

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152659	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 12/17/2024
NAME OF PROVIDER OR SUPPLIER SOUTH BEND WEST DIALYSIS		STREET ADDRESS, CITY, STATE, ZIP COD 5660 NIMTZ PKWY SOUTH BEND, IN 46628		
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E 0000 Bldg. 00	<p>An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62.</p> <p>Survey Dates: December 13, 16, and 17, 2024.</p> <p>Active Census: 44.</p> <p>At this Emergency Preparedness survey, South Bend West Dialysis 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.</p> <p>Survey dates: December 13, 16, and 17, 2024.</p> <p>Census by Service Type: In-Center Hemodialysis: 44 Total Active Census: 44</p> <p>Isolation Room/Waiver: 1</p> <p>Abbreviations: EP Emergency Preparedness FA Facility Administrator PCT Patient Care Technician RN Registered Nurse</p> <p>QR 12/23/24 A2</p>	V 0000		

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

TITLE

(X6) DATE

Melissa

Szymczak

01/15/2025

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 0111 Bldg. 00	<p>494.30 IC-SANITARY ENVIRONMENT</p> <p>Based on observation, policy review and interview, the dialysis facility failed to maintain a sanitary environment within the ICHD treatment area during 2 of 2 days of ICHD treatment area observations, which had the potential to affect 44 active ICHD patients.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. During the flash tour on 12/13/2024 from 9:30 AM - 10:35 AM, in the treatment room observed a kleenex on the floor at Station 12, gloves on the floor at Station 3, and gloves and wrappers from dressings on the floor at Station 2. In the water treatment room, observed scissors with rust lying on the floor between the two carbon filters, scraps of paper in numerous areas and a discolored film on the floor. 2. During an observation in the treatment room on 12/13/2024 at 12:40 PM, observed a yellow-green colored sticky substance on the bottom of a drawer at the catheter station. 3. During an interview on 12/13/2024 at 4:13 PM, when asked who is responsible to pick up debris in the water treatment room, the biomed technician indicated all staff. 4. During an interview on 12/13/2024 at 4:41 PM, when asked why rusted scissors and debris would be on the floor in the treatment room and water treatment room, the director of clinical services indicated those items shouldn't be on the floor. When asked why a sticky substance would be on the bottom of a drawer in the treatment room, the director of clinical services indicated it shouldn't 	V 0111	<p>V111 The Facility Administrator will in-service all teammates on Policy 1-05-01 "Infection Control For Dialysis Facilities" and Policy 8-04-01 "Physical Environment" beginning 12/19/24. Verification of attendance will be evidenced by an in-service signature sheet. Teammates will be educated using surveyor observations as examples with emphasis on, but not limited to the following: 1) PURPOSE: To minimize the spread of infections or bloodborne pathogens in the dialysis facility environment. 2) At the end of each treatment, the dialysis station will be cleaned and disinfected. 3) The dialysis facility will be designed, constructed, equipped, and maintained to provide dialysis patients, teammates, and the public a safe, functional, and comfortable treatment environment. On 12/13/24, the Kleenex tissue on the floor at Station 3 and the gloves, wrappers, and dressings on the floor at Station 2 were removed and disposed of in accordance with facility policy. On 12/13/24, the scissors with rust between the two carbon filters, scraps of paper in numerous areas were remove from the floor in the water treatment</p>	01/15/2025

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V 0113 Bldg. 00	<p>be.</p> <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE</p> <p>Based on observation, record review, and interview, the facility failed to ensure employees performed proper hand hygiene in 4 of 12 observations over 2 of 4 observation periods (PCT 2, 3).</p>	V 0113	<p>area and disposed of in accordance with facility policy. The floor in the water treatment area was cleaned with removal of the discolored film. On 12/13/24, the drawer at the catheter station was cleaned with removal of the yellow-green sticky substance on the bottom of a drawer. The Facility Administrator will conduct observational audits of the physical environment daily x 2 weeks, then weekly x 2 weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the internal audit. Instances of non-compliance will be addressed. The Facility Administrator will review results of the audits with the Medical Director during monthly Quality Assurance and Performance Improvement meetings known as Facility Health Meetings. The Facility Administrator is responsible for ongoing compliance with this plan of correction.</p> <p>1/15/25</p>	01/15/2025

