

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152650		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/16/2013	
NAME OF PROVIDER OR SUPPLIER CARMEL HEALTH AND LIVING DIALYSIS				STREET ADDRESS, CITY, STATE, ZIP CODE 118 MEDICAL DR STE 114 CARMEL, IN 46032			
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V000000	<p>This was a federal ESRD complaint survey.</p> <p>Complaint #: IN00132056 - Unsubstantiated: Lack of sufficient evidence. Deficiencies unrelated to the complaint are cited.</p> <p>Survey Date: 8/16/13</p> <p>Facility #: 012554</p> <p>Medicaid Vendor #: 201056570A</p> <p>Surveyor: Bridget Boston, RN, PHNS</p> <p>Census In-Center Hemodialysis: 19</p> <p>During this survey, Carmel Health and Living Dialysis was found to be out of compliance with the Condition for Coverage 494.110: Quality assessment and performance improvement.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN August 21, 2013</p>			V000000			

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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V000517	<p>494.80(b)(2) PA-F/U REASSESSMENT-WITHIN 3 MO OF INITIAL A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90. Based on clinical record and policy review and staff interview, the facility failed to ensure a follow up comprehensive assessment was conducted within 3 months of the initial assessment in 1 (1) of 5 records reviewed with the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record 1, start of care 3/12/13, evidenced an initial assessment and plan of care dated 4/22/13. The record failed to evidence a reassessment of the patient within 3 months of the initial assessment. 2. The facility's policy titled "Patient Assessment and Plan of Care When Utilizing Falcon Dialysis," revision date March 2013, Policy: 1-14-02, states, "A follow up 90 day re-assessment will be completed to evaluate patient's status and provide information to adjust the patient's plan of care. ... After completion of the 90 day re-assessment, the interdisciplinary team will conduct an IDT meeting to make adjustments to the plan of care. This meeting and initiation of the updated 	V000517	<p>Interdisciplinary Team (IDT) will initiate and develop Comprehensive Re-Assessment followed by Individualized Plans of Care for Patient #1. Facility Administrator (FA) to hold a mandatory in service for all members of the IDT by 8/30/2013. In service will include but not be limited to: Review of Policy & Procedure #1-14-02 Patient Assessment and Plan of Care Utilizing Falcon Dialysis. 1) IDT must ensure that a comprehensive re-assessment is conducted on all new patients within 90 days of completion of initial assessment to reflect the patient's adjustment or lack of adjustment to the treatment modality. 2) Comprehensive re-assessment must be used to develop the patient's treatment plan and expectations for care 3) Plan of Care must be completed within 15 days of completing re-assessment. Attendance is evidenced by TM signature on Clinical In-service Form. FA initiated tracking tool for purposes of planning and tracking patient's Interdisciplinary Assessment/Re Assessment and Plan of Care due dates to ensure completion</p>	08/30/2013	

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	<p>Plan of Care must occur within 15 days of completion of re-assessments."</p> <p>3. On 8/16/13 at 5:12 PM, when asked, employee A indicated there was no further documentation available.</p>		<p>on time. Renal Dietician (RD) will be responsible for managing process and will review with FA weekly to ensure no patients are missed. FA or designee will conduct monthly Medical Record Audits for 100% of new admissions to ensure 90 day re assessment and plans of care are current, individualized, and updated per policy. FA will review results of audits with Medical Director during monthly Quality Improvement Facility Management Meeting (QIFMM), minutes will reflect. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance, minutes will reflect. Medical Director & FA are responsible for compliance with this POC</p>		

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V000556	<p>494.90(b)(1) POC-COMPLETED/SIGNED BY IDT & PT The patient's plan of care must-</p> <p>(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and</p> <p>(ii) Be signed by the team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.</p> <p>Based on clinical record and policy review and interview, the facility failed to ensure the interdisciplinary team reviewed, updated, and implemented the plan of care to reflect the services required to address the patient's needs identified in the 90 day re-assessment for 1 of 3 records reviewed of patients admitted after 3/1/13and required an initial reassessment plan of care (# 1).</p> <p>The findings include:</p> <p>1. Clinical record 1, start of care 3/12/13, evidenced an initial assessment and plan of care dated 4/22/13. The record failed to evidence an update to the initial plan of care and signed by the interdisciplinary team members and the patient or patient designee.</p> <p>2. The facility's policy titled "Patient Assessment and Plan of Care When Utilizing Falcon Dialysis," revision date March 2013, Policy: 1-14-02, states, "A</p>	V000556	<p>IDT will initiate and develop Comprehensive Re-Assessment followed by Individualized Plans of Care for Patient #1 to ensure IDT including patient and/or patient's representative are included in developing individualized Plan of Care and all members' signatures are present verifying involvement. FA to hold a mandatory in service for all members of the IDT by 8/30/2013. In service will include but not be limited to: Review of Policy & Procedure #1-14-02 Patient Assessment and Plan of Care Utilizing Falcon Dialysis. 1) Patient's plan of care must be completed by facilities IDT. IDT consists of at a minimum: Physician treating the patient for ESRD, patient or patient's designated representative, Registered Nurse, Social Worker, and Dietician. Plan of Care must be signed by entire IDT verifying participation in plan of care. 2) IDT must ensure that a comprehensive re-assessment is conducted on all new patients</p>	08/30/2013	

