

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152541	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  08/27/2014
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NAME OF PROVIDER OR SUPPLIER  MERRILLVILLE DIALYSIS CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 8670 BROADWAY MERRILLVILLE, IN 46410
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V000000	<p>This was a federal ERSD [CORE] recertification survey.</p> <p>Survey dates were 8/25/2014, 8/26/2014, 8/27/2014.</p> <p>Facility number: 005166</p> <p>Medicaid number: 200114710A</p> <p>Surveyor: Michelle Weiss RN MSN Public Health Nurse Surveyor</p> <p>Census: 121 InCenter HD: 95 Home HD 3 Home PD: 23</p> <p>Merrillville Dialysis Center was found out of compliance with the Condition for Coverage 42 CFR 494.30 Infection Control.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN September 9, 2014</p>	V000000		
V000110	<p>494.30 CFC-INFECTON CONTROL</p> <p>Based on observation, facility policy and document review, and interview, it was determined the facility failed to ensure</p>	V000110	The Director of Operations (CEO) and Governing Body take seriously their responsibility to ensure that the facility is in compliance with the CfC of Infection Control including	09/17/2014

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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	<p>visible blood was cleaned as required in 1 of 1 observation of a blood spill creating the potential to affect the facilities 24 present Incenter hemodialysis patients and 10 staff (See V 111), failed to follow the Centers for Disease Control (CDC) standards related to glove use in 2 out of 16 skilled dialysis procedures, creating the potential to affect all 95 Incenter hemodialysis patients (See V 113), failed to ensure that items taken into the dialysis station were cleaned and disinfected before being taken back to the nurses station in 1 of 16 observations which had the potential to affect all 26 Incenter Hemodialysis patients who were presently being dialyzed at the facility (See V 116), failed to demonstrate that it disinfected surfaces and equipment per CDC guidelines and facility policy having the potential to affect the subsequent patient at the station with cross contamination all 24 patients currently receiving dialysis, and ten present staff (See V 122), and failed to ensure staff wiped the rubberized port before withdrawing medication in 1 out of 4 Post dialysis procedures involving aseptic technique creating the potential to affect all 94 Incenter hemodialysis (See V 143).</p> <p>The cumulative effect of these systemic problems resulted in the facility being</p>		<p>ensuring blood is cleaned and gloves are used as required, cleaning and disinfection of supplies and surfaces occurs per CDC guidelines and facility policy, and saline ports are disinfected before withdrawing medication. As such, the Governing Body met on 09/16/14 to review the Statement of Deficiencies and to formulate a corrective action plan to bring this facility into compliance with the ESRD Conditions for Coverage. As a result of the citation from the 08/27/14 CMS Recertification survey and to ensure that the facility fully complies with the Centers of Disease Control Standards and as part of the developed plan of correction, the following corrective actions have been implemented:</p> <ul style="list-style-type: none"> <li>·Reeducation and reinforcement of the mandatory requirement that: <ul style="list-style-type: none"> <li>·Direct patient care staff complies with all aspects of the facility cleaning and disinfection policy. Please refer to V-111</li> <li>·PPE is donned per policy including gloves. Please refer to V-113</li> <li>·Surfaces and equipment are disinfected per cleaning and disinfection policies. Please refer to V-116 and V-122</li> <li>·Medication ports are disinfected prior to entering. Please refer to V-143</li> </ul> </li> </ul> <p>Documentation of the education and monitoring process are</p>	

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V000111	<p>found out of compliance with the Condition for Coverage 494.30 Infection Control.</p> <p>494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>Based on observation, facility policy and procedure review, and interview, the facility failed to ensure visible blood was cleaned as required in 1 of 1 observation of a blood spill creating the potential to affect the facilities 24 present InCenter hemodialysis patients and 10 staff.</p> <p>Findings include:</p> <p>1. At station 23, on August 25 at 10:35, there was an observation of discontinuation of dialysis and post dialysis access care by Employee U. At 10:45, blood from the patient's left arm access spilled from beneath the pressure-applied gauze, down the chair, trickling in front of the dialysis machine</p>	V000111	<p>available for review at the facility. To ensure full implementation of the developed plan of correction, the Governing Body has committed to meet at a minimum monthly until the Condition is lifted and compliance has been achieved. The Governing Body is responsible and will continue to monitor the corrective plan through to completion.</p> <p>Immediately on 08/26/14 the Clinical Manager and Education Coordinator retrained all direct patient care staff on policy and procedure related to blood spills in the dialysis clinic. On 09/10/14 the Director of Operations reviewed with the Clinical Manager and by 09/17/14 the Clinical Manager will train all Registered Nurse (RN) and Patient Care Technician (PCT) staff on:</p> <ul style="list-style-type: none"> <li>· FMS-CS-IC-II-155-110A: Cleaning and Disinfection with special attention to: <ul style="list-style-type: none"> <li>o Work Surface Cleaning and Disinfection with visible blood greater than 10ml and other potentially infectious material using bleach solutions: <ul style="list-style-type: none"> <li>§ Use 1:100 bleach to clean surfaces with visible blood</li> </ul> </li> </ul> </li> </ul>	09/17/2014

