POC accepted 7/28/20 CL

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

PRINTED: 06/26/2020
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
	312638	A. BUILDING ______ B. WING ______	C 06/18/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
EAST BRUNSWICK DIALYSIS CENTER	629 CRANBURY ROAD, SUITE 101 EAST BRUNSWICK, NJ 08816

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V 000	INITIAL COMMENTS This was a Federal COVID-19 Focused Infection Control Survey (NJ00136948) conducted on 6/15/2020. East Brunswick Dialysis Center is not in compliance with 42 CFR, Part 494, Conditions for Coverage (CfC) for End Stage Renal Disease Facilities. Condition level deficiencies were evident. The following CfC was found to be out of compliance: CfC: 494.30 Infection Control	V 000	V000 The Governing Body of DaVita East Brunswick has reviewed the statement of deficiency resulting from a recertification survey completed on 06/18/20. The Governing Body has approved and respectfully submits this plan of correction.	
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. Findings include: 1. The facility failed to ensure that staff followed proper procedure for handwashing. (Cross Refer to Tag V 113, Part B) 2. 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) 3. The facility failed to ensure that staff followed	V 110	V110 DaVita East Brunswick Dialysis takes the conditions of coverage seriously. Immediate steps were taken to ensure the facility implement and maintain effective infection control practices. These actions are outlined in depth in the plan of correction for V113, V142 and V147. Members of Governing Body (GB) met on 06/30/20 to review the Statement of Deficiencies resulting from survey conducted 06/18/20 and developed a plan of correction. Members of the Governing Body including the Medical Director, Facility Administrator (FA), Clinical Nurse Manager and Regional Operations Director (ROD) have agreed to meet weekly to monitor the facility's ongoing progress toward compliance including but not limited to: 1) Ensuring the staff followed infection control protocols including performing hand hygiene/donning clean gloves. 2) Ensuring that upon entrance into	07/24/2020

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
[signature]	Group Facility Admin	7-15-2020

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 110	Continued From page 1 proper procedure for Central Venous Catheter (CVC) care. (Cross Refer to Tag V 147)	V 110	V110 Continued the facility, visitors, patients and staff are screened to identify and isolate suspected COVID-19 cases. 3) Ensuring that clinical staff maintained aseptic technique for the care of vascular accesses, including intravascular catheters. Once compliance is achieved, the plan of corrections will be monitored during Governing Body meetings at a minimum of quarterly. This plan of correction will also be reviewed during Facility Health Meetings (FHM-QAPI) and the FA will report progress, as well as any barriers to maintaining compliance, with supporting documentation included in meeting minutes. The FA on behalf of the Governing Body is responsible for compliance with this plan of correction	
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 two (2) out of three (3) observations conducted on 6/18/2020, and review of facility documents, it was determined that the facility failed to ensure that staff perform hand hygiene in accordance with facility policy and procedure. Findings include: Reference #1: Facility policy titled, Infection control for Dialysis Facilities, states, "... 1. Hand hygiene is to be performed upon entering the patient treatment area, prior to gloving, after removal of gloves, after contamination with blood or other infectious material, after patient and dialysis delivery system contact, between patients even if the contact is casual, before touching clean areas such as supplies and on exiting the patient treatment area ..." Reference #2: Facility procedure titled, Handwashing, states, "... Procedure ... 3. Cover hands (palms, back of hands between fingers) and wrists with lather and wash vigorously for a minimum of 15 seconds ..."	V 113		

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V 113	Continued From page 2 1. At 10:23 AM, Staff #7, who had just completed a termination of hemodialysis through a Central Venous Catheter procedure, removed his/her gloves and exited Station #2. Staff #7 then obtained hand soap and began to wash his/her hands in the Clean Sink, located across from the Nurses Station. Staff #7 washed vigorously with soap for one (1) second before rising both hands in the water. Staff #7 did not perform handwashing in accordance with facility procedure. 2. The above findings were confirmed with Staff #2 and Staff #3 at 12:55 PM.	V 113	V113 On 06/30/20 and 07/01/20, following receipt of the Statement of Deficiencies, the Clinical Nurse Manager conducted in-services for all Direct Patient Care Teammates (TMs). At these in-services, the facility policy titled "Infection Control for Dialysis Facilities" was reviewed. Special emphasis was placed on proper glove changing and hand hygiene, including washing vigorously for a minimum of 15 seconds. Verification of attendance is evidenced by TM signature on in service sheet. The Clinical Nurse Manager or designee will audit hand hygiene practices daily for two (2) weeks (expected compliance 95%), then three (3) times a week for two (2) weeks (expected compliance 98%), and weekly thereafter until consistent compliance is demonstrated (expected compliance 100%). Going forward, this will be audited monthly during internal infection control audits. Instances of non-compliance will be addressed immediately. The FA or designee will review the results of the audits with the TMs during homeroom meetings and with the Medical Director at FHM-QAPI with supporting documentation included in the meeting minutes. In addition, the Governing Body will review the meeting minutes to verify improvement plans are being followed, adjusted if needed and are followed for sustainability. The FA on behalf of the Governing Body is responsible for compliance with this plan of correction.	07/24/2020
V 142	IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P CFR(s): 494.30(b)(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 staff interview, and a review of facility documents on 6/18/2020, 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 ten (10) out of 22 days. Findings include: Reference #1: Facility document titled, COVID-19 Response Summary of DaVita's ICHD Public Health Emergency Facility Response,	V 142		

