

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152595	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 06/11/2015
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NAME OF PROVIDER OR SUPPLIER DUNELAND DIALYSIS-COFFEE CREEK	STREET ADDRESS, CITY, STATE, ZIP CODE 3100 VILLAGE POINT STE 101 CHESTERTON, IN 46304
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V 0000 Bldg. 00	<p>This visit was for an ESRD federal recertification survey and for the addition of two training rooms for the home hemodialysis department.</p> <p>Survey dates: June 5, 8, 9, 10, and 11, 2015</p> <p>Facility #: 011217</p> <p>Medicaid Vendor: #200834980</p> <p>Number of In-Center Hemodialysis Patients: 43 Number of Home Hemodialysis Patients: 15 Number of Peritoneal Dialysis Patients: 25</p> <p>This survey included an on-site visit to Wesley Healthcare, a skilled nursing facility in Auburn, contracted with Duneland Dialysis Coffee Creek, to provide dialysis to patients. On-site visit date: 6/9/15</p> <p>QR: JE 6/15/15</p>	V 0000		

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

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V 0111 Bldg. 00	<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. Based on observation, policy review, and interview, the skilled nursing facility (SNF) contracted to provide home dialysis to patients failed to ensure all equipment and medications used for dialysis care were not expired, for 1 of 1 SNF.</p> <p>Findings include</p> <p>1. During observation at the SNF on 6/9/15 at 9:40 AM, the dialysis office/supply room medication cart was observed and found to have expired supplies.</p> <p>A. The medication cart contained 5 bottles of Sodium Citrate 4%. The label stated "B.U.D. (best used date), 11/24/14."</p> <p>B. The supply cart contained 1 urinalysis cup kit with an expiration date of 11/2014.</p> <p>C. The supply closet contained 99 yellow top BD Vacutainer Urinalysis Plus Conical Urine tubes with expiration</p>	V 0111	<p>The Clinic Manager or designee will in-service all staff by 7/11/15 on the following Policy & Procedures: HHD.097 Control & Storage of Medications on the Dialysis Unit & Infection Control. The in-service will include but not be limited to the following: All Medication & supply inventory must be checked monthly & checked for expired (outdated) medications & supplies, expired or outdated medications &/or supplies must be removed from stock & Nurse Manager notified; a schedule will be established & followed to rotate stock to insure that expiration dates are monitored.</p> <p>The expired medications and lab tubes were disposed of per policy by 6/11/15. The monthly medication count sheets were updated to include a column for expiration dates. This form will be submitted monthly to both the Area Technical Manager and the Home Training manager for review. In addition the Area Technical Manager or designee will complete a physical audit weekly X 2 weeks or until 100% compliance is achieved & then monthly per policy. All education &</p>	07/11/2015

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	<p>dates of 01/2015.</p> <p>D. The supply closet contained 95 red top BD Vacutainer Serum Plus Blood Collection tubes with expiration dates of 01/2015.</p> <p>E. The supply closet contained 100 red/black top BD Vacutainer SST Plus Blood Collection tubes with expiration dates of 10/2014.</p> <p>F. The supply closet contained 100 blue top BD Vacutainer Trace Element Serum Plus Blood Collection tubes with expiration dates of 11/2014.</p> <p>2. During interview on 6/9/15 at 9:45 AM, employee R, the registered nurse, indicated the SNF did have a patient who used the Sodium Citrate, but that patient was no longer at the facility.</p> <p>3. The dialysis facility's policy titled "Control and Storage of Medications on the Dialysis Unit," # HHD.097, dated 7/1/13, states, "5. Medication inventory is to be checked monthly. Assess for: ... b. Expired (outdated). ... 6. Remove from stock unused or deteriorated medication and notify the Nurse Manager. 7. Return unused medication to appropriate vendor or manufacturer (if applicable). Pour expired medications, or</p>		<p>the results of these audits will be reviewed in the monthly QAPI Meetings.</p>	

