

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152501		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED  04/19/2013	
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE GARY				STREET ADDRESS, CITY, STATE, ZIP CODE 3290 GRANT ST GARY, IN 46408			
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V000000	<p>[CORE]</p> <p>This visit was an ESRD recertification survey.</p> <p>Survey dates: April 16, 17, 18 and 19, 2013</p> <p>Facility #: 5148</p> <p>Medicaid Vendor #: 100275180A</p> <p>Surveyor: Bridget Boston, RN PH Nurse Surveyor, Team Leader Susan E. Sparks, RN PH Nurse Surveyor</p> <p>Census: 13 Peritoneal Dialysis Patients 117 In-Center Hemodialysis Patients</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN April 29, 2013</p>	V000000					

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

TITLE

(X6) DATE

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

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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. Based on observation and interview, the facility failed to ensure the staff followed standard infection control procedures during 1 (observation 3) of 3 observation periods with the potential to affect all 130 patients.</p> <p>The findings include:</p> <p>1. Observation of the in-center unit on 4/19/13:</p> <p>A. At 9:50 AM, employee E, a registered nurse, was observed in station 8 with patient number 17. She was observed to reach underneath her protective gown and into her left pocket to retrieve an ink pen. She then handed the pen to the patient and a clipboard which had one piece of paper attached, the patient looked at the paper document and was asked to sign the document. After the patient signed the document, the</p>	V000119	<p>V119 - IC-Supply Cart Distant/No Supplies in Pockets</p> <p>By 05/19/13 all staff will be re-trained on clean vs. dirty and preventing cross contamination and clean vs. dirty according to FMS-CS-IC-II-155-110A Cleaning and Disinfection Policy:</p> <ul style="list-style-type: none"> <li>· All reusable supplies (e.g. clipboards, etc.) will be disinfected with 1:100 bleach solution after each patient use when brought to patient station</li> <li>· Proper handling and storage of pens when not in use</li> <li>· Contaminated items must not be placed in clean area</li> </ul> <p>The meeting agenda and attendance records will be available for review at the facility. The Clinical Manager or designee will perform Infection Control audits according to QAI calendar and immediately follow up if issues are identified. The Clinical Manager will report all findings and actions taken during monthly QAI Committee meetings. In the event of discrepancies or</p>	05/19/2013	

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	<p>patient handed the items back to the nurse who carried the clipboard and paper document to a desk located in the center of the dialysis floor without decontaminating the clipboard. She returned the pen back to her pocket without first decontaminating it.</p> <p>B. At 11:05 AM employee F, a personal care technician, was observed with her hands under her protective gown to retrieve a pink pen from her right pocket. She then documented on a paper treatment record at station 4, then returned the pen to her pocket without decontaminating it.</p> <p>C. At 11:15 Am, employee G was observed to pick up a black pen from the top of dialysis machine in station # 5 and then carried to a work area in the middle of the in-center floor that was identified as a "clean" area and was set up for medication preparation. She did not decontaminate the pen before placing in the clean area.</p> <p>2. On 4/19/13 at 1:30 PM, employee C indicated at no time are items to be taken from the pocket, used, and returned to the pocket or taken to another area without decontaminating.</p>		<p>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 Clinical Manager is responsible and the QAI Committee monitors to ensure staff follow standard infection control procedures.</p>		

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V000457	<p>494.70(a)(6) PR-CAN HAVE ADVANCE DIR,TOLD FAC AD P&amp;P The patient has the right to-</p> <p>(6) Be informed about his or her right to execute advance directives, and the facility 's policy regarding advance directives; Based on clinical record and policy review and interview, the facility failed to ensure staff assisted the patient to exercise their right to obtain a Do Not Resuscitate (DNR) Order from the physician for 1 of 11 records reviewed. (# 17).</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>The policy titled "FMCNA Notice of Do Not Resuscitate (DNR) Practices" number FMS-CS-IC-I-101-050D2 dated 4/4/2012 states, "If you do not have a copy [DNR], the facility staff will assist you in obtaining one from your physician."</li> <li>The policy titled "Do Not Resuscitate Order" number FMS-CS-IC-I-101-050A1 dated 4/4/2012 stated, "Prior to the first treatment and again during the comprehensive interdisciplinary nursing assessment, the registered nurse will ask the patient if they have a current DNR order or would like to change their resuscitation status. During the</li> </ol>	V000457	<p>V457 - PR-Can Have Advance Dir, Told Fac AD P&amp;P By 05/19/13 all registered nurses, physicians, and social workers will be re-trained on FMS-CS-IC-I-101-050D2 Patient Notice of DNR Practice Form, FMS-CS-IC-I-101-050A1 Do Not Resuscitate and FMS-CS-IC-I03-005A Patient Rights and Responsibilities Policies with emphasis on:</p> <ul style="list-style-type: none"> <li>· Patient's rights will be respected and protected by the facility</li> <li>· Patients will be informed of his or her rights to execute advance directives and facilities policies regarding advance directives</li> <li>· Prior to the first treatment and again during the CIA nursing assessment the RN will ask the patient if they have a DNR order or would like to change their resuscitation status</li> <li>· During the CIA and then annually the Social Worker will provide general information to the patient and confirm the patients intentions with respect to Advance Directives generally and DNR orders specifically</li> <li>· During the IDT Plan of</li> </ul>	05/19/2013	

