

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

PRINTED: 04/20/2023

FORM APPROVED

OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER  152606		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 03/23/2023	
NAME OF PROVIDER OR SUPPLIER  BALL DIALYSIS AT WINCHESTER				STREET ADDRESS, CITY, STATE, ZIP COD 409 GREENVILLE AVE STE 500 WINCHESTER, IN 47394			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (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 State Department of Health in accordance with 42 CFR 494.62.</p> <p>Survey Dates: March 22 and 23, 2023</p> <p>Census: 35</p> <p>At this Emergency Preparedness survey, Ball Dialysis at Winchester was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.</p>			E 0000			
V 0000  Bldg. 00	<p>This visit was for a CORE Federal recertification survey of an ESRD provider and for a Federal complaint survey of an ESRD Provider.</p> <p>Survey dates: March 22 and 23, 2023</p> <p>Complaint #IN00270520 was investigated and Federal deficiencies, related and unrelated, were cited.</p> <p>Census by Service Type:</p> <p>In-Center Hemodialysis: 35 Home Hemodialysis: 0 Home Peritoneal dialysis: 0 Total Census: 35</p> <p>Isolation Room: 1</p>			V 0000			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Dawn Nelson

Administrator

04/13/2023

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 disclosable 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 0146  Bldg. 00	<p>QR: Area 2 on 4/03/23</p> <p>494.30(c)(2) IC-CATHETERS:GENERAL (2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: <a href="http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html">http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html</a></p> <p>Based on observations, record review and interview, staff interview, and review of policies and procedures, the facility failed to ensure all patients with a central venous catheter (CVC) received care in compliance with facility policy in 1 of 1 observation of patient care technician (PCT) #1 to discontinue hemodialysis with Patient with a CVC and 1 of 1 observation of registered nurse (RN) #1 completed CVC exit site care with a patient with a CVC.</p>			V 0146	<p><b><u>V 146</u></b> On or before April 5, 2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> <li>· Changing the Catheter Dressing Policy &amp; Procedure</li> <li>· Hand Hygiene Policy &amp; Procedure</li> </ul> <p>Emphasis was placed on:</p>		04/21/2023

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	<p>Findings include:</p> <p>1. On 3/22/23 at 10:05 AM, RN #1 was observed as they provided CVC exit site care to a patient with a CVC. RN #1 was observed to remove the old dressing and discarded, then began to cleanse around the exit site and continued with the dressing change. RN #3 failed to completed hand hygiene after removing the old dressing and before cleansing the CVC exit site and applying a new dressing.</p> <p>2. On 3/22/23 at 10:30 AM, PCT # 1 was observed in station #6, with gloved hands, touched the dialysis machine and Patient who was receiving dialysis treatment, then removed their gloves, and exited station 6 without completing hand hygiene. PCT#1 then entered station #10 and began to discontinue dialysis treatment with Patient who received via a CVC; PCT #1 failed to complete hand hygiene discontinuation of dialysis in station #10.</p> <p>At 10:40, observed there was no alcohol hand gel in station #6.</p> <p>3. The facility Clinical Service Procedure, reference # 45664, published 5/02/22 relayed that after removal of the soiled dressing, the clinician is to completed hand hygiene before proceeding to the cleaning step.</p> <p>4. During an interview on 03/22/2023 at 4:45 PM the administrator was advised of observation findings regarding lack of hand hygiene practices during 2 separate observations on the treatment floor. The administrator agreed that she also witnessed this concern.</p>				<ul style="list-style-type: none"> <li>When changing the catheter dressing discard old dressing and perform hand hygiene before cleansing the CVC exit site and applying a new dressing.</li> <li>Staff should change gloves and practice hand hygiene between each patient and/or station to prevent cross-contamination.</li> <li>Alcohol based hand rub dispensers should be installed on the side of each dialysis machine. Effective April 10, 2023, the Clinical Manager or designee will conduct weekly audits with focus on ensuring all staff follow hand hygiene procedures for four weeks or until 100% compliance is achieved utilizing Infection Control Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Tool per QAI calendar. 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</li> </ul>		

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V 0543  Bldg. 00	<p>494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status;</p> <p>Based on record review and interview, the ESRD facility failed to follow their policy and check the patient's blood pressure every 30 minutes during in-center hemodialysis for 4 of 5 patient records reviewed (Patient #1, 5, 8, and 9).</p>	V 0543	<p>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 root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. 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. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 04/21/2023.</p> <p><b>V 543</b> On or before April 5, 2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p>	04/21/2023	

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	<p>Findings include:</p> <p>1. Review of Policy #23502, version 4, "Patient Monitoring and Safety Checks During Hemodialysis Treatment" indicated Patient Monitoring included to monitor and document patient's blood pressures every 30 minutes or more frequently as needed but not to exceed 45 minutes.</p> <p>2. The clinical record review for Patient #1 included the treatment sheets, dated 03/8/23 - 03/20/23, which were reviewed on 03/23/23 and evidenced the following:</p> <p>On 03/10/23 a Blood Pressure (BP) check was documented at 1:02 PM with a follow-up BP check at 02:06 PM (1 hour and 4 minutes later).</p> <p>On 03/13/23, a BP check was documented at 02:03 PM with a follow-up BP check at 03:04 PM (1 hour and 1 minute).</p> <p>On 3/15/23, a BP check was documented at 12:24 PM with a follow-up BP check at 01:38 PM (1 hour and 14 minutes) and a BP check documented at 02:02 PM with a follow-up BP check at 15:01 PM (59 minutes).</p> <p>On 3/20/23, a BP check at 3:33 PM was documented with a follow-up BP check at 04:41 PM (1 hour and 8 minutes).</p> <p>3. Record review for Patient #9, on 3/23/23, included the treatment sheets, dated 03/08/23 - 3/21/23 and evidenced the following documentation:</p> <p>On 03/11/2023 a BP check was documented at</p>				<p>· Patient Assessment and Monitoring Emphasis was placed on:</p> <p>· Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations.</p> <p>Effective April 10, 2023, the Clinical Manager or designee will conduct daily audits with focus on ensuring all patients vital signs are documented every 30 minutes or more as needed but not to exceed 45 minutes for four weeks or until 100% compliance is achieved utilizing Treatment Sheet Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Tool per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>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.</p> <p>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</p>		

