

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152543	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 08/09/2012
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NAME OF PROVIDER OR SUPPLIER ST MARGARET MERCY DIALYSIS CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 5454 HOHMAN AVE HAMMOND, IN 46320
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V0000	<p>This visit was an ESRD recertification survey.</p> <p>Survey dates: August 7, 8, and 9, 2012</p> <p>Facility #: 005132</p> <p>Medicaid Vendor #: 200139260 A</p> <p>Surveyor: Bridget Boston, RN, Public Health Nurse Surveyor - Team Leader Ingrid Miller, RN, Public Health Nurse Surveyor - Team member</p> <p>Census - 97 Clinical Record review - 10</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN August 16, 2012</p>	V0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V0111	<p>494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>Based on observation and interview, the facility failed to ensure bulk dialysis toxic items were stored separate from direct patient use items in 1 of 2 observations with the potential to affect all patients.</p> <p>The findings include:</p> <p>1. On August 7, 2012, at 1:40 PM, along the back center wall of the in-center treatment room, two - plastic, free standing cabinets were observed side by side. The cabinet on the right had both doors ajar and staff were retrieving items from within both cabinets. Five feet from the open cabinet was station # 9 and patient # 3. Upon opening the doors fully on the right cabinet, on the right area of the bottom shelf, six bags of Naturalyte, a bicarbonate concentrate in powder form, were observed. Four of the six bags were under an opened box of blue disposable chux, and two of the six bags were inside the open box of disposable chux. The staff were utilizing the disposable chux on the in - center floor as a barrier during patient care. A white powdery substance was visible surrounding these bags of</p>	V0111	<p>Naturalyte was immediately removed from cabinet containing clean patient supplies and returned to storage area in basement. Shelves were cleaned and supplies reorganized.</p> <p>By 09/07/12 all staff will be trained on maintaining Naturalyte in basement supply room area for storage as required. Going forward the Acting Clinical Manager or designee will spot check supply storage to ensure supplies, including Naturalyte, are stored in designated areas. The Acting Clinical Manager or designee will immediately follow up if issues are identified. The meeting agenda and attendance records are available for review at the facility.</p> <p>The Acting Clinical Manager will discuss identified issues and actions taken during monthly QAI Committee meetings. In the event of discrepancies or problematic outcomes the committee investigates to determine the root cause of deficiencies and develops, implements, and tracks a corrective action plan through to resolution. The Acting Clinical</p>	09/07/2012			

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	<p>Naturalyte on the bottom shelf. Also in the cabinet were white disposable gowns, packaged gauze, and other various packaged products used during hemodialysis.</p> <p>2. On August 7, 2012, at 1:40 PM, the clinical manager indicated she was not aware of the storage of the Naturalyte and indicated it was not proper storage for the toxic substance. She indicated the dialysis storage was in the basement of the building and the bicarbonate was mixed on the second floor of the building inside the in-center unit and the staff probably stored the product in case more bicarbonate needed to be mixed.</p>		<p>Manager is responsible and the QAI Committee monitors to ensure bulk dialysis toxic items are stored separate from direct patient use items.</p>		

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V0113	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>Based on observation and interview, the facility failed to ensure staff changed gloves and performed hand hygiene appropriately during the provision of care in 2 of 2 days of patient care observations creating the potential to affect all of the facility's 97 current patients.</p> <p>The findings include:</p> <p>1. Observations on August 7, 2012:</p> <p>At 2:45 PM, employee K, a patient care technician, was observed providing patient care in dialysis station 16 for patient # 11. Employee K was wearing a face mask with two ties; only the bottom strings were tied and the mask was hanging below her chin. Employee K was observed to reapply the mask to her face and tie around the back of her head, then enter station 16, don gloves and dress the patient's peripheral access site. She then proceeded to remove the second access line. The employee failed to complete hand hygiene after applying her mask and before she donned her gloves.</p>	V0113	<p>By 09/07/12 the Clinical Manager will meet with all direct patient care staff to review and reinforce FMS-CS-IC-II-155-090A Hand Hygiene and FMS-CS-IC-155-080A Personal Protective Equipment Policies with emphasis on correct use of face mask, glove change as required, and decontamination hands using alcohol based hand rub or by washing hands with antimicrobial soap and water after removing gloves and after contact with body fluids or excretions. The meeting agenda and attendance records will be available for review at the facility.</p> <p>The Acting Clinical Manager or designee will continue to perform Infection Control audits according to QAI calendar and immediately follow up if issues are identified. The Acting Clinical Manager will report all findings including disciplinary action to Medical Director and QAI Committee during monthly QAI Committee meetings. In the event of discrepancies or problematic outcomes the committee investigates to determine the root cause of deficiencies and develops, implements, and tracks</p>	09/07/2012			