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	<p>comprehensive interdisciplinary assessment and then annually, the social worker will provide general information to the patient and confirm the patient's intentions with respect to Advance Directives generally and DNR orders specifically. Patients with previously executed DNR orders, or who possess a DNR identification such as a bracelet or wallet card, must provide a copy of the DNR order to the facility for placement in their medical record. Facility staff should assist the patient in obtaining a copy of any existing DNR order from their attending physician or other health care provider. A patient may change his or her resuscitation status at any time by requesting a new DNR order or terminating an existing DNR order."</p> <p>3. The policy titled "Patient Rights and Responsibilities" number FMS-CS-IC-I-101-005A dated 4/4/2012 stated, "Ensure that patient's rights are respected and protected by the facility."</p> <p>4. On 4/19/13 at 12:20 PM, employee A indicated the patient verbalized a desire for a Do Not Resuscitate order and was sent home with the form for a family member to review.</p> <p>5. Clinical record 17, start of care 2/22/13, evidenced a comprehensive</p>		<p>care meeting or during the annual care plan meeting the IDT will address patient resuscitation status with physician and confirm DNR orders are written By 5/10/13, Clinical Record #17 will be updated to address patient DNR status per patient request including a written order for DNR and CIA/POC addendum to address patient status. The Clinical Manager or designee will audit medical records according to QAI calendar and report all deficiencies to the QAI Committee and immediately follow up if issues are identified. The Clinical Manager will report all findings and actions taken to 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 Clinical Manager is responsible and the QAI Committee monitors to ensure staff assist patients to exercise their rights to obtain a DNR Order from the physician.</p>		

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	<p>interdisciplinary assessment (C.I.A.) dated 3/22/13 completed by the Interdisciplinary team that documented the patient was alert and oriented. The document did not include and address the patient's resuscitation status.</p> <p>A. Within the C.I.A., beginning on page 12 of 17, was the Psychosocial Assessment dated 3/25/13 that stated, "How does the patient learn best?" Verbal explanation was chosen by the assessor completing the form, then hand written on the form states, "Blind in / eye - Poor eyesight in the other. ... Resuscitation statement reviewed? ... Yes." Then hand written stated, "Re-educated and DNR reviewed."</p> <p>B. The record evidenced "Multidisciplinary Progress Notes" dated 3/22/13 and completed by employee A that stated, "Initial care plan completed. PT [patient] still wants a DNR, paperwork given to him."</p> <p>C. The document titled "Patient Plan of Care" dated 3/22/13 failed to address the identified need of the patient to obtain a Do Not Resuscitate order from the physician.</p> <p>D. The record evidenced employee I, a physician, visited the patient in the</p>				

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	<p>facility on 2/25/13, 2/27/13, 3/6/13, 3/8/13, 3/11/13, 3/13/13, and 3/22/13.</p> <p>The visit notes failed to evidence the physician was informed and discussed with the patient his / her desire for a DNR or assisted with obtaining a DNR order.</p>				

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V000637	<p>494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must-</p> <p>(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents.</p> <p>Based on administrative record and policy review, observation, and interview, the facility failed to ensure a quality assessment and performance improvement (QAPI) program addressed identified noncompliant infection control practices and included a plan to monitor the noncompliance and a plan to prevent staff from caring for both hepatitis B positive patients and susceptible patients at the same time for 1 of 1 ESRD reviewed creating the potential to affect all of the facility's current 49 hepatitis B susceptible patients.</p> <p>The findings include:</p> <p>1. During in-center observation 1 on 4/16/13 between 9:30 - 11:30 AM, employee D, a registered nurse, was observed to provide direct care to the patients receiving hemodialysis in stations 3, 4, 20, 22, 23, 24, and 21 the isolation</p>	V000637	<p>V637 - QAPI- Indicator-INF Control- Trend Plan Act On 05/01/13 the Governing Body including the Director of Operations (CEO), Clinical Manager, and Medical Director met to review the facility Exposure Control Plan and agreed to increase the size of the Hepatitis B buffer zone assignment to include stations 1-4 and 17-24. By 05/19/13 all staff will be trained on the facility buffer zone and re-trained on FMS-CS-IC-II-155-140A Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+) Policy with emphasis on:</p> <ul style="list-style-type: none"> <li>· Staff caring for HBsAg+ positive patients care only for HBV antibody positive (immune) patients at the same time. This includes nurses and PCTs.</li> <li>· Only when the HBsAg positive patient has left the treatment area and the isolation room/area has been completely</li> </ul>	05/19/2013			

