

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

PRINTED: 01/25/2022

FORM APPROVED

OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152597	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 01/11/2022
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NAME OF PROVIDER OR SUPPLIER LAFAYETTE HOME DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 2 EXECUTIVE DR STE B LAFAYETTE, IN 47905
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (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 0000 Bldg. 00	<p>An Emergency Preparedness survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62, for a Medicare participating End Stage Renal Disease Supplier.</p> <p>Date of survey: 1-11-2022</p> <p>In-Center Hemodialysis: 0; Home Program only</p> <p>Home Hemodialysis census: 12</p> <p>Home Peritoneal Dialysis census: 20</p> <p>Total Census: 32</p> <p>At this Emergency Preparedness survey, Lafayette Home Dialysis, was found to have been in compliance with the requirements of Emergency Preparedness Requirements for Medicare participating providers and suppliers, including staffing and implementation of staffing during a Pandemic, at 42 CFR 494.62.</p>	E 0000		
V 0000 Bldg. 00	<p>This visit was for a Federal Recertification survey and an Infection Control survey of an ESRD provider by the Indiana Department of Health.</p> <p>Date of survey: 1-11-2022</p> <p>Stations: 4 Home training rooms including one isolation room.</p>	V 0000		

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 other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 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 disclosed 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 0595 Bldg. 00	<p>In Center Hemodialysis Patients: 0; Home program only</p> <p>Home Hemo Dialysis census:12</p> <p>Home Peritoneal Dialysis census: 20</p> <p>Total Census: 32</p> <p>494.100(c)(1)(v) H-MEET RD52:2004</p> <p>The facility must meet testing and other requirements of ANSI/AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.</p> <p>Based on record review, observation, and interview, the facility failed to ensure the water testing requirements for the facility training room and home hemodialysis patients were performed as noted in 2 of 2 complete record reviews and 3 of 5 partial focus record reviews during one survey day. (Patients: 5, 1, 6, 9, 10 and water room #3)</p> <p>Findings include:</p> <p>1. On 1-11-2022 at 2:55 PM, a DaVita Incorporated policy titled, "NXStage Pureflow Water Testing Schedule", dated September 2009 and revised September 2016 was provided by the Registered Nurse (RN), Employee I. The policy indicated but was not limited to, " ... AAMI Post PAK ... annual ... supply waterquarterly ...Dialysate Culture ... SAK ... quarterly ... "</p> <p>2. On 1-11-2022 at 2:30 PM, a clinical record review</p>	V 0595	<p>100% of teammates were in-serviced on Policy 12-14-11" Culture, Endotoxin, and AAMI Water Testing Requirements For Pureflow System" beginning 1/14/22. Verification of attendance is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) Testing for dialysate cultures and endotoxins will be performed upon initial installation in the home and quarterly thereafter to be completed within first month of quarter.</p>	02/08/2022

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	<p>of Patient #5 was completed. A review of the water source (TAP), water purifier (PAK) and Dialysate bag (SAK) water samples failed to evidence documentation of a January TAP result.</p> <p>3. On 1-11-2022 at 2:45 PM, a partial clinical record review of Patient #1 was completed. The review indicated no annual PAK sample was obtained and was missing a July quarterly SAK sample result.</p> <p>4. On 1-11-2022 at 2:45 PM, a partial clinical record review of Patient #6 was completed. The review indicated no annual PAK sample was obtained, a 4th quarter SAK sample result and two quarters of TAP results were missing.</p> <p>5. On 1-11-2022 at 2:45 PM, a partial clinical record review of Patient #9 was completed. The review indicated no annual PAK sample was obtained and a first quarter sample result was missing.</p> <p>6. On 1-11-2022 at 2:45 PM, a partial clinical record review of Patient #10 was completed. The review indicated two quarters of TAP results and a first quarter SAK result was missing.</p> <p>7. On 1-11-2022 at 2:45 PM, a review of training room #3 water results found three quarters of TAP results were missing.</p> <p>8. On 1-11-2022 at 4:55 PM, an interview with the RN, Employee I, when queried about the missing results indicated that the Hemodialysis nurse, Employee K completes these tests. Employee I was unable to explain why these results were missing. Employee K was not available.</p>		<p>The dialysate sample for culture and endotoxin should be obtained near or the end of the SAK life. 2) Water quality analysis for municipal water (from tap) should meet the minimum standards of the Safe Drinking Water Act. This is a one-time requirement prior to initial installation in the home. Water quality analysis (AAMI) for well water (from tap) will be performed upon initial installation in the home and quarterly thereafter. 3) AAMI testing on product water quality (post PAK) will be performed upon initial installation in the home environment and at least once a year near the end of the PAK life unless specified more frequently by state regulations. The following water and/or dialysate testing will be completed by 1/31/22: Patient #5 – water source (TAP), water purifier (PAK), and Dialysate bag (SAK); Patient #1 – annual PAK and quarterly SAK; Patient #6 – annual PAK, quarterly SAK, and TAP results;</p>	

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			<p>Patient #9 – annual PAK and quarterly SAK; Patient #10 – quarterly TAP and quarterly SAK; Training Room #3 quarterly TAP. Going forward, annual municipal (TAP) testing will be completed in January of each year. Well (TAP) testing will be completed quarterly beginning in January of each year. Dialysate (SAK) testing will be completed quarterly.</p> <p>The Facility Administrator or designee will audit 100% of facility patients' water and dialysate testing results quarterly to verify compliance with facility policy. Instances of non-compliance will be addressed immediately. The Facility Administrator will review audit results with the Medical Director during Quality Assurance Performance Improvement meetings, known as Facility Health Meeting. The Facility Administrator will be responsible for ongoing compliance with the Plan of Correction.</p>	