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	<p>Findings include:</p> <ol style="list-style-type: none"> Review of an agency policy titled "Infection Control for Dialysis Facilities" indicated hand hygiene will be performed prior to gloving and immediately after removal of gloves. During an observation on 12/13/2024 at 9:45 AM, PCT 2, cleaned the HD machine at Station 5, removed gloves without performing hand hygiene typed on the keyboard at Station 5, then applied gloves without performing hand hygiene, and completed the cleaning of Station 5. During an observation on 12/13/2024 at 10:00 AM, observed PCT 3 at Station 2, PCT 2 applied gloves without performing hand hygiene, placed a clean field under the central venous catheter ports, and then disinfected and connected the central venous catheter (tube inserted into a vein to provide access to the superior vena cava used for dialysis) bloodline of Patient #1. During an observation on 12/16/2024 at 10:00 AM, observed PCT 3 at Station 6, PCT 3 applied gloves without performing hand hygiene, placed a clean field under the central venous catheter ports of Patient #7, and then disinfected and connected the central venous catheter bloodline. PCT 3 removed gloves and without performing hand hygiene moved to station 5 and touched the tubing to begin HD machine testing. <p>During an interview on 12/16/2024 at 10:15 AM, when asked what should be done after removing gloves and putting on clean gloves, PCT 2 indicated she should have used hand sanitizer and had not.</p> <ol style="list-style-type: none"> During an observation on 12/16/2024 at 10:52 		<p>an in-service signature sheet. Teammates will be educated using surveyor observations as examples with emphasis on, but not limited to the following: 1) All teammates, Physicians and Non-Physician (NPP) will perform hand hygiene ... prior to gloving and immediately after removal of gloves...The Facility Administrator will conduct observational audits of the physical environment daily x 2 weeks, then weekly x 2 weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the internal infection control audit. Instances of non-compliance will be addressed. The Facility Administrator will review results of the audits with the Medical Director during monthly Quality Assurance and Performance Improvement meetings known as Facility Health Meetings. The Facility Administrator will report progress, as well as any barriers to maintaining compliance. Action plans will be evaluated for effectiveness and new plans developed when needed until sustained compliance is achieved. Supporting documentation will be included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with this plan of correction.</p> <p>1/15/25</p>	

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V 0114 Bldg. 00	<p>AM, observed PCT 3 at Station 2 PCT 3 removed gloves without performing hand hygiene typed on the keyboard, then applied gloves without performing hand hygiene, and touched the bloodline of Patient #1. PCT 3 removed gloves, applied gloves without performing hand hygiene, and touched the bloodline again of Patient #1.</p> <p>During an interview on 12/16/2024 at 10:59 AM, when asked when hand hygiene is to be completed, PCT 3 indicated she performs hand hygiene between patients. When asked what is done after removing gloves and applying new gloves, PCT 3 indicated nothing unless moving to a different patient.</p> <p>494.30(a)(1)(i) IC-SINKS AVAILABLE</p> <p>Based on record review, observation, and interview, the facility failed to provide warm running water to facilitate hand washing in 3 of 3 sinks in which the running water was checked on the treatment floor.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of an agency policy titled "Infection Control for Dialysis Facilities" indicated sinks should be easily accessible in the treatment area and in other appropriate areas and must be plumbed with both hot and cold water. 2. While on the treatment floor on 12/13/2024, at 12:00 PM and again at 12:25 PM, ran the water at an automatic sink in the medication preparation area for two minutes and the water temperature remained cold. At 12:35 PM, ran the water at an automatic sink in the isolation room for two 	V 0114	<p>V114</p> <p>The Facility Administrator will in-service all teammates on Policy 1-05-01 "Infection Control For Dialysis Facilities" beginning 12/19/24. Verification of attendance will be evidenced by an in-service signature sheet. Teammates will be educated using surveyor observations as examples with emphasis on, but not limited to the following: 1) Sinks should be easily accessible and readily available in the treatment area and in other appropriate areas...2) Sinks must be plumbed with both hot and cold water... On 12/14/24, the Facility Administrator submitted a work order for testing/repair of all sinks in the facility for provision of hot</p>	01/15/2025