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	<p>follow up 90 day re-assessment will be completed to evaluate patient's status and provide information to adjust the patient's plan of care. ... After completion of the 90 day re-assessment, the interdisciplinary team will conduct an IDT meeting to make adjustments to the plan of care. This meeting and initiation of the updated Plan of Care must occur within 15 days of completion of re-assessments. ... If expected outcomes is not achieved, the interdisciplinary team, including the patient's or personal representative and be signed by team members including the patient or patient's personal representative. If patient wishes not to sign the plan of care, this choice will be documented on the plan of care, along with the reason the signature was not provided."</p> <p>3. On 8/16/13 at 5:12 PM, when asked, employee A indicated there was no further documentation available.</p>		<p>within 90 days of completion of initial assessment to reflect the patient's adjustment or lack of adjustment to the treatment modality. 3) Comprehensive re-assessment must be used to develop the patient's treatment plan and expectations for care 4) Plan of Care must be completed within 15 days of completing re-assessment. Attendance is evidenced by TM signature on Clinical In-service Form. FA initiated 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 RD will be responsible for managing process and will review with FA weekly to ensure no patients are missed. FA or designee will conduct Medical Record Audits on 100% of current census to ensure current individualized Comprehensive Assessments and Plan of Care are in place, up-to-date, and plans of care are signed by all members of IDT including patient, or patient designated representative. Thereafter FA or designee will conduct monthly Medical Records audits for 100% of admissions and 10% of census to ensure compliance. FA will review results of audits with Medical Director during monthly QIFMM, minutes will reflect. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance,</p>		

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			minutes will reflect. Medical Director & FA are responsible for compliance with this POC		

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V000560	<p>494.90(b)(4) POC-PTS SEEN BY MED STAFF 1X/MO The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis. Based on clinical record and policy review and interview, the facility failed to ensure all dialysis patients were seen by a nurse practitioner, physician, physician assistant, or clinical nurse specialist at least monthly in 5 of 5 clinical records reviewed (#1, 3, 6, 7, and 8).</p> <p>the findings include:</p> <ol style="list-style-type: none"> 1. Clinical record 1, start of care 3/12/13, failed to evidence the patient was seen a least monthly by a physician, physician assistant, clinical nurse specialist, or a nurse practitioner after the patient was admitted on 3/12/13. 2. Clinical record 3, start of care 5/17/13, failed to evidence the patient was seen by a physician, physician assistant, clinical nurse specialist, or a nurse practitioner since the date of admission 5/17/13. 3. Clinical record 6, start of care 12/23/11, evidenced the most recent annual plan of care was dated 3/11/13. 	V000560	<p>Physician providing care for all identified patients contacted by FA on 8/29/2013, regarding missing progress notes. Physician's office granted access to electronic records system for the Group Facility Administrator and FA to read and print monthly progress notes for all Carmel Health and Living patients only. All progress notes will immediately be obtained for the missing dates of service from 12/2012 to 8/2013 and placed on the patient's medical record. FA or designee will log into the physicians electronic records system monthly to obtain current progress notes. FA and/or GFA will in-service Medical Director on Policy & Procedure #3-03-71 Medical Director Qualifications and Responsibilities during September 2013 QIFMM; attending physician will also be in-serviced by 9/15/2013 on Policy & Procedure #3-02-02 Medical Records Preparation and Charting Guidelines, informing them that the Conditions for Coverage require that all dialysis patients be seen monthly by the</p>	09/15/2013	

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	<p>The record failed to evidence the patient was seen at least monthly by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant since 3/11/13.</p> <p>4. Clinical record 7, start of care 4/23/13, failed to evidence the patient was seen by a physician, physician assistant, clinical nurse specialist, or a nurse practitioner since the patient was transferred to this facility 4/23/13.</p> <p>On 8/16/13 at 1:35 PM, employee C indicated the physician wrote - hand to paper - on "Rounding Reports" and that there were no reports found to be filed for this patient.</p> <p>5. Clinical record 8, start of care 11/2/11, and a resident of the extended care facility in which the dialysis center is located. The most recent documentation by the physician is dated January 2012. The record failed to evidence the patient was seen by a physician, physician assistant, clinical nurse specialist, or a nurse practitioner since the patient was transferred to this facility 4/23/13.</p> <p>On 8/16/13 at 5:12 PM, employee A indicated there was no other documentation.</p> <p>6. On 8/16/13 at 4:48 PM, employee A</p>		<p>physician or physician extender as evidenced by a signed and dated progress note. FA & Medical Director will be responsible to ensure that all patients are seen by Medical Staff: Physician, Nurse Practitioner, Clinical Nurse Specialist or Physician Assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record. Attendance is evidenced by TM signature on Clinical In-service Form. FA will oversee process control and filing of all Physician Progress Notes, in FA absence GFA will be responsible for control. FA or designee will conduct Medical Records Audits monthly for 100% of current census by 9/15/2013 to ensure medical staff progress notes are current and present in medical record. Thereafter FA or designee will conduct monthly Medical Records audits for 10% of census to ensure compliance. FA will review results of audits with Medical Director during monthly QIFMM, minutes will reflect. QIFMM minutes and activities will be reviewed during GB meetings to monitor ongoing compliance, minutes will reflect. Medical Director & FA are responsible for compliance with this POC</p>		

