STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	(X3) DATE SURVEY COMPLETED
	152567		04/23/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESENIUS MEDICAL CARE SEYMOUR	200 E THIRD ST SEYMOUR, IN 47274

(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
V 000 Bldg. 00	This was a Federal ESRD [CORE] recertification survey. Survey Dates: 4-21-15, 4-22-15, & 4-23-15 Facility #: 002497 Medicaid Vendor#: 200202800B QA: JE 4/27/15	V 000		
V 122 Bldg. 00	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, interview, and review of facility policy, the facility failed to ensure dialysis stations had been appropriately cleaned between patients in 2 (#s 1 and 2) of 2 cleaning and disinfection of the dialysis station observations completed. (Employee L) The findings include:	V 122	The Clinical Manager will hold a staff meeting with all staff to review and train on the disinfection of contaminated surfaces, medical devices, and equipment. The Clinical Manager will be responsible to see that all staff understand this policy and will follow the policy in its entirety. The Clinical Manager will do infection control audits weekly for	05/29/2015

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determined that other safegaurds 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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	1. Employee L, a patient care technician (PCT), was observed to clean the dialysis machine and surrounding area at station number 2 on 4-21-15 at 12:25 PM. The PCT was not observed to clean the prime waste container on the side of the dialysis machine. The PCT was not observed to clean the Hansen connectors, the data entry station, or the counters surrounding the dialysis station. The PCT was not observed to clean the fronts of the arms of the dialysis chair. 2. Employee L, a PCT, was observed to clean the dialysis machine and surrounding area at station number 12 on 4-21-15 at 2:30 PM. The PCT was not observed to clean the prime waste container on the side of the machine, the data entry station, or the surrounding countertops. The PCT was not observed to clean the fronts of the arms of the dialysis chair. 3. The clinical manager, employee C, indicated, on 4-23-15 at 9:30 AM, the PCT had not appropriately cleaned and disinfected the dialysis stations. 4. The facility's 1-4-12 "Work Surface Cleaning and Disinfection without Visible Blood using Bleach Solutions" procedure number		the next 4 weeks to ensure ongoing compliance. After the 4 weeks of infection control audits, if compliance has been observed, the Clinical Manager will go to monthly infection control audits of all staff.	

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	FMS-CS-IC-II-155-110C1 states, "Use a cloth wetted with 1:100 bleach solution to clean and disinfect the dialysis station (bed, tables, machine, television, IV pole, B/P cuff, hand sanitizer dispenser and holder, etc.). Place the chair in Trendelenburg position so all surfaces of the chair are accessible. Clean all surfaces."			
V 126 Bldg. 00	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination Vaccinate all susceptible patients and staff members against hepatitis B. Based on clinical record and facility policy review and interview, the facility failed to ensure a hepatitis B susceptible patient had been offered a hepatitis B vaccine in 1 (# 1) of 1 record reviewed of patients admitted less than 90 days. The findings include: 1. The facility's 8-20-14 "Patient Testing and Vaccination for Hepatitis B" policy number FMS-CS-IC-II-155-142A states, "The Hepatitis B vaccine shall be offered to all susceptible patients including peritoneal and home hemodialysis patients . . . A protective antibody response is 10 or more milliinternational units (mIU) per milliliter	V 126	The Clinical Manager will hold a staff meeting with all nurses to ensure understanding and compliance with the Patient Testing and Vaccination for Hepatitis B policy. The Clinical Manager will monitor the Hepatitis B vaccine status for each patient on a weekly basis for 4 weeks to ensure all susceptible patients have been offered the vaccine. Once compliance has been achieved, the Clinical Manager will monitor at least monthly, unless higher monitoring frequency is deemed necessary.	05/29/2015

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	(anti-HB=/>10mIU/mL)." 2. Clinical record number 1 evidenced the patient's first date of dialysis at the facility was 3-28-15. The record included laboratory results dated 3-27-15 that identified a hepatitis B antibody value of less than 3.1. The record failed to evidence the patient had been offered the hepatitis B vaccine. 3. The clinical manager, employee C, stated, on 4-22-15 at 10:15 AM, a hepatitis B vaccine had not been offered to the patient.			
V 147 Bldg. 00	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters. II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations			