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V 0113 Bldg. 00	<p>those with broken seals, down toilet and discard glass single dose/multi-dose vials and ampoules in the sharps container."</p> <p>4. The facility's policy titled "Infection Control," no number, dated 7/1/13, states, "Environmental Practices: 1. Physical environment: a. Designated areas for supplies ... iv. Sterile supplies will be stored in a clean, cool, dry area without sunlight. A schedule will be established to rotate stock and insure that outdates are monitored."</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, policy review, and interview, the facility failed to follow the policies related to glove use in 1 of 1 observation with a transport of lab tubes to the lab supply area.</p> <p>Findings:</p> <p>1. On 6/9/15 at 12:50 PM, Employee H, Registered Nurse, was observed to transport two lab tubes with blood collected from patient #12 from station</p>	V 0113	<p>The Clinic Manager or designee will in-service all staff including Employee H, RN & Employee R, RN by 7/11/15 on the following Policy & Procedures: Personal Protective Equipment, HHD0.79 Vascular Access Cleansing Technique for Fistula, Graft and Central Venous Catheter (CVC) Dressing Change & Infection Control; 800-01: Dialysis Infection Control Precautions. The in-service will include but not be limited to the following: gloves must be worn when anticipating contact</p>	07/11/2015

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	<p>#21 to the lab area in the incenter hemodialysis clinic. Employee H picked up the lab tubes without gloved hands and carried these tubes without gloves to the lab area.</p> <p>2. On 6/9/15 at 12:50 PM, Employee B, facility administrator and clinic manager, indicated the nurse was not to transport the lab specimens with her bare hands.</p> <p>3. A policy titled "Personal Protective Equipment" with a review date of 8/23/15 stated, "Gloves protect the hands from exposure to blood or body fluids ... worn when anticipating contact with blood or other potentially infectious materials ... or when handling items that have or could come in contact with these things."</p>		<p>with blood or other potentially infectious materials or when handling items that have or could have come in contact with blood or other potentially infectious materials & when transporting lab tubes with collected blood to the lab area. Gloves must be removed & discarded after removing old dressings, hand hygiene performed & don clean gloves & gloves must be changed when moving from a 'dirty' area to a 'clean' area that are either environmental or body sites.</p> <p>The Clinic Manager or designee will perform Infection Control- Staff audits daily times two weeks or until 100% compliance is achieved, then weekly times two and then monthly as per the Quality Management (QM Workbook) audit schedule.</p> <p>Any staff found not to be in compliance with policy and procedure will be subject to progressive disciplinary action. The Clinic Manager will review education, disciplinary action and audit results in monthly QAPI and LGB meetings.</p> <p>The Home Training Manager will institute a new policy for Central Venous Care dressing changes for Nx Stage patients and will implement a new checklist to ensure all NxStage patients, caregivers, and staff involved in their care, are trained on catheter care procedures according</p>	

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	<p>Based on observation, policy review, and interview, the skilled nursing facility (SNF), contracted to provide dialysis to patients, failed to ensure dialysis trained staff followed infection control policies and procedures, for 1 of 1 SNF.</p> <p>Findings include</p> <p>1. On 6/9/15 at 10:00 AM, employee R, the registered nurse, was observed providing Central Venous Catheter (CVC) exit site care and initiation of dialysis for patient #9 at the SNF. Employee R failed to follow infection control policies and procedures.</p> <p>A. Employee R placed mask on patient, checked patient's temperature, removed her gloves, then removed thermometer and placed on supply cart. Employee R then donned new gloves. Employee R failed to wash hands or use hand sanitizer in between glove changes.</p> <p>B. During CVC exit site care, employee R removed the old dressing, cleansed the site, then applied the new dressing to the CVC site. Employee R failed to wash hands or use hand sanitizer</p>		<p>to policy. These will be implemented by July 11, 2015. Home Training Manager will visualize the employee working at Wesley Health Care performing catheter dressing change at the July 2015 visit. The Home Training Manager or designee will perform competency audits at Wesley Health Care to ensure proper technique is used weekly X 2 or until 100% compliance is achieved, monthly X 2, quarterly X 2 and then per the QM Workbook Infection Control Staff Audit. The Clinic Manager will review education, and audit results in monthly QAPI and LGB meetings.</p>	