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	<p>on the floor, and a significant amount weeping from the access before more pressure by the nurse was again applied, leaving a visable amount streaking the seat, the left wheel, and brakes of the chair. At 11:15, Employee B cleaned the floor in front of the machine, the machine, and areas of visable blood on the attached side table, except for the chair. The patient had not yet vacated the station. At 11:45 the visable blood on the chair remained. Then the patient and chair were wheeled from the station toward the nurses station, approximately 4 feet away from its original location.</p> <p>2. At 12:00, the visable blood remained on the floor and chair. Employee K assisted the patient, whose access stopped bleeding and was being discharged. The employee cleaned the floor and the chair with 1:100 bleach solution.</p> <p>3. At 12:15, the nurse manager stated, "I wanted to make sure it was done correctly. The nurse knows, it is our policy, to use 1:10 solution that the staff mixes every day."</p> <p>4. Facility Policy titled "Cleaning and Disinfection", document number FMS-CS-IC-II-155-110A, dated 20-MAR-2013, states, "... Clean and</p>		<p>(&lt;10mls) § Use 1:10 bleach dilution to clean surfaces with visible blood &gt;10mls § Clean and disinfect any surfaces contaminated with blood or OPIM immediately or soon as feasible.</p> <p>· FMS-CS-IC-II-155-110C3: Work Surface Cleaning and Disinfection with Visible Blood &gt; than 10 mls and OPIM using Bleach Solutions, with special attention to: o Procedure: § Use a cloth wetted with 1:10 bleach solution to clean the surface § Clean up all visible blood. Discard used cloth and gloves in appropriate waste container. Perform hand hygiene and don new gloves. § After cleaning up all visible blood, using a new cloth wetted with 1:100 bleach solution for a second cleaning of the surface. Make the surface glisteningly wet and let air dry unless otherwise specified by the manufacturer. § Discard the cloth and gloves in the appropriate waste container. Perform hand hygiene. The meeting agenda and attendance records will be available at the facility for review. The Clinical Manager and or designee will perform infection control audits daily for 2 weeks, and then weekly for 2 weeks, then monthly until compliance is</p>	

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V000113	<p>disinfect any surfaces contaminated with blood or OPIM immediately or as soon as feasible... "</p> <p>5. Facility Procedure titled "Work Surface Cleaning and Disinfection with Visible Blood &gt;10mLs and OPIM using Bleach Solutions," FMS-CS-IC-II-155-110C3, dated 04-JAN-2012, states, " ... Use a cloth wetted with 1:10 bleach solution to clean the surface. Clean up all visible blood. Discard used cloth and gloves in an appropriate waste container. Perform hand hygiene and don new gloves. After cleaning up all visible blood use a new cloth wetted with 1:100 bleach solution for a second cleaning of the surface ... ."</p> <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>Based on observation and review of documents, the facility failed to follow the Centers for Disease Control (CDC) standards related to glove use in 2 out of 16 skilled dialysis procedures, creating the potential to affect all 95 Incenter hemodialysis patients. (employees D and U)</p>	V000113	<p>achieved and Condition is lifted. The Clinical Manager will immediately address identified issues and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure that visible blood is cleaned as required.</p> <p>On 09/10/14 the Director of Operations reviewed with the Clinical Manager and by 09/17/14 the Clinical Manager will train all Registered Nurse (RN) and Patient Care Technician (PCT) staff on: . FMS-CS-IC-II-155-090A:Hand Hygiene with special attention to: o Hand Hygiene: § Gloves must be provided to</p>	09/17/2014			

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	<p>Findings:</p> <p>1. On August 25, 2014, at 10:35 central standard time, there was an observation at station 23 of a discontinuation of dialysis and post dialysis access care by Employee U. At 10:45, blood from the patient's left arm access spilled from beneath the pressure-applied gauze, which the patient was holding with an ungloved hand. The nurse had not provided the patient with a glove until after the access site started bleeding, at which time Employee B handed the patient a glove. "Well, it's my blood," the patient said.</p> <p>According to the CMS Interim Final Version 1.2 (2008) originally cited in the Center for Disease Control (CDC), "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients", Vo. 50 No. RR-5, "Gloves must be provided to patients and visitors if these individuals assist with procedures which risk exposure to blood or body fluids, such as when self-cannulating or holding access sites post treatment to achieve hemostasis."</p> <p>2. On August 25, 2014, at 06:30 central standard time, patient care</p>		<p>patients when performing procedures which risk exposure to blood or body fluids, such as when self cannulating or holding access sites post treatment to achieve hemostasis</p> <p>FMS-CS-IC-II-155-080A: Personal Protective Equipment with special attention to:</p> <ul style="list-style-type: none"> <li>o Gloves: <ul style="list-style-type: none"> <li>§ Disposable gloves must be used:</li> <li>§ When touching any part of the dialysis machine or equipment at the dialysis station</li> <li>§ Gloves must be worn appropriately</li> <li>§ Change gloves and practice hand hygiene between each patient and /or station</li> </ul> </li> </ul> <p>The meeting agenda and attendance records will be available at the facility for review.</p> <p>The Clinical Manager and or designee will perform infection control audits daily for 2 weeks, and then weekly for 2 weeks, then monthly until compliance is achieved and Condition is lifted. The Clinical Manager will immediately address identified issues and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a</p>	

