

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152504		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 04/05/2012	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE SOUTHERN INDIANA				STREET ADDRESS, CITY, STATE, ZIP CODE 525 BROADWAY ST JEFFERSONVILLE, IN 47130			
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V0000	<p>This was an ESRD federal recertification survey.</p> <p>Survey Dates: 4-2-12 through 4-5-12</p> <p>Facility #: 005151</p> <p>Medicaid Vendor #: 100075990A</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>Census: 92 incenter, 3 peritoneal dialysis, and 1 home hemodialysis</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN</p> <p>April 11, 2012</p>	V0000					

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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V0111	<p>494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure a sanitary environment was maintained to prevent cross contamination and minimize the transmission of infectious agents by maintaining clean items separate from dirty items in 2 (days 2 and 4) of 4 days of observation.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's October 10, 2008, "Infection Control Overview" policy number FMS-CS-IC,II-155-060A states, "All infection control policies for patient care are consistent with recommendation of the Centers for Disease Control (CDC) . . . Infection control policies includes, but are not limited to: . . . Dialysis unit precautions, (including the use of personal protective equipment). 2. The facility's October 10, 2008, "Dialysis Precautions" policy number FMS-CS-IC-II-155-070A states, "Dialysis Precautions will be followed by all employees with potential exposure to 	V0111	<p><u>V111 494.30 IC- Sanitary Environment</u></p> <p>On 4/10/12 the Director of Operations met with the Clinical Manager to educate and reinforce the Clinical Manager's responsibility to maintain adherence to regulations to ensure maintenance of a sanitary environment and prevent cross contamination.</p> <p>On or before May 5, 2012 all Direct Patient Care staff will be re-educated on :</p> <ul style="list-style-type: none"> -FMS-CS-IC-II-155-060A "Infection Control Overview" Policy -FMS-CS-IC-II-155-070A "Dialysis Precautions" Policy <p>Effective 4/6/12 direct patient care staff have been instructed to place a 12"x17" underpad atop the dialysis machine to form a barrier between the machine and any patient specific supplies placed on the machine. This underpad will be discarded at the completion</p>	05/05/2012			

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	<p>bloodborne pathogens and other potentially infectious material (OPIM) in the dialysis setting . . . The patient treatment area shall have designated 'clean' and 'dirty' areas. Clean area: An area designated for clean and unused equipment and supplies . . . Dirty area: An area where there is a potential for contamination with blood or body fluids . . . Examples of dirty areas include . . . the entire patient station while the patient is dialyzing."</p> <p>3. On 4-3-12 at 9:55 AM, employee A, a registered nurse, was observed to approach patient number 11 with an unlabeled syringe with a clear liquid in it. The employee placed the syringe (a "clean item") on top of the dialysis machine (a "dirty" area), prepared the dialysis tubing for the injection of the contents of the syringe, and then picked the syringe up and injected the contents of the syringe into the dialysis tubing. The employee indicated the syringe contained Epogen, a medication used to treat anemia.</p> <p>4. On 4-3-12 at 11:05 AM, central venous catheter dressing change supplies were observed on top of the dialysis machine in use by patient number 12.</p> <p>5. On 4-5-12 at 10:20 AM, the following observations were made of clean supplies</p>		<p>of each patient's dialysis treatment. After the machine has been cleaned per policy, a new underpad will be placed atop the machine for the initiation of the next patient treatment.</p> <p>Clinical Manager (or designee) will monitor for compliance during monthly infection control audits and routine observations of the treatment area. The Clinical Manager will, effective immediately and on going, present a routine monthly review of the current months Infection Control Audit findings and follow up at each month's QAI meeting monthly. All issues will be addressed by the facility's QAI process. Any identified deficiencies will result in implementation of the corrective action process with the employee. Identified deficiencies/ trends will require initiation of a formal action plan to be followed through until resolution.</p> <p>The QAI minutes will document this activity and are available for review at the facility.</p> <p>Documentation of staff education is available at the facility for review.</p>				

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	<p>on top of dialysis machines that were in use:</p> <p>A. Packaged syringes and clamps on top of the machine at station number 4.</p> <p>B. Clean gloves, clamps, and 2 x 2 gauze pads on top of the machines at stations numbered 9 and 10.</p> <p>C. Packaged tubing on top of the machine at station number 14.</p> <p>D. A packaged Luer lock cap set and 2 x 2 gauze pads on top of the machine at station number 19.</p> <p>6. The above-stated observations were discussed with the facility administrator, employee D, on 4-4-12 at 4:15 PM. The administrator indicated she was unaware clean supplies could not be placed on top of the dialysis machines when the machines were in use. The administrator stated, "The supplies are going to be used for that patient."</p>				

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V0113	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>Based on observation, interview, and facility policy review, the facility failed to ensure staff members followed their own policy with regards to hand hygiene in 2 of 2 initiation of treatment observations (#13 and 14) completed by employee I creating the potential for the transmission of disease causing organisms among all of the facility's 96 dialysis patients and staff.</p> <p>The findings include:</p> <p>1. The facility's October 10, 2008, "Infection Control Overview" policy number FMS-CS-IC-II-155-060A states, "All infection control policies for patient care are consistent with recommendation of the Centers for Disease Control (CDC)."</p> <p>2. The CDC "Guideline for Hand Hygiene in Health-Care Settings", Morbidity and Mortality Weekly Report, October 25, 2002, states, "Indications for handwashing and hand antisepsis . . . Decontaminate hands before having direct contact with patients . . . Decontaminate hands after contact with inanimate</p>	V0113	<p><u>V113 494.30(a)(1) IC-Wear Gloves/Hand Hygiene</u></p> <p>- On or before 5/5/12 all direct patient care staff will be re-educated on:</p> <p>-FMS-CS-IC-II-155-060A "Infection Control Overview" Policy -FMS-CS-IC-II-155-070A "Dialysis Precautions" -FMS-CS-IC-II-155-090A "Hand Hygiene" Policy</p> <p>Clinical Manager (or designee) will monitor for compliance during monthly infection control audits and routine observations of the treatment area. The Clinical Manager will, effective immediately and on going, present a routine monthly review of the current months Infection Control Audit findings and follow up at each month's QAI meeting monthly. All issues will be addressed by the facility's QAI process. Any identified deficiencies will result in implementation of the corrective action process with the employee. Identified</p>	05/05/2012			

