

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152518	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 03/28/2013
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE WARSAW	STREET ADDRESS, CITY, STATE, ZIP CODE 3334 LAKE CITY HWY WARSAW, IN 46580
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V000000	<p>This was a federal ESRD recertification survey.</p> <p>Survey Dates: 3/25/13 - 3/28/13</p> <p>Facility #: 005163</p> <p>Medicaid Vendor #: 100081860B</p> <p>Surveyors: Ingrid Miller, RN, Public Health Nurse Surveyor</p> <p>Census by Service Type:</p> <p>Number of In-Center Hemodialysis Patients: 67 Number of Peritoneal Dialysis Patients: 7 Number of home hemodialysis patients: 0</p> <p>Total: 74</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN April 2, 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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V000111	<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 policies, the facility failed to ensure that 1 of 1 dialysis provided a sanitary and clean environment creating the potential to spread infection causing agents among facility staff and all 67 current incenter hemodialysis patients.</p> <p>Findings</p> <p>1. On 3/25/13 at 4:35 PM, Employee G, patient care technician, was observed to return the Hach Pocket Colorimeter to the plastic storage case after use. This case was observed to be covered in brown stains over the plastic surface of this storage case.</p> <p>The dialysis facility policy titled "Total Chlorine Testing with Hach Meter Colorimeter II" with an effective date of October 3, 2012 stated, "Place all equipment and reagents in the plastic storage case. Store in a clean, dry area."</p> <p>2. On 3/26/13 at 3 PM on the incenter hemodialysis floor, a drainer basket was</p>	V000111	<p>On April 22, 2013 the Governing Body will meet to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution.</p> <p>The Clinical Manager will ensure that all staff members follow "Dialysis Precautions" policies to ensure a safe treatment environment that prevents cross contamination of patients and equipment.</p> <p>The Clinical Manager will meet with the facility Education Coordinator to arrange and schedule staff in-services to further educate all staff members on the following policy "Dialysis Precautions" FMS-CS-IC-II-155-070A. Emphasis was placed on the storing of supplies in designated clean areas. New storage containers for the Hach Colorimeters have been ordered and will be delivered by April 17, 2013. The clean clamps are to be stored in the designated clean area. Plexiglas has been ordered to more clearly divide the clean from the dirty areas. It will be</p>	04/22/2013			

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	<p>observed in the dirty sink located on one end of a long counter on the interior of the treatment floor. This drainage basket was designed to rest on the sides of the sink with holes to let water drain out in the bottom. The basket held approximately 20 blue, dry hemostat clamps. This sink was marked with a sign above it which stated "Dirty Sink."</p> <p>The facility policy titled "Dialysis Precautions" with an effective date of October 10, 2008, stated, "Clean areas shall be clearly marked and designated for the handling and storage of medications and unused supplies and equipment. Clean areas shall be clearly separated from contaminated areas where used supplies, equipment or blood supplies are handled or stored."</p> <p>3. On 3/26/13 at 5 PM, Employee B, clinical manager, indicated the sink was dirty and the clamps in the drainer were considered clean. These clean clamps were not to be in a dirty sink. She also indicated the Hach meter storage case was stained.</p>		<p>installed by April 17, 2013. Training will be completed by April 18, 2013 and an in-service attendance sheet will be available in the facility for review.</p> <p>Clinical Manager or designee will ensure that infection control audits utilizing the QAI Infection Control audit tool are done monthly for 6 months and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate</p> <p>The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p> <p>The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans.</p> <p>The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI</p>				

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V000117	<p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>Based on observation, interview, and review of policies, the facility failed to ensure clean areas were clearly separated from contaminated areas and multiple dose vials were labeled and discarded correctly for 1 of 1 dialysis facility creating the potential to spread infection causing agents among facility staff and all 67 current incenter hemodialysis patients.</p>	V000117	<p>On April 22, 2013 the Governing Body will meet to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution</p> <p>The Clinical Manager is responsible to ensure that all staff members follow "Dialysis Precautions and Cleaning and Disinfection" policies to ensure a safe treatment environment that prevents cross contamination of</p>	04/22/2013			

