

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152620	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  04/03/2014
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NAME OF PROVIDER OR SUPPLIER  CARMEL DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 180 E CARMEL DR CARMEL, IN 46032
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V000000	This visit was an ESRD recertification survey.  Facility: #011591  Dates: March 31 and April 1, 2, and 3, 2014  Medicaid: # 200890530  Surveyors: Tonya Tucker, RN, PHNS Bridget Boston, RN, PHNS  Census: 22 19 In-center Hemodialysis 3 Peritoneal Dialysis  Carmel Dialysis was found out of compliance with the Condition for Coverage 42 CFR 494.110 Quality Assessment and Performance Improvement.	V000000		
V000115	Quality Review: Joyce Elder, MSN, BSN, RN April 10, 2014 494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.	V000115	Facility Administrator (FA) in-serviced all clinical teammates	04/19/2014

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>Based on observation, interview, and review of policy, the facility failed to ensure personal protective equipment (PPE) was utilized appropriately in 1 (employee A) of 3 patient care technicians (PCT) observed while performing patient care to a patient with a central venous catheter (CVC) for infection control procedures creating the potential to affect all of the facility's patients with a CVC.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>On 3/31/14 at 10:40 AM, employee A was observed to perform CVC exit site care and to initiate dialysis in station 9 with patient number 1. The employee was wearing a mask that covered only the bottom lip and half of the top lip. The employee failed to wear the mask so that the nose was covered throughout the exit site care and initiation of dialysis treatment.</li> <li>At 11:08 AM, employee A indicated he/she had not worn the mask appropriately and was not aware until after completing the initiation of dialysis treatment and removal of personal protective equipment.</li> <li>Facility policy with a revision date of March, 2014 titled "Central Venous Catheter (CVC) Procedure" states, "Materials required: ... PPE-personal protective equipment (face protection, including face mask, gloves, fluid resistant/fluid impervious barrier garment) ... Procedure ... 5. Patient and teammate will wear face masks covering the nose and mouth during catheter procedure. ... Rationale ... 5. These measures are vital to preventing the exposure of the catheter and exit site to nasal droplets and infectious bacteria such as methicillin resistant Staph aureus (MRSA) ... "</li> </ol>		<p>(TMs) on the proper use of Personal Protective Equipment (PPE), Policy &amp; Procedure #1-05-01 Infection Control for Dialysis Facilities, and Policy &amp; Procedure #1-04-12A Predialysis Central Venous Catheter (CVC) Care on 4/11/2014, emphasizing to protect themselves from any infectious material masks must be in place covering nose and mouth. Both patient and TM must wear face masks covering nose and mouth during CVC care. Attendance of in-service evidenced by TM signature on in-service form.</p> <p>FA or designee will conduct daily infection control audits daily x 1 month, then weekly x 1 month, then monthly if compliance is met. FA will review audits, and education monthly with Medical Director and Facility Health Team during Facility Health Meeting (FHM), minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction.</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 observation, review of policy, and interview the facility failed to ensure the staff followed standard infection control precautions in 3 of 3 observations of employee A, a patient care technician, while decontaminating the dialysis machine post treatment, with the potential to effect all 19 in-center dialysis patients.</p> <p>Findings include:</p> <p>Observation 1 on 3/31/14 from 10:20 AM through 2 PM:</p> <p>1. On 3/31/14, at 1:40 PM, Employee A was observed cleaning the machine at station 1. Employee A failed to decontaminate the prime bucket attached to the dialysis machine. He rinsed with tap water at the dirty sink only.</p> <p>2. At 12:40 PM, employee A was observed to rinse back the blood to patient 8 in station 12. A blood spill occurred and employee A was observed to place the open end of the tubing in the prime bucket which was attached at the side of the dialysis machine.</p>	V000122	<p>FA in-serviced all clinical TMs on proper disinfection of machines and surfaces including review of Policy &amp; Procedure #1-05-01 Infection Control for Dialysis Facilities on 4/11/2014. TM educated they must remove and disinfect prime container with appropriate bleach solution between patient treatments. Attendance of in-service evidenced by TM signature on in-service form.</p> <p>FA or designee will conduct daily infection control audits daily x 1 month, then weekly x 1 month, then monthly if compliance is met. FA will review audits, and education monthly with Medical Director and Facility Health Team during Facility Health Meeting (FHM), minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction.</p>	04/19/2014

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V000146	<p>The patient care technician concluded and the patient left the incenter floor. The employee proceeded to care for the patient in station 1. At 1:46 PM, he returned and decontaminated the dialysis machine and station. He failed to decontaminate the prime bucket which had held the tubing which contained blood products. He rinsed the prime bucket with tap water at the dirty sink and returned it to the dialysis machine, then walked away.</p> <p>Observation 2 on 4/2/14 from 1250 PM through 2 PM:</p> <p>3. Employee A was observed cleaning the machine at station 12 post treatment and failed to decontaminate the prime bucket attached to the dialysis machine. He rinsed with tap water at the dirty sink only.</p> <p>4. On 4/3/14 at 5 PM, the Clinical Manager indicated the machines are to be totally cleaned.</p> <p>5. The policy titled "Specified Control Methods" number 4-02-03 dated March 2012 stated, "Equipment including the dialysis delivery system, the interior and exterior of the prime container, ... will be wiped clean with a bleach solution of the appropriate strength after completion of procedures." 494.30(c)(2)</p> <p>IC-CATHETERS:GENERAL (2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality</p>						