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	<p>minutes and the water temperature remained cold. At 12:49 PM, ran the water at an automatic sink at the eyewash station for two minutes and the water temperature remained cold.</p> <p>5. During an interview on 12/13/2024 at 4:41 PM, when asked how long it should take for the water to run warm at the sinks in the treatment area, the director of clinical services indicated there is no timeframe.</p> <p>6. While on the treatment floor on 12/16/2024 at 10:46 PM, observed PCT 1 washing hands at a clean sink in front of Station 9. When asked how long it takes for the water to warm up, PCT 1 indicated the water at the automatic sinks never warms up and had reported it a while back.</p>		<p>and cold water. All sinks in the facility will be able to provide hot and cold water by 1/15/25. The work order was completed on 12/27/24 and the Facility Administrator rounded with the Lead Maintenance Technician and verified that hot and cold water was available in each sink. The Facility Administrator will conduct observational audits of the physical environment daily x 2 weeks, then weekly x 2 weeks to verify all sinks provide both hot and cold water in compliance with facility policy. Ongoing compliance will be verified monthly during the internal infection control audit. Instances of non-compliance will be addressed. The Facility Administrator will review results of the audits with the Medical Director during monthly Quality Assurance and Performance Improvement meetings known as Facility Health Meetings. The Facility Administrator will report progress, as well as any barriers to maintaining compliance. Action plans will be evaluated for effectiveness and new plans developed when needed until sustained compliance is achieved. Supporting documentation will be included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with this plan of correction</p>	

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V 0122 Bldg. 00	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL</p> <p>Based on observation and interview, the facility failed to ensure staff stored disinfectants in the treatment area to prevent loss of disinfectant properties to clean and disinfect the dialysis stations and equipment in 1 of 4 treatment floor observation periods completed creating the potential to affect all the facility's 44 current incenter patients.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of an agency policy titled "Utilizing Vascular Access Clamps" indicated vascular access clamps are reusable and disinfected between each use with a bleach solution. 2. Review of an agency policy titled "Infection Control for Dialysis Facilities" indicated a bleach solution is used for routine disinfection of the dialysis station. 3. During an observation 12/16/2024 at 9:46 AM, across from Station 3, observed one uncovered bleach container used for disinfecting clamps. Further observations at 10:08 AM, 10:16 AM, and 10:27 AM evidenced the same container remained uncovered. 4. During an interview on 12/16/2024 at 10:28 AM, when asked when the bleach container should be uncovered, RN 2 indicated the container should be covered. <p>During an interview on 12/16/2024 at 10:44 AM, across from the isolation room, observed an uncovered bleach container used for cleaning the dialysis stations.</p>	V 0122	<p>V122</p> <p>The Facility Administrator will in-service all teammates on Policy 1-04-08 "Utilizing Vascular Access Clamps", Policy 1-05-01 "Infection Control For Dialysis Facilities", and Policy 1-05-08 "Bleach Policy" beginning 12/19/24. Verification of attendance will be evidenced by an in-service signature sheet. Teammates will be educated using surveyor observations as examples with emphasis on, but not limited to the following: 1) Non-disposable items are to be disinfected after each patient use, prior to removal from treatment area/station and if contaminated between uses. 2) For disinfection of vascular access clamps, please refer to policy: Utilizing Vascular Access Clamps. 3) Non-occluding spring loaded vascular access clamps are reusable and disinfected between each use with a 1:100 (one to one hundred) bleach solution. 4) A 1:10 (one to ten) bleach solution is used to clean vascular access clamps visibly contaminated with blood or body fluids. 5) Bleach solution needs to be covered with a secure lid...Note: Without a secure lid, the bleach solution is open to air causing the solution to degrade over time and become less effective. The Facility</p>	01/15/2025

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V 0126 Bldg. 00	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Based on record review and interview, the facility failed to offer the hepatitis B vaccination (protects against the hepatitis B virus which can lead to liver damage, cirrhosis, and liver cancer) to all employees when hired for 1 of 1 PCT hired in 2024	V 0126	<p>Administrator will conduct observational audits daily x 2 weeks, then weekly x 2 weeks to verify that disinfection of equipment is performed in compliance with facility policy with all bleach containers covered with a secure lid. Ongoing compliance will be verified monthly during the internal infection control audit. Instances of non compliance will be addressed. The Facility Administrator will review results of the audits with the Medical Director during monthly Quality Assurance and Performance Improvement meetings known as Facility Health Meetings. The Facility Administrator will report progress, as well as any barriers to maintaining compliance. Action plans will be evaluated for effectiveness and new plans developed when needed until sustained compliance is achieved. Supporting documentation will be included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the plan of correction</p>	01/15/2025