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	<p>after removing old dressing and prior to placing clean dressing to CVC site.</p> <p>2. During interview on 6/9/15 at 2:00 PM, employee R indicated they did not change gloves after removing the old dressing and prior to placing clean dressing because the gloves were not dirty.</p> <p>3. The facility's policy titled "Vascular Access Cleansing Technique for Fistula, Graft, and Central Venous Catheter (CVC) Dressing Change," # HHD.079, dated 7/1/13, states "Procedure for Central Venous Catheter Dressing Change: ... 6. Remove and discard dressings and tape on and around catheter and its site. ... 8. Remove and discard gloves. Wash hands and don sterile gloves."</p> <p>4. The facility's policy titled "Infection Control," no number, dated 7/1/13, states "Personnel: ... 3. Attire: ... vi. Gloves should be changed when moving from a "dirty" area to a "clean" area either environmental or body sites. vii. A new pair of clean gloves will be used with each procedure involving access site care, vascular access cannulation, administration of parenteral medications or to perform invasive procedures. ... viii. It may be necessary to change</p>			

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V 0143 Bldg. 00	<p>gloves multiple times when caring for one patient."</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, interview, and review of policy, the facility failed to ensure medications were labeled with the date and time of opening and the initials of who had opened the medication and that medications were not expired for 1 of 1 facility with the potential to affect all the patients of the facility.</p> <p>Findings</p> <p>Regarding a Medication not labeled with date and time of opening</p> <p>1. On 6/5/15 at 10:10 AM, a multi - dose vial of epogen was observed at the medication preparation station in the incenter hemodialysis room opened and not labeled with the time and date the medication had been opened.</p> <p>2. On 6/5/15 at 10:10 AM, Employee C, Registered Nurse, indicated the vial was not labeled when it was opened.</p>	V 0143	<p>The Clinic Manager or designee in-serviced all staff including the home department staff on 6/6/15 regarding the following Policy & Procedure: Epogen Administration & Dosing Guidelines & Administration of Medications. The in-service will include but not be limited to the following: Multi-dose vials of Epogen expire 21 days after opening & must be labeled upon opening to document the time of first entry & expired medications must be discarded and inventory adjusted on a monthly basis.</p> <p>The Clinic Manager will instruct all employees by 7/11/15 to begin highlighting the expiration column on the monthly medication count sheet when medications are within 90 days of expiration so that careful attention will be paid to disposing of the medication before expiration.</p> <p>The Nurse Manager of Home Training Department or designee will conduct weekly audits X 2 or</p>	07/11/2015

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	<p>3. The policy titled "Epogen Administration and Dosing Guidelines" with a review date of 10/14/13 stated, "Once opened, multi - dose vials of Epogen expire at 21 days. Vials must be labeled to document the time of first entry."</p> <p>Regarding an expired medication in the home peritoneal department</p> <p>4. On June 5, 2015, at 10:35 AM, a medication cabinet in the peritoneal dialysis department in patient room #2 was observed to hold an expired tube of opened Gentamycin sulfate cream. The medication had been marked as opened on 10/16/13. The expiration date on the tube was 5/15.</p> <p>5. On June 5, 2015, at 10:35 AM, Employee I, Home Department Manager, indicated the cream was expired and needed to be discarded.</p> <p>6. The policy titled "Administration of Medications" with a date of 5/1/15 stated, "Expired medications will be discarded and inventory adjusted on a monthly basis."</p>		<p>until 100% compliance is achieved & then monthly as per policy during monthly inventory procedure.</p> <p>Any staff found not to be in compliance with policy and procedure will be subject to progressive disciplinary action. The Clinic Manager will review education, disciplinary action and audit results in monthly QAPI and LGB meetings.</p>	

