

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

PRINTED: 07/30/2021
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152659	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/22/2021
NAME OF PROVIDER OR SUPPLIER SOUTH BEND WEST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 5660 NIMTZ PKWY SOUTH BEND, IN 46628	
(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
E 000	<p>Initial Comments</p> <p>A Recertification (CORE) Survey and COVID-19 Focused Infection Control Survey were conducted by Healthcare Management Solutions, LLC on behalf of Centers for Medicare & Medicaid Services (CMS).</p> <p>An unannounced on-site Recertification (CORE) Survey and COVID-19 Focused Infection Control Survey (ASPEN #2VJU11) conducted at DaVita South Bend West End Stage Renal Disease (ESRD) facility from 07/19/21 to 07/22/21 resulted in no findings respective to the Emergency Preparedness Program Condition for Coverage under 42 CFR 494.62.</p> <p>Survey Dates: 07/19/21 to 07/22/21</p> <p>Total Facility Census: 50</p> <p>In-Center Hemodialysis: 50</p> <p>Home Hemodialysis (HHD): 0</p> <p>Peritoneal Dialysis (PD): 0</p> <p>Nocturnal: 0</p> <p>Pediatrics: 0</p> <p>Sample Size: 5</p> <p>Supplemental: 0</p> <p>V 000</p> <p>Network 9 was contacted after entrance.</p> <p>INITIAL COMMENTS</p> <p>A Recertification (CORE) Survey and COVID-19</p>	E 000	V 000	

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 000	<p>Continued From page 1</p> <p>Focused Infection Control Survey were conducted by Healthcare Management Solutions, LLC on behalf of Centers for Medicare & Medicaid Services (CMS).</p> <p>An unannounced on-site Recertification (CORE) Survey and COVID-19 Focused Infection Control Survey (ASPEN #2VJU11) conducted at DaVita South Bend West Dialysis End Stage Renal Disease (ESRD) facility from 07/19/21 to 07/22/21 resulted in a finding of substantial compliance respective to applicable Conditions for Coverage (CfC) under 42 CFR 494, Subpart A through D with the following standard-level deficiencies listed below.</p> <p>Total Facility Census: 50</p> <p>In-Center Hemodialysis: 87</p> <p>Home Hemodialysis (HHD): 0</p> <p>Peritoneal Dialysis (PD): 0</p> <p>Nocturnal: 0</p> <p>Pediatrics: 0</p> <p>Sample Size: 5</p> <p>Supplemental: 0</p> <p>Network 9 was contacted after entrance. IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK CFR(s): 494.30(a)(1)(i)</p> <p>Staff members should wear gowns, face shields,</p>	V 000		
V 115		V 115		

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V 115	<p>Continued From page 2</p> <p>eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spouting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the facility failed to ensure two of two contracted medical staff (Medical Doctor (MD) 1 and Nurse Practitioner (NP) 1) wore appropriate personal protective equipment (PPE) and attire while on the treatment floor. The lack of appropriate PPE and footwear while on the treatment floor has the potential to expose staff to infectious pathogens.</p> <p>Findings include:</p> <p>1. On 7/20/21 at 9:54 AM observed NP1 on the treatment floor at station #8 wearing a gown, mask, and gloves. NP1 was not wearing a face shield. Observed NP1 remove a staple from patient (P)5 left forearm by the fistula site and expel pus from the dehisced wound by squeezing with both thumbs.</p> <p>On 7/20/21 at 9:55 AM during an interview, patient care technician (PCT) 4 confirmed the wound on P5's left arm was infected from a previous procedure.</p> <p>On 07/20/21 at 11:53 AM during a telephone interview Medical Director 1 stated the medical group should wear gown and mask, and gloves, if touching the patient during an assessment and a</p>	V 115		