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V000116	<p>technician D, was observed holding a glove over the tips of her fingers to touch a computer screen at the dialysis station.</p> <p>The May 2013 "Protocol for Hand Hygiene and Glove Use Observations" by the Centers for Disease Control and Prevention states, "... In general, gloves should be worn prior to contact with patients at the treatment station and potentially contaminated surfaces (e.g., dialysis machine, environmental surfaces) ... Holding a glove in one's hand instead of wearing it is not considered acceptable ... ."</p> <p>494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT 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. -- 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. -- 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>Based on observation and review of facility policy, the facility failed to ensure</p>	V000116	<p>corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure gloves are worn as required per CDC and facility policy.</p> <p>Immediately on 08/26/14 the Clinical Manager and Education Coordinator retrained all direct patient care staff on policy and</p>	09/17/2014			

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	<p>that items taken into the dialysis station were cleaned and disinfected before being taken back to the nurses station in 1 of 16 observations which had the potential to affect all 26 Incenter Hemodialysis patients who were presently being dialyzed at the facility. (Employee U)</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>On August 25, 2014, at 06:40 Central Standard time, the nurse, employee U, listened to lung sounds as part of an assessment at station 10 using a stethoscope. The stethoscope was not disinfected before it was returned to a clean area. It was then set down on the clean counter at the nurses station where medications were prepared.</li> <li>The policy FMS-CS-IC-II-155123A &amp; C, "Cleaning and Disinfection of the Stethoscope", March, 2013, states, " ... The stethoscope should be wiped with either 70% isopropyl alcohol wipe or cloth dampened with 1:100 hypochlorite solution after each use ... ."</li> </ol>		<p>procedure related to cleaning and disinfection of items brought to station.</p> <p>On 09/10/14 the Director of Operations reviewed with the Clinical Manager and by 09/17/14 the Clinical Manager will train all Registered Nurse (RN) and Patient Care Technician (PCT) staff on:</p> <ul style="list-style-type: none"> <li>§ FMS-CS-IC-II-155-123-A: Policy: Cleaning and Disinfection with special emphasis on: <ul style="list-style-type: none"> <li>o Policy: All reusable instruments and equipment will be thoroughly cleaned and disinfected prior to being returned to a clean area (including stethoscope).</li> </ul> </li> <li>FMS-CS-IC-II-155-123C: Procedure: Cleaning and Disinfection with special emphasis on: <ul style="list-style-type: none"> <li>o Using 70% alcohol or 1:100 hypochlorite solution to clean stethoscope diaphragm: <ul style="list-style-type: none"> <li>The stethoscope should be wiped with either a 70% alcohol wipe or cloth after each use.</li> </ul> </li> </ul> </li> </ul> <p>The meeting agenda and attendance records will be available at the facility for review. The Clinical Manager and or designee will perform infection control audits daily for 2 weeks, and then weekly for 2 weeks, then monthly until compliance is achieved and Condition is lifted. The Clinical Manager will immediately address identified issues and report findings and</p>	

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V000122	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>Based on policy and document review and observations of 2 out of 18 dialysis procedures requiring standard infection control precautions, the facility failed to demonstrate that it disinfected surfaces and equipment per CDC guidelines and facility policy having the potential to affect the subsequent patient at the station with cross contamination all 24 patients</p>	V000122	<p>actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure items taken into the dialysis station are cleaned and disinfected before being taken back to the nurses' station.</p> <p>Immediately on 08/26/14 the Clinical Manager and Education Coordinator retrained all direct patient care staff on policy and procedure related to cleaning and disinfection of surfaces, equipment, and blood spills in the dialysis clinic. On 09/10/14 the Director of Operations reviewed with the Clinical Manager and by 09/17/14 the Clinical Manager will train all</p>	09/17/2014

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	<p>currently receiving dialysis, and ten present staff. (Employees B and U)</p> <p>Findings:</p> <p>1. On August 25, 2014, at 10:45 AM, at station 22, several employees, including patient care technician, employee B were observed cleaning and disinfecting the dialysis station. The television screen and TV controls were not disinfected. The television is a Direct Touch System.</p> <p>FMS-CS-IC-II-155-120A policy from the facility's Bloodborne Pathogen Program titled "Cleaning Individual Patient Televisions and Direct Touch Systems" dated 04-JAN-2012 states, " ... The television shall be cleaned after each patient treatment. The television screen should be cleaned with a 1:100 bleach solution ... ."</p> <p>2. At station 23, on August 25 at 10:35, there was an observation of discontinuation of dialysis and post dialysis access care by Employee U. At 10:45, blood from the patient's left arm access spilled from beneath the pressure-applied gauze, down the chair, trickling in front of the dialysis machine on the floor, and a significant amount weeping from the access before more pressure by the nurse was again applied,</p>		<p>Registered Nurse (RN) and Patient Care Technician (PCT) staff on:</p> <ul style="list-style-type: none"> <li>· FMS-CS-IC-II-155-110A: Policy: Cleaning and Disinfection with special attention to: <ul style="list-style-type: none"> <li>o Work Surface Cleaning and Disinfection with visible blood greater than 10ml and other potentially infectious material using bleach solutions: <ul style="list-style-type: none"> <li>§ Use 1:100 bleach to clean surfaces with visible blood (&lt;10mls)</li> <li>§ Use 1:10 bleach dilution to clean surfaces with visible blood &gt;10mls</li> <li>§ Clean and disinfect any surfaces contaminated with blood or OPIM immediately or soon as feasible.</li> </ul> </li> </ul> </li> <li>· FMS-CS-IC-II-155-120A: Policy: Cleaning Individual Patient Televisions and Direct Touch Systems with special attention to : <ul style="list-style-type: none"> <li>o General cleaning: <ul style="list-style-type: none"> <li>o The television shall be cleaned after each patient treatment.</li> <li>o The television screen should be cleaned with a 1:100 bleach solution.</li> <li>o Use dampened cloth; ring out excess of 1:100 bleach solution. DO NOT use a saturated cloth to clean any part of the television.</li> <li>o Any blood contamination should be cleaned immediately.</li> <li>o Do not use spray liquids or aerosol cleaners for cleaning the television.</li> </ul> </li> </ul> </li> </ul>	