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	<p>(PCT 2).</p> <p>Findings include:</p> <p>1. Review of an agency policy titled "Teammate Health Monitoring Program" indicated new teammates will be offered the Hepatitis B Vaccination.</p> <p>2. Review of the personnel records of PCT 2, with hire date of 09/09/2024, included a form titled "Hepatitis B Vaccine Teammate Consent/Declination" that indicated PCT 2 had been offered the hepatitis vaccine series by the facility on 12/13/2024. Documentation failed to evidence the facility offered the hepatitis B vaccination at time of hire.</p> <p>During an interview on 12/17/2024 at 1:10 PM, when asked why PCT 2 did not receive an offer for the hepatitis B vaccine upon hire, the FA indicated the offer of the hepatitis B vaccine fell through the cracks.</p>		<p>"Teammate Hepatitis B Monitoring And Follow-Up Guidance". Verification of attendance will be evidenced by an in-service signature sheet. Teammates will be educated using surveyor observations as examples with emphasis on, but not limited to the following: 1) New teammates will be: Screened for Hepatitis B...2) Offered Hepatitis B Vaccination (after Bloodborne pathogen training)...3) New teammates who are not able to provide documentation of hepatitis B surface antibodies of 10 mIU/ml or greater from any time in the past, regardless of documentation indicating completion of the hepatitis B vaccine series, will be screened for hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (anti-HBs) within 10 days and offered the vaccination as indicated by their results. The Hepatitis B vaccine series was offered to PCT 2 on 12/13/24. The first dose of vaccine in the series was administered to PCT 2 on 12/13/24. Documentation of consent for the vaccine series will be maintained in the PCT 2's file. The Facility Administrator will audit one hundred percent (100%) of teammate files to verify compliance with facility policy. The Facility Administrator will audit one hundred percent (100%) of teammates within ten (10) days</p>	

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V 0143 Bldg. 00	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS Based on record review, observation, and interview, the medical director failed to ensure the policies and procedures related to patient care and safety were followed in 1 of 1 observation of the use of a muti use medicaiton vial.		V 0143	<p>of hire for documentation of screening for Hepatitis B monthly x 3 months to verify compliance with facility policy. Ongoing compliance will be verified annually with audit of one hundred percent (100%) teammate files. Instances of non-compliance will be addressed. The Facility Administrator will review results of the audits with the Medical Director during monthly Quality Assurance and Performance Improvement meetings known as Facility Health Meetings. The Facility Administrator will report progress, as well as any barriers to maintaining compliance. Action plans will be evaluated for effectiveness and new plans developed when needed until sustained compliance is achieved. Supporting documentation will be included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with this plan of correction.</p> <p>1/15/25</p>
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	<p>Findings include:</p> <p>1. Review of an agency document titled "Parenteral (intravenous) Medication Preparation and Administration" indicated multiple dose vials are labeled with the date opened.</p> <p>2. During an observation on 12/16/2024 at 9:40 AM, observed an opened multiple dose vial of Heparin (prevents clotting in the blood circuit) at the medication prep area. Observation of the vial failed to evidence the date opened.</p> <p>During an interview on 12/16/2024 at 10:55 AM, when asked to look at the vial of Heparin at the medication prep area, RN 2 indicated the vial was missing the date of when opened.</p>		<p>be educated using surveyor observations as examples with emphasis on, but not limited to the following: 1) Medications containing a preservative must be discarded 28 days after opening or accessed (e.g., needle punctured), unless the manufacturer specifies a different (shorter or longer) date or as directed by the manufacturer as in the case of vaccines or state specific pharmacy regulations. 2) Each vial is labeled with the initials of the person opening the vial and the expiration date. The Facility Administrator will conduct observational audits daily x 2 weeks, then weekly x 2 weeks to verify all opened multidose vials are labeled with the initials of the person opening the vial and the expiration date. Ongoing compliance will be verified monthly during the internal medication audit. Instances of non-compliance will be addressed. The Facility Administrator will review results of the audits with the Medical Director during monthly Quality Assurance and Performance Improvement meetings known as Facility Health Meetings. The Facility Administrator will report progress, as well as any barriers to maintaining compliance. Action plans will be evaluated for effectiveness and new plans developed when needed until</p>	

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