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	<p>Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: <a href="http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html">http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html</a></p> <p>Based on observation, interview, and review of policy and procedure, the facility failed to ensure the patient care technician (PCT) provided central venous catheter care in accordance with facility policy in 2 (patient #1 and #9) of 2 observations of care of patients with a central venous catheter completed by a patient care technicians (employee A and D) creating the potential to affect all facility patients with a central venous catheter.</p> <p>Findings include:</p> <p>1. On 3/31/14 at 10:40 AM, employee A was observed to perform CVC exit site care in station 9 with patient number 1. The employee was wearing a mask that covered only the bottom lip and half of the top lip. The employee failed to wear the mask to cover the nose throughout the performance of exit site care.</p> <p>At 11:08 AM, employee A indicated he/she</p>	V000146	FA in-serviced all clinical TMs on the proper use of PPE, Policy & Procedure #1-05-01 Infection Control for Dialysis Facilities, and Policy & Procedure #1-04-12A Predialysis Central Venous Catheter (CVC) Care on 4/11/2014 emphasizing the necessity of keeping face mask over nose to prevent the spread of infections, and TMs must cleanse catheter lumen exiting the skin to the catheter hub and skin under lumen, use aseptic technique, clean exit site with germicidal moistened gauze starting at exit site and working outward in concentric circles, using fresh germicide moistened gauze starting at exit site cleanse entire length of catheter limbs. TMs must keep the field around the patient's exit site clean to prevent cross contamination of the field. Attendance of in-service evidenced by TM signature on	04/19/2014			

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V000147	<p>had not worn the mask appropriately and was not aware until after completing the initiation of dialysis treatment and removal of personal protective equipment.</p> <p>2. Facility policy with a revision date of March, 2014 titled "Central Venous Catheter (CVC) Procedure" states, "Materials required: ... PPE-personal protective equipment (face protection, including face mask, gloves, fluid resistant/fluid impervious barrier garment) ... Procedure ... 5. Patient and teammate will wear face masks covering the nose and mouth during catheter procedure. ... Rationale ... 5. These measures are vital to preventing the exposure of the catheter and exit site to nasal droplets and infectious bacteria such as methicillin resistant Staph aureus (MRSA) ... "</p> <p>3. On 3/31/14 at 10:55 AM, employee D, a patient care technician, was observed performing access site care with patient 9 in station 6. To cleanse the access site, the PCT used one swab to make small circular motions starting from the point nearest the access site, overlapping until the entire area surrounding the access was wiped with the one swab. The PCT then returned the tip of the swab to the CVC access itself and wiped the catheter with this same swab.</p> <p>On 4/3/14 at 5 PM, the facility administrator indicated the procedure described was not appropriate and the PCT's are to have another swab available in the event they contaminate or need to repeat the cleansing of the access site.</p> <p>494.30(a)(2) IC-STAFF</p>		<p>in-service form.</p> <p>FA or designee will conduct daily infection control audits daily x 1 month, then weekly x 1 month, then monthly if compliance is met. FA will review audits, and education monthly with Medical Director and Facility Health Team during FHM, minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction.</p>				

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	<p><b>EDUCATION-CATHETERS/CATHETER CARE</b> Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.</p> <p>II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>Based on observation, interview, and review of policy and procedure, the facility failed to ensure the patient care technician (PCT) provided central venous catheter care in accordance with facility policy in 2 (patient #1 and #9) of 2 observations of care of patients with a central venous catheter completed by</p>	V000147	FA in-serviced all clinical TMs on the proper use of PPE, Policy & Procedure #1-05-01 Infection Control for Dialysis Facilities, and Policy & Procedure #1-04-12A Predialysis Central Venous Catheter (CVC) Care on 4/11/2014 emphasizing the necessity of keeping face mask over nose to prevent the	04/19/2014			