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V 0541 Bldg. 00	<p>494.90 POC-GOALS=COMMUNITY-BASED STANDARDS The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care were individualized to address the patients needs in 1 of 2 clinical records (#10) reviewed of a home hemodialysis patient in a long term care facility.</p> <p>The findings include</p> <p>1. Clinical record number 10 included a "Patient Plan of Care" established by the interdisciplinary team on 2/27/15. The plan of care stated, "Active access site</p>	V 0541	<p>The Director of Operations or designee will in-service IDT team including Home Department Manager, Employee I and Registered Nurse by 7/11/15 on the following Policy & Procedure: Quality Control Program. The in-service will include but not be limited to the following: The plan of care must be developed to follow the progression of each patient, be individualized & to determine what needs are to be met with input from all healthcare providers; the patient's plan of care must include measurable &</p>	07/11/2015

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	<p>created 10/31/14 ... description internal jugular catheter ... current status currently used ... Goals ... achieve adequate vascular access [graft / fistula or perm access]. Patient specific goal ... 4/27/15 ... suggest referral to vascular surgeon."</p> <p>Clinical record number 10 included a "Patient Plan of Care" established by the interdisciplinary team on 3/30/14. The plan of care stated, "Active access sites created on 10/31/14 ... description internal jugular catheter current status currently used ... Goals ... achieve adequate vascular access [graft / fistula or perm access]. Patient specific goal ... 6/15/15."</p> <p>2. On 6/10/15 at 1:35 PM, Employee I, Home Department Manager and Registered Nurse, indicated the patient's plan of care was not individualized. Due to this patient's condition and frequent hospitalizations, a new vascular access site had not been planned and was not achievable at this time. No referral had occurred.</p> <p>3. The policy titled "Quality Control Program" with a date of 1/1/12 stated, "A plan of care is developed to follow the progression of patients, and to determine what needs are to be met, with input from all healthcare providers ... A patient's</p>		<p>expected outcomes.</p> <p>The Home Training Manager has updated the Plan of Care, for clinical record #10, to address the rationale for the patient not being scheduled for surgery to create a permanent access. The Home Training Nurse Manager and another designated IDT member will audit monthly for 12 months the Plans of Care for Home Training patients to ensure that all patients have assessment and documentation for permanent access placement or rationale for not proceeding with permanent access placement. All education & audit results will be reviewed at the Monthly QAPI meetings.</p>	

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V 0544 Bldg. 00	<p>plan of care must include measurable and expected outcomes ... b. estimated timetables to meet medical / psychosocial needs</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. Based on clinical record review and interview, the facility failed to ensure the blood flow rate on the prescription was followed for 1 of 5 incenter hemodialysis records (#1) reviewed.</p> <p>Findings</p> <p>1. Clinical record #1 included hemodialysis orders that identified the blood flow rate (BFR) was to be 350 milliliters per minute.</p> <p>The flow sheet dated 5/12/15 evidenced BFRs of 200, 203, and 250 during the treatment with no explanation as to why the BFR was not followed.</p>	V 0544	<p>The Clinic Manager or designee will in-service all staff by 7/11/15 on the following Policy & Procedure: Preparing & Operating the Fresenius 2008K Medisystems Streamline Airless System with Locksite Access Sites. The in-service will include but not be limited to the following: Staff must verify that all settings are entered as ordered & if not, documentation must be present as to why settings are not as per orders including physician notification if indicated.</p> <p>The Clinic Manager or designee will audit 25% of patient flowsheets which includes patient #1 daily x 2 weeks or until 100% compliance is achieved, monthly x 2 and then bimonthly as per the Quality</p>	07/11/2015

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V 0754 Bldg. 00	<p>2. On 6/10/15 at 12:45 PM, the facility administrator indicated this may have been an access day and documentation was being looked for.</p> <p>3. The policy with a review date of "Preparing and operating the Fresenius 2008K Utilizing Medisystems Streamline Airless System with Locksite Access sites" with a date of 4/10/15 stated, "Verify the machine and dialyzer are safe for operation and that all settings are entered as ordered ... if no problems notes, slowly increase the blood flow to the prescribed rate."</p> <p>494.180(a)(2) GOV-ADM RESP FOR FISCAL OPERATIONS The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to- (2) Fiscal operations;</p> <p>Based on document review and interview, the governing body failed to ensure the affiliation agreement between</p>	V 0754	<p>Management Workbook Flowsheet audit schedule.</p> <p>Any staff found not to be in compliance with policy and procedure will subject to progressive disciplinary action. The Clinic Manager will review education, disciplinary action and audit results in monthly QAPI and LGB meetings.</p> <p>The Local Governing Body (LGB) reviewed the affiliation agreement at an LGB meeting on June 18, 2015. So long as the dialysis center</p>	06/18/2015