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	<p>objects, (including medical equipment) in the immediate vicinity of the patient."</p> <p>3. On 4-2-12 at 4:25 PM, employee I, a patient care technician (PCT), was observed to initiate the dialysis treatment on patient number 13. With gloves hands, the PCT inserted the needles into the patient's access, secured them, and attached the extension tubing. The PCT then touched the tubing on the dialysis machine, the machine front, and then the dialyzer. The PCT then connected the tubing on the dialysis machine to the extension tubing connected to the patient without changing her gloves or cleansing her hands.</p> <p>4. On 4-2-12 at 4:45 PM, employee I was observed to initiate the dialysis treatment on patient number 14. With gloves hands, the PCT inserted the needles into the patient's access, secured them, and attached the extension tubing. The PCT then touched the tubing on the dialysis machine, the machine front, and then the dialyzer. The PCT then connected the tubing on the dialysis machine to the extension tubing connected to the patient without changing her gloves or cleansing her hands.</p> <p>5. The above-stated observations were discussed with the facility administrator</p>		<p>deficiencies/ trends will require initiation of a formal action plan to be followed through until resolution.</p> <p>The QAI minutes will document this activity and are available for review at the facility.</p> <p>Documentation of staff education is available at the facility for review.</p>		

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	on 4-4-12 at 4:15 PM. The administrator was unable to provide any information and/or documentation related to these observations. The administrator stated, "Okay."			

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V0216	<p>494.40(a) OZONE-SYS REQUIREMENTS/MONITORING 5.3.4.2 Ozone generators: system requirements/monitoring Ozone can be used for bacterial control only in systems constructed from ozone-resistant materials (see AAMI 5.3.3 for suitable piping materials).</p> <p>5.3.4.2 Ozone generators Refer to RD62:2001, 4.3.15 Ozone disinfection systems: When used to control bacterial proliferation in water storage and distribution systems, an ozone generator shall be capable of delivering ozone at the concentration and for the exposure time specified by the manufacturer.</p> <p>6.3.4 Bacterial control devices 6.3.4.2 Ozone generators Ozone generators should be monitored for ozone output at a level specified by the manufacturer. The output of the ozone generator should be measured by the ozone concentration in the water. A test based on indigo trisulfonate chemistry, or the equivalent, should be used to measure the ozone concentration ...each time disinfection is performed. An ozone-in-ambient-air test should be conducted on a periodic basis, as recommended by the manufacturer, to ensure compliance with the OSHA permissible exposure limit of 0.1 ppm. A log sheet should be used to indicate that monitoring has been performed.</p> <p>Based on disinfection record review, facility policy review, and interview, the facility failed to ensure it had followed its own policy regarding testing for the absence of ozone after disinfection of the</p>	V0216	<p><u>V216 494.40(a) OZONE SYS REQUIREMENTS/MONITORING</u></p> <p>On 4/9/12 and 4/17/12 Technical Program Manager and Clinical Manager met with employees</p>	04/17/2012	

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	<p>solution delivery system in 4 of 4 times ozone was used to disinfect the solution delivery system creating the potential to affect all of the facility's 92 current incenter hemodialysis patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's 09-01-04 "Concentrate Mixing and Handling" policy number 153-090-012 states, "Test for the absence of Ozone prior to preparation of the first batch of concentrate if Ozone was used the preceding treatment day." 2. The facility's "Solution Delivery System Log Form SDS-1" evidenced ozone had been used to disinfect the system on 1-15-12, 1-29-12, 2-11-12, and 3-4-12. The log failed to evidence a test for the absence of Ozone had been completed prior to the preparation of the first batch of concentrate on the day after the Ozone had been used to disinfect the system. 3. The Chief Biomedical Technician, employee R, indicated, on 4-4-12 at 10:15 AM, the test for the absence of Ozone should have been documented on the SDS-1 form. 		<p>responsible for completing Ozone disinfection of the SDS system to review findings of this survey.</p> <p>Staff was re-educated on:</p> <ul style="list-style-type: none"> ·FMS 153-090-012 "Concentrate Mixing and Handling" Policy. ·Specifically, to test for the absence of ozone prior to mixing the first batch of concentrate if ozone was used the preceding treatment day. ·Procedure for testing for presence of ozone. ·Acceptable limit. ·Actions to take if result higher than acceptable limit. ·Document results of residual test on the SDS-1 Log <p>Technical Department compliance personnel will audit SDS-1 log as part of the monthly QAI technical audit. Any issues with compliance will be addressed by the facility's QAI process. Any identified deficiencies will result in implementation of the corrective action process with the employee. Identified deficiencies/ trends will require initiation of a formal action</p>				

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			<p>plan to be followed through until resolution.</p> <p>The QAI minutes will document this activity and are available for review at the facility.</p> <p>Documentation of staff education is available at the facility for review.</p>	