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	<p>leaving a visible amount streaking the seat, the left wheel, and brakes of the chair. At 11:15, Employee B cleaned the floor in front of the machine, the machine, and areas of visible blood on the attached side table, except for the chair. The patient had not yet vacated the station. At 11:45 the visible blood on the chair remained. Then the patient and chair were wheeled from the station toward the nurses station, approximately 4 feet away from its original location.</p> <p>A. At 12:00, the visible blood remained on the floor and chair. Employee K assisted the patient, whose access stopped bleeding and was being discharged. The employee cleaned the floor and the chair with 1:100 bleach solution.</p> <p>B. At 12:15, the nurse manager stated, "I wanted to make sure it was done correctly. The nurse knows it is our policy to use 1:10 solution that the staff mixes every day."</p> <p>C. Facility Policy titled "Cleaning and Disinfection", document number FMS-CS-IC-II-155-110A, dated 20 -MAR-2013, states, "... Clean and disinfect any surfaces contaminated with blood or OPIM immediately or as soon as feasible... ."</p>		<p>FMS-CS-IC-II-155-110C3: Procedure: Work Surface Cleaning and Disinfection with Visible Blood &gt; than 10 mls and OPIM using Bleach Solutions, with special attention to: o Procedure: § Use a cloth wetted with 1:10 bleach solution to clean the surface § Clean up all visible blood. Discard used clothe and gloves in appropriate waste container. Perform hand hygiene and don new gloves. § After cleaning up all visible blood, using a new cloth wetted with 1:100 bleach solution for a second cleaning of the surface. Make the surface glisteningly wet and let air dry unless otherwise specified by the manufacturer. § Discard the cloth and gloves in the appropriate waste container. Perform hand hygiene. The meeting agenda and attendance records will be available at the facility for review. The Clinical Manager and or designee will perform infection control audits daily for 2 weeks, and then weekly for 2 weeks, then monthly until compliance is achieved and condition is lifted. The Clinical Manager will immediately address identified issues and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee</p>	

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V000143	<p>D. Facility Procedure titled "Work Surface Cleaning and Disinfection with Visible Blood &gt;10 mLs [milliliters] and OPIM using Bleach Solutions," FMS-CS-IC-II-155-110C3, dated 04 -JAN-2012, states, " ... Use a cloth wetted with 1:10 bleach solution to clean the surface. Clean up all visible blood. Discard used cloth and gloves in an appropriate waste container. Perform hand hygiene and don new gloves. After cleaning up all visible blood use a new cloth wetted with 1:100 bleach solution for a second cleaning of the surface ... ."</p> <p>494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and</p> <p>Based on observation and review of policy, the facility failed to ensure staff wiped the rubberized port before withdrawing medication in 1 out of 4 Post dialysis procedures involving aseptic technique creating the potential to affect all 94 Incenter hemodialysis. (Employee C)</p> <p>Findings:</p>	V000143	<p>investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure that the facility disinfects surfaces and equipment per CDC guidelines and facility policy.</p> <p>Immediately on 08/26/14 the Clinical Manager and Education Coordinator retrained all direct patient care staff on policy and procedure related to disinfecting medication port. On 09/10/14 the Director of Operations reviewed with the Clinical Manager and by 09/17/14 the Clinical Manager will train all Registered Nurse (RN) and Patient Care Technician (PCT) staff on: · FMS-CS-IC-120-040-A: Medication Preparation and</p>	09/17/2014			

