

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART			STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517		
(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	
V000000	<p>This was an ESRD federal recertification survey.</p> <p>Survey dates: August 14, 15, 16, and 19, 2013</p> <p>Facility #: 7697</p> <p>Medicaid vendor #: 200032320B</p> <p>Surveyor: Ingrid Miller, MS, BSN, RN, PHNS</p> <p>Hemodialysis incenter census: 119 active patients</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN August 22, 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.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(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			
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 facility policy and procedure, the facility failed to ensure staff followed infection control policies during the provision of care in 2 of 4 observations (Employees H and P) creating the potential for the transfer of disease causing organisms among staff and all 119 patients.</p> <p>Findings</p> <p>1. On 8/14/13 at 2:30 PM, Employee H, Registered Nurse, was observed to be charting at a computer terminal at station 18. Employee H was not wearing a protective gown despite being at the patient station area with patient #1 present.</p> <p>A. On 8/15/13 at 3:55 PM, Employee C, the clinical manager, indicated the staff nurse should wear a protective gown when at the chairside of a patient.</p> <p>B. The agency policy titled "Personal Protective Equipment" with a date of</p>	V000111	<p>On 8/16/13, the Operations Manager and Clinic Manager in-serviced the staff including employee H on maintaining a sanitary environment focusing on the policy Personal Protective Equipment (FMS-CS-IC-II-155-080A) with specific focus on the appropriate uses of the fluid resistant gown. On 8/21/13, the Clinic Manager in-serviced the staff including employee P on the procedure Drawing Blood Work Pre-Treatment Using an AVF/AVG or Catheter (FMS-CS-IC-II-135-016C) with specific focus to step #6 which states "Immediately dispose the intact Vacutainer adapter and holder into the biohazardous waste sharp container" for the purpose of maintaining a sanitary environment. Starting on August 28h, Clinic Manager or designee will conduct an audit daily including observation of proper gown usage and disposal of Vacutainers per policy and procedure. Audit will be completed daily for a period of 4 weeks then continue weekly until reviewed by QAI. Frequency of ongoing audits will be determined through the QAI Committee upon</p>	08/21/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
	<p>March 20, 2013 and document number of FMS - CS - IC II -155 080 A stated, "Employees shall use personal protective equipment namely the combination of a fluid - resistant gown ... in accordance with the type of patient contact expected and anticipated exposure."</p> <p>2. On 8/19/13 at 11:45 AM, a used vacutainer was found at the chairside of patient #10 at station #14. No staff was monitoring the used vacutainer. Employee P was cleaning station #13 at this time. Employee P, licensed practical nurse and patient care technician, indicated leaving the vacutainer after completing a lab draw and cleaning two stations before other patients came in. She indicated that the vacutainer once used should be disposed of immediately into biohazard waste.</p> <p>A. On 8/19/13 at 11:50 AM, Employee C, the clinical manager, indicated the used vacutainer had not been disposed of immediately after use.</p> <p>B. The facility procedure titled "Drawing Blood Work Pretreatment using an AVG / AVF or Catheter" with an effective date of January 4, 2012 stated, "Immediately dispose the intact Vacutainer adapter and holder into the biohazardous waste sharp container."</p>		<p>review of audit findings and resolution of the issues. The results of the audit will be documented and reported in Governing Body meetings and at QAI. Any evidence of non-compliance will be immediately brought to the attention of the Director of Operations by the Clinical Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can be found in the employee file. The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee. The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee. The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 08/19/2013
--	---	--	---

NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART	STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517
---	---

(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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART			STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517		
(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	
V000115	<p>494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK</p> <p>Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.</p> <p>Based on observation, interview, and review of policy, the facility failed to ensure staff had properly donned protective gowns in 1 of 4 observations (Employee H) creating the potential to affect all of the facility's 119 active patients.