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V0541	<p>494.90 POC-GOALS=COMMUNITY-BASED STANDARDS</p> <p>The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care included measurable outcomes and estimated timetables to achieve the outcomes in 10 (#s 1 through 10) of 10 records reviewed creating the potential to affect all of the facility's 96 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included a plan of care (PoC) dated 12-15-11. The PoC failed to evidence estimated timetables to achieve the following outcomes:</p> <p>A. Adequacy of 1.2 or greater every treatment.</p>	V0541	<p><u>V541 494.90 POC-Goals= Community Based On April 19, 2012 the Director of Operations met with the Clinical Manager to reiterate her role and responsibility in the oversight and development of the patient's Interdisciplinary Assessment and Plan of Care as per the Federal Regulations and FMS Policy inclusive of the expectations of full compliance going forward. To ensure that the Interdisciplinary Team (IDT) is knowledgeable of the Federal and facility requirements for development and implementation of a written, individualized patient Plan of Care that specifies/documents the care and services necessary to address the patient's individual needs, on May 3, 2012, the</u></p>	05/03/2012			

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	<p>B. Continue to meet estimated dry weight (EDW) without complications.</p> <p>C. Tunneled catheter will remain free of infection and continue to provide adequate dialysis.</p> <p>D. The PoC failed to evidence any expected and measurable psychosocial outcomes.</p> <p>2. Clinical record number 2 included a PoC dated 7-28-11. The PoC failed to evidence estimated timetables to achieve the following outcomes:</p> <p>A. Adequacy of 1.2 or greater.</p> <p>B. Continue to meet EDW without complications.</p> <p>C. Maintain hemoglobin (Hgb) between 10-12.</p> <p>D. Tunneled catheter will remain free of infection and remain patent while continuing to provide adequate dialysis of 1.2 or greater.</p> <p>E. Albumin greater than or equal to 4.0.</p> <p>F. Phosphorous (PO4) 3.0 to 5.5.</p>		<p>Director of Operations and Operations Manager will conduct an in-service on the following Plan of Education:</p> <ul style="list-style-type: none"> ·Reeducation and reinforcement on FMC Comprehensive Interdisciplinary Assessment and Plan of Care Policy #FMS-CS-IC-I-110-125 A with emphasis on the Plan of Care components. ·Reeducation and reinforcement that the Plan of Care must include: <ul style="list-style-type: none"> - realistic, measurable, patient specific goals - realistic, individualized specific Interdisciplinary interventions to assist the patient to achieve desired outcomes - realistic estimated timetables for achieving goals. ·Reeducation and Reinforcement that the Plan of Care must include estimated timetables to achieve or maintain all goals including: <ul style="list-style-type: none"> - Maintaining adequate Kt/v 1.2 or greater - Maintaining EDW without complications - Maintaining tunneled catheter free of infection - Identifying and Establishing psychosocial goals. - Maintaining Hgb 10-11 - Maintaining Albumin >=4.0 - Maintaining Phosphorus 3.0-5.5 - Maintaining patent fistula - Preventing falls To ensure no reoccurrence of this 		

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	<p>G. The PoC failed to evidence any expected and measurable psychosocial outcomes.</p> <p>3. Clinical record number 3 included a PoC dated 5-19-11. The PoC failed to evidence estimated timetables to achieve the following outcomes:</p> <p>A. PO4 3.0 to 5.5.</p> <p>B. The PoC failed to evidence any expected and measurable psychosocial outcomes.</p> <p>4. Clinical record number 4 included a PoC dated 11-17-11. The PoC failed to evidence estimated timetables to achieve the following outcomes:</p> <p>A. Adequacy 1.2 or greater.</p> <p>B. Continue to meet EDW without complications.</p> <p>C. Hgb 10-12.</p> <p>D. Arteriovenous fistula (AVF) to remain patent and continue to provide adequate dialysis of 1.2 or greater.</p> <p>E. Albumin will continue greater than or equal to 4.0.</p>		<p>deficiency, the Clinical Manager will review each completed Comprehensive Interdisciplinary Assessment and Plan of Care prior to filing in the patient record. Clinical Manager will confirm with review that goals and timetables have been addressed by all IDT members. In the event this review finds deficiencies the Clinical Manager will review the CIA/ POC with the IDT team for further development. Additionally, the Clinical Manager will formalize a report for the monthly QAI meeting, detailing compliance gaps noted with the CIA/POC review. This report will include corrective actions implemented to correct deficiencies. QAI committee will review and determine further action as necessary to maintain compliance. The QAI minutes document this activity and are available for review at the facility. The Clinical Manager is responsible and the QAI committee monitors for compliance.</p>				

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	<p>F. The PoC failed to evidence any expected and measurable psychosocial outcomes.</p> <p>5. Clinical record number 5 included a PoC dated 3-22-12. The PoC failed to evidence any expected and measurable psychosocial outcomes.</p> <p>6. Clinical record number 6 included a PoC dated 4-28-11. The PoC failed to evidence estimated timetables to achieve the following outcomes:</p> <p>A. Maintain adequacy of 1.2 or greater.</p> <p>B. Continue to meet EDW without complications, client blood pressure to decrease and not hospitalized.</p> <p>C. Hgb to increase to 10-12.</p> <p>D. Tunneled catheter to remain free of infection and continue to provide adequacy 1.2 or greater, access continue to remain patent.</p> <p>E. Albumin greater than or equal to 4.0.</p> <p>F. The PoC failed to evidence any expected and measurable psychosocial outcomes.</p>						