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	<p>indicated the physicians document in an electronic records system that the facility staff do not have access to read or rights to import into the facility's electronic medical record. The physician did not provide a copy in another format or make anything available to the facility staff. Employee A indicated, when asked, the facility staff do not know what this physician, employee F, documents for any of his patients as the facility staff do not have access to the documentation.</p> <p>7. The policy titled "Medical Director Qualifications and Responsibilities" number 3-03-71, revision date May 2013 stated, "MD responsibilities include, ... Ensuring that 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 non-physician providers."</p> <p>8. The facility policy titled "Medical Record Preparation and Charting Guidelines" stated, "Patient medical records are legal documents serving several important purposes: ... Facilitating medical care and treatment - enabling members of the treatment team and future caregivers to understand the patient's diagnosis, history, and course of treatment. ... Providing evidence that</p>						

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	<p>services were furnished when reasonable and necessary, ... Establishing compliance with applicable licensure requirements and conditions of participation in payer programs. ... All entries must be accurate. ... Documentation is to be completed at the time of service. ... Corrections to the Medical Record ... Late Entries - If unable to chart immediately after rendering a service or at time of an observation, the teammate is to make the appropriate entry as soon as possible. Documentation done within the same day would not be considered a 'Late Entry.' Documentation done the following day would need to have the entry labeled as "late entry."</p>				

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V000625	<p>494.110 CFC-QAPI</p> <p>Based on administrative record and facility policy review and interview, it was determined the facility failed to ensure a quality assessment and performance improvement (QAPI) program was developed and implemented in 8 of 8 months reviewed (See V 626); failed to ensure there was an ongoing quality assurance program that achieved measurable improvement in health outcomes and reduction of medical errors and included the identification and resolution of infection control practice noncompliance and the management of patients with diagnosis of active MRSA infections for 8 of the previous 8 months reviewed (See V 627); failed to ensure there was an ongoing quality assurance program that measured, analyzed, and tracked quality indicators or other aspects of performance that influence or relate to the desired outcomes for 8 of the previous 8 months reviewed for 1 of 1 facility (See V 628); failed to ensure there was an ongoing quality assurance program that included adequacy of dialysis for 8 of the previous 8 months reviewed (See V 629); failed to ensure there was an ongoing quality assurance program that included and monitored nutritional status and desired outcomes for 8 of the previous 8 months reviewed (See V 630); failed to</p>	V000625	<p>DaVita Carmel Health and Living takes the condition for coverage very seriously, immediate steps were taken to ensure to ensure facilities QAPI Program analyzes data, develops plans/interventions for improvement of care, and re-evaluates focusing on health outcomes and safety of patients. These actions are outlined in depth in the POC for V626, V627, V628, V629, V630, V631, V632, V633, V636, V637, V638, and V639. Governing Body Meeting was held on 8/28/2013 upon receiving Statement of Deficiencies from survey ending on 8/16/2013 with Medical Director and FA. Members of the Governing Body that include FA and Medical Director have agreed to meet bi-weekly to monitor the facility's ongoing progress towards compliance including but not limited to: 1) Ensuring facility has effective QAPI program and all members of the quality improvement committee participate in meetings; 2) Ensuring QAPI program is comprehensive including plans of action, intervention, evaluation of indicators not meeting facility goals, and those plans are re-evaluated for effectiveness with new interventions initiated as needed to achieve improvement in health outcomes, reduction of</p>	08/28/2013			

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	ensure there was an ongoing quality assurance program that included mineral metabolism and renal bone disease and desired outcomes for 8 of the previous 8 months reviewed (See V 631); failed to ensure there was an ongoing quality assurance program that included anemia management for 8 of the previous 8 months reviewed (See V 632); failed to ensure there was an ongoing quality assurance program that included vascular access for 8 of the previous 8 months reviewed (See V 633); failed to ensure there was an ongoing quality assurance program that included medical injuries and medical errors for 8 of the previous 8 months reviewed (See V 634); failed to ensure there was an ongoing quality assurance program that included patient satisfaction and grievances for 8 of the previous 8 months reviewed (See V 636); failed to ensure an ongoing quality assurance program included infection control for 8 of the previous 8 months reviewed (See V 637); failed to ensure there was an ongoing quality assurance program that continuously monitored its performance, took actions that resulted in performance improvement, and tracked performance to ensure improvements were sustained for 8 of the previous 8 months reviewed (See V 638); and failed to ensure there was an ongoing quality assurance program that set priorities for		medical errors, and incidence of infections; 3) QAPI program includes goals, evaluation, interventions regarding but not limited to Adequacy, Nutrition, Mineral Metabolism/Renal Bone Disease, Anemia, Vascular Access, Medical Injuries, and Medical Errors, Patient Satisfaction/Grievances, and Infection Control; 4) QAPI program reviews Internal/External audits, identifies and immediately addresses and prioritizes problems affecting health and safety of patients; 5) QAPI Program ensures dialysis facility sets priorities for performance improvement, considering prevalence and severity of identified issues and addressing the priority to improvement activities that affect patient safety, and clinical outcomes. GB will review QIFMM 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 QIFMM and the FA will report progress, as well as any barriers to maintaining compliance, with supporting documentation included in the meeting minutes		