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	<p>1. On August 25, 2014, at 11:20, Employee C was observed to withdraw saline using a syringe from a saline bag from the self-sealing rubberized port without first wiping with alcohol or disinfecting.</p> <p>2. FMS-CS-IC-I-120-040A policy titled "Medication Preparation and Administration" dated 30-DEC-2013 states, "... The following steps must be taken to ensure infection control ... Disinfect IV ports prior to accessing, using friction and 70% alcohol, iodophor or chlorhexidine/alcohol agent. Allow to dry prior to accessing ... ."</p>		<p>Administration with special attention to:</p> <ul style="list-style-type: none"> <li>o Infection Control: <ul style="list-style-type: none"> <li>· Disinfect IV port prior to accessing, using friction and 70% alcohol, iodophor or chlorhexidine/alcohol agent. Allow to dry prior to accessing.</li> <li>· Cleanse the diaphragm of a vial prior to accessing the vial. If the vial is a multidose vial, cleanse the diaphragm with alcohol each time the vial is accessed with a needle, using friction and 70% alcohol. Allow to dry before inserting a device into the vial.</li> </ul> </li> </ul> <p>The meeting agenda and attendance records will be available at the facility for review. The Clinical Manager and or designee will perform infection control audits daily for 2 weeks, and then weekly for 2 weeks, then monthly until compliance is achieved and condition is lifted. The Clinical Manager will immediately address identified issues and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure staff wipe rubberized port before</p>	

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V000543	<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; Based on policy and record review and interview, the facility failed to monitor and provide an assessment to monitor the patient's volume status in 3 of 12 charts reviewed. (#3, 5, 12)</p> <p>Findings.</p> <p>1. The dialysis treatment record dated 8-23-14 for patient #3 failed to evidence there was a pre, intradialytic, or post dialysis registered nurse (RN) assessment. The blood pressure documented was 91/62 pretreatment at 06:37 AM.</p> <p>2. The dialysis treatment record dated 8-11-14 for patient #5 evidenced the patient care technician changed monitoring of blood pressure to every 15 minutes for hypotension and blood pressures were documented 88/50, 76/38, 92/47, and 105/52. There was a RN assessment post dialysis that did not include information about patient's volume status. The RN did not address</p>	V000543	<p>withdrawing medication.</p> <p>On 09/10/14 the Director of Operations reviewed with the Clinical Manager and by 09/17/14 the Clinical Manager will train all Registered Nurse (RN) and Patient Care Technician (PCT) staff on:</p> <ul style="list-style-type: none"> <li>- FMS-CS-IC-I-110-131A: Patient Evaluation Pre Dialysis Treatment <ul style="list-style-type: none"> <li>o Policy: <ul style="list-style-type: none"> <li>§ All direct care patient care staff (licensed or unlicensed) may obtain pretreatment data for patient evaluation</li> <li>§ If the PCT/LPN notes any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the patient care technician MUST report the changes in the patient condition to a registered nurse who will further assess the patient prior to initiation of the treatment.</li> <li>§ Guidelines for Nursing Assessment: <ul style="list-style-type: none"> <li>o Patient assessment is a nursing responsibility and cannot be delegated to unlicensed staff. Nurses assess the patient</li> </ul> </li> </ul> </li> </ul> </li> </ul>	09/17/2014

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	<p>the post dialysis blood pressure which was 97/41.</p> <p>3. The dialysis treatment record dated 8-7-14 for patient #12 failed to evidence a RN assessment pre, intradialytic, or post dialysis. The patient dialyzed for 3:45 hours starting at 11:47 AM.</p> <p>4. Facility policy and procedure FMS-CS-IC-1-110-131A revision dated 04-JUL-2012 states, "... All direct patient care staff (licensed and unlicensed) may obtain pretreatment data for patient evaluation ... If the PCT/LPN notes any changes or abnormal finding in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the patient care technician MUST report the changes in the patients condition to a registered nurse who will further assess the patient prior to initiation of treatment ..."</p> <p>5. The policy titled "Patient Evaluation PreDialysis Treatment" document number FMS-CS-IC-1-110-131C dated 04-JUL-2012 states, "... Patient assessment is a nursing responsibility and can not be delegated to unlicensed patient care staff. Nurses assess the patient pretreatment as warranted by the patient's condition ..."</p>		<p>pretreatment as warranted by the patient's condition.</p> <ul style="list-style-type: none"> <li>· FMS-CS-IC-I-110-133A Monitoring During Patient Treatment policy with special emphasis on <ul style="list-style-type: none"> <li>o Unusual observations, findings and the inability to reach prescribed orders must be promptly reported to the nurse</li> </ul> </li> <li>· FMS-CS-IC-I-110-132C Patient Evaluation Post Dialysis Treatment Procedure with special emphasis on: <ul style="list-style-type: none"> <li>o Data Collection: Blood pressure <ul style="list-style-type: none"> <li>§ Orthostatic hypotension is well recognized as a risk factor for falls, syncope and cardiovascular events. All ambulatory patients should be evaluated for orthostatic hypotension post treatment.</li> <li>o Guidelines for nursing assessment post treatment: <ul style="list-style-type: none"> <li>§ Patient assessment is a nursing responsibility and cannot be delegated to unlicensed patient care staff. Nurses assess the patient post treatment as warranted by the patient's condition.</li> </ul> </li> </ul> </li> </ul> <p>The meeting agenda and attendance records will be available at the facility for review. The Clinical Manager and or designee will perform treatment flowsheet audits daily for 2 weeks, and then weekly for 2 weeks, and then monthly</p> </li></ul>	