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	<p>7. Clinical record number 7 included a PoC dated 12-15-11. The PoC failed to evidence estimated timetables to achieve the following outcomes:</p> <p>A. Adequacy to continue to be 1.2 or greater every month.</p> <p>B. Continue to meet EDW without complications.</p> <p>C. Hgb to be between 10 - 12.</p> <p>D. Continue to provide adequate dialysis 1.2 or , catheter to remain patent and free of infection.</p> <p>E. Albumin will improve toward goal.</p> <p>F. Will maintain weight usual range.</p> <p>G. The PoC failed to evidence any expected and measurable psychosocial outcomes.</p> <p>8. Clinical record number 8 included a PoC dated 3-15-12. The PoC failed to evidence measurable and expected outcomes and estimated timetables for the dialysis access or for the patient's psychosocial status.</p> <p>9. Clinical record number 9 included a</p>			

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	<p>PoC dated 5-27-11. The PoC failed to evidence measurable and expected outcomes and estimated timetables for the dialysis access.</p> <p>A. The PoC failed to evidence an estimated timetable to achieve an albumin outcome of PO4 of 3.0 to 5.5 and an albumin level of greater than or equal to 4.0.</p> <p>B. The PoC failed to evidence any expected and measurable psychosocial outcomes.</p> <p>10. Clinical record number 10 included a PoC dated 4-28-11. The PoC failed to evidence estimated timetables to achieve the following outcomes:</p> <p>A. Continue to meet adequacy of 1.2 or greater.</p> <p>B. Continue to meet EDW without experiencing problems.</p> <p>C. Hgb 10-12.</p> <p>D. Tunneled catheter will continue to provide adequate dialysis of 1.2 or greater and remain free of infection.</p> <p>E. No falls.</p>			

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	<p>F. Albumin greater than or equal to 4.0.</p> <p>G. The PoC failed to evidence any expected and measurable psychosocial outcomes.</p> <p>11. The facility administrator, employee D, was unable to provide any additional documentation and/or information when asked regarding these findings on 4-4-12 at 4:15 PM.</p> <p>12. The facility's February 2, 2011 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The Plan of Care must include measurable and expected outcomes and an estimated timetable to achieve these outcomes."</p>				

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V0551	<p>494.90(a)(5) POC-VA MONITOR/PREVENT FAILURE/STENOSIS The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care provided for the monitoring and maintenance of accesses in 2 (#s 8 and 9) of 10 records reviewed creating the potential to affect all of the facility's 96 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 8 included a plan of care dated 3-15-12 that identified the patient as a home peritoneal dialysis patient. The plan of care failed to include interventions to monitor and maintain the patient's peritoneal catheter. 2. Clinical record number 9 included a plan of care dated 5-27-11 that identified the patient as a home hemodialysis patient. The plan of care failed to include interventions to monitor and maintain the patient's hemodialysis access. 3. The facility administrator, employee D, was unable to provide any additional documentation and/or information when asked regarding these findings on 4-4-12 	V0551	<p><u>V 551 494.90 (a) (5) POC VA-Monitor/Prevent Failure/Stenosis</u></p> <p>-</p> <p>-</p> <p>On May 3, 2012 a mandatory educational class is scheduled for all members of the IDT and will be conducted by the Director of Operations and Operations Manager. The class will address all aspects of the CIA/POC. The instructor will also address the FMS-138-020-091 policy regarding the requirement for providing vascular access monitoring and PD catheter access monitoring for patency, catheter, tunnel and exit site on the POC. The attendance record will be available at the facility for review.</p> <p>On or before 5/3/2012, the Home Therapy Program Manager will have reviewed the Plan of Care for all home therapy patients and met with the IDT to ensure that there has been an addendum to the current POC addressing the maintenance of patency of both the vascular access and</p>	05/03/2012			

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	<p>at 4:15 PM.</p> <p>4. The facility's February 2, 2011 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Provide vascular access monitoring . . . Provide PD Catheter access monitoring for patency, catheter, tunnel, or exit site infection."</p>		<p>peritoneal catheter. Therefore, as of that date, all patient's POCs will be complete and current and available for review at the facility.</p> <p>The POC is maintained in each patient's medical record. The Home Therapy Manager will review each POC monthly and report findings to the QAI committee.</p>	

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V0552	<p>494.90(a)(6) POC-P/S COUNSELING/REFERRALS/HRQOL TOOL The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care included interventions to address identified needs and to monitor patients' psychosocial status in 10 (#s 1 through 10) of 10 records reviewed and failed to evidence the use of a standardized mental and physical assessment tool to measure the patient's psychosocial status in 3 (#s 1, 7, and 9) of 6 records reviewed included in the administration of the assessment tool creating the potential to affect all of the facility's 96 current patients.</p> <p>The findings include:</p> <p>Regarding interventions to monitor patients' psychosocial status:</p> <p>1. Clinical record number 1 included an initial plan of care established by the interdisciplinary team (IDT) on 10-27-11.</p>	V0552	<p>- - <u>V552 494.90(a)(6) POC-P/S Counseling/Referrals/HRQOL Tool</u> - On 4/19/2012 the Clinical Manager, Director or Operations and Operations Manager met with the assigned MSW to review the citations from the April 2-5 CMS survey and to review the responsibilities of the social worker in the development of the patient's Comprehensive Intradisciplinary Assessment and POC (CIA/POC) To ensure that the Social Worker (MSW) and the Interdisciplinary Team are knowledgeable on the Federal Requirements for the Plan of Care inclusive but not limited to monitoring the patient's psychosocial status with</p>	05/03/2012			