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	<p>a patient care technicians (employee A and D) creating the potential to affect all facility patients with a central venous catheter.</p> <p>Findings include:</p> <p>1. On 3/31/14 at 10:40 AM, employee A was observed to perform CVC exit site care in station 9 with patient number 1. The employee was wearing a mask that covered only the bottom lip and half of the top lip. The employee failed to wear the mask to cover the nose throughout the performance of exit site care.</p> <p>At 11:08 AM, employee A indicated he/she had not worn the mask appropriately and was not aware until after completing the initiation of dialysis treatment and removal of personal protective equipment.</p> <p>2. Facility policy with a revision date of March, 2014 titled "Central Venous Catheter (CVC) Procedure" states, "Materials required: ... PPE-personal protective equipment (face protection, including face mask, gloves, fluid resistant/fluid impervious barrier garment) ... Procedure ... 5. Patient and teammate will wear face masks covering the nose and mouth during catheter procedure. ... Rationale ... 5. These measures are vital to preventing the exposure of the catheter and exit site to nasal droplets and infectious bacteria such as methicillin resistant Staph aureus (MRSA) ... "</p> <p>3. On 3/31/14 at 10:55 AM, employee D, a patient care technician, was observed performing access site care with patient 9 in station 6. To cleanse the access site, the</p>		<p>spread of infections, and TMs must cleanse catheter lumen exiting the skin to the catheter hub and skin under lumen, use aseptic technique, clean exit site with germicidal moistened gauze starting at exit site and working outward in concentric circles, using fresh germicide moistened gauze starting at exit site cleanse entire length of catheter limbs. TMs must keep the field around the patient's exit site clean to prevent cross contamination of the field. Attendance of in-service evidenced by TM signature on in-service form.</p> <p>FA or designee will conduct daily infection control audits daily x 1 month, then weekly x 1 month, then monthly if compliance is met. FA will review audits, and education monthly with Medical Director and Facility Health Team during FHM, minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction.</p>				

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V000516	<p>PCT used one swab to make small circular motions starting from the point nearest the access site, overlapping until the entire area surrounding the access was wiped with the one swab. The PCT then returned the tip of the swab to the CVC access itself and wiped the catheter with this same swab.</p> <p>On 4/3/14 at 5 PM, the facility administrator indicated the procedure described was not appropriate and the PCT's are to have another swab available in the event they contaminate or need to repeat the cleansing of the access site.</p> <p>494.80(b)(1) PA-FREQUENCY-INITIAL-30 DAYS/13 TX An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.</p> <p>Based on clinical record review, facility policy and procedure review, and interview, the facility failed to ensure an initial comprehensive assessment had been completed within 30 calendar days in 1 of 5 records reviewed creating the potential to affect all new admissions of the facility. (#4)</p> <p>Findings include:</p> <p>1. Clinical record #4 evidenced the patient's first date of dialysis was 6/5/13. The record failed to evidence the initial comprehensive assessment had been completed within 30 days. The assessment was completed on 7/26/13 by the registered nurse, employee C and on 7/23/13 by the registered dietician, employee G, and the social worker,</p>	V000516	<p>FA to hold a mandatory in service for all members of the Interdisciplinary Team (IDT) by 4/11/2014. In service will include but not be limited to: Review of Policy &amp; Procedure Patient Assessment and Plan of Care Utilizing Falcon Dialysis, 1) IDT must ensure that a comprehensive assessment will be conducted on all new patients within 30 calendar days or 13 outpatient dialysis sessions beginning with the first outpatient dialysis treatment, 2) IDT must complete initial plan of care based on the findings from comprehensive assessment on all new patients within 30 calendar days or 13 outpatient dialysis sessions beginning with the first outpatient</p>		

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V000557	<p>employee L.</p> <p>2. On 4/2/14 at 11 AM, employee E (facility administrator) indicated the initial comprehensive assessment was not completed within the required timeframe.</p> <p>3. The facility policy with a revision date of March, 2013 titled "Patient assessment and plan of care when utilizing falcon dialysis" states, "Assessment: ... 4. A comprehensive assessment will be conducted on all new patients within 30 calendar days (or 13 outpatient dialysis sessions for hemodialysis) beginning with the first outpatient dialysis treatment or per state guidelines. ... ."</p> <p>494.90(b)(2) POC-INITIAL IMPLEMENTED-30 DAYS/13 TX Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.</p> <p>Based on clinical record review, policy review, and interview, the facility failed to ensure the initial plan of care was completed within 30 days after admission in 1 of 5 records reviewed creating the potential to affect all new patients of the facility. (#4)</p>	V000557	<p>dialysis treatment. Attendance of in-service is evidenced by IDT signature on in-service form.</p> <p>FA initiated a manual tracking tool for purposes of planning and tracking patient's Interdisciplinary Assessment/Re-Assessment and Plan of Care due dates to ensure completion on time. Social Worker is managing process and will review with FA weekly to ensure all care plan and assessments are completed according to policy and procedure. FA will review audits and education monthly with Medical Director and Facility Health Team during FHM, minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction.</p> <p>FA to hold a mandatory in service for all members of the IDT by 4/11/2014. In service will include but not be limited to: Review of Policy &amp; Procedure Patient Assessment and Plan of Care Utilizing Falcon Dialysis, 1) IDT must ensure that a comprehensive assessment will be</p>		