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	<p>room with patient number 4, a Hepatitis B positive patient dialyzing. The nurse was providing care to patients receiving hemodialysis on the north end of the room; stations 1 through 4, 17 through 20, and 22, 23, and 24 at the same time.</p> <p>2. On 4/16/13 at 9:40 AM, employee C, a registered nurse indicated the buffer zone was considered to be stations to the immediate right and left of the isolation room, stations 17, 18, 19, 20, 22, 23, and 24. He indicated the stations 1 through 4 were not part of the buffer zone. The employee indicated only the nurses assign the patients to stations and the hepatitis status is reflected on the assignment sheet for the nurses and that prevents a susceptible patient to be placed in the stations considered to be the buffer zone. The employee indicated the hepatitis B positive patients dialyze on Tuesdays, Thursdays, and Saturdays.</p> <p>3. April 16, 2013, at 10:45 AM, a registered nurse, employee H indicated the isolation buffer zone are stations 24, 23, 22 and 21. Chair 21 is the isolation room and is in the corner of the room. The registered nurse is responsible for chairs 1, 2, 3, 4, 17, 18, 19, 20, 21, 22, 23, and 24. This formed a</p>		<p>disinfected and there are no further tasks to be done in the isolation room/area can these staff members care for susceptible patients.</p> <p>On 05/01/13 the Director of Operations/CEO met with the Clinical Manager, Charge Nurse and Medical Director to review QAI process related to:</p> <ul style="list-style-type: none"> <li>· Documenting audit results, plan for improvement, and actions taken for improvement.</li> <li>· Reporting infection control audits and follow up to determine compliance.</li> </ul> <p>The meeting agendas and attendance records are available for review at the facility.</p> <p>The Clinical Manager or designee will perform Infection Control audits according to QAI calendar including verify compliance with Hepatitis B Exposure Control standards as stated above and immediately follow up if issues are identified.</p> <p>The Director of Operations or designee will audit QAI documentation monthly for completeness and verify documentation and reporting occur as required.</p> <p>The Clinical Manager will report all findings 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</p>				

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	<p>horseshoe shape at the north end of the treatment floor.</p> <p>4. The facility staff schedule for the month of April evidenced two registered nurses were scheduled to provide the direct care to the in-center hemodialysis patients on Tuesdays, Thursdays, and Saturdays, April 2, 4, 6, 9, 11, 13, 16, 18, 20, 23, 25, and 27, 2013.</p> <p>5. The facility's QAPI meeting minutes dated 3/29/13 identified an Infection Control Observation result of 50%. The document stated, "Process Improvement Plan in place or needed? Yes. ... New Plan ... Findings / Discussions / Actions / Plan / Timeline: The area educator did a needs assessment. The infection control portion of the audit scored 50% compliance for staff members. The charge nurse will make rounds in the treatment area every 2 hours and report staff non-compliance to the clinic manager."</p> <p>The document identified the facility with one Hepatitis B positive patient with 38 % of the susceptible patients completing the vaccination series. The minutes state, "Have all new patients been offered vaccine this month? Yes. ... Hepatitis vaccine record up to date? Yes."</p>		a corrective action plan through to resolution. The Clinical Manager is responsible and the QAI Committee monitors to ensure the QAPI program addresses identified noncompliant infection control practices and includes plans to monitor noncompliance and prevent staff from caring for both Hepatitis B positive and susceptible patients.		

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	<p>6. The facility's auditing tool titled "In-center Clinical Educational Needs Assessment" dated 3/21/13 was an observational audit of non compliance to infection control practices. The audit identified 6 of 12 areas were not met (50%). These areas where non compliance was identified were: 1) Environment free from spills and splashes (blood, bicarb), 2) Patient station disinfected per policy and procedure, 3) 1:100 and 1:10 bleach solution prepared and handled appropriately, 4) Handling of clean supplies appropriately - clean, dirty, sterile, multi use, 5) Portable electronic devices brought to the patient care floor, and 6) Appropriate PPE including the isolation room per policy and procedures.</p> <p>The document included an audit of hemodialysis procedures, assessments, water room logs, access care with a total observation score of 63 %.</p> <p>7. On 4/18/13 at 11:00 AM, central time, the regional operations manager indicated the registered nurse is not the primary care staff, that the technician was the primary care giver, and the facility policy was that the registered nurse could</p>						

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	<p>take care of other patients.</p> <p>8. On 4/19/13 at 1:30 PM, employee C indicated a corporate educator conducted the infection practice audit dated 3/21/13 and there was no documentation to evidence a follow up was conducted to address the noncompliance with infection practice standards identified. He indicated the charge nurse and manager were spending more time on the in-center floor observing and verbally educating the staff and that there was not any documentation to support the actions taken and follow up audits to determine if the compliance was improving.</p> <p>9. The policy titled "Quality Assessment and Performance Improvement (QAI) for FMS Inpatient Services Programs" with revision date 2/1/13 stated, "The objectives of the QAI program: ... Identify aspects of care that are essential in determining quality of patient care in the inpatient setting. Monitoring, evaluation, and improvement activities are focused on those identified aspects of care and criteria / factors that have an impact on patient outcomes and clinical performance. Quality indicators should be selected in accordance with the following: ... High risk, problem prone processes. ... Quality indicators are composed of objective and measurable</p>				

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	criteria, based on current knowledge and clinical experience, and can be identified and monitored through: Direct observation, audit [sic] of documentation."				