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	<p>The plan of care identified issues with "ability to follow the treatment prescription", "mental health concerns . . . hx of D [history of depression]", and "transportation resources."</p> <p>A. The plan failed to evidence individualized, patient-specific interventions to address the identified needs and monitor the patient's psychosocial status.</p> <p>B. The record included a 90-day plan of care established by the IDT on 12-15-11 that identified issues with "Insurance or financial resources."</p> <p>The plan of care failed to evidence individualized, patient-specific interventions to address the identified needs and monitor the patient's psychosocial status.</p> <p>2. Clinical record number 2 included a plan of care established by the IDT on 7-28-11. The plan of care identified issues with "ability to meet activities of daily living" and "mental health concerns".</p> <p>The plan of care failed to evidence individualized, patient-specific interventions to address the identified needs and to monitor the patient's</p>		<p>appropriately documented interventions, on May 3, 2012 the Director of Operations and Operations Manager will present the following Plan of Education to the Interdisciplinary Team Memebers:</p> <ul style="list-style-type: none"> · Reeducation and reinforcement that the Plan of Care must reflect information obtained in the psychosocial assessment of the Comprehensive Patient Assessment. · Reeducation and reinforcement that the IDT must provide the necessary Social Work and monitoring interventions with appropriated documentation in the Plan of Care including patient counseling, education, and referrals. · Reeducation and reinforcement that the Plan of Care must include interventions individualized to meet the psychosocial needs of the patient and aimed at optimizing the patient's adjustment to kidney failure and treatment as measured by a standardized mental and physical assessment tool (KDQOL-survey tool) at regular intervals or more frequently as needed. 				

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	<p>psychosocial status.</p> <p>3. Clinical record number 3 included a plan of care established by the IDT on 5-19-11. The plan of care failed to evidence individualized, patient-specific interventions to monitor the patient's psychosocial status.</p> <p>4. Clinical record number 4 included a plan of care established by the IDT on 11-17-11. The plan of care failed to evidence individualized, patient-specific interventions to monitor the patient's psychosocial status.</p> <p>5. Clinical record number 5 included a plan of care established by the IDT on -22-12. The plan of care identifies issues with "insurance or financial resources." The plan failed to evidence interventions to address the identified needs and to monitor the patient's psychosocial status.</p> <p>6. Clinical record number 6 included a plan of care established by the IDT on 4-28-11. The plan of care identifies issues with "insurance of financial resources." The plan failed to evidence interventions to address the identified</p>		<p>·Reeducation and reinforcement that the Social Worker is expected to assist the patient in achieving their psychosocial goals.</p> <p>·Reeducation and reinforcement that counseling services to patients and their families should be directed to help the patient cope with kidney failure, follow the treatment plan and achieve rehabilitation goals.</p> <p>To ensure no reoccurrence of this deficiency, the Clinical Manager will review each completed Comprehensive Interdisciplinary Assessment and Plan of Care prior to filing in the patient record. Clinical Manager will confirm with review that psychosocial assessment, goals and timetables have been addressed by the MSW and IDT members. In the event this review finds deficiencies the Clinical Manager will review the CIA/ POC with the IDT team for further development.</p> <p>Additionally, the Clinical Manager will formalize a report for the monthly QAI meeting, detailing compliance gaps</p>		

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	<p>needs and to monitor the patient's psychosocial status.</p> <p>7. Clinical record number 7 included an initial plan of care established by the IDT on 9-30-11 that identified issues with "ability to follow the treatment prescription educ [education] deficit", "coping and adjustment to dialysis", and "eligibility for federal, state or local resources."</p> <p>A. The plan failed to evidence individualized, patient-specific interventions to address the identified needs and to monitor the patient's psychosocial status.</p> <p>B. The record included a 90-day plan of care established on 12-15-11. The plan identified issues with "coping and adjustment to dialysis getting back to 'normal' life", "advance directives / end of life concern want info on living will", and "transplant info."</p> <p>The plan failed to evidence individualized, patient-specific interventions to address the identified needs and to monitor the patient's psychosocial status.</p> <p>8. Clinical record number 8 included a plan of care established by the IDT on</p>		<p>noted with the CIA/POC review. This report will include corrective actions implemented to correct deficiencies. QAI committee will review and determine further action as necessary to maintain compliance.</p> <p>The QAI minutes document this activity and are available for review at the facility</p>				

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	<p>3-15-12. The plan failed to evidence individualized, patient-specific interventions to address the identified needs and to monitor the patient's psychosocial status.</p> <p>9. Clinical record number 9 included a 90-day plan of care established by the IDT on 5-27-11. The plan identified issues with "mental health concerns (depression . . . substance abuse, etc.) Bipolar disorder hx of ETOL [history of alcohol] abuse currently receiving treatment for both."</p> <p>The plan failed to evidence individualized, patient-specific interventions to address the identified needs and to monitor the patient's psychosocial status.</p> <p>10. Clinical record number 10 included a plan of care established by the IDT on 4-28-11. The plan failed to evidence individualized, patient-specific interventions to monitor the patient's psychosocial status.</p> <p>11. The facility's February 2, 2011, "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not</p>			

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	<p>limited to the following: . . . Psychosocial Status: Provide necessary monitoring and social work interventions, including counseling services and appropriate referrals."</p> <p>12. The facility administrator, employee D, was unable to provide any additional documentation and/or information when asked regarding these findings on 4-4-12 at 4:15 PM.</p> <p>Regarding the use of the standardized mental and physical assessment tool:</p> <p>1. During an interview with the medical social worker, on 4-5-12 at 9:55 AM, the social worker, employee N, indicated the KDQOL measurement tool was used to assess the patient's mental and physical status.</p> <p>2. The facility's November 19, 2008 "Social Work Services" policy number FMS-138-030-010 states, "The standardized mental and physical assessment tool will be administered with patients within 3 months after the completion of the initial comprehensive assessment of new patients and at minimum, annually."</p> <p>3. The facility's February 2, 2011</p>				