</p> <p>The findings</p> <ol style="list-style-type: none"> On 8/14/13 at 2:30 PM, Employee H, Registered Nurse, was observed to be charting at a computer terminal at station 18. Employee H was not wearing a protective gown despite being at the patient station area with patient #1 present. On 8/15/13 at 3:55 PM, Employee C, the clinical manager, indicated the staff nurse should wear a protective gown 	V000115	<p>On 8/16/13, the Operations Manager and Clinic Manager in-serviced the staff including employee H on Personal Protective Equipment (FMS-CS-IC-II-155-080A) with specific focus on the appropriate uses of the fluid resistant gown to protect against spurting or spattering of blood. Starting on August 28th, Clinic Manager or designee will conduct an audit daily including observation of proper gown. Audit will be completed daily for a period of 4 weeks then continue weekly until reviewed by QAI. Frequency of ongoing audits will be determined through the QAI Committee upon review of audit findings and resolution of the issues. The results of the audit will be documented and reported in Governing Body meetings and at QAI. Any evidence of non-compliance will be immediately brought to the attention of the Director of Operations by the Clinical</p>	08/28/2013	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART			STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>when at the chairside of a patient.</p> <p>3. The agency policy titled "Personal Protective Equipment" with a date of March 20, 2013 and document number of FMS - CS - IC II -155 080 A stated, "Employees shall use personal protective equipment namely the combination of a fluid - resistant gown ... in accordance with the type of patient contact expected and anticipated exposure."</p>		<p>Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can be found in the employee file. The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee. The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee. The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(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			
V000116	<p>494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT</p> <p>Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.</p> <p>-- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.</p> <p>-- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.</p> <p>Based on observation, interview, and review of facility procedure, the facility failed to ensure staff had properly disposed of a used vacutainer in 1 of 4 observations (Employee P) creating the potential to affect all of the facility's 119 active patients.</p> <p>Findings</p> <p>1. On 8/19/13 at 11:45 AM, a used vacutainer was found at the chairside of patient #10 at station #14. No staff was monitoring the used vacutainer. Employee P was cleaning station #13 at this time. Employee P, licensed practical nurse and patient care technician, indicated leaving the vacutainer after completing a lab draw and cleaning two</p>	V000116	On 8/21/13, the Clinic Manager in-serviced the staff including employee P on the procedure Drawing Blood Work Pre-Treatment Using an AVF/AVG or Catheter (FMS-CS-IC-II-135-016C) with specific focus to step #6 which states "Immediately dispose the intact Vacutainer adapter and holder into the biohazardous waste sharp container". Starting on August 28th, Clinic Manager or designee will conduct an audit daily including observation of disposal of Vacutainers per policy and procedure. Audit will be completed daily for a period of 4 weeks then continue weekly until reviewed by QAI. Frequency of ongoing audits will be determined through the QAI Committee upon review of audit findings and	08/21/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART			STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>stations before other patients came in. She indicated that the vaccutainer once used should be disposed of immediately into biohazard waste.</p> <p>2. On 8/19/13 at 11:50 AM, Employee C, the clinical manager, indicated the used vaccutainer had not been disposed of immediately after use.</p> <p>3. The facility procedure titled "Drawing Blood Work Pretreatment using an AVG / AVF or Catheter" with an effective date of January 4, 2012 stated, "Immediately dispose the intact Vaccutainer adapter and holder into the biohazardous waste sharp container."</p>		<p>resolution of the issues. The results of the audit will be documented and reported in Governing Body meetings and at QAI. Any evidence of non-compliance will be immediately brought to the attention of the Director of Operations by the Clinical Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can be found in the employee file. The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee. The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee. The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(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			
V000121	<p>494.30(a)(4)(i) IC-HANDLING INFECTIOUS WASTE [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- (i) Handling, storage and disposal of potentially infectious waste;</p> <p>Based on observation, interview, and review of facility procedure, the facility failed to ensure staff had properly disposed of a used vaccutainer in 1 of 4 observations (Employee P) creating the potential to affect all of the facility's 119 active patients.</p> <p>Findings</p> <p>1. On 8/19/13 at 11:45 AM, a used vaccutainer was found at the chairside of patient #10 at station #14. No staff was monitoring the used vaccutainer. Employee P was cleaning station #13 at this time. Employee P, licensed practical nurse and patient care technician, indicated leaving the vaccutainer after completing a lab draw and cleaning two stations before other patients came in. She indicated that the vaccutainer once used should be disposed of immediately into biohazard waste.