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	<p>performance improvement, considered prevalence and severity of problems, and gave priority to improvement activities that affected clinical outcomes or patient safety for 8 of the previous 8 months reviewed (See V 639) with the potential to affect all patients.</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to look at aggregate data and facility-based assessment and improvement of care as required by this Condition for Coverage 494.110: Quality assessment and performance improvement.</p>				

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V000626	<p>494.110 QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.</p> <p>Based on administrative record and facility policy review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was developed and implemented in 8 (December 2012 and January, February, March, April, May, and July of 2013) of 8 months reviewed creating the potential to affect all of the facility's current patients.</p> <p>The findings include:</p> <p>1. Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012.</p>	V000626	<p>FA will gather, and analyze facility aggregate data identify trends and establish current baseline information to present in next QIFMM meeting scheduled 9/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis that QIFMM team must develop, implement, maintain, and evaluate an effective, data-driven</p>	09/10/2013			

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	<p>2. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be printed for review nor could the information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will be maintained in a</p>		<p>quality assessment and performance improvement program with participation by all members of team. QIFMM Team must measure, analyze and track quality indicators or other aspects of performance that reflect processes of care and facility operations; importance of having an ongoing and comprehensive QIFMM process that includes tracking, trending, data analysis, action plan development and effective implementation dates related for facility indicators. Specific emphasis was placed on 1) Analyzing data collected, 2) Continuous evaluation of indicators not meeting facility goals, 3) Identifying root causes for underperformance, 4) Developing action plans, 5) Reviewing current action plans in place, evaluating their effectiveness, and initiating new plans as needed to meet goals. 6) Tracking performance over time to ensure improvements are sustained, 7) Ensuring meeting minutes reflect discussion, actions and evaluation by team. Team is responsible to ensure that all areas of the QIFMM are completed for effective QAPI program. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or Regional Operations Director (ROD) will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly</p>		

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	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. ... After completion and signatures (including review and signature by facility medical director if he / she was unable to personally attend a particular meeting) a copy of Quality Improvement and Facility Management Meeting (QIFMM) Minutes is to be forwarded via fax to the Regional or Divisional Office (depending on the process established within each division)."		thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC		

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V000627	<p>494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT</p> <p>The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.</p> <p>Based on policy, administrative document, and clinical record review and interview, the facility failed to ensure there was an ongoing quality assurance program that achieved measurable improvement in health outcomes and reduction of medical errors and included the identification and resolution of infection control practice noncompliance and the management of patients with diagnosis of active MRSA infections for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <p>1. Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012.</p>	V000627	<p>FA and ICM will gather, and analyze facility data identify trends and establish current baseline information for health outcomes including incidence of infection, hospitalizations and mortality to present in next QIFMM meeting scheduled 9/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis that QIFMM Team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for health outcomes including incidence of infections, patient hospitalization, and mortality. Any identified</p>	09/10/2013	

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	<p>2. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be printed for review nor could the information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. Clinical record 1 evidenced the patient was a resident of an extended care facility (ECF) and was dependent upon the ECF staff for routine daily care. The record evidenced an order for an antibiotic, Vancomycin 500 milligrams intravenously, with every dialysis treatment, three times a week beginning 6/12/13 and discontinued on 6/23/13.</p> <p>A. The facility infection log evidenced the patient was diagnosed with a methicillin resistant staphylococcus aureus (MRSA) infection to the patient's central venous catheter (CVC) access on 6/7/13.</p>		<p>underperformance will be reviewed to identify root causes and will have action plan identified that will result in performance improvement, assist to minimize infection transmission, hospitalization, and 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, QIFMM meeting minutes must reflect discussion, actions and evaluation by team. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC</p>				

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	<p>B. The record evidenced laboratory values were evaluated and the patient's white blood cell count was elevated on 7/6/13 at 14700, on 7/20/13 was 37100, and on 7/27/13 was 22100.</p> <p>C. At 6 PM on 8/16/13, when asked, employee A indicated there was no documentation or update to the plan of care available for review to evidence additional instructions given to the ECF primary caregivers, infection control monitoring, or instructions / reeducation given to the dialysis staff.</p> <p>4. Clinical record 6, start of care 12/23/11, evidenced the last treatment was 5/21/13.</p> <p>A. The hospital log indicated the patient was treated in the hospital for unknown cause on 5/16/13 and 5/22/13.</p> <p>B. On 8/16/13 at 4:28 PM, employee A indicated there was no documentation in the patients medical record to explain why the patient was hospitalized and the cause of the patient's death.</p> <p>C. Reviewed hospital discharge records received by the facility on 8/16/13 at 5:36 PM. The discharge summary stated, "Date of Admission: 5/22/2013</p>				