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	<p>"Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Psychosocial Status: Oversee measurement of appropriate psychosocial status, using the KDQOL tool at regular intervals, or more frequently as needed."</p> <p>4. Clinical record number 1 evidenced a 90-day plan of care established by the IDT on 12-15-11. The plan of care failed to evidence the KDQOL assessment tool had been administered and utilized in planning the patient's care.</p> <p>5. Clinical record number 7 evidenced a 90-day plan of care established by the IDT on 12-15-11. The plan failed to evidence the KDQOL assessment tool had been administered and utilized in planning the patient's care.</p> <p>6. Clinical record number 9 evidenced a 90-day plan of care established by the IDT on 5-27-11. The plan failed to evidence the KDQOL assessment tool had been administered and utilized in planning the patient's care.</p> <p>7. The facility administrator, employee D, was unable to provide any additional</p>			

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	documentation and/or information when asked regarding these findings on 4-4-12 at 4:15 PM.				

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V0559	<p>494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC</p> <p>If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must-</p> <p>(i) Adjust the plan of care to reflect the patient's current condition;</p> <p>(ii) Document in the record the reasons why the patient was unable to achieve the goals; and</p> <p>(iii) Implement plan of care changes to address the issues identified in paragraph (b) (3)(ii) of this section.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care identified reasons why goals had not been attained and included changes to address identified reasons in 3 (#s 3, 7, and 9) of 10 records reviewed creating the potential to affect all of the facility's 96 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 3 included laboratory results that identified the patient's phosphorous (PO4) levels were above the desired level of 3.5 to 5.5 milligrams per deciliter (mg/dL), according to the Centers for Medicare and Medicaid Services (CMS) Measurement Assessment Tool (MAT), as follows: 11-16-11: 6.7, 12-21-11: 5.8, 1-18-12: 7.2, 2-15-12: 5.7, and 3-21-12: 6.7</p>	V0559	<p><u>V 559 494.90(b)(3)</u> <u>POC-OUTCOME NOT ACHIEVED-ADJUST POC</u></p> <p>-</p> <p>On April 19, 2012 the Director of Operations met with the Clinical Manager to reiterate her role and responsibility in the oversight and development of the patient's Interdisciplinary Assessment and Plan of Care as per the Federal Regulations and FMS Policy inclusive of the expectations of full compliance going forward.</p> <p>To ensure that the Interdisciplinary Team (IDT) is knowledgeable of the Federal and facility requirements for development and implementation of a written,</p>	05/03/2012			

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	<p>mg/dL.</p> <p>The record failed to evidence the interdisciplinary team (IDT) had identified the reasons for the increase PO4 levels of calcium or had adjusted the plan of care to address the identified reasons.</p> <p>2. Clinical record number 7 included laboratory results that identified the patient's albumin levels were below the desired level of 4.0 mg/dL according to the CMS MAT as follows: 11-16-11: 2.8, 12-21-11: 2.9, 1-23-12: 3.1, 2-15-12: 3.1, and 3-21-12: 2.8.</p> <p>A. The record failed to evidence the IDT had identified the reasons for the decreased albumin levels or had adjusted the plan of care to address the identified reasons.</p> <p>B. The record included laboratory results that identified the patient's PO4 levels were below and then above the desired level of 3.5 to 5.5 mg/dL according to the CMS MAT as follows: 1-23-12: 1.6, 2-15-12: 7.2, and 3-2-12: 7.2.</p> <p>The record failed to evidence the IDT had identified the reasons for the decreased and then increased level of PO4</p>		<p>individualized patient Plan of Care that specifies/documents the care and services necessary to address the patient's individual needs, on May 3, 2012, the Director of Operations and Operations Manager will conduct an in-service on the following Plan of Education:</p> <ul style="list-style-type: none"> ·Reeducation and reinforcement on FMC Comprehensive Interdisciplinary Assessment and Plan of Care Policy #FMS-CS-IC-I-110-125 A with emphasis on the Plan of Care and updates to the Plan of Care. ·Reeducation and reinforcement regarding identifying, documenting and developing the Plan of Care to address root causes/reasons patient's indicator not in goal. ·Monthly or annual completion of the Plan of Care based on the patient Comprehensive Assessment and the Interdisciplinary Team's determination of the stability of the patient. ·If patient declared unstable, the IDT should complete a new Comprehensive Interdisciplinary Assessment 		

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	<p>or had adjusted the plan of care to address the identified reasons.</p> <p>3. Clinical record number 9 included laboratory results that identified the patient's PO4 levels were above the desired level of 3.5 to 5.5 mg/dL according to the CMS MAT as follows: 2-12-12: 8.6 and 3-8-12: 8.4 mg/dL.</p> <p>The record failed to evidence the IDT had identified the reasons for the increased PO4 levels or had adjusted the plan of care to address the identified reasons.</p> <p>4. The facility administrator, employee D, was unable to provide any additional documentation and/or information when asked regarding these findings on 4-4-12 at 4:15 PM.</p> <p>5. The facility's February 2, 2011, "Comprehensive Interdisciplinary Assessment and Plan of Care" policy FMS-138-020-091 states, "If the patient specific expected outcome as determined by the attending physician, IDT and patient for the Plan of Care is not achieved within the identified timeframe: . . . If the patient is unable to achieve the desired outcomes, the team must adjust the Plan of Care to reflect the patient's current condition, and document in the</p>		<p>and Plan of Care in their entirety monthly until patient is determined stable by the IDT.</p> <p>·The Assessment/Update section of the Plan of Care should be updated monthly for patients identified as stable, but not meeting expected goal within the established time frame.</p> <p>·Documentation that indicators previously meeting goal which fall out of goal are addressed on the care plan. This facility will implement a monthly review system in which patients with any indicator not in goal will be discussed and reviewed by the IDT team. This review will be documented on a one page, indicator specific update page to the patient's Plan of Care.</p>		

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	medical record the reason(s) why the patient is unable to achieve the goal. Implement the Plan of Care changes to address the identified issues."			

