

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

Printed: 03/22/2022  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>152649</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>03/15/2022</b>
NAME OF PROVIDER OR SUPPLIER <b>APPLESEED DIALYSIS</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>1833 MAGNAVOX WAY FORT WAYNE, IN 46804</b>		
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V 000	<p><b>INITIAL COMMENTS</b></p> <p>A Recertification (CORE) survey was conducted by Healthcare Management Solutions, LLC on behalf of Centers for Medicare &amp; Medicaid Services (CMS).</p> <p>An unannounced on-site Recertification survey (ASPEN #79E511) conducted at the above-named End Stage Renal Disease (ESRD) facility from 03/14/22 to 03/15/22 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: 84 In-Center Hemodialysis: 0 Home Hemodialysis (HHD): 17 Peritoneal Dialysis (PD): 67 Nocturnal: 0 Pediatrics: 0 Sample Size: 7 Network 9 was contacted after entrance.</p>	V 000			
V 196	<p><b>CARBON ADSORP-MONITOR, TEST FREQUENCY</b> CFR(s): 494.40(a)</p> <p>6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.</p> <p>Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.</p>	V 196	<p>V196 The Facility Administrator (FA) or designee held mandatory in-service(s) for all clinical teammates on Policy 8-02-03 "Color Vision Evaluation" and DaVita "Teammate Color Vision Test Results" form beginning 3/28/2022. Verification of attendance at the in- service will be evidenced by a signature sheet. Teammates will be instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) PURPOSE: To establish guidance for screening teammates/patients/ helpers for the ability to differentiate colors and for the use of test strips or kits utilizing color based readings. 2) Documentation of the color vision evaluation will be documented in the teammate's file and/or patient's medical record. Continued on page 2</p>	4/13/22	

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 196	<p>Continued From page 1</p> <p>Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L].</p> <p>Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.</p> <p>This Standard is not met as evidenced by: Based on document review, policy review, and interview, the facility failed to complete color blind testing per policy for four of four staff (Registered Nurse (RN)2, RN3, Patient Care Technician (PCT)1, and Registered Dietician (RD)) whose personnel files were reviewed for testing. This had the potential to affect all 14 home hemodialysis patients receiving services from the facility.</p> <p>Findings include:</p> <p>Review of facility policy titled, "Color Blind Evaluation," dated 10/2017, revealed, "Purpose: To establish guidance for screening teammates/patients/helpers for the ability to differentiate colors for the use of test strips or kits utilizing color-based readings. Documentation of the color vision evaluation will be documented in the teammate's file and/or patient's medical record."</p> <p>Review of form used to document the color-blind</p>	V 196	V196 Continued from page 1  3) Use the Adult section of the Pseudo-Isochromatic 16 plate Score Sheet in the first section of the kit to determine the response to each plate. 4) Test teammate for plates 1-9. Foreach plate, write the teammate response and circle the correct response below. Color vision evaluations were performed for facility teammate on 3/14/22. Documentation of completed evaluation results will be maintained in each teammate's file. The FA or designee will audit 100% of color vision screening forms for the next 6 screenings completed to verify compliance with facility policy. Ongoing compliance will be verified annually with teammate file audits. Instances of non-compliance will be addressed immediately. The Facility Administrator will review audit findings with the Medical Director during monthly Quality Assurance Performance Improvement meetings, known as Facility Health Meetings, with supporting documentation in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction.		

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V 196	<p>Continued From page 2</p> <p>test titled, "Color Blind Vision Test Results," dated 10/17, revealed, "Use the adult section of the Pseudo-Isochromatic I6 plate Score Sheet in the first section of the kit to determine the response to each plate. Test teammate/patient/helper for plates 1-9 or I-18 if using 730050 Color Check Color Vision Plate. For each plate, write the teammate/patient/helper response and circle the correct response below."</p> <p>Review of the "Color Vision Test Results," completed 01/31/22 located in the personnel file for RN2 revealed the color-blind test plate numbers 1-8 documented RN2's response to the test. Number 9 was circled as normal however there was no number written in the space to indicate RN2's response.</p> <p>Review of the "Color Vision Test Results," completed on 07/14/21 located in the personnel file for RN3 revealed the color-blind test 1-9 documented with RN3's response. Numbers 10-17 were circled as normal. RN3s response for plates 10-17 were not documented. Number 18 was not circled to identify normal or color visions defect or RN3's response to plate number 18.</p> <p>Review of the "Color Vision Test Results," completed on 07/15/19 located in the personnel file for RD revealed Color blind test of the RD revealed. Numbers 1-17 were circled as normal, with RDs response to the test not documented. Number 18 was not circled to identify normal or color visions defect or RDs response to plate number 18.</p> <p>Review of the personnel file for PCT1 revealed an older form titled, "Color Vision Test Results," dated 03/08 and completed on 06/05/1, revealed a color-blind test which had numbers 1-9 for</p>	V 196			

