

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 04/16/2014
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CARMEL	STREET ADDRESS, CITY, STATE, ZIP CODE 12400 N MERIDIAN ST CARMEL, IN 46032
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V000000	This was a Federal ESRD complaint investigation survey.	V000000		
V000113	<p>Complaint #: IN00139179; Substantiated, no deficiencies related to the allegations are cited.</p> <p>Complaint #: IN00147493; Substantiated, Federal deficiencies related to the allegations are cited. Unrelated deficiencies are also cited.</p> <p>Survey Dates: 4-14-14, 4-15-14, & 4-16-14</p> <p>Facility #: 011350</p> <p>Medicaid Vendor #: 200858170</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN April 23, 2014</p> <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, interview, and facility policy review, the facility failed to ensure its staff had cleansed hands and donned gloves at the appropriate time in 2 (patients numbered 6 and 7) of 2 medication administration observations completed creating the potential to affect all of the facility's 51 current patients.</p>	V000113	The Director of Operations met with the Governing Body on 5/2/14 and provided education on the following policy: "Emergency Medications, Equipment and Supplies" FMS-CS-IC-II-130-007A Emphasis was placed on the supplies and equipment that must be immediately available, including an	05/09/2014

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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	<p>The findings include:</p> <ol style="list-style-type: none"> 1. Employee L, a registered nurse (RN), was observed to administer 2 intravenous (IV) medications to patient number 6 on 4-15-14 at 11:10 AM. The RN brought the syringes to the patient's station, touched the computer keyboard, and cleansed only the tips of her fingers of both hands with alcohol before donning clean gloves. The RN was then observed to inform the patient of the medications to be given and administer the medications in the appropriate port. 2. Employee C, a RN, was observed to administer 2 IV medications to patient number 7 on 4-16-14 at 9:25 AM. The RN brought the syringes to the patient's station, touched the computer keyboard, and donned clean gloves without cleansing her hands. The RN was then observed to inform the patient of the medications to be given and administer the medications in the appropriate port. 3. The facility's 9-25-13 "Medication Preparation and Administration" procedure number FMS-CS-IC-I-120-040C states, "Wash hands. Apply PPE [personal protective equipment] . . . Take the medication to the patient's chair or bedside . . . Administer the medication via the appropriate route and/or port into the extracorporeal circuit . . . Document the medication administration in the patient's medical record." <p>The facility's 12-30-13 "Medication Preparation and Administration" policy number FMS-CS-IC-I-102-040A states, "The following steps must be taken to ensure</p>		<p>oral airway. The Governing Body approved and implemented an emergency cart inventory list.</p> <p>On 5/1/14 the Clinical Manager and Education Coordinator educated all staff on the following policy: - "Emergency Medications, Equipment and Supplies" FMS-CS-IC-II-130-007A Education included: - review of the emergency cart inventory list - location of the emergency cart inventory list - monthly review of the emergency cart inventory list All training documentation is on file at the facility.</p> <p>The Clinic Manager/designee will audit the emergency cart inventory list monthly to ensure compliance.</p> <p>The Clinical Manager is responsible to present all audit findings related to the monthly checks to the QAI Committee.</p>		

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	<p>infection control. Perform hand hygiene prior to . . . administering medications."</p> <p>4. The facility's 1-4-12 "Infection Control Overview" policy number FMS-CS-IC-II-155-060A states, "Mandatory Components of Program Adherence to standard and dialysis precautions."</p> <p>The Centers for Disease Control "Standards Precautions" states, "IV. Standard Precautions . . . IV.A. Hand Hygiene. IV.A.1. During the delivery of healthcare, avoid unnecessary touching of surfaces in close proximity to the patient to prevent both contamination of clean hands from environmental surfaces and transmission of pathogens from contaminated hands to surfaces . . . Perform hand hygiene: IV.A.3.a. Before having direct contact with patients. IV.A.3.b. After contact with blood, body fluids or excretions, mucous membranes, nonintact skin, or wound dressings. IV.A.3.c. After contact with a patient's intact skin (e.g., when taking a pulse or blood pressure or lifting a patient). IV.3.d. If hands will be moving from a contaminated-body site to a clean-body site during patient care. IV.A.3.e. After contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. IV.A.3.f. After removing gloves . . . IV.F.5. Include multi-use electronic equipment in policies and procedures for preventing contamination and for cleaning and disinfection, especially those items that are used by patients, those used during delivery of patient care, and mobile devices that are moved in and out of patient rooms frequently . . . IV.B. Personal protective equipment (PPE) . . . IV.B.2. Gloves. IV.B.2.a. Wear gloves when it can be</p>			