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V000638	<p>6. Policy document number FMS-CS-IC-1-110-132C dated 04-JUL-2012 titled "Patient Evaluation Post Dialysis Treatment" states, "Orthostatic hypotension is well recognized as a risk factor for falls, syncope, and cardiovascular events. All ambulatory patients should be evaluated for orthostatic hypotension post treatment ... Patient assessment is a nursing responsibility and cannot be delegated to unlicensed patient care staff. Nurses assess the patient post treatment as warranted by the patient condition ..."</p> <p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Based on clinical record and document review and interview, the facility failed to ensure trending, analysis of root causes, evaluation of plan, or revision of the performance improvement plan was completed in 6 months of quality assessment performance improvement documents in 1 out of 3 focus areas with the potential to affect all 124 facility patients.</p>	V000638	<p>according to the QAI Workflow Calendar until compliance is achieved. The Clinical Manager will immediately address identified issues and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure assessment to monitor the patient's volume status.</p> <p>As a result of the citations from the 08/27/14 survey and, as is the commitment of the Governing Body to ensure that it's Quality Assessment Improvement (QAI) program provides complete data collection, analysis, trending and documentation, the following actions have occurred: ·On 09/12/14, the Regional Quality Manager met with the Clinical Manager to educate and</p>	09/17/2014

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	<p>Findings:</p> <p>1. Patient record #12 and hospital discharge analysis evidenced patient admission and discharge from the hospital with pneumonia from 3-11-14 to 3-14-14, 4-22-14 to 4-25-14, 6-10-14 to 6-13-14, and 7-17-14 to 7-22-14.</p> <p>2. On 3-28-14, the quality assessment and performance improvement (QAPI) documentation goal states, "Decrease hospitalization rate over 5% over the next 3 months." The action plan states, "RNs [registered nurses] to monitor and adjust EDW appropriately. RNs and access coordinator will work to decrease catheter rate."</p> <p>A. On 4-17-14, the QAPI documentation goal states, "Pts [patients] have been assigned to each RN, each RN is to monitor patients EDW, labs, and watch for trending."</p> <p>B. On 6-26-14, the QAPI documentation notes state, "No change in hospital days noted. Continue to monitor x 1 more month."</p> <p>C. On 7-28-14, the QAPI documentation notes state, "March Hospital days 13.2 June hospital days</p>		<p>reinforce the Clinical Manager's responsibility to monitor the trends and status of QAI action plans and follow through to resolution, verifying goals have been met or plan updated. As a result of this meeting, the Clinical Manager will implement, as part of the monthly QAI process, the following actions by 09/17/14:</p> <ul style="list-style-type: none"> <li>·The QAI hospitalization record updated to include more specific information related to hospital events with documented evaluation of possible trends</li> <li>·Monthly QAI meeting review of hospitalization events and trends and a review of actions taken to address dialysis related hospitalizations and trends</li> </ul> <p>Based on findings the QAI Committee will assess for an opportunity for improvement. If an opportunity for improvement is identified, the QAI Committee will initiate a formal action plan to be followed through to a resolution. The formal action plan will be revised monthly as necessary to achieve targets. QAI minutes document this activity and will be available for review at the facility. The Clinical Manager is responsible and the QAI Committee monitors to ensure that trending, analysis of root causes, evaluation of plan, or revision of the performance improvement plan is completed.</p>	

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V000639	<p>12.3. Improvement to continue."</p> <p>3. The facility Quality Assessment and Performance dashboard review of 6 months of data failed to evidence a revision of the hospitalization action plan.</p> <p>4. Review of the hospitalization record, four separate patients were admitted to the hospital with pneumonia in the last 6 months on 3-31-14, 4-25-14 to 5-11-14, 5-9-14 to 5-11-14, and 6-2-14 to 6-10-14.</p> <p>5 In an interview with the employee T on August 27, 2014, at 9:30 AM, QAPI documentation and hospital discharge analysis were reviewed. The nurse manager stated, "We missed a trend."</p> <p>494.110(c) QAPI-PRIORITIZING IMPROVEMENT ACTIVITIES The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety.</p> <p>Based on clinical record and document review and interview, the facility failed to incorporate or identify areas needing improvement in 1 out of 3 focus areas</p>	V000639	As a result of the citations from the 08/27/14 survey and, as is the commitment of the Governing Body to ensure that it's Quality Assessment Improvement (QAI) program provides complete data collection, analysis, trending and	09/17/2014