</p>	V000121	<p>On 8/21/13, the Clinic Manager in-serviced the staff including employee P on the handling of infectious waste and specifically on the procedure Drawing Blood Work Pre-Treatment Using an AVF/AVG or Catheter (FMS-CS-IC-II-135-016C) with specific focus to step #6 which states "Immediately dispose the intact Vacutainer adapter and holder into the biohazardous waste sharp container". Starting on August 28th, Clinic Manager or designee will conduct an audit daily including observation of disposal of Vacutainers per policy and procedure. Audit will be completed daily for a period of 4 weeks then continue weekly until reviewed by QAI. Frequency of ongoing audits will be determined through the QAI Committee upon review of audit findings and resolution of the issues. The results of the audit will be documented and reported in Governing Body meetings and at QAI. Any evidence of non-compliance will be immediately brought to the</p>	08/21/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART			STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>2. On 8/19/13 at 11:50 AM, Employee C, the clinical manager, indicated the used vacutainer had not been disposed of immediately after use.</p> <p>3. The facility procedure titled "Drawing Blood Work Pretreatment using an AVG / AVF or Catheter" with an effective date of January 4, 2012 stated, "Immediately dispose the intact Vacutainer adapter and holder into the biohazardous waste sharp container."</p>		<p>attention of the Director of Operations by the Clinical Manager. Appropriate intervention and corrective action will be taken for infraction of the policy. The CM is responsible. Any corrective action given can be found in the employee file. The CM is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee. The Director of Operations is responsible to ensure that the CM presents all data, as required and defined within the POC, to the QAI Committee. The QAI Committee is responsible to provide oversight and ensure resolution is occurring.</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(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			
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>						

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
	<p>control head.</p> <p>Based on observation, interview, and review of policy, the dialysis clinic failed to ensure that 2 of 2 water softener observations had the salt level above the brine level with the potential to affect all 119 patients of the dialysis clinic.</p> <p>Findings</p> <ol style="list-style-type: none"> On 8/14/13 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 2 inches above the salt pellet level. On 8/15/13 at 9:25 AM, the water softener in the water treatment room was observed to be about two thirds full with the brine level about 2 inches above the salt pellet level. On 8/15/13 at 9:25 AM, Employee 0, the biotechnician, agreed the brine level was above the salt level. The facility policy titled "Technical Policy and Standards Manual Water Treatment 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 about the level of the brine solution in the tank." 	V000190	<p>The Clinical Manager is responsible to ensure that all staff members follow Water Softener Precautions as outlined in policy 153-020-021. The Clinical Manager and Operations Manager in-serviced staff members on 8/19/13 on the following policy- 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 8/28/13 and an in-service attendance sheet will be available in the facility for review. 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. The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. 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. The QAI Committee is responsible to analyze the results and determine a root cause analysis then develop a new Plan</p>	08/28/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 08/19/2013
--	---	--	---

NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART	STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517
---	---

(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
			of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(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			
V000451	<p>494.70 PR-PTS INFORMED OF RIGHTS WHEN BEGIN TX The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.</p> <p>Based on clinical record review, staff interview, and policy and procedure review, the facility failed to ensure the patients and / or their representative had been provided with their rights and responsibilities when they began their treatment in 1 (record #3) of 12 records reviewed creating the potential to affect all of the active 119 incenter hemodialysis patients.</p> <p>The findings include</p> <ol style="list-style-type: none"> 1. Clinical record #3 evidenced the patient's first dialysis at the facility was 4/28/13. The record failed to evidence any information on patients rights and responsibilities had been provided to the patient and / or representatives. 2. On 8/19/13 at 5:25 PM, Employee C, the clinic manager, indicated record #3 failed to evidence any information on patient rights and responsibilities. 3. On 8/19/13 at 5:31 PM, Employee B, 	V000451	<p>On 8/26/13, the Director of Operations educated the Clinic Manager, Charge Nurse, Master Social Worker and Clinic Secretaries on the policy Patient Admission document FMS-CS-IC-I-103-009A with emphasis on ensuring that all new patients and/or representatives receive their Rights and Responsibilities within the first six (6) treatments. A chart audit will begin on 8/28/13 for all active patients to ensure that all patients have received their Rights and Responsibilities and will be completed by 8/30/13. For any chart found to be out of compliance for failing to show documentation of Rights and Responsibilities provided to the patient, the Clinic Manager or designee will provide Rights and Responsibilities and obtain authorized signature at the next dialysis treatment day. The Clinic Manager or designee will audit every new patient's medical records within the first six (6) days of treatments to ensure that all new patients have received their Rights and Responsibilities for 3 consecutive months. After 3</p>	08/30/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART			STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>the director of operations, indicated record #3 failed to evidence any information on patient rights and responsibilities.