], Staff #3 confirmed the above findings and stated that all responses to all screening log questions should be documented.	V 142		

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V 147	IC-STAFF EDUCATION-CATHETERS/CATHETER CARE CFR(s): 494.30(a)(2) Recommendations for Placement of Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters. II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients. VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections]. This STANDARD is not met as evidenced by: Based on observation and review of facility policy, conducted on [redacted] it was determined that the facility failed to ensure staff followed	V 147		

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V 147	Continued From page 9 proper procedure for Central Venous Catheter (CVC) care during one (1) o[redacted]) observations (Patient [redacted]. Findings include: Reference #1: Facility procedure titled, Initiating Treatment Using a Central Venous Catheter with an Optiflux Single Use Ebeam Dialyzer, states, "... Preparing the Catheter: Disinfection of the Catheter Connections, Heparin removal, Flushing the Catheter and Heparin Administration ... 4. Using the same sterile alcohol pad (or other antiseptic such as chlorhexidine, povidone if required by the hospital) applying friction to remove any blood, residue, move from the hub at least several centimeters towards the body of the catheter. (Steps 3 and 4 should take 10 - 15 seconds) 5. Hold the limb while allowing the antiseptic to dry. 6. Immediately attach a sterile empty 10 mL syringe to limit exposure to air. Repeat steps 1-6 for venous catheter limb ... 1. In Station #29 at [redacted] Staff #11 initiated [redacted] treatment through a CVC on Patient [redacted]. After scrubbing the catheter hub and limb with alcohol pads, Staff #11 let go of the catheter and touched the patient, allowing the end to touch the patient's clothing. Staff #11 then attached an empty syringe to Patient [redacted] CVC. Staff #11 did not hold the limb while allowing the alcohol to dry in accordance with facility policy.	V 147		

accepted 7/17/20 CP

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

PRINTED: 07/01/2020
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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V 000	INITIAL COMMENTS This was a Federal COVID-19 Focused Infection Control Survey (NJ00136966) conducted on 6/25/2020. Fresenius Medical Care John J DePalma Renal Center is not in compliance with 42 CFR, Part 494, Conditions for Coverage (CfC) for End Stage Renal Disease Facilities. A Condition level deficiency was evident. The following CfC was found to be out of compliance: CfC: 494.30 Infection Control	V 000		
V 110	CFC-INFECTION CONTROL CFR(s): 494.30 This CONDITION is not met as evidenced by: Based on observation, document review, and staff interview, it was determined that the facility failed to implement and maintain effective infection control practices to prevent transmission of COVID-19. Findings include: 1. The facility failed to ensure that upon entrance into the facility, visitors, patients, and staff are screened to identify and isolate suspected COVID-19 cases. (Cross Refer to Tag V 142) 2. The facility failed to ensure that staff followed proper procedure for Central Venous Catheter (CVC) care. (Cross Refer to Tag V 147)	V 110		
V 142	IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P CFR(s): 494.30(b)(1)	V 142		

RECEIVED
JUL 10 2020
By

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

[signature] Clinical Manager 7/10/2020

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FMC-JOHN J. DEPALMA RENAL CENTER
Plan of Correction for
Infection Control
Provider Identification Number: 31-2509
Date of Survey: 6/25/20

V110 (V110-148) 494.30 Infection Control

The Governing Body of this facility acknowledges its responsibility to ensure all staff follow approved policies and procedures for infection control, identify concerns in infection control technique and continue to develop, analyze and revise action plans regarding infection control concerns to ensure ongoing compliance.

The Governing Body on July 6, 2020, reviewed the Statement of Deficiencies and developed the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution.

The Governing Body began meeting weekly beginning July 6, 2020 to review the results of the progress on the Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The Governing Body will determine when the frequency of these meetings may be reduced to the regular quarterly schedule.

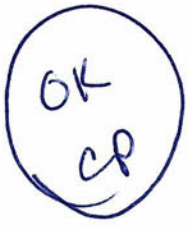
Effective immediately:

- The Clinical Manager will analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee.
- A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda.
- The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues.
- The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.
- The Governing Body, at its meeting of July 6, 2020, designated the Director of Operations (DO) to serve as Plan of Correction Monitor and provide additional oversight. They will participate in QAPI and Governing Body meetings. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement of Deficiency through to resolution as well as ensure the Governance of the Facility is presented current and complete data to enhance their governance oversight role.

Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAI Committees ongoing monitoring of facility activities. These are available for review at the facility.

The responses provided for V142 and V147 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies as cited within this Condition are corrected to ensure ongoing compliance. Refer to specific V-Tags.