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V000625	<p>Findings include:</p> <p>1. Clinical record #4 evidenced the patient's first date of dialysis was 6/5/13. The record failed to evidence the initial plan of care was completed within 30 days after admission.</p> <p>2. On 4/2/14 at 10:55 AM, employee E (facility administrator) indicated the first treatment date was 6/5/13, the patient had 22 in-center dialysis treatments from admission until 7/26/13 when the registered nurse, employee C, completed the comprehensive assessment, and the initial plan of care was not completed within the required timeframe. The employee indicated the initial plan of care was completed on 8/23/13.</p> <p>2. The facility policy with a revision date of March 2013 titled "Patient assessment and plan of care when utilizing falcon dialysis" states, "Plan of care: ... 10. An initial plan of care, based on the findings from the comprehensive assessment, will be completed on all patients new to dialysis within 30 calendar days (or 13 outpatient dialysis sessions for hemodialysis) beginning with the first outpatient dialysis treatment or per state guidelines. ... ."</p> <p>494.110 CFC-QAPI</p> <p>Based on quality assurance performance improvement (QAPI) document and facility policy review and interview, it was determined</p>			V000625	<p>conducted on all new patients within 30 calendar days or 13 outpatient dialysis sessions beginning with the first outpatient dialysis treatment, 2) IDT must complete initial plan of care based on the findings from comprehensive assessment on all new patients within 30 calendar days or 13 outpatient dialysis sessions beginning with the first outpatient dialysis treatment. Attendance of in-service is evidenced by IDT signature on in-service form.</p> <p>FA initiated a manual tracking tool for purposes of planning and tracking patient's Interdisciplinary Assessment/Re-Assessment and Plan of Care due dates to ensure completion on time. Social Worker is managing process and will review with FA weekly to ensure all care plan and assessments are completed according to policy and procedure. FA will review audits and education monthly with Medical Director and Facility Health Team during FHM, minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction.</p> <p>DaVita Carmel Dialysis takes the conditions of coverage very seriously, immediate steps were taken to ensure facilities QAPI Program collects data and develops</p>		05/03/2014

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	<p>the facility failed to ensure its QAPI program included monitoring of fluid and blood pressure management and the percent of eligible patients that completed and refused the physical and mental functioning survey in 6 of 6 months reviewed creating the potential to affect all of the facility's 22 current patients (See V 628); failed to ensure the QAPI program included a review and evaluation of known adverse events and hospitalizations in 6 of 6 months reviewed creating the potential to affect all of the facility's 22 current patients (See V 634); and failed to ensure patient complaints / grievances were reviewed as part of the QAPI program for 6 of 6 months reviewed and failed to ensure an Action Plan was reviewed and interventions and goals developed in response to the annual satisfaction survey in 5 of 5 months reviewed and creating the potential to affect all of the facility's 22 current patients (See V 636).</p> <p>The cumulative effect of these systemic problems resulted in the facility being out of compliance with the Condition for Coverage 494.110 Quality Assessment and Performance Improvement.</p>		<p>plans for improvement of care. These actions are outlined in depth in the Plan of Correction (POC) for V628, V634, and V636.</p> <p>Governing Body (GB) meeting was held on 4/09/2014 to review the deficiencies received as a result of a survey concluded on 4/3/2014. Members of the GB including the Medical Director, FA, and Regional Operations Director (ROD) have agreed to meet monthly to monitor the facility's ongoing progress towards compliance including but not limited to: 1) Ensuring QAPI program is comprehensive including evaluation of indicators, developing plans of action and intervention for those; indicators not meeting facility goals, and those plans are re-evaluated for effectiveness with new interventions initiated as needed. 2) QAPI program is comprehensive including fluid and blood pressure management, KDQOL, patient hospitalization, adverse events and incidents (AOR) that occur in the facility, tracks and patient satisfaction/grievances that are supported with goals, analysis, and interventions. GB will review FHM minutes to ensure minutes reflect, action plans are evaluated for effectiveness, new plans developed as applicable. Once compliance is achieved, POC will be monitored during GB meetings at a minimum of quarterly. This POC will also be reviewed during FHM and the FA will report progress, as well as any</p>	

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V000628	<p>494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS</p> <p>The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves.</p> <p>Based on quality assurance performance improvement (QAPI) document and facility policy review and interview, the facility failed to ensure its QAPI program included monitoring of fluid and blood pressure management and the percent of eligible patients that completed and refused the physical and mental functioning survey in 6 (October, November, December 2013, January, February, and March 2014) of 6 months reviewed creating the potential to affect all of the facility's 22 current patients.</p> <p>The findings include:</p> <p>1. The facility's QAPI meeting minutes, dated 2-28-13, 4-3-13, 4-18-13, 5-17-13, and 6-20-13, failed to evidence the facility had monitored fluid and blood pressure management by the review and evaluation of the percentage of Intradialytic weight loss, blood pressure variances pre and post dialysis, and Intradialytic symptoms of depletion and the percent of eligible patients eligible and completed and refused the physical and mental functioning survey.</p>			V000628	<p>barriers to maintaining compliance, with supporting documentation included in the meeting minutes.</p> <p>FA conducted mandatory in-service for all QAPI members on 4/11/2014. In-service included but was not limited to review of Policy &amp; Procedure #1-14-06: "Continuous Quality Improvement Program" with emphasis that team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for quality indicators including fluid and blood pressure management by reviewing percentage of intradialytic weight loss, variances, and trends of adverse occurrences, and health outcomes including KDQOL-36 Assessment Survey that tracks and trends health outcome measures including Physical and Mental functioning of patients. Team must review any identified underperformance and analyze to identify root causes and have action plan identified that will include a timeline and result in performance improvement, and will track change in performance over time to ensure improvements are sustained. FHM</p>		