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V000408	<p>reasonably anticipated that contact with blood or potentially infectious materials, mucous membranes, nonintact skin, or potentially contaminated intact skin . . . could occur.</p> <p>4. The Clinic Manager, employee M, indicated, on 4-16-14 at 10:30 AM, employees C and L had not followed the facility's infection control and medication administration policies and procedures while administering medications.</p> <p>494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure it had implemented its own medical emergency policies and procedures in 1 (# 1) of 1 record reviewed of a patient that had experienced cardiac arrest creating the potential to affect all of the facility's 51 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 1 evidenced the patient had experienced cardiac arrest on 4-7-14. A treatment flow sheet evidenced the patient care technician (PCT), employee F, had checked the patient at 1:05 PM and had</p>	V000408	<p>The Education Coordinator re-educated all staff members on 5/1/2014 on the following procedures/policies:</p> <ul style="list-style-type: none"> · "Patient Emergency Treatment" FMS-CS-OC-II-130-002A · "Guidelines for Staff Response During Cardiopulmonary Arrest" FMS-CS-IC-II-130-005A <p>Emphasis will be placed on proper documentation and completion of the "Cardiac Arrest Record". An in-service attendance sheet is available in the facility for review.</p>	

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	<p>documented, "Resting Comfortably; UF [ultrafiltration] on; avis green light." Employee B, a registered nurse (RN), documented at 4:14 PM, "At 13:05 PM [1:05 PM] called to return pts [patient's] blood when noted pt staring; not breathing and without pulse. Pt talking just seconds before. 911 called and [employee N, a physician] called over who was rounding in the unit. Code equipment gathered and backboard in place. CPR [Cardiopulmonary Resuscitation] began."</p> <p>A. The record failed to evidence the facility's "Cardiopulmonary Resuscitation Record" form had been completed per the facility's policy.</p> <p>B. The Clinic Manager, employee M, stated, on 4-16-14 at 10:30 AM, "We did not complete the 'Cardiopulmonary Resuscitation Record' form for patient number 1."</p> <p>C. The Clinic Manager stated, on 4-16-14 at 10:30 AM, "I talked to the nurse [employee B] about her charting on the code. She stated she had estimated the times since she charted after it was all over. I reviewed with her the need for accuracy regarding code charting. The nurse indicated it may have been 1:06 PM or 1:07 when the patient was found."</p> <p>2. The facility's 10-3-12 "Guidelines for Staff Response during Cardiopulmonary Arrest" policy number FMS-CS-IC-II-130-005A states, "Document arrest information on the Cardiopulmonary Resuscitation Record form."</p> <p>3. The facility's 10-3-12 "Patient Emergency Treatment" policy number</p>		<p>The Clinical Manager is responsible to ensure that all staff members are educated semi-annually regarding staff response during a cardiac arrest.</p> <p>The Clinical Manager will audit education compliance quarterly via the QAI calendar.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p>	

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V000409	<p>FMS-CS-IC-II-130-002A states, "All staff interventions and patient response should be documented in the patient's medical record, treatment record, and the Cardiopulmonary Arrest Record. Documentation should be factual and consistent throughout the record." 494.60(d)(1) PE-ER PREP STAFF-INITIAL/ANNUAL/INFORM PTS The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following: (i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of- (A) What to do; (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and (D) How to disconnect themselves from the dialysis machine if an emergency occurs.</p> <p>Based on interview, the facility failed to ensure all staff had received training to include the address of the facility in the event of a medical emergency in 1 (employee D) of 2 employees interviewed creating the potential to affect all of the facility's 51 current patients.</p>	V000409	<p>The Education Coordinator re-educated all staff members on 5/1/14 on the following procedures/policies: · "Patient Emergency Treatment" FMS-CS-OC-II-130-002A · "Guidelines for Staff Response During Cardiopulmonary</p>	

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V000413	<p>The findings include:</p> <ol style="list-style-type: none"> Employee D, a patient care technician (PCT), was asked the address of the facility on 4-15-14 at 9:05 AM. The employee was unable to provide the address of the facility and asked employee G, another PCT, what the address was. Employee G was able to provide the address of the facility. The facility's Clinic Manager, employee M, stated, on 4-16-14 at 10:30 AM, "I will quiz all employees and ensure they know the address or where to find it." <p>494.60(d)(3) PE-ER EQUIP ON PREMISES-02, AED, SUCTION Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.</p> <p>Based on observation, facility policy review, administrative record review, and interview, the facility failed to ensure it had all emergency equipment available and had established and implemented a policy specific to this facility for required emergency equipment and medications creating the</p>	V000413	<p>Arrest" FMS-CS-IC-II-130-005A · "FMS Facility Emergency Information Directory" FMS-CS-IC-II-130-013D2 Emphasis will be placed on emergency facility information. An in-service attendance sheet is available in the facility for review.</p> <p>The Clinical Manager is responsible to ensure that all staff members are educated semi-annually regarding staff response during a cardiac arrest.</p> <p>The Clinical Manager will audit compliance quarterly via the QAI calendar.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p> <p>The Director of Operations met with the Governing Body on 5/2/14 and provided education on the following policy: · "Emergency Medications, Equipment and Supplies" FMS-CS-IC-II-130-007A Emphasis was placed on the supplies and equipment that must be</p>				