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	<p>with the potential to affect all 124 facility patients.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Patient record #12 and hospital discharge analysis evidenced patient admission and discharge from the hospital with pneumonia from 3-11-14 to 3-14-14, 4-22-14 to 4-25-14, 6-10-14 to 6-13-14, and 7-17-14 to 7-22-14.</li> <li>2. On 3-28-14, the quality assessment and performance improvement (QAPI) documentation goal states, "Decrease hospitalization rate over 5% over the next 3 months." The action plan states, "RNs [registered nurses] to monitor and adjust EDW appropriately. RNs and access coordinator will work to decrease catheter rate." <ul style="list-style-type: none"> <li>A. On 4-17-14, the QAPI documentation goal states, "Pts [patients] have been assigned to each RN, each RN is to monitor patients EDW, labs, and watch for trending."</li> <li>B. On 6-26-14, the QAPI documentation notes state, "No change in hospital days noted. Continue to monitor x 1 more month."</li> <li>C. On 7-28-14, the QAPI</li> </ul> </li> </ol>		<p>documentation, the following actions have occurred:</p> <ul style="list-style-type: none"> <li>·On 09/12/14, the Regional Quality Manager met with the Clinical Manager to educate and reinforce the Clinical Manager's responsibility to monitor the trends and status of QAI action plans and follow through to resolution, verifying goals have been met or plan updated. As a result of this meeting, the Clinical Manager will implement, as part of the monthly QAI process, the following actions by 09/17/14: <ul style="list-style-type: none"> <li>·The QAI hospitalization record updated to include more specific information related to hospital events with documented evaluation of possible trends</li> <li>·Monthly QAI meeting review of hospitalization events and trends and a review of actions taken to address dialysis related hospitalizations and trends</li> </ul> </li> </ul> <p>Based on findings the QAI Committee will assess for an opportunity for improvement. If an opportunity for improvement is identified, the QAI Committee will initiate a formal action plan to be followed through to a resolution. The formal action plan will be revised monthly as necessary to achieve targets. QAI minutes document this activity and will be available for review at the facility. The Clinical Manager is responsible and the QAI Committee monitors to ensure that trending, analysis of root</p>	

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V000715	<p>documentation notes state, "March Hospital days 13.2 June hospital days 12.3. Improvement to continue."</p> <p>3. The facility Quality Assessment and Performance dashboard review of 6 months of data failed to evidence a revision of the hospitalization action plan.</p> <p>4. Review of the hospitalization record, four separate patients were admitted to the hospital with pneumonia in the last 6 months on 3-31-14, 4-25-14 to 5-11-14, 5-9-14 to 5-11-14, and 6-2-14 to 6-10-14.</p> <p>5 In an interview with the employee T on August 27, 2014, at 9:30 AM, QAPI documentation and hospital discharge analysis were reviewed. The nurse manager stated, "We missed a trend."</p> <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&amp;P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on clinical record and facility policy review and interview, the medical director failed to ensure all personnel had followed facility policy for monitoring</p>	V000715	<p>causes, evaluation of plan, or revision of the performance improvement plan is completed.</p> <p>The Medical Director of the facility takes seriously his responsibility to ensure all policy and procedures related to patient care are adhered to. Immediately upon</p>	09/17/2014

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	<p>blood pressures in 6 out of 11 records reviewed creating the potential to affect all of the facility's 95 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>Policy FMS-CS-IC-I-110-133A Issued 04-JUL-2012 titled "Patient Monitoring During Treatment" states, "... Vital signs will be monitored at the initiation of dialysis and with every 30 minutes, or more frequently, as needed ..."</li> <li>Treatment record number 3 included 2 of 6 hemodialysis treatment flow sheets that failed to evidence the facility staff had checked the patient at least every 30 minutes. <ul style="list-style-type: none"> <li>A. The treatment flowsheet dated 8-21-14 evidenced the facility staff had checked the patient at 10:01 AM and not again until 10:57 AM, a period of 56 minutes between treatment checks.</li> <li>B. The treatment flowsheet dated 8-12-14 evidenced the facility staff had checked the patient 07:17 AM and not again until 08:20 AM, a period of 1 hour and 3 minutes.</li> </ul> </li> <li>Treatment record number 4 included 2 out of 6 hemodialysis flowsheets that</li> </ol>		<p>receiving the SOD the Clinical Manager reviewed the deficiencies with the Medical Director.</p> <p>On 09/10/14 the Director of Operations reviewed with the Clinical Manager and by 09/17/14 the Clinical Manager will train all Registered Nurse (RN) and Patient Care Technician (PCT) staff on:</p> <ul style="list-style-type: none"> <li>· FMS-CS-IC-I110-133A Patient Monitoring During Patient Treatment <ul style="list-style-type: none"> <li>o Monitoring the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary</li> <li>o Notify the physician as determined by the clinical judgment of the charge nurse leader.</li> </ul> </li> </ul> <p>The meeting agenda and attendance records will be available at the facility for review. The Clinical Manager and or designee will perform treatment flowsheet audits daily for 2 weeks, and then weekly for 2 weeks, and then monthly according to the QAI Workflow Calendar until compliance is achieved. The Clinical Manager will immediately address identified issues and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements,</p>	

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NAME OF PROVIDER OR SUPPLIER  MERRILLVILLE DIALYSIS CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 8670 BROADWAY MERRILLVILLE, IN 46410
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	<p>failed to evidence the facility had checked the patient every 30 minutes.</p> <p>A. The treatment flowsheet dated 8-13-14 evidenced the facility staff checked the patient at 09:32 AM and not again until 10:33 AM, a period of 1 hour and 1 minute.]</p> <p>B. The treatment flowsheet dated 8-13-14, evidenced the facility staff checked the patient at 10:33 AM and not again until 11:13 AM, a period of 45 minutes.</p> <p>4. Treatment record number number 5 included 2 out of 6 hemodialysis flowsheets that failed to evidence the facility had checked the patient every 30 minutes.</p> <p>A. The treatment flowsheet dated 8-22-14 evidenced the facility staff checked the patient at 12:57 PM and then not again until 1:56 PM, a period of 59 minutes.</p> <p>B. The treatment flowsheet dated 8-13-14 evidenced the facility staff checked the patient at 12:43 PM and then not again until 1:26 PM, a period of 43 minutes.</p> <p>5. Treatment record number 7 included 3</p>		<p>and tracks a corrective action plan through to resolution of the issue at hand. The Medical Director as Chairperson of the QAI Committee oversees QAI activities. The Clinical Manager is responsible and the QAI Committee inclusive of the medical director monitors to ensure all personnel follow facility policy for monitoring blood pressures.</p>	