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V000634	<p>2. During a review of the facility QAPI program on 4/3/14 at 2 PM with the facility administrator, the administrator indicated the social worker tracked the number of patients which completed the physical and mental functioning survey but that was not included in the QAPI data or minutes.</p> <p>3. The facility policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date September 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee ... Facility administrators (FA) conduct periodic Facility Health Meetings (FHM, formerly known as QIFMM) with the CQI committee to review issues and indicators regarding facility's management and performance. FHMs are conducted monthly. Written documentation and plans of action will be documented within the FHM application known as Facility Health Record and be maintained in a confidential manner. Copies of the QI meeting minutes will be provided upon request to CMS. ... The facility will measure, analyze, and track quality indicators or other aspects of performance. ... Patient Safety, including ... Patient Satisfaction and grievances. ... Continuous monitoring of the above indicators will be reflected in the meeting minutes."</p> <p>494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification.</p>	V000634	<p>minutes must reflect discussion, actions and evaluation by team. Verification of attendance at in-service will be evidenced by TM's signature on in-service form.</p> <p>MSW will be responsible to present at FHM and review percentage of patients who have completed, and returned KDQOL survey, as well as the percentage of those who have refused; team will work to determine possible barriers for patients not completing and returning surveys for processing. CSS will attend FHM or review meeting minutes for the next 3 months to ensure compliance, minutes are comprehensive, and reflective of actions taken. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction.</p>			Facility Health Meeting will be held on 4/18/2014 to analyze facility data,	

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	<p>Based on quality assurance performance improvement (QAPI) document and facility policy review and interview, the facility failed to ensure the QAPI program included a review and evaluation of adverse events and hospitalizations in 6 (October, November, December 2013, January, February, and March 2014) of 6 months reviewed creating the potential to affect all of the facility's 22 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>1. The facility's "Adverse Event Report Log" dated 10/1/13 through 3/31/14 evidenced 4 infiltrations, 4 unexpected hospital transfers, 2 unknown blood loss episodes, 1 prolonged bleedings greater than 30 minutes, and 2 clotted accesses.</li> <li>2. The hospitalization log for the time period 10/1/13 through 3/20/14 listed 48 hospitalizations, eight of which listed the reason for the hospital admission. There was no reason listed for the remaining forty hospitalizations.</li> <li>3. The facility QAPI meeting minutes, dated 10/25/13, 11/22/13, 12/19/13, 1/24/14, 2/21/14, and 3/21/14, failed to evidence the facility had investigated the adverse events and hospitalizations to determine root causes and to formulate and implement a plan to address any identified reasons and prevent future occurrences.</li> <li>4. On 4/3/14 at 2 PM, the facility administrator indicated the meeting minutes did not evidence discussion of the adverse events and hospitalizations. She indicated these are discussed and not documented.</li> </ol>		<p>and identify trends for hospitalizations and adverse patient occurrences. Trends will be reviewed to identify root causes and will have action plan identified that will result in performance improvement. Team will track change in performance over time to ensure improvements are sustained.</p> <p>FA conducted mandatory in-service for all QAPI members on 4/11/2014. In-service included but was not limited to review of Policy &amp; Procedure #1-14-06: "Continuous Quality Improvement Program" with emphasis that facility health team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for health and safety outcomes including Hospitalizations, Medical Injuries, Medical Errors, Adverse Occurrences. Team must evaluate specific causes of hospitalizations and adverse patient occurrences with analysis of trends to ensure patients safety. Team must annually review Dialysis Facility Report .Any identified underperformance will be reviewed to identify root causes and will have action plan identified that will result in performance improvement, and will track change in performance over time to ensure improvements are sustained. Action plans must be re-evaluated for effectiveness with new interventions initiated as needed. FHM minutes must reflect discussion, actions and evaluation by</p>				