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V0562	<p>494.90(d) POC-PT/FAMILY EDUCATION & TRAINING The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care included interventions to address identified educational needs in 4 (#s 1, 5, 8, and 9) of 10 records reviewed creating the potential to affect all of the facility's 96 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included an initial plan of care (PoC) dated 10-27-11 that identified additional education was needed regarding "quality of life" and "rehabilitation". The PoC failed to evidence interventions to address these identified needs.</p> <p>The record included a 90-day PoC dated 12-15-11 that identified additional education was needed regarding "fluid management", "vascular access", and diabetes self-management to include "footchecks". The PoC failed to evidence</p>	V0562	<p><u>V 562 494.90(d) POC-Pt/Family Education & Training</u></p> <p>To ensure that the Interdisciplinary Team (IDT) is knowledgeable of the Federal and facility requirements for development and implementation of a written, individualized patient Plan of Care that specifies/documents the care and services necessary to address the patient's individual needs, on May 3, 2012, the Director of Operations and Operations Manager will conduct an in-service on the following Plan of Education:</p> <p>·Reeducation and reinforcement on FMC Comprehensive Interdisciplinary Assessment and Plan of Care Policy #FMS-CS-IC-I-110-125 A with emphasis on the Plan of Care</p>	05/03/2012			

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	<p>interventions to address these identified needs.</p> <p>2. Clinical record number 5 included a PoC dated 3-22-12 that identified additional education was needed regarding "dietary management" and "diet integration of HD and DM guidelines, per monthly labs." The PoC failed to evidence interventions to address these identified needs.</p> <p>3. Clinical record number 8 included a PoC dated 3-15-12 that identified additional education was needed regarding "dietary management". The PoC failed to evidence interventions to address this identified need.</p> <p>4. Clinical record number 9 included a PoC dated 5-27-11 that identified additional education was needed regarding "dietary management" and "medication regime adherence". The PoC failed to evidence interventions to address these identified needs.</p> <p>5. The facility administrator, employee D, was unable to provide any additional documentation and/or information when asked regarding these findings on 4-4-12 at 4:15 PM.</p> <p>6. The facility's February 2, 2011</p>		<p>components.</p> <ul style="list-style-type: none"> ·Reeducation and Reinforcement regarding identifying patient's educational needs, documenting educational needs and developing a patient specific Plan of Care to address identified educational needs. ·Reeducation and Reinforcement that the Plan of Care should document all identified educational needs with all IDT members participating in the development of the plan to address the educational needs of the patient. <p>To ensure no reoccurrence of this deficiency, the Clinical Manager will review each completed Comprehensive Interdisciplinary Assessment and Plan of Care prior to filing in the patient record. Clinical Manager will confirm with review that patient's education needs were assessed by all IDT members. Clinical Manager will confirm addressed needs are documented on the Plan of Care, and goals and timetables are established by the IDT members. In the event this</p>				

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	"Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-138-020-091 states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Patient Education and Training: Include education and training for patients and family members or caregivers as applicable."		review finds deficiencies the Clinical Manager will review the CIA/ POC with the IDT team for further development. Additionally, the Clinical Manager will formalize a report for the monthly QAI meeting, detailing compliance gaps noted with the CIA/POC review. This report will include corrective actions implemented to correct deficiencies. QAI committee will review and determine further action as necessary to maintain compliance.		

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V0597	<p>494.100(c)(1)(vi) H-PROVIDE ORDERED SUPPLIES/EQUIPMENT Services include, but are not limited to, the following: (vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.</p> <p>Based on administrative record and policy review and interview, the facility failed to ensure the home patient's water treatment system had been disinfected per the facility's policy in 1 (# 9) of 1 home hemodialysis patient record reviewed with the potential to affect all the facility's home hemodialysis patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility's 11-02-05 "Water Treatment Equipment" policy number 153-020-030 states, "Membranes must be cleaned and disinfected at the intervals specified by the manufacturer or quarterly, whichever is more frequent. Records of cleaning and disinfection will be maintained on the Equipment Repair Record log ER-1." 2. The facility's home hemodialysis water treatment equipment maintenance and disinfection records (form ER-1) for patient number 9 failed to evidence the patient's reverse osmosis (RO) machine 	V0597	<p><u>V597 494.100(c)(1)(vi) H-Provide Ordered Supplies/Equipment</u></p> <p>On April 26, 2012 a mandatory in service is scheduled for the Home Department Technical staff, conducted by the Technical Program Manager. The class will address The Water Treatment Equipment Policy in the Fresenius Medical Services manual #153-020-030 -regarding the requirement for proper documentation of all maintenance and disinfection on the Equipment Repair Record log ER-1. The attendance record will be available at the facility for review.</p> <p>Effective immediately and on-going, the Technical Program Manager (or designee) will conduct a monthly audit of all Home Hemodialysis equipment assigned to the Southern Indiana facility #1434 to ensure</p>	04/26/2012			