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V 142	Continued From page 3 states, "... March 2, 2020 ... DaVita launched an internal website COVID-19 Resources to serve as a centralized resource for current guidance related to the PHE [Public Health Emergency] (interim guidance related to the PHE supersedes clinical policies and procedures, as applicable, until further notice ... March 13, 2020 ... DaVita released guidance to facilities to limit entrance to essential persons only. Facilities were asked to conduct entrance evaluations for 100% of people attempting to enter ..." Reference #2: Facility document titled, COVID-19 Response Entrance Evaluation Tracker, states, "... Instructions ... Evaluate 100% of people entering your facility (except for transportation drivers and delivery personnel who will ONLY be in the lobby and ONLY for less than 2 [two] minutes) with each question below. Document the evaluation below; if any "yes" answers or temperature 100.4 [degrees] or higher, escalate the evaluation to a licensed nurse ... New cough, fever sore throat or shortness of breath? ... Newly experiencing two or more of the following symptoms: 1. Shaking/chills 2. Headache 3. Loss of taste or smell 4. Muscle pain ... Prolonged close contact with suspected or confirmed COVID+ person? ... Has someone told you that you are COVID-19 positive in the last week? ..." 1. At 12:15 PM, the Entrance Evaluation Tracker forms, for the operating days 5/25 through 6/18/2020, were reviewed for completion of responses to the following questions, "... New cough, fever sore throat or shortness of breath? ... Newly experiencing two or more of the following symptoms: 1. Shaking/chills 2. Headache 3. Loss of taste or smell 4. Muscle	V 142	V142 In order to make certain that our Entrance Evaluations are complete and include all patients, TMs and anyone else entering the facility, a TM was hired who began work on June 29. The sole responsibility of this TM is to screen anyone entering the facility in compliance with our facility documents "COVID-19 Response Summary of DaVita's ICHD Public Health Emergency Facility Response" and "COVID-19 Response Entrance Evaluation Tracker". In-services for all TMs will be held on 07/08/20 and 07/09/20 to educate all TMs on the Entrance Evaluation process emphasizing; 1) everyone entering the facility including all TMs, patients and visitors must be evaluated using the COVID-19 Entrance Evaluation form. 2) All portions of the evaluation form must be completed for each individual. Verification of attendance will be evidenced by TM signature on the in-service sheet. It will be emphasized that any TM can be asked to perform these duties while the responsible TM is away from his / her post. The Entrance Evaluation Tracker will be reviewed for inclusion of all TMs, patients and visitors, as well as completion of each item on the tracker by the Clinical Nurse Manager or designee daily for two (2) weeks (expected compliance 95%), then three (3) times a week for two (2) weeks (expected compliance 98%), and weekly thereafter until consistent compliance is demonstrated (expected compliance 100%). Going forward, this will be audited monthly during internal infection control audits. Instances of non-compliance will be	07/24/2020

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V 142	Continued From page 4 pain ... Prolonged close contact with suspected or confirmed COVID+ person? ... Has someone told you that you are COVID-19 positive in the last week? ..." There lacked documented evidence that the screening questions were answered during the times listed below: a. On 5/25/2020, three (3) out of forty patients/visitors lacked documented evidence of their response to the screening questions indicated on the COVID-19 Response Entrance Evaluation Tracker. b. On 5/26/2020, ten (10) out of 32 patients and two (2) out of two (2) employees lacked documented evidence of their response to the screening questions indicated on the COVID-19 Response Entrance Evaluation Tracker. c. On 5/27/2020, four (4) out of 41 patients lacked documented evidence of their response to the screening questions indicated on the COVID-19 Response Entrance Evaluation Tracker. d. On 6/2/2020, two (2) out of 32 patients listed lacked documented evidence of their response to the screening questions indicated on the COVID-19 Response Entrance Evaluation Tracker. e. On 6/4/2020, one (1) out of 32 patients and three (3) out of three (3) employees lacked documented evidence of their response to the screening questions indicated on the COVID-19 Response Entrance Evaluation Tracker. f. On 6/6/2020, one (1) out of 32 patients lacked documented evidence of his/her response to the	V 142	V142 Continued addressed immediately. The FA or designee will review the results of the audits with the TMs during homeroom meetings and with the Medical Director at the FHM-QAPI with supporting documentation included in the meeting minutes. In addition, the Governing Body will review the meeting minutes to verify improvement plans are being followed, adjusted if needed and are followed for sustainability. The FA on behalf of the Governing Body is responsible for compliance with this plan of correction.	