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	<p>2. Observations on August 9, 2012:</p> <p>A. At 9:20 AM, employee I, a registered nurse, was observed to clean dialysis machine #12 in station 6. After she completed cleaning the machine, she removed her gloves, donned another pair of gloves, and then approached the patient in station 10. She went to the dialysis machine in station 10 and touched the face of the machine. She then removed her gloves, applied an alcohol based gel to her hands and rubbed the palms of her hands three times only. She then donned another pair of gloves and proceeded to access another patient. Employee I failed to complete adequate hand hygiene after removing her gloves.</p> <p>B. At 9:30 AM, employee N was observed preparing the dialysis machine in station 19 for the next patient. He removed his gloves, applied the alcohol based gel to the palms of his hands and rubbed together three times. He then went into station 15, donned gloves, touched the patient and dialysis machine, removed gloves, applied alcohol based gel to his hands (palms only), rubbed palms together four times, donned gloves and went into station 18, machine 5, and began providing care to patient # 10. Employee N failed to complete adequate hand hygiene each time he removed his</p>		a corrective action plan through to resolution. The Acting Clinical Manager is responsible and the QAI Committee monitors to ensure staff change gloves and perform hand hygiene appropriately during provision of care.				

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	<p>gloves.</p> <p>C. At 10:05 AM, employee H was observed to terminate dialysis treatment of patient # 12 in station 15. Three times, while terminating treatment, she placed her hands on her face mask and readjusted her mask. She failed to remove her gloves and decontaminate her hands once she placed her hands on her mask and readjusted her mask.</p> <p>3. On August 9, 2012 at 10:45 AM, employee F indicated the staff were to complete appropriate hand hygiene after removing soiled gloves and before donning a new pair.</p>			

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V0403	<p>494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.</p> <p>Based on observation of the dialysis machines, review of the manufacturer's preventative maintenance recommendations and the preventative maintenance logs, and interview, the facility failed to ensure the dialysis machines were maintained per manufacturer's recommendations for 17 of 24 dialysis machines with the potential to affect all patients receiving treatments from these machines.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The 2008 T Machine Operator's Manual, page 169, states, "The Diasafe Plus filter is intended for the preparation of ultra - pure dialysate. If the machine has a Diasafe Plus filter, it should be replaced at least every 90 days (3 months)." 2. The policy titled Technical Policy and Standards Manual" states, "Purpose: To establish a minimum criteria for routine preventative maintenance on all facility 	V0403	<p>By 08/07/12 diasafe filters were replaced on 26 dialysis machines including machine #7, 15, 22, 23, and 24.</p> <p>On 08/15/12 the Technical Supervisor met with all Biomedical Technicians to review and reinforce FMS-CS-IC-II-140 045A Diasafe Filter Maintenance with emphasis on 90 day or less diasafe filter change as required. Going forward filter changes will continue to be documented on ER-1 Log.</p> <p>The Technical Supervisor or designee will audit machine maintenance, including diasafe filter changes, per the QAI Calendar and immediately notify the Acting Clinical Manager and address identified issues. Audit findings and actions taken will be reported to the Medical Director and QAI Committee during monthly QAI Committee meetings. In the event of discrepancies or problematic outcomes the committee investigates to determine the root cause of deficiencies and</p>	08/15/2012			

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	<p>water treatment equipment, medical equipment, ... Policy: The facility will establish a preventative maintenance (PM) program using this following criteria: The preventative maintenance program for medical equipment, ... will be in accordance with the equipment manufactures printed recommendations."</p> <p>3. On August 7, 2012, at 3 PM, an in-center observation evidenced that 5 of 7 dialysis machines, not servicing patients at the time and located on the treatment floor, had a diasafe filter that was 90 days old or older. Dialysis machine # 7, 15, 22, 23, and 24 each evidenced a diasafe filter with a label on the exterior of the filter and a hand written date of 2/16/12 to identify the last time the filter was changed.</p> <p>4. On August 7, 2012, at 4:10 PM, employee R indicated the diasafe filters were to be changed every 3 months.</p> <p>5. Review of the preventative maintenance and repair logs for the dialysis machines # 7, 15, 22, 23, and 24 evidenced the diasafe filters were not changed as recommended by the manufacturer:</p> <p>A. Documentation for dialysis machine # 7 evidenced the diasafe filter</p>		<p>develops, implements, and tracks a corrective action plan through to resolution. The Technical Supervisor and Acting Clinical Manager are responsible and the QAI Committee monitors to ensure equipment is maintained and operated in accordance with manufacturer's recommendations.</p>				

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	<p>was changed on 11/22/11, 9/16/12, and 7/17/12. (Dates are correct as on the documentation.)</p> <p>B. Documentation for dialysis machine # 15 evidenced the diasafe filter was changed on 2/16/12 and 2/24/12.</p> <p>C. Documentation for dialysis machine # 22 evidenced the diasafe filter was changed on 2/16/12 and 6/22/12.</p> <p>D. Documentation for dialysis machine # 23 evidenced the diasafe filter was changed on 2/16/12 and 6/14/12.</p> <p>E. Documentation for dialysis machine # 24 evidenced the diasafe filter was changed on 2/16/12 and 6/6/12.</p> <p>6. On 8/8/12 at 10 AM, employee A indicated all dialysis machines were checked after patients had been removed from treatment on 8/7/12 and 17 of their 24 dialysis machines on the floor and used for treatment on 8/7/12 had a diasafe filter older than 90 days. Employee A indicated all were changed before treatment began on 8/8/12 and the facility had failed to follow the manufacturer's recommendations and their own policy for the frequency to change the diasafe filters.</p>						