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	<p>had been disinfected quarterly. The records evidenced the RO had been disinfected on 4-14-11 and not again until 9-22-11.</p> <p>3. The home program nurse, employee P, stated, on 4-4-12 at 2:00 PM, "It does not appear the RO was disinfected quarterly as required."</p>		<p>that all maintenance and disinfections have been done per FMC policy. Therefore, all patient's home water treatment systems maintenance and disinfections will be complete and current, and available for review at the facility.</p> <p>The equipment and water treatment records will be maintained at the facility. The Technical Program Manager (or designee) will review each Southern Indiana facility #1434 Home Hemodialysis ER-1 log monthly and report findings to the QAI committee. This report will include corrective actions implemented to correct deficiencies. QAI committee will review and determine further action as necessary to maintain compliance.</p>		

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V0715	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must-</p> <p>(2) Ensure that-</p> <p>(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers;</p> <p>Based on observation, interview, and facility policy and clinical record review, the medical director failed to ensure facility policies regarding medication administration had been followed in 1 of 1 observation and 1 (# 1) of 1 clinical records reviewed of a patient that had received as needed medications during the dialysis treatment creating the potential to affect all of the facility's 92 current incenter hemodialysis patients.</p> <p>The findings include:</p> <p>1. The facility's January 12, 2011, "Medication and Preparation and Administration" policy number FMS-132-080-104 states, "Filled syringes do not have to be labeled if drawn up and administered immediately. These unlabeled, filled syringes must not be placed down at any time. Only one unlabeled, filled syringe can be drawn up and administered at one time."</p> <p>A. On 4-3-12 at 9:55 AM, employee</p>	V0715	<p><u>V715.494.150(c)(2)(i) MD Resp-Ensure All Adhere to P&P</u></p> <p>The Medical Director of this facility acknowledges his responsibility to ensure all staff adhere to policy and procedure defined by Fresenius policy and the Conditions of Coverage.</p> <p>On April 19, 2012 the Director of Operations, Operations Manager and Clinical Manager met with the Medical Director to review results of the CMS survey conducted April 2-5, 2012 and requirements as defined with the Conditions for Coverage, Fresenius Medical Staff Bylaws and "Responsibilities of the Medical Director" for ensuring that all policies and procedures related to patient care are adhered to by all members of the patient care staff including the medical staff.</p>	04/19/2012			

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	<p>A, a registered nurse, was observed to approach patient number 11 with an unlabeled syringe with a clear liquid in it. The employee placed the syringe on top of the dialysis machine, prepared the dialysis tubing for the injection of the contents of the syringe, and then picked the syringe up and injected the contents of the syringe into the dialysis tubing. The employee indicated the syringe contained Epogen, a medication used to treat anemia.</p> <p>B. The above-stated observation was discussed with the facility administrator, employee D, and the Director of Operations, employee Q, on 4-3-12 at 10:05 AM. The employees indicated they were unaware their policy specified the unlabeled syringe could not be laid down at any time.</p> <p>2. The facility's 9-20-06 "Principles and Processes of Medication Administration" procedure number 132-080-105 states, "Document the time, drug name, dose and route of medication . . . Document all symptoms leading to PRN [as needed] drug administration on the Hemodialysis Treatment Sheet, or electronic medical record. Chart the patient's response to PRN [as needed] medications or any adverse reactions that may occur with any medication administration, in the medical</p>		<p>On April 10, 2012 all facility RNs were reinserviced and reeducated on FMS Policy #132-080-104 "Medication and Preparation and Administration" policy and FMS Policy #132-080-105 "Principles and Processes of Medication Administration" policy. The attendance record is available at the facility for review.</p> <p>Effective immediately all medication syringes are to be labeled per policy.</p> <p>All administrations of PRN medications shall be documented on the patient's treatment sheet, or in the electronic medical record with the following information included:</p> <ul style="list-style-type: none"> ·Symptoms leading to PRN medication administration ·Patient's response to PRN medications ·Any adverse reactions that may occur with any medication administration. <p>Clinical Manager (or designee) will monitor adherence to policy with:</p> <ul style="list-style-type: none"> ·Monthly audits of each RN to observe medication 		

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	<p>record, or the Hemodialysis Treatment Sheet and in the progress notes."</p> <p>A. Clinical record number 1 included hemodialysis treatment flow sheets that evidenced the patient had received acetaminophen 650 milligrams by mouth during treatments on 3-7-12, 3-14-12, 3-16-12, 3-19-12, and 3-23-12. The flow sheets failed to evidence documentation of the symptoms leading up to the administration of the medication and the response to the as needed medication.</p> <p>B. The facility administrator, employee D, was unable to provide any additional documentation and/or information when asked on 4-4-12 at 4:15 PM. The administrator indicated it was facility policy to document the reason for a prn medication and the response.</p>		<p>preparation and administration for 3 months.</p> <p>·Monthly audits of treatment records for all patients who received PRN medication administration for 3 months.</p> <p>Additionally, the Clinical Manager will formalize a report for the monthly QAI meeting, detailing compliance gaps noted with medication administration. This report will include corrective actions implemented to correct deficiencies. Medical Director with QAI committee will review and determine further action as necessary to maintain compliance. If the Medical Director determines continued deficiencies – he will escalate them to the Governing Body and Regional Vice President’s attention to ensure timely corrective actions and resolution.</p> <p>The QAI minutes document this activity and are available for review at the facility.</p>		