Completion Date: 7/31/20



FMC-JOHN J. DEPALMA RENAL CENTER
Plan of Correction for
Infection Control
Provider Identification Number: 31-2509
Date of Survey: 6/25/20

V142 IC-O-sight: monitor activities & implement P&P

Beginning on June 26, 2020, the Clinical Manager (CM), or Education Coordinator (EC) or designee held staff meetings, elicited input, and reinforced the expectations and responsibilities of the facility staff on the following Policies & Procedures:

FMS-CS-IC-II-155-221A Coronavirus Disease Screening and Infection Control Practices in Fresenius Kidney Care (FKC) Dialysis Clinics.

COVID-19 Employee and Physician Screening Form

COVID-19 Patient and Visitor Screening Form

Emphasis was placed on:

- Ensuring suspected COVID positive staff, patients and visitors are immediately identified and isolated prior to admittance to the dialysis treatment floor.
- Ensuring all patients, visitors, staff, physicians, and physician extenders entering the dialysis clinic must be screened for ongoing signs and symptoms of COVID-19 prior to admittance to the dialysis treatment floor.
- Screening requirements includes daily monitoring of patients, visitor, staff, physician and physician extender temperature.
- Screening requirements includes if the individual is presents or is experiencing flu-like symptoms or any combination of the following symptoms: cough, shortness of breath, difficulty breathing, fever >/=100.0 degrees Fahrenheit, chills, repeated shaking with shills, muscle pain, headache, sore throat, new loss of taste or smell, congestion or runny nose, nausea or vomiting, diarrhea.
- Facility will utilize screening documents to record temperature and screening of symptoms and close contact exposure.
- In the event the patients, visitor, staff, physician and physician extender experiences flu like symptoms or a combination of any of the following symptoms, the facility will take precaution and adhere to policies and procedure to protect them and others from the respiratory illness.
- Ensure compiled data related to COVID-19 screening logs for patients, visitors, staff, physician and physician extenders are reviewed in QAI with Interdisciplinary team (IDT) and Medical Director.

The in-services will be completed by July 13, 2020 with documentation of the training on file at the facility.

For immediate compliance, a daily tracking tool was developed and utilized to ensure patients, visitors, staff, physicians, and physician extenders entering the dialysis clinic are screened and documentation is complete. The POC specific auditing tool will be used for the audits by the Clinical Manager (CM) or Charge Nurse (CN) or designee for 2 weeks. Once compliance is sustained, the Governing Body will decrease frequency to weekly for 4 weeks then resume regularly scheduled audits based on QAI calendar. Monitoring will be done through the QAI for 3 months to ensure 100% compliance and then monthly for 6 months.

Issues of non-compliance will include re-education and counseling.

The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.

Documentation of education, monitoring, QAI, and Governing Body is available for review.

The Clinic Manager is responsible for overall compliance.

Completion Date: 7/31/20

FMC-JOHN J. DEPALMA RENAL CENTER
Plan of Correction for
Infection Control
Provider Identification Number: 31-2509
Date of Survey: 6/25/20

V147 IC-Staff education-catheters/catheter care

Beginning July 8, 2020, the Clinical Manager (CM) or designee held staff meetings, elicited input, and reinforced the expectations and responsibilities of the facility staff on the following Policies & Procedures:

FMS-CS-IC-I-105-002A - Initiation of Treatment Using a Central Venous Catheter and Optiflux® Single Use E-beam Dialyzer Policy

FMS-CS-IC-II-155-070A - Dialysis Precautions

Emphasis was placed on:

- Ensuring Aseptic technique is followed when accessing a central venous catheter (CVC).
- Ensuring Registered Nurse (RN) staff are preventing any potential cross contamination, holding the catheter limb while allowing the antiseptic to dry, preventing the disinfected catheter limb from touching contaminated surfaces.

The in-services will be completed by July 9, 2020 with documentation of the training on file at the facility.

For ongoing compliance, beginning July 9, 2020, the Clinical Manager or designee will conduct daily audits on all shifts to ensure RN staff are adhering to policies and procedure until 100% compliance is observed. A POC specific auditing tool will be used for the audits. Once compliance is sustained, the Governing Body will decrease frequency to weekly for 4 weeks then resume regularly scheduled audits based on QAI calendar. Monitoring will be done through the Clinic audit checklist.

The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.

Documentation of education, monitoring, QAI, and Governing Body is available for review.

The Clinic Manager is responsible for overall compliance.

Completion Date: 7/31/20

OK 7/17/20 CP