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	<p>Findings</p> <p>Regarding clean clamps in a dirty sink</p> <p>1. On 3/26/13 at 3 PM on the incenter hemodialysis floor, observation noted a drainer basket on one end of a long counter on the interior of the treatment floor. This drainage basket was designed to rest on the sides of the sink and there were holes to let water drain out in the bottom. The basket held approximately 20 blue, dry hemostat clamps. This sink was marked with a sign above it which stated, "Dirty Sink."</p> <p>2. On 3/26/13 at 5 PM, Employee B, clinical manager, indicated the sink was dirty and the clamps in the drainer were considered clean. These clean clamps were not to be in a dirty sink.</p> <p>3. The facility policy titled "Dialysis Precautions" with an effective date of October 10, 2008 stated, "Clean areas shall be clearly marked and designated for the handling and storage of medications and unused supplies and equipment. Clean areas shall be clearly separated from contaminated areas where used supplies, equipment or blood supplies are handled or stored."</p>		<p>patients and equipment.</p> <p>The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members on the following policies "Dialysis Precautions" FMS-CS-IC-II-155-070A, "Cleaning and Disinfection" FMS-CS-IC-II-155-110A with emphasis placed on clean versus contaminated areas and where clamps should be stored after use until disinfected. The policy on "Medication Preparation" FMS-CS-IC-I-120-040A was reviewed with emphasis on ensuring that all opened vials should be labeled with date, time and initialed as well as proper storage/discard procedures. Training will be completed on April 18, 2013 and an in-service attendance sheet will be available in the facility for review.</p> <p>Clinical Manager or designee will ensure that infection control audits utilizing the QAI Infection Control audit tool are done monthly for 6 months and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to address the issue with each employee including corrective action as appropriate</p> <p>The Clinical Manager is</p>		

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	<p>Regarding multi-dose vials not dated or initialed</p> <p>4. On 3/28/13 at 11 AM, a 30 cc (cubic centimeter) multi-dose bottle of heparin sodium for intravenous or subcutaneous use was observed on a counter in the medication treatment area. The bottle was opened, left unattended, and was not marked with a date or time or initials when it had been opened.</p> <p>A. On 3/28/13 at 10:30 AM, Employee N, patient care technician, indicated the bottle was not signed or dated and should be discarded. Employee N was observed to throw the bottle of heparin into a waste can near the medication preparation area.</p> <p>B. On 3/28/13 at 10:35 AM, Employee T, Registered Nurse, indicated the bottle was not signed or dated as required by policy and was not to be discarded into the trash.</p> <p>C. On 3/28/13 at 11:05 AM, Employee B, the clinical manager, indicated a multi-dose vial should be dated and initialed by the nurse when opened and glass medication vials should be discarded into a biohazard receptacle. She also indicated she did not know who had opened the vial or left the vial</p>		<p>responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p> <p>The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans.</p> <p>The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.</p>		

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	<p>unattended.</p> <p>5. The policy titled "Medication Preparation" with an effective date of July 4, 2012, stated, "When preparing medications if the vial is not used immediately in its entirety, the nurse must place the date and time the vial was opened on the medication label along with the nurse initials. Label any open multi-dose vial that is not used immediately and store vial accordingly. All medications will be kept in a locked cabinet except when in use."</p>				

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V000190	<p>494.40(a) SOFTENERS-AUTO REGENERATE/TIMERS/SALT LVL 5.2.4 Softeners: auto regen/timers/salt/salt level Prior to exhaustion, softeners should be restored; that is, new exchangeable sodium ions are placed on the resin by a process known as "regeneration," which involves exposure of the resin bed to a saturated sodium chloride solution.</p> <p>5.2.4 Softeners Refer to RD62:2001, 4.3.10 Automatically regenerated water softeners: Automatically regenerated water softeners shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.</p> <p>The face of the timers used to control the regeneration cycle should be visible to the user.</p> <p>6.2.4 Softeners Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated.</p> <p>The softener brine tank should be monitored daily to ensure that a saturated salt solution exists in the brine tank. Salt pellets should fill at least half the tank. Salt designated as rock salt should not be used for softener regeneration since it is not refined and typically contains sediments and other impurities that may damage O-rings and pistons and clog orifices in the softener</p>			

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	<p>control head.</p> <p>Based on observation, interview, and policy review, the dialysis clinic failed to ensure that 1 of 1 water softener had the salt level over the water level with the potential to affect all of the patients of the dialysis clinic.</p> <p>Findings</p> <ol style="list-style-type: none"> On 3/25/13 at 4:45 PM, the water softener in the water treatment room was observed to be about two - thirds full with the brine level about 8 inches above the salt pellet level. On 3/26/13 at 1:20 PM, Employee B, clinical manager, indicated the brine level should be below the level of the salt pellets in the water softener. The dialysis policy titled "Technical Policy and Standards Manual Water Treatment 05-Equipment" with an effective date of 5/24/96 stated, "Water Softener Precautions ... Regeneration cycle ... 3. The top level of the salt pellets in the brine tank must be maintained above the level of the brine solution in the tank." 	V000190	<p>On April 22, 2013 the Governing Body will meet to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution</p> <p>The Clinical Manager is responsible to ensure that all staff members follow "Water Softener Precautions" as outlined in policy 153-020-021.</p> <p>The Clinical Manager met with the facility Equipment Technician to arrange and schedule staff in-services to re-educate all staff members on the following policies "Water Softener Precautions" 153-020-021 with emphasis on ensuring the top level of the salt pellets in the brine tank must be maintained above the level of the brine solution in the tank. Training will be completed on April 18, 2013 and an in-service attendance sheet will be available in the facility for review.</p> <p>The Water Softener Log will be utilized daily and the Clinical Manager or RN designee will sign off that the tank is adequately filled daily before starting patients on dialysis.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by</p>	04/22/2013			