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	<p>Date of Death 5/26/13. ... Causes of Death: Persistent Methicillin-resistant Staphylococcus aureus bacteremia with suspected endovascular source, probable endocarditis."</p> <p>5. The infection log listed patient 8 with an infection in their fistula on 7/8/13. Clinical record 8 evidenced a start of care as 11/3/11.</p> <p>On 8/14/13 at 5 PM, when asked, Employee C indicated the patient's infection was diagnosed as a MRSA infection in the fistula access.</p> <p>6. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will be maintained in a confidential manner. Copies of the QI meeting minutes will be provided upon</p>				

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	request to CMS. ... The facility will measure, analyze, and track quality indicators or other aspects of performance. ... After completion and signatures (including review and signature by facility medical director if he / she was unable to personally attend a particular meeting) a copy of Quality Improvement and Facility Management Meeting (QIFMM) Minutes is to be forwarded via fax to the Regional or Divisional Office (depending on the process established within each division)."			

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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 administrative document, clinical record, and policy review and interview, the facility failed to ensure there was an ongoing quality assurance program that measured, analyzed, and tracked quality indicators or other aspects of performance that influence or related to the desired outcomes for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. 	V000628	<p>FA will gather, and analyze facility data identify trends and establish current baseline information for quality indicators including but not limited to Adequacy, Nutritional status, Mineral Metabolism and Renal Bone Disease, Anemia Management, Vascular Access, Medical Injuries, and Medical Errors, Hospitalizations, Infections, Mortality, Immunizations, Patient Satisfaction/Grievances, and Patient Safety, as well as results of Internal/External audits to present in next QIFMM meeting scheduled 9/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program</p>	09/10/2013			

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	<p>Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be printed for review nor could the information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will 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</p>		<p>emphasizing QIFMM Team must measure, analyze and track quality indicators including but not limited to Adequacy, Nutritional status, Mineral Metabolism and Renal Bone Disease, Anemia Management, Vascular Access, Medical Injuries, and Medical Errors, Hospitalizations, Infections, Mortality, Immunizations, Patient Satisfaction/Grievances, and Patient Safety, as well as review Internal/External audits. Any identified underperformance will be analyzed to identify root causes and will 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. Action plans must be re-evaluated for effectiveness with new interventions initiated as needed, QIFMM meeting minutes must reflect discussion, actions and evaluation by team. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system</p>		

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	indicators or other aspects of performance. ... After completion and signatures (including review and signature by facility medical director if he / she was unable to personally attend a particular meeting) a copy of Quality Improvement and Facility Management Meeting (QIFMM) Minutes is to be forwarded via fax to the Regional or Divisional Office (depending on the process established within each division)."		monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC		

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V000629	<p>494.110(a)(2)(i) QAPI-INDICATOR-ADEQUACY OF DIALYSIS</p> <p>The program must include, but not be limited to, the following: (i) Adequacy of dialysis.</p> <p>Based on policy and document review and interview, the facility failed to ensure there was an ongoing quality assurance program that included adequacy of dialysis for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be 	V000629	<p>FA will gather, and analyze facility data, identify trends and establish current baseline information for quality indicators including Adequacy to present in next QIFMM meeting scheduled 9/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis that QIFMM Team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for quality indicators including Adequacy of Dialysis. 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</p>	09/10/2013			

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	<p>printed for review nor could the information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will 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. ... Adequacy of Dialysis (Kt / V). ... After completion and signatures (including review and signature by facility medical director if he / she was unable to personally attend a particular meeting) a copy of Quality Improvement</p>		<p>re-evaluated for effectiveness with new interventions initiated as needed. QIFMM meeting minutes must reflect discussion, actions and evaluation by team. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC</p>		

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	and Facility Management Meeting (QIFMM) Minutes is to be forwarded via fax to the Regional or Divisional Office (depending on the process established within each division)."			

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NAME OF PROVIDER OR SUPPLIER CARMEL HEALTH AND LIVING DIALYSIS				STREET ADDRESS, CITY, STATE, ZIP CODE 118 MEDICAL DR STE 114 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			
V000630	<p>494.110(a)(2)(ii) QAPI-INDICATOR-NUTRITIONAL STATUS The program must include, but not be limited to, the following: (ii) Nutritional status.</p> <p>Based on policy and document review and interview, the facility failed to ensure there was an ongoing quality assurance program that included and monitored nutritional status and desired outcomes for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be 	V000630	<p>FA and Renal Dietician will gather, and analyze facility data, identify trends and establish current baseline information for quality indicators including Nutrition status to present in next QIFMM meeting scheduled 09/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis that QIFMM Team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for quality indicators including Nutrition status. 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</p>	09/10/2013			

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	<p>printed for review nor could the information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will 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. ... Nutritional Status (Albumin). ... After completion and signatures (including review and signature by facility medical director if he / she was unable to personally attend a particular meeting) a copy of Quality Improvement</p>		<p>re-evaluated for effectiveness with new interventions initiated as needed. QIFMM meeting minutes must reflect discussion, actions and evaluation by team. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC</p>				

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	and Facility Management Meeting (QIFMM) Minutes is to be forwarded via fax to the Regional or Divisional Office (depending on the process established within each division)."				