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152595	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 06/11/2015
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NAME OF PROVIDER OR SUPPLIER DUNELAND DIALYSIS-COFFEE CREEK	STREET ADDRESS, CITY, STATE, ZIP CODE 3100 VILLAGE POINT STE 101 CHESTERTON, IN 46304
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	<p>the dialysis facility and a skilled nursing facility with patients who were receiving home hemodialysis treatments had been reviewed since December 11, 2013.</p> <p>Findings</p> <p>1. The agreement with a title of "Affiliation Agreement" and date of December 11, 2013 stated, "This affiliation agreement is made and entered into this 11th day of December 2013, by and between [the name of the long term care facility] and Duneland Dialysis." This agreement evidenced the dialysis clinic was to offer home hemodialysis to patients and to train the nursing home staff to care for these patients.</p> <p>2. On 6/11/15 at 10:45 AM, the director of operations indicated the agreement was not to be continued upon the discharge of the current patients.</p> <p>3. A letter addressed to the skilled nursing facility [noted in finding #1] with a date of 11/3/14 and signature of the general counsel of the dialysis facility evidenced the dialysis facility intended to end the agreement when the patients were discharged and the dialysis facility was not accepting any new patients.</p>		<p>is providing Home Hemodialysis services to patients of Wesley Healthcare, the LGB will review the affiliation agreement on a quarterly basis to ensure that the parties' duties and responsibilities under that agreement are being met. In the event the dialysis center enters into future affiliation agreements with skilled nursing facilities with Home Hemodialysis patients, the LGB will review such agreements on a quarterly basis to ensure that the parties' duties and responsibilities are being met. The Nurse Managers of both the Home Training Department and In-Center Departments and the Director of Operations will monitor to ensure compliance with this policy.</p>	

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V 0770 Bldg. 00	<p>494.180(g)(3) GOV-TRANSFER AGREEMENT W/HOSP FOR INPT CARE (3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must: (i) Ensure that hospital services are available promptly to the dialysis facility ' s patients when needed. (ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.</p> <p>Based on document review and interview, the medical director failed to ensure the affiliation agreement between the dialysis facility and a skilled nursing facility included the hospital or hospitals to be used in event of a patient emergency during home hemodialysis treatment of home hemodialysis patients being dialyzed in a skilled nursing facility with patients admitted for home dialysis services.</p> <p>Findings</p> <p>1. The agreement with a title of "Affiliation Agreement" and date of December 11, 2013, stated, "Patient</p>	V 0770	<p>A policy will be implemented, by 6/26/15 to specify the emergency management guidelines for use by the employees of Wesley Healthcare, including the designation of a specific hospital to which home hemodialysis patients will be sent in the case of an emergency. The medical director will ensure that all future affiliation agreements between the dialysis center and skilled nursing facilities with home hemodialysis patients will specify the manner in which emergencies involving home hemodialysis patients will be managed, including the designation of a specific hospital to which such patients will be sent in the case of an emergency. The Medical Director, Director of Operations, and Nurse Manager will review all</p>	06/26/2015

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	<p>emergencies. In the event of a medical emergency involving a resident receiving home dialysis services as contemplated by this agreement, the SNF [skilled nursing facility] shall coordinate the transfer of such resident to a hospital or other appropriate health care provider." This agreement did not evidence which hospital the SNF would send the patient to in the event of an emergency.</p> <p>2. On 6/11/15 at 10:45 AM, the director of operations indicated the agreement did not include name of the hospital (s) that the patient would be transferred to in the event of an emergency.</p>		<p>future affiliation agreements with skilled nursing facilities with home hemodialysis patients to ensure compliance with this policy and minutes of LGB meeting will be completed for this review.</p>	