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V 115	<p>Continued From page 3</p> <p>face shield might be worn if the medical group were working with blood or body fluids.</p> <p>2. 7/21/21 at 9:55 AM during an observation MD1 entered the treatment area wearing open toe shoes. MD1 went to station #11 and sat on P9s left side while P9 was holding the left arm fistula site after being removed from dialysis treatment. P9s fistula site was bleeding enough to saturate the barrier underneath left arm.</p> <p>During an interview on 07/21/21 at the time of the observation, PCT2 stated "no" when asked if open toe shoes are allowed on the treatment floor. PCT2 observed MD1 with open toe shoes at station #11 and stated, "our staff are not allowed to wear open toe shoes but doctors, I am not sure of their rules"</p> <p>During an interview on 07/21/21 at 1:01 PM the Facility Administrator 1 stated the contracted medical group should adhere to facility policies when in the facility. Facility Administrator 1 was asked if opened toe shoes could be worn on the treatment floor by staff. Facility Administrator 1 stated, "No, we do not allow staff to wear open toe shoes on the dialysis treatment floor." Facility Administrator 1 stated the contracted medical group should adhere to facility policy and protocol when in the facility.</p> <p>Review of the facility policy last revised October 2020, titled, "Infection Control for Dialysis Facilities" revealed, "Appropriate PPE will be worn whenever there is potential for contact with body fluids ..."</p> <p>Review of the facility policy titled, "Personal Protective Equipment (PPE) Hazard Assessment"</p>	V 115		

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V 115	Continued From page 4 revised April 2017 revealed, "Touching blood, body fluids and/or mucous membranes, PPE required I, II, II." A key identified, #II as "face shield or goggles and ..." V 116 IC-IF TO STATION=DISP/DEDICATE OR DISINFECT CFR(s): 494.30(a)(1)(i)	V 115 V 116		
<p>Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.</p> <p>-- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.</p> <p>-- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.</p> <p> This STANDARD is not met as evidenced by: Based on observation, record review and interview, the facility failed to ensure one of two medical staff (Medical Doctor (MD) 1) cleaned a stethoscope in between patient use. Failure to clean the stethoscope after every patient had the potential to serve as a vehicle for transmission of infectious disease and affect 50 patients currently receiving dialysis treatments at this facility.</p> <p>Findings include:</p> <p>On 07/21/21 at 10:54 AM during an observation,</p>				

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V 116	<p>Continued From page 5</p> <p>MD1 removed a stethoscope from around his/her neck and listened to the lungs of the patient at station #10. MD1 then placed the stethoscope back around his/her neck without cleaning it. MD1 walked to station #8, removed the stethoscope from around his/her neck and listened to the patients lungs without the benefit of cleaning it.</p> <p>Review of facility policy titled, "Infection Control For Dialysis Facilities," revised October 2020 revealed "Non-disposable items are to be disinfected between patients ... Stethoscopes will be disinfected with alcohol prep pad ..."</p> <p>On 07/21/2021 at 1:01 PM during an interview, Facility Administrator 1 stated the contracted medical group should adhere to facility policies.</p> <p>IC-SUPPLY CART DISTANT/NO SUPPLIES IN POCKETS CFR(s): 494.30(a)(1)(i)</p> <p>If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies.</p> <p>Do not carry medication vials, syringes, alcohol swabs or supplies in pockets.</p> <p>This STANDARD is not met as evidenced by: Based on observation, policy review, and interview, the facility failed to have an adequate supply of disposable gloves that fit staff on one of two survey days. This had the potential to cause cross contamination of all 12 stations and affect all 50 patients being treated at this facility.</p>	V 116		
V 119		V 119		

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V 119	<p>Continued From page 6</p> <p>Findings include:</p> <p>During an observation on 07/21/21 at 10:00 AM, Patient Care Technician (PCT) 3 left station #1 and walked to station #3 and pulled out a handful of disposable gloves for use in station #1. PCT ran out of the retrieved gloves during initiation of patient care at station #1 and returned to station #3 and brought back the box of gloves from station #3 to station #1.</p> <p>During an interview on 07/21/21 at the time of the observation, PCT3 stated the facility was short of gloves and he/she needed to go to another station to get gloves that fit.</p> <p>During an interview on 07/21/21 at 10:40 AM, PCT4 stated, "Yes we are short on gloves." PCT4 confirmed each computer stand was a dedicated station with hand sanitizer and gloves specific to that station.</p> <p>On 07/21/21 at 11:00 AM observed PCT1 during initiation of dialysis for P2 at station # 8. PCT1 left the station and walked to station #9 and took the box of gloves from station #9 and brought them back to station #8.</p> <p>During an interview on 07/21/21 at 11:00 AM PCT1 stated the facility was short on gloves.</p> <p>On 07/21/2021 at 1:01 PM during an interview about the glove shortage, facility Administrator 1 confirmed the facility was low on the size gloves that fit staff. Facility Administrator 1 confirmed that the computer stands on the floor that contained gloves and hand sanitizer were dedicated to the stations. Facility Administrator 1</p>	V 119		