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V000631	<p>494.110(a)(2)(iii) QAPI-INDICATOR-CKD-MBD The program must include, but not be limited to, the following: (iii) Mineral metabolism and renal bone disease.</p> <p>Based on policy and document review and interview, the facility failed to ensure there was an ongoing quality assurance program that included mineral metabolism and renal bone disease and desired outcomes for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; 	V000631	<p>FA and Renal Dietician will gather, and analyze facility data, identify trends and establish current baseline information for quality indicators including Mineral Metabolism and Renal Bone Disease to present in next QIFMM meeting scheduled 9/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis that QIFMM Team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for quality indicators including Mineral Metabolism and Renal Bone Disease. 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</p>	09/10/2013			

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	<p>therefore, the documents cannot be printed for review nor could the information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will 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. ... Mineral Metabolism and Renal Bone Disease. ... After completion and signatures (including review and signature by facility medical director if he / she was unable to personally attend a</p>		<p>over time to ensure improvements are sustained. Action plans must be re-evaluated for effectiveness with new interventions initiated as needed. QIFMM meeting minutes must reflect discussion, actions and evaluation by team. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC</p>				

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	particular meeting) a copy of Quality Improvement and Facility Management Meeting (QIFMM) Minutes is to be forwarded via fax to the Regional or Divisional Office (depending on the process established within each division)."			

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V000632	<p>494.110(a)(2)(iv) QAPI-INDICATOR-ANEMIA MANAGEMENT The program must include, but not be limited to, the following: (iv) Anemia management. Based on policy and document review and interview, the facility failed to ensure there was an ongoing quality assurance program that included anemia management for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be 	V000632	<p>FA and Anemia Manger to analyze facility data identify trends and establish current baseline information for Anemia Management to present in next QIFMM meeting scheduled 09/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis that QIFMM Team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for quality indicators including Anemia Management. 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</p>	09/10/2013	

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	<p>printed for review nor could the information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will 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. ... Anemia Management. ... After completion and signatures (including review and signature by facility medical director if he / she was unable to personally attend a particular meeting) a copy of Quality Improvement and Facility</p>		<p>re-evaluated for effectiveness with new interventions initiated as needed. QIFMM meeting minutes must reflect discussion, actions and evaluation by team. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC</p>		

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	Management Meeting (QIFMM) Minutes is to be forwarded via fax to the Regional or Divisional Office (depending on the process established within each division)."			

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V000633	<p>494.110(a)(2)(v) QAPI-INDICATOR-VASCULAR ACCESS The program must include, but not be limited to, the following: (v) Vascular access.</p> <p>Based on policy and document review and interview, the facility failed to ensure there was an ongoing quality assurance program that included vascular access for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be printed for review nor could the 	V000633	<p>FA and Vascular Access Manager to analyze facility data identify trends and establish current baseline information for Vascular Access to present in next QIFMM meeting scheduled 9/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis that QIFMM Team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for quality indicators including Vascular Access. 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</p>	09/10/2013	

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	<p>information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will 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. ... Vascular access. ... After completion and signatures (including review and signature by facility medical director if he / she was unable to personally attend a particular meeting) a copy of Quality Improvement and Facility Management Meeting (QIFMM) Minutes</p>		<p>with new interventions initiated as needed. QIFMM meeting minutes must reflect discussion, actions and evaluation by team. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC</p>		

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V000634	<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> <p>Based on policy and document review and interview, the facility failed to ensure there was an ongoing quality assurance program that included medical injuries and medical errors for 8 of the previous 8 months reviewed (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the 	V000634	<p>FA to analyze facility data identify trends and establish current baseline information for Medical Injuries, Medical Errors including review of trends of adverse patient occurrences to present in next QIFMM meeting scheduled 9/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis that QIFMM Team must set measurable goals, timelines, conduct ongoing monitoring/evaluation, and initiate interventions for health outcomes including Medical Injuries, and Medical Errors. Team must measure, analyze, and track adverse outcomes to ensure patients safety. Team must review sentinel events, and review trends of adverse patient occurrences. Any identified</p>	09/10/2013			

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	<p>documents electronically, and she did not; therefore, the documents cannot be printed for review nor could the information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will 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. ... Review of trends of adverse patient occurrences including falls and blood loss."</p>		<p>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. QIFMM meeting minutes must reflect discussion, actions and evaluation by team. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC</p>				