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	<p>10:31 AM with the next follow-up BP at 11:33 AM (1 hour and 2 minutes) and a BP at 12:02 PM with a follow up BP check at 01:05 PM (1 hour and 3 minutes).</p> <p>On 03/16/2023 a BP check was documented at 10:31 AM with a follow-up BP check at 11:32 AM (1 hour and 1 minute later.)</p> <p>4. The clinical record for Patient #5 included review of the treatment sheets, dated 03/8/23 - 03/20/23, reviewed on 03/23/23, and evidenced the following:</p> <p>On 03/08/23, a BP check was documented at 10:33 AM with a follow-up BP check at 11:41 AM (1 hour and 9 minutes later).</p> <p>On 03/10/23, a BP check was documented at 7:44 AM with a follow-up BP check at 8:34 AM (50 minutes later) and a BP check at 10:05 AM with a follow-up BP check at 11:03 AM (57 minutes later).</p> <p>On 3/15/23, a BP check at 7:37 AM with a follow-up BP check at 8:31 AM (54 minutes later).</p> <p>On 3/17/23, a BP check at 10:32 AM with a follow-up BP check at 11:48 AM (1 hour and 16 minutes later).</p> <p>5. The review of the clinical record for Patient #8 included treatment sheets, dated 03/09/23 - 3/21/23, on 03/23/23 and evidenced the following:</p> <p>On 03/09/23, a BP check at 7:39 AM with a follow-up BP check at 8:31 AM (52 minutes later).</p> <p>On 03/11/23, a BP check at 6:41 AM with a follow-up BP check at 8:03 AM (1 hour and 22 minutes later) and an additional BP check at 9:06 AM (57 minutes later).</p>				<p>through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>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.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 04/21/2023.</p>		

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V 0544  Bldg. 00	<p>On 03/14/23, a BP check at 6:07 AM with a follow-up BP check at 7:04 AM (57 minutes later).</p> <p>6. During an interview on 03/23/2023 at 12:00 PM the Administrator agreed that blood pressure checks should be completed every 30 minutes</p> <p>494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.</p> <p>Based on record review and interview, the ESRD facility failed to ensure dialysate flow rate (DFR) and blood flow rate (BFR) were set according to physician orders for 3 of 5 patient records reviewed (Patient #1, 8, and 9).</p> <p>Findings include:</p> <p>1. Review of Policy #23502, Version 4, "Patient Monitoring and Safety Checks During Hemodialysis Treatment" indicated the Safety Check indicated Machine Checks are to include to Monitor and document Machine Checks every 30 minutes, Machine Checks to include, verify the DFR, BFR is set and functioning per treating physician order.</p> <p>2. Patient #1 Treatment Sheets dated 03/08/2023-03/20/2023 were reviewed on 03/23/2023 and evidenced the following:</p> <p>A. On 3/10/23 the physician ordered BFR was 400. Patient #1's treatment began at 12:17 PM with a</p>			V 0544	<p><b>V 544</b></p> <p>On or before April 5, 2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <ul style="list-style-type: none"> <li>· Patient Assessment and Monitoring</li> </ul> <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> <li>· Check prescribed blood flow is being achieved or reason is documented in medical record if unable to meet prescribed blood flow</li> <li>· Check dialysate flow rate setting is correct, and the prescribed flow is being delivered. Effective April 10, 2023, the Clinical Manager or designee will conduct daily audits with focus on ensuring the dialysate flow rate (DFR) and blood flow rate (BFR) are set according to physician order, or justification documented</li> </ul>		04/21/2023

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	<p>BFR of 400. Patient #1 ran a BFR of 375 beginning at 01:02 PM and for the remainder of the treatment without documentation of why the ordered BFR was not obtained or set at 400.</p> <p>B. On 03/14/23 the physician ordered BFR was 400. Patient 1's treatment ran a BFR of 450 for the entire treatment without documentation as to why was above the ordered 400 BFR.</p> <p>3. Patient #9 Treatment Sheets dated 03/08/23-03/21/23 reviewed on 03/23/23 evidenced the following:</p> <p>On 03/14/2023 the physician ordered the BFR was 400. Patient # 8's treatment ran a BFR of 325 to 350 throughout their treatment.</p> <p>4. Patient #8 Treatment Sheets dated 03/09/23 - 03/21/23 were reviewed on 03/23/23 evidenced the following:</p> <p>A. The 3/09 and 3/16, the physician ordered DFR was 700; Patient's DFR was documented as ran at 500 for the entire treatments.</p> <p>B. The 3/11, 3/14, and 3/21/23 the physician ordered BFR was 350; Patient's DFR ran at 400 for the entire treatment on 3/11, ran a BFR of 400 to 450 throughout the entire treatment on 3/14, and ran a BFR of 400 the entire treatment on 3/21/23.</p> <p>5. During an interview on 03/23/23 at 12:00 PM the Administrator agreed that if the Dialysate Flow Rate and Blood Flow Rate are different than the physician order, staff must document a reason why.</p>				<p>if unable to achieve for four weeks or until 100% compliance is achieved utilizing Treatment Sheet Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Tool per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>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.</p> <p>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.</p> <p>The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by</p>		



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					<p>the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 04/21/2023.</p>		