</p> <p>4. The facility policy titled "Patient Admission" document number FMS-CS-103-009A, effective date October 3, 2012, stated, "All new admissions will receive the following information: Patients Rights and Responsibilities within the first six [6] treatments."</p>		<p>months of compliance, audits will move to monthly medical chart review following the QAI calendar. The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. 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. 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>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(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			
V000455	<p>494.70(a)(4) PR-PRIVACY & CONFIDENTIALITY-RECORDS The patient has the right to-</p> <p>(4) Privacy and confidentiality in personal medical records; Based on observation, clinical record review, facility document review, and interview, the dialysis failed to ensure the confidentiality of medical record information in 4 (patients #2, #3, #6, and #7) of 12 medical records reviewed with the potential to affect all of the 119 active incenter hemodialysis patients.</p> <p>Findings</p> <p>1. On 8/14/13 at 6:00 PM, a large stack of papers were observed on the receptionist desk in the lobby entrance. The top document was face up and able to be read. This document included patient names and health information. No staff were present at the lobby receptionist desk at the time.</p> <p>The document stated, "Facility 6952 Nephrology Inc. - El [Elkhart] Date: 08/13/2013 shift 2 Chairside follow-up report [patient #7] medication not administered per unable to administer as prescribed, iron sucrose [venofer] dose ... [patient #2] patient missed treatment, patient was a no-show ... [patient # 3]</p>	V000455	<p>On 8/15/13, the Clinic Manager and Operations Manager, in-serviced the staff on policy Patient Rights and Responsibilities document FMS-CS-IC-I-103-005A with emphasis on right to privacy and confidentiality in all aspects of treatment and right to privacy and confidentiality in personal medical records and the FMCNA Notice of Privacy Practices, COR-COMP-PS-0-001-001D1. On 8/26/13, the Director of Operations reiterated to the Clinic Manager, Charge Nurse, Master Social Worker and Clinic Secretaries our pledge to guard patients' protected health information (PHI). Director of Operations has requested quotes for enclosing the secretary/receptionist area in the lobby with a physical barrier to assist in protecting PHI. This barrier will be installed no later than 9/16/13. Clinic Manager or designee will monitor the secretary/receptionist area on a daily basis to ensure that patient PHI is not visible. Any noted violations to our pledge will bring immediate disciplinary action to parties involved. The Clinical Manager is responsible to report</p>	09/16/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
	<p>patient missed treatment, patient was a no-show due to other ... [patient #6] patient was a no show due to other."</p> <p>2. The agency document titled "FMCNA [Fresenius Medical Care North America] Patient Rights" with a copyright date of 2009 stated, "Privacy and confidentiality in your personal medical records."</p> <p>3. The agency document titled "FMCNA Notice of Privacy Practices" with an effective date of 7/15/2009 stated, "Our pledge regarding health information, FMCNA collects information about you ... Where this information identifies you or could be used to identify you it is considered 'protected health information,' or 'PHI.' We understand that health information about you and your health is personal. We are committed to protecting the confidentiality of your PHI ... we are required by law to make sure that health information that identifies you is kept private ... give you this notice of our legal duties and privacy practices with respect to your PHI, and ... follow the terms of the notice that is currently in effect."</p> <p>4. On 8/14/13 at 6:05 PM, Employee A, operations manager, and Employee D, charge nurse, indicated the patients' rights to privacy and confidentiality for patients #2, 3, 6, and 7 was not maintained as</p>		<p>a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. 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. 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>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 08/19/2013
---	--	--	--

NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART	STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517
---	---

(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
	required.			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(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			