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V000636	<p>494.110(a)(2)(viii) QAPI-INDICATOR-PT SATIS & GRIEVANCES The program must include, but not be limited to, the following: (viii) Patient satisfaction and grievances. Based on policy and document review and interview, the facility failed to ensure there was an ongoing quality assurance program that included patient satisfaction and grievances for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be 	V000636	<p>FA and MSW to analyze facility data identify trends and establish current baseline information for Patient Satisfaction and Grievances to present in next QIFMM meeting scheduled 9/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis on QIFMM Team must report, measure, analyze, track and trend Patient Satisfaction and Grievances. 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</p>	09/10/2013			

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	<p>printed for review nor could the information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will 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 satisfaction and grievances."</p>		<p>needed. QIFMM 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 QIFMM. Supporting documentation will be included in the meeting minutes with evaluation of complaints, action plans, resolution, and follow up with patients noted. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC</p>		

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V000637	<p>494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must-</p> <p>(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents.</p> <p>Based on facility hospitalization logs, administrative document, and policy review and interview, the facility failed to ensure an ongoing quality assurance program included infection control for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The administrative document titled "Hospitalization Log" evidenced three patients were hospitalized in the past 6 months with infections. 2. Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. One document 	V000637	<p>FA and ICM to analyze facility data identify trends and establish current baseline information incidence of infection, hospitalization, and vaccination rates to present in next QIFMM meeting scheduled 9/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis that QIFMM Team must report, measure, analyze, track and all incidence of infection, as well as analyze vaccination rates for Hepatitis B, Influenza, and Pneumococcal to identify trends</p>	09/10/2013	

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	<p>presented for review was titled "Monthly Infection Control Clinical Practice Audit" and dated 8/15/13 and completed by employee B, a registered nurse.</p> <p>3. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13 and employee A discovered, on 8/15/13, there was no facility QAPI documents within the facility, including infection control audits dated after November 2012. There was no other documentation to evidence.</p> <p>4. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will be maintained in a confidential manner. Copies of the QI meeting minutes will be provided upon</p>		<p>and establish baseline information on infection incidence. QIFMM team must provide continuous monitoring of indicators, identifying root causes for underperformance, develop recommendations and action plans to minimize infection transmission, and promote immunizations. Action plans must be re-evaluated for effectiveness with new interventions initiated as needed. QIFMM meeting minutes must reflect discussion, actions and evaluation by team. ICM and FA responsible for maintaining Infection Control Log, Hospitalization Log, and Vaccination Log, and bringing Logs for review with the Medical Director during monthly QIFMM. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with</p>				

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	request to CMS. ... The facility will measure, analyze, and track quality indicators or other aspects of performance. ... Infection Control, including Incidence of infections, Vaccination rates for Hepatitis B, Influenza, and Pneumococcal."		this POC	

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V000638	<p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE</p> <p>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.</p> <p>Based on policy and document review and interview, the facility failed to ensure there was an ongoing quality assurance program that continuously monitored its performance, took actions that resulted in performance improvement, and tracked performance to ensure improvements were sustained for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI 	V000638	<p>FA will gather, and analyze facility aggregate data identify trends and establish current baseline information to present in next QIFMM meeting scheduled 9/10/2013. Any identified 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. FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program with emphasis that QIFMM team must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program with participation by all members of team. QIFMM Team must measure, analyze and track quality indicators or other aspects of performance that reflect processes of care and facility operations; importance of having an ongoing and comprehensive QIFMM process that includes</p>	09/10/2013	

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	<p>documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be printed for review nor could the information be reviewed electronically because the system is constantly updating itself.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will be maintained in a confidential manner. Copies of the QI meeting minutes will be provided upon request to CMS. ... Any area identified as underreporting will be reviewed to identify root causes for under performance, will have an action plan identified that will result in performance improvement, and will track this change</p>		<p>tracking, trending, data analysis, action plan development and effective implementation dates related for facility indicators. Specific emphasis was placed on 1) Analyzing data collected, 2) Set measurable goals and continuously evaluate, track and trend indicators not meeting facility goals, 3) Identifying root causes for underperformance, 4) Developing action plans and timelines. 5) Reviewing current action plans in place, evaluating their effectiveness, and initiating new plans as needed to meet goals. 6) Tracking performance over time to ensure improvements are sustained, 7) Ensuring meeting minutes reflect discussion, actions and evaluation by team. Team is responsible to ensure that all areas of the QIFMM are completed for effective QAPI program. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program, and minutes reflective of actions taken. If attendance via teleconference attendance record will reflect. GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes</p>				

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	in performance over time to ensure improvements are sustained. "		and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC		