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V 196	Continued From page 3 testing. The instructions read, "Use the Adult section of the Pseudo-Isochromatic 16 plate Score Sheet in the first section of the kit to determine the response to each plate. Test teammate for plates 1-9. For each plate, write the teammate response and circle the correct response below." PCT1s color blind test revealed numbers 1-8 documented with PCT1s response to the test. Number 9 was not circled to identify normal or color visions defect or PCT1's response documented.  During an interview on 03/14/22 at 1:56 PM, the Facility Administrator confirmed that 4 of 4 records had color blind tests that were not complete with the staff response for each plate reviewed. Facility Administrator stated the tests were inconsistent in which testing plates were used (1-9 or 1-18) and stated, "technically they are only required to perform 1-9." The Facility Administrator confirmed that PCT1's color blind test was outdated and should have been redone when they implemented their new testing process and confirmed the four of the four (RN2, RN3, PCT1, and RD) tests were not documented consistently or per policy and testing instructions.	V 196			
V 401	PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT CFR(s): 494.60  The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.  This Standard is not met as evidenced by: Based on observation, interview, and policy review, the facility failed to maintain a safe environment for two of two observation days by	V 401	V401 The Facility Administrator (FA) or designee held mandatory in-service(s) for all clinical teammates on Policy 1-05-01 "Infection Control For Dialysis Facilities" beginning 3/28/2022. Verification of attendance at the in- service will be evidenced by a signature sheet. Teammates will be instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) The expiration date will be checked on all disposable supplies before the package is opened and the contents are used. 2) The contents of packages will not be used beyond the expiration date on the package. The  Continued on page 5	4/13/22	

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V 401	<p>Continued From page 4</p> <p>not removing expired supplies from the facility inventory. Failure to remove expired items provided the potential for staff to use supplies that were no longer viable or were deemed unusable by the manufacturer and had the potential to negatively affect the care of all 84 home therapy patients at this facility.</p> <p>Findings include:</p> <p>Review of facility policy titled, "Infection Control for Dialysis Facilities," dated 10/21, revealed, "The expiration date will be checked on all disposable supplies before the package is opened and the contents used. The contents of packages will not be used beyond the expiration date on the package."</p> <p>During an observation on 03/15/22 at 8:08 AM, review of supplies in the home program patient training room revealed an expired bag of solution found on the peritoneal dialysis machine cart in the training room. The bag was labeled "Baxter Lot #Y326603 6000-liter bag of Peritoneal Dialysis Solution Low Calcium 2.5 milliequivalents (mEq)/liter with 4.25% Dextrose with an expiration date of "Dec 2021."</p> <p>During an interview on 03/15/22 at 8:08 AM Patient Care Technician (PCT)2 stated if the product was not for use (only used for training), it would have "training" written across the package, so staff would know not to use it. PCT2 confirmed the bag of fluids on the peritoneal dialysis machine cart was expired and should not have been in the patient training room.</p> <p>During an observation on 03/15/22 at 8:15 AM in the home program patient training room revealed three manufactures packages labelled "Next</p>	V 401	<p>V401 Continued from page 4</p> <p>following expired supplies were removed from the facility on 3/15/22 and replaced with non-expired supplies: 1) 6000 liter bag of Peritoneal Dialysis solution Low Calcium 2.5 milliequivalents (mEQ) with 4.25% Dextrose with expiration date Dec 2021; (3) packages of Next Stage tubing with lot # 00479100 expiration date 03/07/2022: (1) six (6) milliliter vacutainer expired 02/28/22. The FA or designee will complete audits weekly for (4) weeks; then every other week for (4) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly x 3 months. Instances of non-compliance will be addressed immediately. The Facility Administrator will review audit findings with the Medical Director during monthly Quality Assurance Performance Improvement meetings, known as Facility Health Meetings, with supporting documentation in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction.</p>		