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V000715	<p>potential to affect all of the facility's 51 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The emergency treatment cart and equipment was observed during a tour of the treatment floor on 4-14-14 at 6:20 PM. The emergency equipment failed to include an oral airway. 2. The "AED [automatic external defibrillator] / Emergency Cart Daily Checklist" failed to evidence an oral airway as a part of the emergency equipment. 3. The Clinic Manager, employee M, stated, on 4-15-14 at 11:00 AM, "We do not have an oral airway in our emergency equipment." The manager stated, at 1:30 PM, "We do not have a policy specific to this facility regarding the content of the crash cart to include supplies." 4. The facility's 6-19-13 "Emergency Medications, Equipment and Supplies" policy number FMS-CS-IC-II-130-007A states, "The following minimum emergency supplies and equipment must be on the premises at all times, clean, functional, accessible and immediately available: . . . Oral Airway. It is the responsibility of the Medical Director in conjunction with the Governing Body and medical staff to determine the medications and equipment that are to be kept in the emergency cart/box or as required by state and/or local regulations or ESRD licensure states." <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that-</p>		<p>immediately available, including an oral airway. The Governing Body approved and implemented an emergency cart inventory list.</p> <p>On 5/1/14 the Clinical Manager and Education Coordinator educated all staff on the following policy: - "Emergency Medications, Equipment and Supplies" FMS-CS-IC-II-130-007A Education included: - review of the emergency cart inventory list - location of the emergency cart inventory list - monthly review of the emergency cart inventory list All training documentation is on file at the facility.</p> <p>The Clinic Manager/designee will audit the emergency cart inventory list monthly to ensure compliance.</p> <p>The Clinical Manager is responsible to present all audit findings related to the monthly checks to the QAI Committee.</p>				

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	<p>(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;</p> <p>Based on clinical record and facility policy review and interview, the medical director failed to ensure the facility's policy regarding monitoring patients during treatments had been adhered to in 5 (#s 1, 2, 3, 4, and 5) of 5 records reviewed creating the potential to affect all of the facility's 51 current patients.</p> <p>The findings include:</p> <p>1. The facility's 7-4-12 "Patient Monitoring During Patient Treatment" policy number FMS-CS-IC-I-110-133A states, "Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary."</p> <p>2. Clinical record number 1 failed to evidence the patient had been monitored every 30 minutes as required by facility policy.</p> <p>A. A hemodialysis treatment flow sheet dated 3-7-14 evidenced the patient had been checked at 1:01 PM and not again until 1:41 PM, a period of 40 minutes between checks.</p> <p>B. A hemodialysis treatment flow sheet dated 3-10-14 evidenced the patient had been checked at 10:12 AM and not again until 11:01 AM, a period of 49 minutes between checks. The flow sheet evidenced the patient had been checked at 1:38 PM and not again until 2:25 PM, a period of 47</p>	V000715	<p>The Director of Operations met with the Medical Director on 5/2/14 to review his requirements as defined in the Condition for Coverage and Medical Staff Bylaws to ensure that all policies and procedures relative to patient admission, patient care, infection control and patient safety are adhered to by all individuals who treat patients in the facility.</p> <p>The Education Coordinator re-educated all staff members on 5/1/2014 on the following policy: · "Patient Monitoring During Patient Treatment" FMS-CS-IC-I-110-133A</p> <p>An in-service attendance sheet is available in the facility for review.</p> <p>The Clinical Manager/designee will audit treatment sheets daily for 2 weeks, weekly for 4 weeks to ensure compliance. Ongoing compliance will be monitored via the monthly QAI medical record audit.</p> <p>Any deviation from the monitoring policy will be addressed with the employee by the Clinical Manager and may include corrective action.</p> <p>The Clinical Manger will report all findings to the QAI Committee.</p>	05/09/2014