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V0516	<p>494.80(b)(1) PA-FREQUENCY-INITIAL-30 DAYS/13 TX An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.</p> <p>Based on clinical record and policy review and interview, the facility failed to ensure the initial comprehensive assessment of the patient's needs was completed within 13 hemodialysis treatment days or 30 calendar days in 1 of 10 records reviewed. (patient #3)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. A review of clinical record #3, start of care 3/27/12, included an initial comprehensive assessment which evidenced the Psychosocial Assessment was completed by the Qualified Master Social Worker on 5/24/12, more than 30 days after the patient's first treatment in the facility. 2. On 8/9/12 at 2:38 PM, the clinic manager indicated the patient's initial interdisciplinary comprehensive assessment was late and not completed until 5/24/12. 3. The facility policy titled "Comprehensive Interdisciplinary 	V0516	<p>By 09/07/12 the Acting Clinical Manager will meet with the interdisciplinary team to review and reinforce FMS-CS-IC-I-110-125A Comprehensive Patient Assessment (CIA) and Plan of Care (POC) Policy with emphasis on:</p> <ul style="list-style-type: none"> o Assessment must be conducted on all new patients and a plan of care developed and implemented within the later of 30 calendar days or 13 outpatient Hemodialysis sessions beginning with the first outpatient dialysis session o Frequency of patient assessment and plan of care as determined by findings and whether the patient is determined to be stable or unstable; at least annually for stable patients <p>The meeting agenda and attendance records will be available for review at the facility.</p> <p>The Acting Clinical Manager or designee will perform Medical Record audits per the QAI Calendar including verifying that patient assessments are completed at the required</p>	09/07/2012

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	Assessment and Care Plan" number FMS - CS - IC - I - 110 - 125A, effective date July 4, 2012, presented to the surveyor on 8/9/12 by the clinic manager, stated, "An initial comprehensive interdisciplinary assessment must be conducted on all new patients and a plan of care developed and implemented within the later of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session."		frequency by all team members. The Acting Clinical Manager will immediately address identified issues. Audit findings and actions taken will be reported to the Medical Director and QAI Committee during monthly QAI Committee meetings. In the event of discrepancies or problematic outcomes the committee investigates to determine the root cause of deficiencies and develops, implements, and tracks a corrective action plan through to resolution. The Acting Clinical Manager is responsible and the QAI Committee monitors to ensure the initial CIA is completed within the latter or 30 calendar days or 13 Hemodialysis sessions beginning with the first dialysis session.	

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V0557	<p>494.90(b)(2) POC-INITIAL IMPLEMENTED-30 DAYS/13 TX Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.</p> <p>Based on interview and review of clinical records and policy, the facility failed to ensure the development and implementation of an initial plan of care within 13 hemodialysis treatment days or 30 calendar days in 1 of 10 records reviewed. (#3)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. A review of clinical record #3, start of care 3/27/12, evidenced a Comprehensive Interdisciplinary Plan of Care completed on 5/24/12, more than 30 days after the patient's first treatment in the facility. 2. On 8/9/12 at 2:38 PM, the clinic manager indicated the patient's interdisciplinary care plan was late and not completed until 5/24/12. 3. The facility policy titled "Comprehensive Interdisciplinary Assessment and Care Plan" number FMS - CS - IC - I - 110 - 125A, effective date July 4, 2012, presented to the surveyor on 8/9/12 by the clinic manager, stated, "An 	V0557	<p>By 09/07/12 the Acting Clinical Manager will meet with the interdisciplinary team to review and reinforce FMS-CS-IC-I-110-125A Comprehensive Patient Assessment (CIA) and Plan of Care (POC) Policy with emphasis on:</p> <ul style="list-style-type: none"> o Assessment must be conducted on all new patients and a plan of care developed and implemented within the later of 30 calendar days or 13 outpatient Hemodialysis sessions beginning with the first outpatient dialysis session o Frequency of patient assessment and plan of care as determined by findings and whether the patient is determined to be stable or unstable; at least annually for stable patients <p>The meeting agenda and attendance records will be available for review at the facility.</p> <p>The Acting Clinical Manager or designee will perform Medical Record audits per the QAI Calendar including verifying that patient plans of care are completed at the required</p>	09/07/2012			

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	initial comprehensive interdisciplinary assessment must be conducted on all new patients and a plan of care developed and implemented within the later of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session."		frequency by all team members. The Acting Clinical Manager will immediately address identified issues. Audit findings and actions taken will be reported to the Medical Director and QAI Committee during monthly QAI Committee meetings. In the event of discrepancies or problematic outcomes the committee investigates to determine the root cause of deficiencies and develops, implements, and tracks a corrective action plan through to resolution. The Acting Clinical Manager is responsible and the QAI Committee monitors to ensure the initial POC is implemented within the latter or 30 calendar days or 13 Hemodialysis sessions beginning with the first dialysis session.		