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			<p>the Governing Body.</p> <p>The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans.</p> <p>The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.</p>		

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V000196	<p>494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY 6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.</p> <p>Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.</p> <p>Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L]. Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly. Based on observation, interview, and review of procedures, the facility failed to ensure the chlorine testing had been completed in accordance with facility policy and procedure in 1 of 2 water tests observed creating the potential to affect all of the facility's 67 in-center</p>	V000196	The Clinic Manager scheduled an in-service for all employees that perform the Chlorine/ Chloramines testing on April 18, 2013 to review the procedure of Total Chlorine Test Using a	04/18/2013

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	<p>hemodialysis patients.</p> <p>The findings include</p> <ol style="list-style-type: none"> On 3/25/13 at 4:25 PM, Employee G, patient care technician, was observed to complete a routine water test for chlorine using a Hach Pocket Colorimeter by adding the contents of the N, N-diethyl-p-phenylene-diamine (DPD) Total Chlorine Reagent Powder Pillow to the reverse osmosis water sample using a small glass container, putting a cap on the sample, and then gently shaking the water and powder in the capped container for unknown amount of time. She conducted the water test without using a timing device to ensure the contents of the sample and powder were mixed per procedure for 20 seconds. On 3/25/13 at 4:35 PM, Employee G indicated counting to 20 seconds in her head for the required 20 seconds while mixing the DPD Total Chlorine Reagent Powder with the reverse osmosis water sample. The facility procedure titled "Total Chlorine Test Using Hach Pocket Colorimeter II" with an effective date of October 3, 2012, stated, "Remove the sample cell and add the contents of one DPD total chlorine reagent powder 		<p>Hach Pocket Colorimeter FMS-CS-IC-II-140-210C1. Emphasis was placed on steps #9 and #10 which states to "remove the sample cell and add the contents of one DPD total chlorine reagent powder pillow. Cap the cell and gently shake for 20 seconds." The staff will be instructed to use the clock that is in the water room with the second hand to ensure accuracy of time.</p> <p>The Clinic Manager or RN designee will ensure that staff is using the clock by observing the chlorine testing for 2 weeks. An audit sheet will be used to record observations and reported to the Clinical Manager.</p> <p>The Clinical Manager is responsible for reporting findings the QAI committee during the QAI monthly meetings</p> <p>The Director of Operations is responsible to ensure all documentation required as part of</p>				

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	pillow. Cap the cell and gently shake for 20 seconds."		the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to provide oversight until ongoing resolution has been determined.		

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE WARSAW				STREET ADDRESS, CITY, STATE, ZIP CODE 3334 LAKE CITY HWY WARSAW, IN 46580			
(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			
V000634	<p>494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS</p> <p>The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification.</p> <p>Based on administrative record review and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program was in place that systematically monitored all work - related injuries and illnesses for staff for 1 of 1 facility with the potential to affect all staff working at the dialysis facility.</p> <p>Findings</p> <p>1. The facility's QAPI program documents failed to evidence the facility monitored staff work - related injuries and illnesses.</p> <p>2. A facility document titled "OSHA [Occupational Safety and Health Administration]" with a date of 2012 evidenced one staff needle stick injury for Employee I, patient care technician, on 9/3/2012.</p> <p>Attached to the document was a document from an emergency room visit at Kosciusko Community Hospital for Employee I on 9/3/12 for the treatment of</p>	V000634	<p>On April 1, 2013 the Operations Manager facilitated a call with the QAI committee to review V634, which states that all work related injuries and illnesses for staff with the potential to affect all staff working at the facility must be reviewed in QAI. It is the Clinic Manager's responsibility to utilize the QAI Meeting Minute Template to report, analyze, trend and develop action plans as necessary for all indicators defined within QAI. Additionally to utilize the Minutes to document all QAI Committee activities. Going forward the Clinic Manager will report all injuries including Staff and Patients in the section titled "Patient Safety". The Governing Body, through its ongoing monitoring of the QAI committee, will ensure the immediate and on going identification of potential and actual problems to Staff/Patient safety and take appropriate steps to identify the root causes of problems and to develop, implement and track corrective actions through to resolution of those problems. Any issues/problems will be addressed via the above-specified process, documented in the QAI Minutes,</p>	04/22/2013			

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	<p>a needle stick injury.</p> <p>3. On 3/28/13 at 11:15 AM, Employee B, the clinical manager, indicated the QAPI program did not evaluate staff injuries or illnesses and there was no policy for including the staff injuries and illnesses into the QAPI program.</p>				<p>and formally reported to the Governing Body by the Minutes. Minutes of both QAI Committee and Governing Body meetings will be available for review at the facility. On April 22, 2013 the QAI committee and Governing Body will meet to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution. The OSHA employee injury logs for CY 2012 and 2013 First Qtr will be presented and reviewed.</p>		