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V 142	Continued From page 5 screening questions indicated on the COVID-19 Response Entrance Evaluation Tracker. g. On 6/8/2020, four (4) out of 39 patients lacked documented evidence of their response to the screening questions indicated on the COVID-19 Response Entrance Evaluation Tracker. h. On 6/10/2020, two (2) out of 44 patients lacked documented evidence of their response to the screening questions indicated on the COVID-19 Response Entrance Evaluation Tracker. i. On 6/11/2020, one (1) out of 29 patients and seven (7) out of eight (8) employees lacked documented evidence of their response to the screening questions indicated on the COVID-19 Response Entrance Evaluation Tracker. j. On 6/17/2020, six (6) out of 41 patients lacked documented evidence of their response to the screening questions indicated on the COVID-19 Response Entrance Evaluation Tracker. (i) During an interview at 12:16 PM, Staff #8 confirmed that he/she completed patient screening for 6/17/2020 and stated that while he/she asks everyone all the questions, he/she "must not have written down the answers to the questions" on nine (9) of the patients. Staff #8 stated that one (1) of the patients listed was screened by another staff member who should have documented the responses to the questions. 2. Staff #3 confirmed the above findings and stated that responses to all 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, staff interview, and review of facility policy, it was determined that the facility failed to ensure staff followed proper procedure	V 147	V147 At the in-services conducted by the Clinical Nurse Manager on June 30 and July 1, the facility policy titled "Central Venous Catheter (CVC) with Clearguard HD Antimicrobial with End Caps" was reviewed with all Direct Patient Care TMs, in addition to Policy 1-05-01 "Infection Control for Dialysis Facilities ". The Clinical Nurse Manager stressed the importance of proper hand hygiene when caring for patients with CVCs emphasizing that gloves must be changed and hand hygiene performed when moving from a dirty task to a clean task. Verification of attendance will be evidenced by TM signature on in-service sheet. The Clinical Nurse Manager or designee will perform audits daily for two (2) weeks (expected compliance 95%), then three (3) times a week for two (2) weeks (expected compliance 98%), and weekly thereafter until consistent compliance is demonstrated (expected compliance 100%). Going forward, this will be audited monthly during internal infection control audits. Instances of non-compliance will be addressed immediately. The Facility Administrator (FA) or designee will review the results of the audits with the TMs during homeroom meetings and with the Medical Director at the Facility Health Meetings (FHM-QAPI) with supporting documentation included in the meeting minutes. In addition, the Governing Body will review the meeting minutes to verify improvement plans are being followed, adjusted if needed and are followed for sustainability. The FA on behalf of the Governing Body is responsible for compliance with this plan of correction.	07/24/2020

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V 147	Continued From page 7 for Central Venous Catheter (CVC) care during two (2) of two (2) observations (Patient #3 and Patient #4). Findings include: Reference #1: Facility procedure titled, Central Venous Catheter (CVC) with Clearguard HD Antimicrobial End Caps Procedure, states, "... Use Dialysis Precautions and aseptic technique throughout procedure ... 30. Clamp arterial catheter limb and blood line. Aseptically disconnect arterial blood line from arterial CVC limb. Attach a 10 ml syringe filled with normal saline to arterial catheter limb. ... 31. Clamp venous catheter limb and blood line. Aseptically disconnect venous blood line and connect 10 ml syringe with normal saline to the venous catheter limb. ..." Reference #2: Facility policy titled, Infection control for Dialysis Facilities, states, "... 1. Hand hygiene is to be performed upon entering the patient treatment area, prior to gloving, after removal of gloves, after contamination with blood or other infectious material, after patient and dialysis delivery system contact, between patients even if the contact is casual, before touching clean areas such as supplies and on exiting the patient treatment area ..." 1. In Station #2 at 10:16 AM, Staff #7 disconnected the red access line from Patient #3's Central Venous Catheter (CVC). Staff #7 then touched buttons on the hemodialysis delivery system and disconnected the blue access line from Patient #3's CVC. Staff #7 did not perform hand hygiene after contact with the dialysis delivery system.	V 147		

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V 147	Continued From page 8 2. In Station #14 at 10:35 AM, Staff #6 disconnected the blue access line from Patient #4's CVC. Staff #6 then touched the hemodialysis delivery system and disconnected the red access line from Patient #4's CVC. Staff #6 did not perform hand hygiene after contact with the dialysis delivery system. 3. The above findings were confirmed with Staff #2 and Staff #3 at 12:55 PM.	V 147		