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	suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients. VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].			
	Based on observation, interview, and review of facility policy, the facility failed to ensure access of a central venous catheter (CVC) had been completed in an aseptic manner in 1 (# 1) of 2 discontinuation of dialysis using a CVC observations completed. (Employee K) The findings include: 1. The facility's 1-6-14 "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" procedure number FMS-CS-IC-I-105-028C states, "Using a new sterile alcohol pad, scrub threads of the luer lock (hub) vigorously using back and forth friction for 15 seconds . . . Immediately attach a 10 mL [milliliter] syringe to the catheter limb." 2. Employee K, a patient care technician (PCT), was observed to discontinue the	V 147	The Clinic Manager will hold a staff meeting to review with all staff the policy on termination of treatment using a CVC and Optiflux Single Use Ebeam Dialyzer and ensure staff understand it. The Clinic Manager will observe each staff member weekly for 4 weeks on proper termination of treatment using a CVC to ensure total staff compliance, including cleansing the CVC hubs for at least 15 seconds prior to disconnecting the lines from the catheter limbs and attaching normal saline filled syringes.	05/29/2015

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	dialysis treatment on patient number 1 on 4-21-15 at 2:25 PM. The PCT was observed to cleanse the open connections with alcohol pads for only 4 seconds for the arterial port and only 2 seconds for the venous port prior to attaching the normal saline filled syringes. 3. The above-stated observations were presented to the clinical manager, employee C, on 4-23-15 at 9:30 AM. The manager indicated the open connections should have been cleaned for at least 15 seconds.			
V 407 Bldg. 00	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). Based on clinical record and facility policy review and interview, the facility failed to ensure patients had been monitored at least every 30 minutes per the facility's own policy in 1 (# 1) of 4 records reviewed. The findings include: 1. The facility's 8-20-14 "Patient Monitoring During Patient Treatment" policy number FMS-CS-IC-I-110-133A states, "Vital signs will be monitored at	V 407	The Clinical Manager will meet with the interdisciplinary team to ensure understanding and compliance of the Patient Monitoring During Patient Treatment policy, including vital signs and safety checks being completed and documented at least every 30 minutes. The Clinical Manager will review 10% of patient charts and flow sheets each month to ensure vital signs and safety checks are documented and completed per policy.	05/29/2015

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	the initiation of dialysis and every 30 minutes, or more frequently, as needed . . . Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible . . . Check machine settings and measurements and document at the initiation of dialysis and at every safety check." 2. Clinical record number 1 included hemodialysis treatment flow sheets, dated 3-28-15, 3-31-15, and 4-4-15, that evidenced the patient had not been monitored at least every 30 minutes per the facility's own policy. A. A hemodialysis treatment flow sheet dated 3-28-15 evidenced vital signs and a safety check had been completed at 1:34 PM and not again until 2:32 PM, a period of 58 minutes between checks. B. A hemodialysis treatment flow sheet dated 3-31-15 evidenced vital signs and a safety check had been completed at 10:26 AM and not again until 11:35 AM, a period of 59 minutes between checks. C. A hemodialysis treatment flow sheet dated 4-4-15 evidenced vital signs and a safety check had been completed at 10:33 AM and not again until 11:33 AM, a period of 60 minutes between checks.			

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	3. The clinical manager, employee C, indicated, on 4-23-15 at 9:30 AM, patients were to be monitored at least every 30 minutes.			
V 543 Bldg. 00	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on clinical record and facility policy review and interview, the facility failed to ensure the patient's blood pressure had been monitored at least every 30 minutes per facility policy in 1 (# 1) of 4 records reviewed. The findings include: 1. The facility's 8-20-14 "Patient Monitoring During Patient Treatment" policy number FMS-CS-IC-I-110-133A states, "Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently, as needed" 2. Clinical record number 1 included hemodialysis treatment flow sheets, dated 3-28-15, 3-31-15, and 4-4-15, that evidenced the patient's blood pressure had not been monitored at least every 30	V 543	The Clinical Manager will meet with the interdisciplinary team to ensure understanding and compliance of the Patient Monitoring During Patient Treatment policy, including vital signs and safety checks being completed and documented at least every 30 minutes. The Clinical Manager will review 10% of patient charts and flow sheets each month to ensure vital signs and safety checks are documented and completed per policy.	05/29/2015

