

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152609		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/08/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CARMEL				STREET ADDRESS, CITY, STATE, ZIP CODE 12400 N MERIDIAN ST CARMEL, IN 46032			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE
V000000	<p>This visit was an ESRD federal complaint investigation survey.</p> <p>Complaint: # IN00132098 - Substantiated: Federal deficiencies related to the allegation are cited.</p> <p>Survey date: August 8, 2013</p> <p>Facility #: 011350</p> <p>Medicaid Vendor: #200858170</p> <p>Surveyor: Bridget Boston, RN, PHNS</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN August 19, 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: 152609		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/08/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CARMEL				STREET ADDRESS, CITY, STATE, ZIP CODE 12400 N MERIDIAN ST CARMEL, IN 46032			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
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 and interview, the facility failed to ensure a sanitary environment was maintained to prevent cross contamination and minimize the transmission of infectious agents by maintaining clean items separate from dirty items in 2 (#s 1 and 2) of 7 infection control observations completed creating the potential for spread of infection causing agents among facility staff and patients. (employee A and C)</p> <p>The findings include:</p> <p>Observations on August 8, 2013:</p> <p>1. Observation number 1 was conducted at 12:38 PM. Employee A, a patient care technician, was observed in station 5 with patient 5. She placed multiple pieces of white 2 X 2 unwrapped gauze on the left trayside table which was attached to the dialysis chair, there was no barrier under the gauze. She obtained a roll of tape from a common cart in the middle of the treatment floor, tore the tape at chairside and placed directly onto the same tray top, draped from the edge. There was no</p>	V000111	<p>On Tuesday August 27th , 2013 the Governing Body met 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 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. The Clinical Manager will hold a staff in-service to educate all staff members on the following policy "Dialysis Precautions" FMS-CS-IC-II-155-070. Emphasis was placed on using a barrier between the bed-side table and supplies and maintaining clean items separate from dirty items such as ink pens. Training will be completed by September 6th 2013 and an in-service attendance sheet will be available in the facility for review. Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool, are done daily for 1 week, weekly for 4 weeks then ongoing monitoring will occur per the QAI calendar.</p>	09/06/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152609	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/08/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CARMEL			STREET ADDRESS, CITY, STATE, ZIP CODE 12400 N MERIDIAN ST CARMEL, IN 46032		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>barrier under the torn pieces of tape and she then returned the roll of tape to the common cart. She then was observed to terminate dialysis with patient 5 in station number 5 and applied the gauze dressing and tape to the patient's access / insertion sites.</p> <p>2. Observation number 2 was conducted at 12:40 PM. Employee C, a patient care technician, was observed at the center work station on the in-center. She removed a pen from her right pant leg pocket without completing hand hygiene. She utilized the pen, wrote on documents, and then returned the pen to the same pocket without decontaminating. When employee C lifted the right side of her gown to return the writing utensil to her pocket, additional writing utensils were observed extending from the pocket.</p> <p>3. On 8/8/13 at 6:30 PM, the area manager indicated the employees' practices were not in compliance with the facility's infection control procedures.</p>		The Clinical Manager will report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152609		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/08/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CARMEL				STREET ADDRESS, CITY, STATE, ZIP CODE 12400 N MERIDIAN ST CARMEL, IN 46032			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
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. Based on observation and interview, the facility failed to ensure personal protective equipment was utilized appropriately in 1 (employee A) of 2 patient care observations of infection control procedures of the patient care technician terminating dialysis in patients with a central venous catheter creating the potential to affect all of the facility's 51 current patients.</p> <p>The findings include:</p> <p>1. On 8/8/13 at 2:35 PM, employee A was observed to terminate dialysis on patient 6, whose access was a central venous catheter in station 2. Employee A terminated dialysis without applying a clean disposable mask and covered the employees nose and mouth. The employee wore the same mask as worn prior to the termination of dialysis.</p>	V000115	<p>The Clinical Manager is responsible to ensure that all staff members follow "Hand Hygiene and Personal Protective Equipment" policies to ensure a safe treatment environment that prevents cross contamination of patients and equipment. 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 "Hand Hygiene" FMS-CS-IC-II-155-090A and "Personal Protective Equipment" FMS-CS-IC-II-155-080A with emphasis placed on appropriate mask usage, when terminating a treatment with a central venous catheter. Training will be completed on September 6th 2013 and an in-service attendance sheet is available in the facility for review in addition an audit with skills checks will be completed by September 6th 2013 The Clinical Manager will hold a counseling session for</p>	09/06/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152609	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/08/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CARMEL			STREET ADDRESS, CITY, STATE, ZIP CODE 12400 N MERIDIAN ST CARMEL, IN 46032		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	2. On 8/8/13 at 6:30 PM, the area manager indicated the employees' practices were not in compliance with the facility's infection control procedures.		Employee A to discuss policy violations on August 8th 2013. as noted in the SOD. Expectations for improvement were discussed and documented. Emphasis and focus in this counseling session was Appropriate use of face masks during termination of treatment with a central venous catheter The Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks and then monthly for 3 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 The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152609		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/08/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CARMEL				STREET ADDRESS, CITY, STATE, ZIP CODE 12400 N MERIDIAN ST CARMEL, IN 46032			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