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V 119	<p>Continued From page 7</p> <p>pointed out, station 1 and 2 shared one computer stand with hand sanitizer and gloves that was dedicate to those two stations (1 and 2), and station 3 had a separate dedicated computer stand.</p> <p>Review of the facility policy titled, "Infection Control for Dialysis Facilities," revised October 2020 revealed "Items taken into the dialysis station will be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before taken into a common clean area or used on another patient."</p> <p>PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU CFR(s): 494.60(b)</p> <p>The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.</p> <p>This STANDARD is not met as evidenced by: Based on observation, policy review and interview, the facility failed to dispose of expired product in one of one storage rooms (clean supply room). This has the potential to affect all patients receiving liquid protein supplements.</p> <p>Findings include:</p> <p>On 07/20/21 at 8:50 AM, an observation of the clean storage area revealed one open box which contained a single 32-ounce (oz) bottle of liquid protein with an expiration date of 05/21.</p>	V 119		
V 403		V 403		

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V 403	<p>Continued From page 8</p> <p>On 07/20/21 at the time of the observation, the Group Facility Administrator 2 and Patient Care Technician (PCT) 2 confirmed the 32 oz bottle of liquid protein dated 05/21 was expired.</p> <p>On 07/21/21 at 2:20 PM during an interview Facility Administrator 1 stated liquid protein is considered a medication, because only nurses are allowed to administer it.</p> <p>Review of the facility policy titled, "Medication Policy" last revision date October 2020 revealed, "All medications are checked monthly for expiration dates ... Disposal of all expired medications, including all over the counter and nutritional product samples are removed from the treatment floor and inventory areas and disposed of per state/local regulations."</p>	V 403		
V 504	<p>PA-ASSESS B/P, FLUID MANAGEMENT NEEDS CFR(s): 494.80(a)(2)</p> <p>The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>Blood pressure, and fluid management needs.</p> <p>This STANDARD is not met as evidenced by: Based on observation, policy review, record review and interview, the facility failed to ensure that two of two unstable patients (Patient (P) 3 and P5) from a sample of five records reviewed had pre and/or post dialysis assessment. Failure to complete the assessment has the potential for staff to miss significant changes in the health status of the individual and can affect all of the</p>	V 504		

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V 504	<p>Continued From page 9</p> <p>current dialysis patients receiving care at the facility.</p> <p>Findings include:</p> <p>Review of medical record "Treatment Sheet" for patient (P)3 revealed on 7/13/21, P3 had a baseline blood pressure (B/P) of 149/73. At the end of treatment B/P was recorded as 207/88 and 211/102. A Patient Care Technician's (PCT) note on the treatment sheet next to the elevated B/P indicated nursing was notified. Review of nursing notes for 07/13/21 revealed a post dialysis assessment narrative by a Registered Nurse (RN) was not completed or documented in the medical record.</p> <p>Review of the medical record "Treatment Sheet" for P5 revealed on 07/13/21, P5 was dialyzed for 46 minutes of the three-hour prescribed treatment time. Review of nursing documentation in the medical record for 07/13/21 revealed an RN narrative assessment was not complete.</p> <p>During an interview on 07/21/21 at 3:30 PM, Facility Administrator 1 confirmed an RN did not document a post assessment or nursing notes for P3 on 07/13/21. Facility Administrator 1 also confirmed an RN did not document why P5 was unable to complete dialysis and an RN did not complete pre-or post-assessment nursing documentation for P5 on 07/13/21. In addition, Facility Administrator 1 stated P3 and P5 should have had an assessment or narrative notes documented in the medical record.</p> <p>Review of the facility policy titled, "Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment" revealed, "Pre-Treatment</p>	V 504		

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V 504	Continued From page 10 Data Collection/Assessment ... The nurse will assess the patient pre-treatment as warranted by the patient's condition. ... Post Treatment Data Collection/Assessment ... If an abnormal finding(s) or concern is identified post treatment, this needs to be reported to the licensed nurse. The licensed nurse will assess the patient prior to discharge ... the following are considered abnormal findings and should be reported to the licensed nurse and documented in the patient's medical record ... If standing systolic BP greater than 140 mm/hg ... Standing diastolic BP greater than 90 mm/hg ..."	V 504		