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	<p>out of 6 hemodialysis flowsheets that failed to evidence the facility had checked the patient every 30 minutes.</p> <p>A. The treatment flowsheet dated 8-18-14 evidenced the facility staff checked the patient at 8:47 AM and then not again until 9:46 AM, a period of 59 minutes.</p> <p>B. The treatment flowsheet dated 8-4-14 evidenced the facility staff checked the patient at 06:16 AM then not again until 7:15 AM, a period of 59 minutes.</p> <p>C. The treatment flowsheet dated 8-4-14 evidenced the facility staff checked the patient at 08:44 AM and then not again until 9:43 AM, a period of 59 minutes.</p> <p>6. Treatment record number 8 included 4 out of 6 hemodialysis flowsheets that failed to evidence the facility had checked the patient every 30 minutes.</p> <p>A. The treatment flowsheet dated 8-22-14 evidenced the facility had checked the patient at 6:45 AM and then not again until 8:13 AM, a period of 1 hour and 28 minutes.</p> <p>B. The treatment flowsheet dated 8-18-14 evidenced the facility had checked the patient at 09:21 AM and then not</p>			

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	<p>again until 10:22 AM, a period of 1 hour and 1 minute.</p> <p>C. The treatment flowsheet dated 8-13-14 evidenced the facility had checked the patient at 07:19 AM then at 09:13 AM, a period of 2 hours and 4 minutes.</p> <p>D. The treatment flowsheet dated 8-4-14 evidenced the facility had checked the patient at 09:09 AM then at 10:12 AM, a period of 1 hour and 3 minutes.</p> <p>7. Treatment record number 10 included 6 out 6 hemodialysis flowsheets that failed to evidence the facility had checked the patient every 30 minutes.</p> <p>A. The treatment flowsheet dated 8-18-14 evidenced the facility had checked the patient at 1:53 PM then at 2:45 PM, a period of 52 minutes.</p> <p>B. The treatment flowsheet dated 8-11-14 evidenced the facility had checked the patient at 11:42 AM then at 12:33 PM, a period of 51 minute</p> <p>C. The treatment flowsheet dated 8-13-14 evidenced the facility had checked the patient at 3:07 PM then at 4:07 PM, a period of 1 hour.</p> <p>D. The treatment flowsheet dated 8-8</p>			

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V000765	<p>-14 evidenced the facility had checked the patient at 12:11 PM then at 1:32 PM, a period of 1 hour and 20 minutes.</p> <p>E. The treatment flowsheet dated 8-6 -14 evidenced the facility had checked the patient at 2:32 PM then at 4:04 PM, a period of 1 hour 36 minutes.</p> <p>F. The treatment flowsheet dated 8-4 -14 evidenced the facility had checked the patient at 2:46 PM then at 4:03 PM, a period of 1 hour, 19 minutes.</p> <p>494.180(e) GOV-INTERNAL GRIEVANCE SYS ID/IMPLEMENTED The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services.</p> <p>The grievance process must include-</p> <p>(1) A clearly explained procedure for the submission of grievances. (2) Timeframes for reviewing the grievance. (3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.</p> <p>Based on the Grievance Log review and interview, the facility failed to fully</p>	V000765	On 09/10/14 The Director of Operations reviewed with the Clinical Manager the facility	09/17/2014			

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	<p>implement the internal grievance process creating the potential to affect the facility's 124 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>Notes from the facility's Patient Grievance Log dated 02/20/14 to 8/11/14 failed to evidence an entry complaint involving Patient # 10.</li> <li>In an interview with the Nurse Manager, employee T, on 8/25/14 at 1330 Central standard time, the nurse manager indicated some concerns had been addressed with Patient #10. The nurse manager indicated this patient's concern was investigated and the patient's family member verbalized understanding, but it was not recorded with a mutually acceptable resolution or the result documented.</li> </ol>		<p>grievance process with special attention to:</p> <ul style="list-style-type: none"> <li>FMS –CS-IC-I-103-006A Patient Grievance Policy: <ul style="list-style-type: none"> <li>Review the patient grievance report daily</li> <li>Meet with the patient /representative within 5 days to discuss the grievance, resolve it as quickly as possible, and provide periodic updates to the patient</li> <li>Document actions taken on the patient grievance report and report this information to the QAI committee</li> </ul> </li> </ul> <p>The Clinical Manager will address and document grievances and resolution and review grievance log at QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure the facility fully implements the internal grievance process, including documenting a mutually acceptable resolution.</p>		