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	minutes per the facility's own policy. A. A hemodialysis treatment flow sheet dated 3-28-15 evidenced vital signs and a safety check had been completed at 1:34 PM and not again until 2:32 PM, a period of 58 minutes between checks. B. A hemodialysis treatment flow sheet dated 3-31-15 evidenced vital signs and a safety check had been completed at 10:26 AM and not again until 11:35 AM, a period of 59 minutes between checks. C. A hemodialysis treatment flow sheet dated 4-4-15 evidenced vital signs and a safety check had been completed at 10:33 AM and not again until 11:33 AM, a period of 60 minutes between checks. 3. The clinical manager, employee C, indicated, on 4-23-15 at 9:30 AM, patients were to be monitored at least every 30 minutes.			
V 550 Bldg. 00	494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient			

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	must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. Based on observation, facility policy review, and interview, the facility failed to ensure arteriovenous fistulas (AVF) access sites had been appropriately cleaned prior to needle insertion in 1 (# 2) of 2 access of AVF for initiation of dialysis observations and failed to ensure needle sites had been treated appropriately after needle removal in 3 (#s 1, 2, and 3) of 3 discontinuation of dialysis observations completed. (Employees D, I, K, and L) The findings include: Regarding cleaning the access site: 1. On 4/22/2015 at 11:15 AM, employee I, a patient care technician (PCT), was observed while accessing the peripheral dialysis access site for patient number 10. The PCT first cleaned the site with antiseptic then listened to the site by placing the head of her stethoscope on the patient's arm. The PCT then failed to reclean the patient's arm with antiseptic before puncturing the skin over the access site with a needle.	V 550	The Clinic Manager will hold a staff meeting to review with all staff the policy on Post Treatment Fistula Needle Removal and ensure all staff understand it. The Clinic Manager will observe each staff member weekly for 4 weeks on post treatment fistula needle removal to ensure total staff compliance, including removing the used gauze and replacing the sites with clean dressing once hemostasis is achieved, as well as proper cleaning of access site.	05/29/2015

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	Regarding discontinuation and post needle insertion site care: 1. Employee L, a patient care technician (PCT), was observed to discontinue the dialysis treatment on patient number 6 on 4-21-15 at 12:10 PM. The PCT removed the needles from the arterial and venous sites and applied gauze and tape. The patient applied pressure to both needle removal sites with a gloved hand. After approximately 10 minutes, the patient was observed to remove the glove. The PCT was not observed to inspect the site for bleeding or apply clean gauze to the needle insertion sites prior to the patient leaving the facility. 2. On 4-22-15 at 11:10 AM, observation noted patient number 8 preparing to leave the dialysis facility after the treatment had been completed and the needles had been removed. Observation noted the gauze and tape over both needle insertion sites were blood-soaked and a small amount of blood was observed on the patient's upper left arm at the sites. The registered nurse (RN), employee D, observed the blood-soaked gauzes and the blood on the patient's arm and cleaned the patient's arm. The RN was not observed to change the blood-soaked gauze on the needle insertion sites. The patient was observed to leave the facility			

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	with the blood-soaked gauze still in place. 3. The clinical manager, employee C, was informed of the above-stated observations on 4-23-15 at 9:30 AM. The manager indicated the gauze dressings should have been changed prior to the patients leaving the facility. 4. The facility's 3-26-14 "Post Treatment Fistula Needle Removal" procedure number FMS-CS-IC-I-115-013C states, "Once hemostasis has been achieved, remove the gauze used for hemostasis and replace the sites with Band-Aids or adhesive dressing or clean tape with gauze." 5. On 4/21/2015 at 3:06 PM employee K, a patient care tech (PCT), was observed to discontinue the dialysis treatment on patient number 7. The PCT was observed to remove the arterial and venous needles and place gauze dressings on the patient's needle insertion sites. The PCT was not observed to replace the blood soiled bandage to ensure that it was clean and dry prior to discharge from the treatment area.			
V 559	494.90(b)(3)			