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V 401	Continued From page 5 Stage" that contained tubing, lot #00479100 with an expiration date of expired 03/07/2022.  During an interview on 03/15/22 at 8:15 AM PCT 1 stated it was the tubing to be used for bags hung on the intravenous (IV) poles. PCT 1 confirmed the three packages of tubing were expired and should not have been in the patient treatment room.  During an observation on 03/15/22 at 8:25 AM in the home program patient training room revealed one 6 milliliter (ml) vacutainer (laboratory tube) expired 02/28/22.  During an interview 03/15/22 at 8:25 AM PCT1 confirmed the tube was expired and should not have been in the patient treatment room.	V 401		
V 587	H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS CFR(s): 494.100(b)(2),(3)  The dialysis facility must - (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient ' s medical record.  This Standard is not met as evidenced by: Based on interview, record review, and policy review, the facility failed to retrieve complete (weight, blood pressure, and temperature) self-monitoring data for three of five sampled self-care peritoneal dialysis (PD) (a dialysis modality utilizing the patients' peritoneal lining to remove toxins and excess fluid) patients (Patient (P)4, P5 and P 6). Failure to make and document reasonable efforts to retrieve complete	V 587	V587 The Facility Administrator (FA) or designee held mandatory in-service(s) for all clinical teammates on Policy 5-01-21 "Home Dialysis Monitoring and Ongoing Patient Education" beginning 3/28/2022. Verification of attendance at the in- service will be evidenced by a signature sheet. Teammates will be instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) Retrieve and review complete self-monitoring data and other information from Peritoneal Dialysis patients or their designated caregivers at least every two (2) months. 2) Retrieve and review home treatment records at least weekly. 3) Maintain information in the patient's medical record. 4) The facility interdisciplinary team monitors the patient's status to determine if the patient is following the individualized treatment plan and/or is having any problems at home. The Facility Administrator or designee will audit 100% of home patient treatment records monthly x 3 months to verify compliance with Continued on page 7	4/13/22

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V 587	<p>Continued From page 6</p> <p>self-monitoring data from self-care patients had the potential to impede opportunities to monitor and determine the status of the 67 self-care PD patients.</p> <p>Findings include:</p> <p>Review of the facility's home therapy policy titled, "Home Dialysis Monitoring and Ongoing Patient Education," dated 04/2021, revealed, "...Retrieve and review complete self-monitoring data and other information from peritoneal dialysis patients or their designated caregivers at least every two months. Retrieve and review home treatment records at least weekly. Maintain information in the patient's medical record. The facility interdisciplinary team monitors the patient's status to determine if the patient is following the individualized treatment plan and/or is having any problems at home."</p> <p>1. Review of P4's handwritten treatment records titled, "Daily Home CCPD (Continuous cyclor-assisted peritoneal dialysis) Record" for self-care and treatment 01/01/22 through 02/28/22 revealed: January 2022 had missing information as follows: January 4-23 lacked AM and PM weights. January 30 and 31 lacked AM and PM weights. January 14 lacked PM blood pressure (BP) and pulse. January 14-23 lacked PM BP and pulse. January 30 and 31 lacked PM BP and pulse. The column titled "Effluent (the fluid that comes out of the abdomen after being filtered during dialysis) clear/cloudy" lacked documentation January 1-23 and January 30 &amp; 31. February 2022 lacked documents for self-documented treatment sheets. A 03/03/22 at 3:03 PM "Progress Note Report"</p>	V 587	V587 Continued from page 6 facility policy. Ongoing compliance will be verify with 10% of home treatment records audited monthly x 3 months. The Facility Administrator audit findings with the Interdisciplinary Team (IDT) and Medical Director during monthly Quality Assurance Performance meetings, known as Facility Health meetings for development of action plans as needed. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction.		

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V 587	<p>Continued From page 7</p> <p>revealed P4 forgot to bring February's treatment sheets and was to bring them in on 03/08/22.</p> <p>2. Review of P5's handwritten treatment records titled, "Daily Home CCPD Record" for self-care and dialysis treatment 01/01/22 through 02/28/22 revealed: January 1-10 lacked any documentation for treatments. January 16-31 lacked AM weight, BP, and pulse. February 1-7 lacked Heparin used and the dialysate used. February 2-6 lacked AM weight, BP, and pulse. February 8-21 lacked any documentation for treatments. A handwritten note on the bottom of the treatment sheet "re-educate on the completion of Tx (treatment) sheets this date" initialed by RN reviewer (RN3).</p> <p>3. Review of P6s handwritten treatment records for self-care 01/01/22 through 02/28/22 revealed, no treatment flowsheets were found. The most current self-care treatment sheets dated November/December 2021 were confirmed as November 2021 by signature of RN reviewer (RN1) on 12/07/21. Next treatment sheet found was for the month of August signed off by RN reviewer (RN1) 12/07/21.</p> <p>Interview on 03/15/22 at 10:00 AM regarding the missing treatment sheets for P4, P5 and P6, the Facility Administrator stated "that is why the patients were placed on the unstable list" due to habitually missed treatments or failure to turn in treatment sheets for evaluation and assessment of their home therapy. Facility Administrator confirmed the facility currently did not have a system for closing the loop to ensure missing treatments and missing treatment sheets were consistently addressed for compliance before the</p>	V 587			

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V 587	Continued From page 8 patient became unstable.	V 587			