V000544	<p>494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.</p> <p>Based on policy review, clinical record review, and interview, the facility failed to ensure the blood flow rate prescription was followed for 3 of 12 records (#1, #9, #11) reviewed with the potential to affect all 119 patients of the facility.</p> <p>Findings</p> <p>1. Clinical record #1 included hemodialysis orders that identified the blood flow rate (BFR) was to be 500 ml / min (milliliters per minute). The flow sheet dated 8/7/13 evidenced a BFR of 450 with no explanation as to why the BFR prescription was not followed.</p> <p>3. Clinical record # 9 included hemodialysis orders that identified BFR was to be 500 ml / min. The flow sheet dated 4/11/13 evidenced a BFR of 450 with no explanation as to why the BFR prescription was not followed.</p> <p>4. Clinical record # 11 included hemodialysis orders that identified BFR</p>	V000544	<p>On 8/21/13, the Clinic Manager and Operations Manager in-serviced the staff on the Patient Monitoring During Patient Treatment document FMS-CS-IC-I-110-133 with emphasis on ensuring that the patient's treatment is delivered according to the physician's prescription. If unable to achieve prescribed Blood Flow Rate, the Patient Care technician will document the reason and interventions taken on the patient's flowsheet. The Patient Care technician will notify the nurse of the inability to achieve the Prescribed Blood Flow Rate and document notification on the flowsheet. The nurse will assess the patient's access and notify the physician. Specific assessment/observation, interventions and follow-up including outcome will be documented by the staff on the patient's flowsheet. The Clinical Manager or designee will review treatment sheets daily for 2 weeks, then weekly for 4 weeks to ensure that patient's blood flow rate is delivered as prescribed, or if unable to achieve, the action taken is documented; on-going</p>	08/21/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART			STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>was to be 500 ml / min. The flow sheet dated 7/16/13 evidenced a BFR of 450 with no explanation as to why the BFR prescription was not followed.</p> <p>5. On 8/19/13 at 5:10 PM, the clinical manager indicated the blood flow rates were to match the orders unless an explanation was given on the treatment flow sheets. The BFR prescription was not followed.</p> <p>6. The facility policy titled "Patient Monitoring During Patient Treatment" document number FMS-CS-IC-I-110-133 revision date 7/4/12 states, "Documentation of monitoring will be completed on the treatment record. Appropriate interventions in response to changes in vital signs, treatment parameters, or machine adjustments shall be documented in the treatment record."</p>		<p>monthly audits will follow as part of the QAI program. The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. 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. 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>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(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			
V000715	<p>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 interview, observation, and review of facility policy and procedure, the medical director failed to ensure all policies and procedures related to infection control and patient care and safety were followed for 1 of 1 facility with the potential to affect all the facility's 119 patients.</p> <p>Findings</p> <p>1. On 8/14/13 at 2:20 PM, the door from the waiting room was observed closed but not locked. There was no receptionist or other staff in the lobby / waiting room. The door bell was rung with no response. The door to the treatment room was opened and any patient or visitor could enter without observation or permission from the facility staff.</p> <p>A. The facility policy titled "Physical Security and Facility Access Policy" with a review date of April 4, 2012 stated, "Purpose: to assure a secure and safe environment for all staff, visitors, and</p>	V000715	<p>The Medical Director met with the members of the Governing Body on 8/27/13 to review and approve the final plan of correction to ensure that citations and responses cited and detailed in V111, V115, V116, V121, V190, V451, V455, V544, and V727 appropriately address the root cause of each citation; additionally, the Medical Director reviewed identified action plans, auditing tools, and techniques which will monitor and measure adherence to policies and procedures and confirm that corrective actions are instituted to ensure resolution of the areas of deficiency. The Medical Director with Governing Body also reviewed the policy on Physical Security and Facility Access document FMS-CS-IC-I-101-035A with emphasis on "Doors from the waiting area to the treatment area should remain closed and locked at all times while still allowing emergency access/exit". Staff re-inserviced on 8/15/13 and sign-in sheet presented. Disciplinary action will follow for</p>	08/27/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
	<p>patients while on FMS [Fresenius Medical Services] properties ... Doors from the waiting area to the treatment area should remain closed and locked at all times while still allowing emergency access / exit."</p> <p>B. On 8/14/13 at 6:05 PM, Employee D, charge nurse, and Employee A, operations manager, indicated the policy of the clinic is to lock the door between the waiting room and the treatment room per facility policy.</p> <p>2. The medical director failed to ensure the facility followed its policy titled "Personal Protective Equipment" with a date of March 20, 2013, and document number of FMS - CS - IC II -155 080 A which stated, "Employees shall use personal protective equipment namely the combination of a fluid - resistant gown ... in accordance with the type of patient contact expected and anticipated exposure." (see V 111, V 115).</p> <p>3. The medical director failed to ensure the facility followed its procedure titled "Drawing Blood Work Pretreatment using an AVG / AVF or Catheter" with an effective date of January 4, 2012, which stated, "Immediately dispose the intact Vacutainer adapter and holder into the biohazardous waste sharp container." (see</p>		any employee found to violate this policy. The Medical Director is responsible to review the results of the Plan of Correction and ensuing activities and reports weekly as a member of the Governing Body and to provide oversight monthly ongoing through the QAI Committee. The Medical Director acknowledges his role to ensure that any issues not resolved will be reviewed with a new root cause analysis and Plan of Action until all issues as cited within the Statement of Deficiency have been resolved and resolution sustained.				