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V000639	<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. Based on policy and document review and interview, the facility failed to ensure there was an ongoing quality assurance program that set priorities for performance improvement, considered prevalence and severity of problems, and gave priority to improvement activities that affected clinical outcomes or patient safety for 8 of the previous 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 	V000639	<p>FA conducted mandatory in-service for all QIFMM members on 8/29/2013. In-service included but was not limited to review of Policy & Procedure #1-14-06: Continuous Quality Improvement Program emphasizing dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified issues and addressing the priority to improvement activities that affect patient safety, and clinical outcomes, preparation for the meeting and required documentation of discussion and action plans in the meeting minutes emphasized. Attendance is evidenced by TM signature on Clinical In-service Form. GFA and/or ROD will attend in person or via teleconference each QIFMM for the next three months and at a minimum of quarterly thereafter to ensure comprehensive QAPI program and that prioritization of issues is correctly identified, and documented regarding priority level and progress being made. If attendance via teleconference attendance record will reflect.</p>	08/29/2013			

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	<p>8/15/13, there was no facility QAPI documents within the facility dated after November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be printed for review nor could the information be reviewed electronically because the system is constantly updating itself. Employee A indicated she was responsible to ensure the facility administrators are compliant.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will 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. ... Any area identified as underreporting will be reviewed to identify root causes for under performance, will have an action plan identified that will result in performance improvement, and will track this change in performance over time to ensure improvements are sustained."</p>		GFA will also log into electronic QIFMM system monthly to ensure that each month is uploaded to system for future retrieval. QIFMM minutes and activities will also be reviewed during GB meetings to monitor ongoing compliance. Medical Director & FA are responsible for compliance with this POC				

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V000712	<p>494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program.</p> <p>Based on quality assurance document and policy review and interview, the medical director failed to ensure a quality assurance program was in place after November 2012 and all members of interdisciplinary team participated in the facility's quality assessment and performance improvement program for the previous 8 of 8 months (December 2012 and January, February, March, April, May, June, and July 2013) reviewed for 1 of 1 facility and the potential to affect all patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Administrative QAPI documents titled "Quality Improvement Facility Management Meetings (QIFMMs)" were reviewed. The most recent document was dated November 2012. On 8/14/13 at 2:48 AM, the corporation's area group administrator, employee A, indicated the previous administrator was terminated on 8/5/13. Employee A indicated she discovered, on 8/15/13, there was no facility QAPI documents within the facility dated after 	V000712	<p>Immediate steps were taken to ensure facilities QIFMM Program is monitored/reviewed by Governing Body including Medical Director who assumes operational responsibility to ensure QAPI Program analyzes data, develops plans/interventions for improvement of care, and re-evaluates focusing on health outcomes and safety of patients. Members of the GB including the FA and Medical Director have agreed to meet bi-weekly to review QIFMM program including but not limited to: 1) Ensuring facility has effective QAPI program and all members of the quality improvement committee participate in meetings; 2) Ensuring QAPI program is comprehensive including setting measurable goals, timelines, conducts ongoing monitoring/evaluation, and initiate interventions for indicators including Patient Safety, Infection Control, Adequacy, Nutrition, Medical Injuries/Errors, Mineral Metabolism, Anemia Management, Vascular Access, Growth/Capacity, Mortality, Hospitalization, Emergency Transfers, Patient Satisfaction and Grievances; 3) Ensuring</p>	08/28/2013			

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	<p>November 2012. She indicated the previous administrator was to save the documents electronically, and she did not; therefore, the documents cannot be printed for review nor could the information be reviewed electronically because the system is constantly updating itself.</p> <p>3. The policy titled "Continuous Quality Improvement Program" policy number 1-14-06, revision date March 2013 stated, "Each dialysis facility will have a continuous Quality Improvement (CQI) Committee comprised of at least the following individuals from the disciplinary team: Facility Medical Director. Facility Administrator (F / A) / designee. Registered Nurse. BioMed Technician. Registered Dietician. Social Worker. ... Written documentation and plans of actions will be documented on the Quality Improvement and Facility Management Meetings (QIFMM) minutes form and will 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. ... After completion and signatures (including review and signature by facility medical director if he / she was unable to personally attend a particular</p>		<p>team reviews Internal/External audits, identifies and immediately addresses and prioritizes problems affecting health and safety of patients; 4) QAPI Program ensures dialysis facility sets priorities for performance improvement, considering prevalence and severity of identified issues and addressing the priority to improvement activities that affect patient safety, and clinical outcomes; 5) Ensuring plans of action are developed for all indicators not meeting facility goals, and those plans are re-evaluated for effectiveness with new interventions initiated as needed to meet goals; 5) QAPI program tracks performance over time to ensure improvements are sustained; 5) Ensuring meeting minutes reflect discussion, actions and evaluation by team. GB will review QIFMM minutes to ensure minutes reflect action plans are evaluated for effectiveness, new plans developed as applicable. Once compliance is achieved QAPI program will be monitored during GB meetings at a minimum of quarterly. Medical Director & FA are responsible for compliance with this POC</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152650	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/16/2013
NAME OF PROVIDER OR SUPPLIER CARMEL HEALTH AND LIVING DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 118 MEDICAL DR STE 114 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	
	meeting) a copy of Quality Improvement and Facility Management Meeting (QIFMM) Minutes is to be forwarded via fax to the Regional or Divisional Office (depending on the process established within each division)."				