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Bldg. 00	POC-OUTCOME NOT ACHIEVED-ADJUST POC 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- (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section. Based on clinical record and facility policy review and interview, the facility failed to ensure the plan of care had been updated to address identified barriers to the patient completing dialysis treatments in 1 (# 2) of 4 records reviewed. The findings include: 1. Clinical record number 2 included physician orders dated 12-23-14 that identified the treatment time as 4 hours. The record evidenced the patient shortened dialysis treatments related to family and transportation issues. A. A hemodialysis treatment flow sheet dated 3-28-15 evidenced the patient received treatment for 3 hours and 34 minutes. The treatment sheet states, "Pt [patient] wanted to end tx [treatment] at	V 559	The Clinical Manager will hold an all staff meeting to review and ensure compliance and understanding of the Comprehensive Interdisciplinary Assessment and Plan of Care policy with all staff members. The Clinical Manager will review all patients that discontinued treatment early on a weekly basis to review reasons and trends. The Clinical Manager will also meet with the interdisciplinary team to discuss these issues and ensure the plan of care is updated to reflect the patient's current condition. The interdisciplinary team will work with the patient in an attempt to eliminate any barriers the patient is having in completing their treatment.	05/29/2015

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	1100." B. A hemodialysis treatment flow sheet dated 3-31-15 evidenced the patient received treatment for 3 hours and 9 minutes. The treatment sheet states, "Short tx, AMA [against medical advice] signed. Pt aware of consequences of running short tx." C. A hemodialysis treatment flow sheet dated 4-4-15 evidenced the patient received treatment for 3 hours and 2 minutes. The treatment sheet states, "Pt came off earlier than expected due to system clotting . . . AMA signed. Pt aware of consequences, including early death." D. A hemodialysis treatment flow sheet dated 4-7-15 evidenced the patient received treatment for 58 minutes. The treatment sheet states, "EDW [estimated dry weight] not attained r/t [related to] pt had to come off machine early due to issues with children." E. A hemodialysis treatment flow sheet dated 4-11-15 evidenced the patient received treatment for 3 hours and 12 minutes. The flow sheet states, "Pt signed off AMA with 51 min left." F. A hemodialysis treatment flow			

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	sheet dated 4-16-15 evidenced the patient received treatment for 2 hours and 47 minutes. The flow sheet states, "Signed AMA to end tx early due to need to take [parent] to appt [appointment]." G. A hemodialysis treatment flow sheet dated 4-18-15 evidenced the patient received treatment for 3 hours and 31 minutes. The flow sheet states, "pt ended tx early r/t transportation issue. AMA signed. pt aware of consequences." 2. Clinical record number 2 failed to evidence coordination and collaboration among the interdisciplinary team to implement plan of care changes to address identified issues related to the patient shortening treatments. A. A medical social services (MSS) note dated 11-13-14 states, "Having some trouble w [with] 13 yr old [child] behavior and school attendance . . . has a history of anxiety . . . Pt has some anxiety during tx [treatment]." B. A physician note dated 3-3-15 states, "half-heartedly pursuing tx." C. A note completed by the physician's nurse dated 1-22-15 states, "wants decrease in HD [hemodialysis] run time or schedule change to better			