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V000636	<p>5. The University of Michigan 2013 Dialysis Facility Report evidenced the facility's hospitalizations for congestive heart failure was 25.7 % while the United States average is 21.8 %. The hospitalizations for cardiac dysrhythmia for this facility was 17.1 % with the U.S. average being 13.1%.</p> <p>6. The facility policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date September 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee ... Facility administrators (FA) conduct periodic Facility Health Meetings (FHM, formerly known as QIFMM) with the CQI committee to review issues and indicators regarding facility's management and performance. FHMs are conducted monthly. Written documentation and plans of action will be documented within the FHM application known as Facility Health Record and be maintained in a confidential manner. Copies of the QI meeting minutes will be provided upon request to CMS. ... The facility will measure, analyze, and track quality indicators or other aspects of performance. ... Patient Safety, including ... Patient Satisfaction and grievances. ... Continuous monitoring of the above indicators will be reflected in the meeting minutes."</p> <p>494.110(a)(2)(viii) QAPI-INDICATOR-PT SATIS &amp; GRIEVANCES The program must include, but not be limited to, the following: (viii) Patient satisfaction and grievances.</p> <p>Based on quality assurance and performance improvement (QAPI) meeting minutes and</p>	V000636	<p>team. Verification of attendance at in-service will be evidenced by teammate's signature on in-service form.</p> <p>CSS will attend FHM or review meeting minutes for the next 3 months to ensure compliance, minutes are comprehensive, and reflective of actions taken. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction.</p> <p>Facility Health Meeting will be held on 4/18/2014 reviewed patient grievances with evaluation of complaints, action plans, resolution,</p>				

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	<p>facility policy review and interview, the facility failed to ensure patient complaints / grievances were reviewed as part of the QAPI program for 6 of 6 months reviewed (October, November, December 2013, January, February, and March 2014) and failed to ensure an Action Plan was reviewed and interventions and goals developed in response to the annual satisfaction survey in 5 (November, December 2013, January, February, and March 2014) of 5 months reviewed and creating the potential to affect all of the facility's 22 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>On 3/31/14 at 10:30 AM, two patients were observed sitting in the lobby. One patient, who requested to remain anonymous, laughed when an unexpected guest knocked on the office window and then the treatment room door. The individual indicated, when asked, there was not enough staff to answer the door when patients arrive and patients wait 30 minutes to be placed onto treatment. There was rarely anyone in the office with which to speak.</li> <li>The facility's complaint log identified in January 2014 four patients complained about staffing and the need to wait to be placed onto treatment. <ol style="list-style-type: none"> <li>The log identified two patients complained on 2/7/14 regarding the care received from a patient care technician.</li> <li>The log identified three patients complained about their treatments beginning late on 2/12/14.</li> <li>Four patient complained in February that</li> </ol> </li> </ol>		<p>and follow up with the patients. Trends will be reviewed to identify root causes and will have action plan identified that will result in performance improvement. Patient satisfaction survey will also be reviewed and include detailed plan put in-place to address identified areas for improvement.</p> <p>FA conducted mandatory in-service for all QAPI members on 4/11/2014. In-service included but was not limited to review of Policy &amp; Procedure #1-14-06: "Continuous Quality Improvement Program" with emphasis that team must report, measure, analyze, track and trend Patient Satisfaction, and Grievances. Any identified underperformance must be reviewed to identify root causes and will have action plan identified. Action plans must be re-evaluated for effectiveness with new interventions initiated as needed. FHM meeting minutes must reflect discussion, actions and evaluation by team. MSW will be responsible for maintaining Grievance Log, and will bring for review with Medical Director during monthly FHM. Supporting documentation will be included in the meeting minutes with evaluation of complaints, action plans, resolution, and follow up with patients noted. Verification of attendance at in-service will be evidenced by teammate's signature on in-service form.</p> <p>CSS will attend FHM or review</p>				

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	<p>they were waiting over 30 minutes to begin their scheduled treatment.</p> <p>3. The facility administrator indicated, on 4/3/14 at 2 PM, the facility's QAPI meeting minutes did not evidence a review of specific patient complaints. She indicated the annual patient satisfaction survey was conducted last fall and provided the results. She indicated the Action Plan related to the annual satisfaction survey was to educate the patients. She provided a 2 page document titled "CAHPS Action Plan" which stated, "Staff to continue to offer monthly education to patients on suggested topics such as access care ... . To be implemented by 1/21/14." She indicated there was not documentation in the QAPI documents related to the implementation of the Action Plan and any measurable results.</p> <p>The undated QAPI meeting minutes stated, "All CAHPS results were reviewed and action plans were made in the areas that needed improvement." The QAPI meetings failed to include the action plans, goals, and a date to review the implementation of a plan.</p> <p>4. The QAPI meeting minutes, dated 10/25/13, 11/22/13, 12/19/13, 1/24/14, 2/21/14, and 3/21/14, failed to evidence the facility had investigated the complaints to determine the root cause of the complaints and to formulate a plan to address any identified reasons and prevent future occurrences and failed to evidence the Interdisciplinary Team formulated an Action Plan in response to the Annual survey.</p> <p>5. The facility policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date September 2013</p>		<p>meeting minutes for the next 3 months to ensure compliance, minutes are comprehensive, and reflective of actions taken. FHM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction.</p>				