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 and interview, the facility failed to ensure supplies that could not be decontaminated were disposed of and not used on another patient or returned to a clean area or common supply in 1 of 7 infection control observations creating the potential to spread infectious and communicable disease to all 51 in-center patients of the facility (employee A).</p> <p>The findings include:</p> <p>1. On 8/8/13 at 12:38 PM, employee A, a patient care technician, was observed in station 5 with patient 5. She placed multiple pieces of white 2 X 2 unwrapped gauze on the left trayside table which was attached to the dialysis chair. There was</p>	V000116	The Clinical Manager is responsible to ensure that all staff members follow "Hand Hygiene and Personal Protective Equipment" policies to ensure a safe treatment environment that prevents cross contamination of patients and equipment. 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 "Hand Hygiene" FMS-CS-IC-II-155-090A and "Personal Protective Equipment" FMS-CS-IC-II-155-080A with emphasis placed on appropriate mask usage, when terminating a treatment with a central venous catheter. Training will be completed on September 6th 2013 and an in-service	09/06/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152609		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/08/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CARMEL				STREET ADDRESS, CITY, STATE, ZIP CODE 12400 N MERIDIAN ST CARMEL, IN 46032			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
	<p>no barrier under the gauze. She obtained a roll of tape from a common cart in the middle of the treatment floor, tore the tape at chairside, and placed directly onto the same tray top, draped from the edge. There was no barrier under the torn pieces of tape. She then returned the roll of tape to the common cart. She then was observed to terminate dialysis with patient 5 in station number 5 and applied the gauze dressing and tape to the patient's access / insertion sites.</p> <p>2. On 8/8/13 at 6:30 PM, the area manager indicated the employees' practices were not in compliance with the facility's infection control procedures.</p>		<p>attendance sheet is available in the facility for review in addition an audit with skills checks will be completed by September 6th 2013 The Clinical Manager will hold a counseling session for Employee A to discuss policy violations on August 8th 2013. as noted in the SOD. Expectations for improvement were discussed and documented. Emphasis and focus in this counseling session was Appropriate use of face masks during termination of treatment with a central venous catheter The Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks and then monthly for 3 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 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: 152609		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/08/2013	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CARMEL				STREET ADDRESS, CITY, STATE, ZIP CODE 12400 N MERIDIAN ST CARMEL, IN 46032			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
V000119	<p>494.30(a)(1)(i) IC-SUPPLY CART DISTANT/NO SUPPLIES IN POCKETS</p> <p>If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies.</p> <p>Do not carry medication vials, syringes, alcohol swabs or supplies in pockets.</p> <p>Based on observation and interview, the facility failed to ensure the staff followed standard infection control procedures during 1 (observation 2) of 7 observations of of infection control procedures with the potential to affect all 51 current patients (employee C)</p> <p>The findings include:</p> <p>1. On 8/8/13 at 12:40 PM, employee C, a patient care technician, was observed at the center work station on the in-center. She removed a pen from her right pant leg pocket without completing hand hygiene. She utilized the pen, wrote on documents, and then returned the pen to the same pocket without decontaminating. When employee C lifted the right side of her gown to return the writing utensil to her pocket, there were additional writing utensils observed extending from the pocket.</p>	V000119	<p>On August 27th the Governing Body met to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution. Clinic Manager addressed cross-contamination issues with supplies/carts and proper hand hygiene with staff through staff in-services that will be completed by September 6th 2013. Proper hand hygiene should be used before and after using a pen, touching supplies and changing gloves as described in policy FMS-CS-IC-II-155-090A. Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done weekly for 4 weeks monthly for 3 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</p>	09/06/2013			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152609	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 08/08/2013
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CARMEL			STREET ADDRESS, CITY, STATE, ZIP CODE 12400 N MERIDIAN ST CARMEL, IN 46032		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	2. On 8/8/13 at 6:30 PM, the area manager indicated the employees' practices were not in compliance with the facility's infection control procedures.		employee including corrective action as appropriate. Clinical Manager will hold a counseling session for Employee A to discuss policy violations on August 8th 2013 as noted in the SOD. Expectations for improvement were discussed and documented. Emphasis and focus in this counseling session was on proper hand hygiene. The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.		