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	accommodate child care responsibilities." D. A MSS note dated 3-26-15 states, "Pt did stay whole tx today . . . says has shortened due to issues with [the patient's] children . . . follow up monthly." E. A MSS note dated 4-7-15 states, "Pt also has had no further issue with child care." The record evidenced the patient continued to shorten treatments on 4-11-15, 4-16-15, and 4-18-15 related to other issues. 3. The clinical manager, employee C, was unable to provide any additional information and/or documentation when asked on 4-23-15 at 9:30 AM. 4. The facility's 7-4-12 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "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 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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V 638 Bldg. 00	494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Based on quality assessment and performance improvement (QAPI) document and facility policy review and interview, the facility failed to ensure a performance improvement plan had been implemented for the improvement of decreasing percentage of patients who did not meet the desired goal in 4 (December 2014 and January, February, and March of 2015) of 4 months reviewed. The findings include: 1. The facility's QAPI meeting minutes dated 12-23-14, 1-26-15, 2-24-15, and 3-17-15 failed to evidence an action plan had been developed and implemented to address the decreasing percentage of patients that met the desired phosphorous laboratory value of 3.5 to 5.5 mg/dL (milligrams per deciliter) according to the Centers for Medicare and Medicaid Services Measures Assessment Tool. A. The QAPI meeting minutes dated 12-23-14 evidenced the percentage of	V 638	The Director of Operations and Clinical Manager will meet with the QAPI team and address the importance of monitoring all indicators, including individualizing the composite bone and mineral indicator into all three categories: Calcium, IPTH, and Phosphorus. The Director of Operations will request the numbers in each of these three categories monthly in order to evalutate trends. The Director of Operations, Clinical Manager, and Registered Dietician will look for trends in these areas and ensure an action plan with root cause analysis is initiated if a negative trend is observed.	05/29/2015

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	patients that met the desired phosphorous goal was 60.5. B. The QAPI meeting minutes dated 1-26-15 evidenced the percentage of patients that met the desired phosphorous goal was 56.8. C. The QAPI meeting minutes dated 2-24-15 evidenced the percentage of patients that met the desired phosphorous goal was 47.6. D. The QAPI meeting minutes dated 3-17-15 evidenced the percentage of patients that met the desired phosphorous goal was 45.2. 2. The Director of Operations, employee M, stated, "We usually implement a plan if there is a decline for 3 months in a row. We did not implement an action plan. We considered it stable and no plan was necessary. There was not more than a 3 point drop except from January to February." 3. The facility's 4-4-12 "Quality Assessment Performance Improvement Program" policy number FMS-CS-IC-I-101-001A states, "QAI Program activities for each facility or program include: . . . Review of aggregate patient data by modality to			

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	identify opportunities for improvement for clinical outcomes, and track progress by: 1. Evaluating clinical indicators monthly . . .2. Identify commonalities among patients who do not reach the minimum expected patient targets. 3. Develop a plan to address those causes. 4. Implement the plan. 5. Monitor the effectiveness of the plan. 6. Adjust portions of the plan that are not successful."			
V 715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on clinical record and facility policy review and interview, the medical director failed to ensure the facility's medication administration policy had been implemented in 2 (#s 3 and 4) of 2 records reviewed of patients that received as needed medications during the treatment. The findings include: 1. Clinical record number 3 included a	V 715	The Clinic Manager will meet with all nursing staff to review the Medication Preparation and Administration policy to ensure all nursing staff understand it. The Clinic Manager will review all PRN medications given each week for 4 weeks to ensure patient response to the PRN medication is documented to ensure compliance. Once compliance is achieved, the Clinic Manager will monitor all PRN medications and patient response	05/29/2015

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	hemodialysis treatment flow sheet dated 3-31-15 that evidenced the registered nurse (RN), employee D, had administered acetaminophen at 7:52 AM to patient 3 for complaints of a headache. The flow sheet failed to evidence the patient's response to the medication. 2. Clinical record number 4 included a hemodialysis treatment flow sheet dated 3-28-15 that evidenced the RN, employee E, had administered acetaminophen at 7:29 AM to patient #4 for complaints of "pain L [left] ribs under L breast." The flow sheet failed to evidence the patient's response to the medication. 3. The clinical manager, employee C, was unable to provide any additional documentation and/or information when asked on 4-23-15 at 9:30 AM. 4. The facility's 1-28-15 "Medication Preparation and Administration" policy number FMS-CS-IC-I-120-040A states, "Document all patient symptoms leading to PRN [as needed] drug administration and patient's response to the PRN medication on treatment sheet or electronic record."		on a monthly basis.	