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V000715	<p>stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee ... Facility administrators (FA) conduct periodic Facility Health Meetings (FHM, formerly known as QIFMM) with the CQI committee to review issues and indicators regarding facility's management and performance. FHMs are conducted monthly. Written documentation and plans of action will be documented within the FHM application known as Facility Health Record and be maintained in a confidential manner. Copies of the QI meeting minutes will be provided upon request to CMS. ... The facility will measure, analyze, and track quality indicators or other aspects of performance. ... Patient Safety, including ... Patient Satisfaction and grievances. ... Continuous monitoring of the above indicators will be reflected in the meeting minutes."</p> <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&amp;P The medical director must-</p> <p>(2) Ensure that-</p> <p>(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;</p> <p>Based on observation, interview, and clinical</p>	V000715	Governing Body Meeting was held on 4/9/2014 upon receiving Statement of Deficiencies from survey ending on 4/3/2014 with Medical Director, FA, and ROD. Statement of Deficiencies reviewed regarding deficiencies including but not limited to Infection Control, Central Venous Catheter Care, and Patient Assessment & Plan of Care. Medical Director acknowledges that	

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	<p>record and policy and procedure review, the medical director failed to ensure all personnel had adhered to facility policies and procedures relative to patient care and infection control in 3 of 5 patient care observations #1, 3, and 4) with the potential to affect all patients of the facility. (Employee A and patient #4)</p> <p>Findings include:</p> <p>1. The facility policy with a revision date of March, 2014 titled "Central Venous Catheter (CVC) Procedure" states, "Materials required: ... PPE-personal protective equipment (face protection, including face mask, gloves, fluid resistant/fluid impervious barrier garment) ... Procedure ... 5. Patient and teammate will wear face masks covering the nose and mouth during catheter procedure. ... Rationale ... 5. These measures are vital to preventing the exposure of the catheter and exit site to nasal droplets and infectious bacteria such as methicillin resistant Staph aureus (MRSA) ... "</p> <p>A. On 3/31/14 at 10:40 AM, employee A was observed to perform CVC exit site care and to initiate dialysis in station 9 with patient number 1. The employee was wearing a mask that covered only the bottom lip and half of the top lip. The employee failed to wear the mask to cover the nose throughout the exit site care and initiation of dialysis treatment.</p> <p>B. On 3/31/14 at 11:08 AM, employee A indicated he/she had not worn the mask appropriately and was not aware until after completing the initiation of dialysis treatment and removal of personal protective equipment.</p>		<p>he is responsible to ensure facility TMs are trained and follow policy &amp; procedure, and deficiencies identified need corrected timely with the support of facility team. Plans of Correction have been developed and initiated to correct identified deficiencies and sustain compliance. Medical Director will review progress of TM education, results of audits, and adherence to this plan of correction during monthly FHM. FA will report progress, as well as any barriers to maintaining compliance, with supporting documentation included in the meeting minutes. Action plans will be evaluated for effectiveness, new plans developed as applicable to achieve 100% compliance with TM adherence to policy and procedure. FHM minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction.</p>	

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	<p>2. The facility policy with a revision date of March, 2013 titled "Patient assessment and plan of care when utilizing falcon dialysis" states, "Assessment: ... 4. A comprehensive assessment will be conducted on all new patients within 30 calendar days (or 13 outpatient dialysis sessions for hemodialysis) beginning with the first outpatient dialysis treatment or per state guidelines. ... ."</p> <p>A. Clinical record #4 evidenced the patient's first date of dialysis was 6/5/13. The record failed to evidence the initial comprehensive assessment had been completed within 30 days. The assessment was completed on 7/26/13 by the registered nurse, employee C and on 7/23/13 by the registered dietician, employee G, and the social worker, employee L.</p> <p>B. On 4/2/14 at 11 AM, employee E (facility administrator) indicated the initial comprehensive assessment was not completed within the required timeframe.</p> <p>3. The facility policy with a revision date of March 2013 titled "Patient assessment and plan of care when utilizing falcom dialysis" states, "Plan of care: ... 10. An initial plan of care, based on the findings from the comprehensive assessment, will be completed on all patients new to dialysis within 30 calendar days (or 13 outpatient dialysis sessions for hemodialysis) beginning with the first outpatient dialysis treatment or per state guidelines. ... ."</p> <p>A. Clinical record #4 evidenced the patient's first date of dialysis was 6/5/13. The record failed to evidence the initial plan of care was completed within 30 days after admission.</p>			