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART			STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>V 111, V 116, V 121)</p> <p>4. The medical director failed to ensure the facility followed its policy titled "Technical Policy and Standards Manual Water Treatment Equipment" with an effective date of 5/24/96 which stated, "Water Softener Precautions ... Regeneration cycle ... 3. The top level of the salt pellets in the brine tank must be maintained about the level of the brine solution in the tank." (See V 190)</p> <p>5. The medical director failed to ensure the facility followed its policy titled "Patient Monitoring During Patient Treatment" document number FMS-CS-IC-I-110-133 revision date 7/4/12 which stated, "Documentation of monitoring will be completed on the treatment record. Appropriate interventions in response to changes in vital signs, treatment parameters, or machine adjustments shall be documented in the treatment record." (see V 544)</p>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(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			
V000727	<p>494.170(a) MR-PROTECT PT RECORDS FM LOSS/CONFIDENTIAL The dialysis facility must-</p> <p>(1)Safeguard patient records against loss, destruction, or unauthorized use; and (2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following: (i) The transfer of the patient to another facility. (ii) Certain exceptions provided for in the law. (iii) Provisions allowed under third party payment contracts. (iv) Approval by the patient. (v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.</p> <p>Based on observation, clinical record review, facility document review, and interview, the dialysis failed to ensure the confidentiality of medical record information in 4 (patients #2, #3, #6, and #7) of 12 medical records reviewed with the potential to affect all of the 119 active incenter hemodialysis patients.</p> <p>Findings</p> <p>1. On 8/14/13 at 6:00 PM, a large stack of papers were observed on the receptionist desk in the lobby entrance. The top document was face up and able to be read. This document included patient names and health information. No staff</p>	V000727	<p>On 8/15/13, the Clinic Manager and Operations Manager, in-serviced the staff on policy Patient Rights and Responsibilities document FMS-CS-IC-I-103-005A with emphasis on right to privacy and confidentiality in all aspects of treatment and right to privacy and confidentiality in personal medical records and the FMCNA Notice of Privacy Practices, COR-COMP-PS-0-001-001D1. On 8/26/13, the Director of Operations reiterated to the Clinic Manager, Charge Nurse, Master Social Worker and Clinic Secretaries our pledge to guard patients' protected health information (PHI) and the importance of safeguarding the entire patient record against loss,</p>	08/26/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/19/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART				STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
	<p>were present at the lobby receptionist desk at the time.</p> <p>The document stated, "Facility 6952 Nephrology Inc. - El [Elkhart] Date: 08/13/2013 shift 2 Chairside follow-up report [patient #7] medication not administered per unable to administer as prescribed, iron sucrose [venofer] dose ... [patient #2] patient missed treatment, patient was a no-show ... [patient # 3] patient missed treatment, patient was a no-show due to other ... [patient #6] patient was a no show due to other."</p> <p>2. The agency document titled "FMCNA [Fresenius Medical Care North America] Patient Rights" with a copyright date of 2009 stated, "Privacy and confidentiality in your personal medical records."</p> <p>3. The agency document titled "FMCNA Notice of Privacy Practices" with an effective date of 7/15/2009 stated, "Our pledge regarding health information, FMCNA collects information about you ... Where this information identifies you or could be used to identify you it is considered 'protected health information,' or 'PHI.' We understand that health information about you and your health is personal. We are committed to protecting the confidentiality of your PHI ... we are required by law to make sure that health</p>		<p>destruction or unauthorized use. Director of Operations has requested quotes for enclosing the secretary/receptionist area in the lobby with a physical barrier to assist in protecting PHI. This barrier will be installed no later than 9/16/13. Clinic Manager or designee will monitor the secretary/receptionist area on a daily basis to ensure that patient PHI is not visible. Any noted violations to our pledge will bring immediate disciplinary action to parties involved. The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152530	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 08/19/2013
--	---	--	---

NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY ELKHART	STREET ADDRESS, CITY, STATE, ZIP CODE 700 WATERBURY PARK DR ELKHART, IN 46517
---	---

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
	<p>information that identifies you is kept private ... give you this notice of our legal duties and privacy practices with respect to your PHI, and ... follow the terms of the notice that is currently in effect."</p> <p>4. On 8/14/13 at 6:05 PM, Employee A, operations manager, and Employee D, charge nurse, indicated the patients' rights to privacy and confidentiality for patients #2, 3, 6, and 7 was not maintained as required.</p>			