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V000726	<p>B. On 4/2/14 at 10:55 AM, employee E (facility administrator) indicated the first treatment date was 6/5/13 and the patient had 22 in-center dialysis treatments from admission until 7/26/13 when the registered nurse, employee C, completed the comprehensive assessment, and the initial plan of care was not completed within the required timeframe. The employee indicated the initial plan of care was completed on 8/23/13.</p> <p>494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE</p> <p>The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.</p> <p>Based on clinical record review, facility policy review, and interview, the facility failed to ensure accurate records were maintained on all patients in 2 of 3 in-center records reviewed in which the attending physician was employee J creating the potential to affect all patients of the facility (#3 and #4)</p> <p>Findings include:</p> <p>1. Clinical record #3 evidenced the patient's first date of dialysis was 6/17/13. The record evidenced documents electronically signed</p>	V000726	<p>Attending Physician will conduct patient assessment, and document current progress notes on Patients 3, and 4 that reflect patient's current vascular access in use for hemodialysis treatments. Physician will be educated to utilize Davita rounding forms when doing patients rounds in the facility to ensure accurate substantial rounding is being completed at least monthly. FA or designee will verify rounding documents are reviewed for accuracy monthly during chart audits.</p> <p>FA in-serviced all TMs on Policy &amp; Procedure # 3-02-02 Medical Records Preparation and Charting</p>				

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	<p>by employee J, an attending physician, dated 12/18/13, 1/10/14, 2/7/14, and 3/17/14 titled "Dialysis Rounds-Comp" that stated, "This patient was personally seen for a comprehensive visit as part of routine monthly dialysis care. A review of the dialysis treatment, blood pressure, estimated dry weight and recent lab values was made. These were discussed with the patient and staff as necessary. ... Vascular Access Assessment 'Patient currently dialyzing via tunneled catheter. Patient referred to surgery for vascular access. New fistula ... ."</p> <p>A. The record contained documents dated 12/18/13, 1/10/14, 2/7/14, and 3/17/14 titled "Post Treatment" that state, "Prescription information ... Primary access: 'AV [arteriovenous] fistula - arm (left lower)' Secondary Access: 'N/A [not applicable]' ... VITALS ... Primary Access: 'AV fistula - arm (left lower)' Secondary Access: 'N/A' ... "</p> <p>B. On 4/3/14 at 10 AM, employee E (facility administrator) indicated the patient has used the AV fistula in the left lower arm as the primary access for dialysis treatments since 11/26/13 until present day.</p> <p>C. On 4/3/14 at 10:05 AM, employee K (area corporate nurse specialist) indicated the information on the documents electronically signed by the physician dated 12/18/13, 1/10/14, 2/7/14, and 3/17/14 titled "Dialysis Rounds-Comp" contained inaccurate information regarding the patient's vascular assess.</p> <p>2. Clinical record #4 evidenced the patient's first date of dialysis was 6/5/13. The record evidenced documents electronically signed by employee J dated 12/18/13, 1/10/14,</p>		<p>Guidelines on 4/11/2014 with emphasis that patient documentation must be complete, accurate for treatment and services provided as well as patient responses to care. At a minimum monthly medical progress notes should be documented and available in patients facility medical record that physician or non-physician practitioner (nurse practitioner, clinical nurse specialist or physician assistant) who functions in lieu of the physician has seen each patient, and addressed patient status and plan. Attendance of in-service to be evidenced by TMs signature on in-service form.</p> <p>FA and Administrative Assistant (AA) completed 100% patient chart audits by 4/3/2014 to ensure monthly physician progress notes are current, accurate, and present in medical record. AA will notify FA of any identified missing/inaccurate documents for immediate correction by 4/21/2014. AA will continue to maintain charts by completing 10% monthly chart audits, FA will review chart audits with AA monthly to ensure accuracy and completion. FA will review audits and education monthly with Medical Director and Facility Health Team during FHM, minutes will reflect.</p> <p>FA and Medical Director are responsible for compliance with this plan of correction</p>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152620	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED  04/03/2014
NAME OF PROVIDER OR SUPPLIER  CARMEL DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 180 E CARMEL DR CARMEL, IN 46032		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>2/7/14, and 3/26/14 titled "Dialysis Rounds-Comp" that stated, "This patient was personally seen for a comprehensive visit as part of routine monthly dialysis care. A review of the dialysis treatment, blood pressure, estimated dry weight and recent lab values was made. These were discussed with the patient and staff as necessary. ... Vascular Access Assessment 'Patient currently dialyzing via tunneled catheter. Patient referred to surgery for vascular access creation'."</p> <p>A. The record contained documents dated 12/18/13, 1/10/14, 2/7/14, and 3/26/14 titled "Post Treatment" that state, "Prescription information ... Primary access: 'AV [arteriovenous] fistula - arm (left lower)' Secondary Access: 'N/A [not applicable]' ... VITALS ... Primary Access: 'AV fistula - arm (left lower)' Secondary Access: 'N/A' ... "</p> <p>B. On 4/2/14 at 11:05 AM, employee E (facility administrator) indicated the patient has a left lower arm fistula which was placed 8/15/13. The employee indicated the patient has been using this access since 10/21/13 to present day.</p> <p>3. The facility policy with a revision date of September 2013 titled "Medical Record Preparation and Charting Guidelines" states, "Policies and Procedures: ... B. General Procedures and requirements ... 6. All entries must be accurate. Inaccurate records can adversely affect patient care and false statements in a medical record ... ."</p>				