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	<p>minutes between checks.</p> <p>C. A flow sheet dated 3-12-14 evidenced the patient had been checked at 1:38 PM and not again until 3:01 PM, a period of 1 hour and 23 minutes between checks.</p> <p>D. A flow sheet dated 3-17-14 evidenced the patient had been checked at 12:16 PM and not again until 1:04 PM, a period of 48 minutes between checks. The flow sheet evidenced the patient was not checked after the 1:04 PM check until 2 PM, a period of 56 minutes between checks.</p> <p>E. A flow sheet dated 3-19-14 evidenced the patient had been checked at 10:18 AM and not again until 11:18 AM, a period of 1 hour between checks. The flow sheet evidenced the patient had been checked at 12:06 PM and not again until 1:00 PM, a period of 54 minutes between checks. The flow sheet evidenced the patient had been checked at 2:00 PM and not again until 3:36 PM, a period of 1 hour and 36 minutes between checks.</p> <p>F. A flow sheet dated 3-21-14 evidenced the patient had been checked at 12:30 PM and not again until 1:15 PM, a period of 45 minutes between checks.</p> <p>G. A flow sheet dated 4-2-14 evidenced the patient had been checked at 12:10 PM and not again until 12:50 PM, a period of 40 minutes between checks. The flow sheet evidenced the patient had been checked at 3:02 PM and not again until 3:45 PM, a period of 43 minutes between treatment checks.</p> <p>H. A flow sheet dated 4-4-14 evidenced</p>				

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	<p>the patient had been checked at 2:10 PM and not again until 3 PM, a period of 50 minutes between treatment checks.</p> <p>I. A flow sheet dated 4-7-14 evidenced the patient had been checked at 12:03 PM and not again until 12:45 PM, a period of 42 minutes between treatment checks.</p> <p>3. Clinical record number 2 failed to evidence the patient had been monitored every 30 minutes as required by facility policy.</p> <p>A. A hemodialysis treatment flow sheet dated 3-19-14 evidenced the patient had been checked at 3:36 PM and not again until 4:39 PM, a period of 1 hour and 3 minutes between treatment checks.</p> <p>B. A hemodialysis treatment flow sheet dated 3-21-14 evidenced the patient had been checked at 4:42 PM and not again until 5:40 PM, a period of 58 minutes between treatment checks. The flow sheet evidenced the patient had been checked at 6:08 PM and not again until 6:56 PM, a period of 48 minutes between treatment checks.</p> <p>C. A flow sheet dated 3-26-14 evidenced the patient had been checked at 6 AM and not again until 6:40 AM, a period of 40 minutes between treatment checks.</p> <p>D. A flow sheet dated 4-7-14 evidenced the patient had been checked at 2:45 PM and not again until 3:26 PM, a period of 41 minutes between treatment checks.</p> <p>E. A flow sheet dated 4-11-14 evidenced the patient had been checked at 2:06 PM and not again until 3:02 PM, a period of 56</p>			

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	<p>minutes between treatment checks.</p> <p>F. A flow sheet dated 4-14-14 evidenced the patient had been checked at 10:08 AM and not again until 11:10 AM, a period of 1 hour and 2 minutes between treatment checks.</p> <p>4. Clinical record number 3 failed to evidence the patient had been monitored every 30 minutes as required by facility policy.</p> <p>A. A hemodialysis treatment flow sheet dated 3-22-14 evidenced the patient had been checked at 5:50 AM and not again until 6:34 AM, a period of 44 minutes between treatment checks.</p> <p>B. A hemodialysis treatment flow sheet dated 3-25-14 evidenced the patient had been checked at 9:32 AM and not again until 10:31 AM, a period of 59 minutes between treatment checks.</p> <p>C. A flow sheet dated 3-29-14 evidenced the patient had been checked at 5:48 AM and not again until 6:33 AM, a period of 45 minutes between treatment checks.</p> <p>D. A flow sheet dated 4-10-14 evidenced the patient had been checked at 7:33 AM and not again until 8:13 AM, a period of 40 minutes between treatment checks.</p> <p>E. A flow sheet dated 4-12-14 evidenced the patient had been checked at 5:47 AM and not again until 6:33 AM, a period of 46 minutes between treatment checks.</p> <p>5. Clinical record number 4 failed to evidence the patient had been monitored</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 04/16/2014
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	<p>every 30 minutes as required by facility policy.</p> <p>A. A hemodialysis treatment flow sheet dated 3-20-14 evidenced the patient had been checked at 8:03 AM and not again until 8:43 AM, a period of 40 minutes between treatment checks.</p> <p>B. A hemodialysis treatment flow sheet dated 3-25-14 evidenced the patient had been checked at 5:48 AM and not again until 6:33 AM, a period of 45 minutes between treatment checks. The flow sheet evidenced the patient had been checked at 9:34 AM and not again until 10:16 AM, a period of 42 minutes between treatment checks.</p> <p>C. A flow sheet dated 4-3-14 evidenced the patient had been checked at 5:46 AM and not again until 6:32 AM, a period of 46 minutes between treatment checks.</p> <p>D. A flow sheet dated 4-5-14 evidenced the patient had been checked at 5:56 AM and not again until 7:06 AM, a period of 1 hour and 10 minutes between treatment checks.</p> <p>E. A flow sheet dated 4-8-14 evidenced the patient had been checked at 5:55 AM and not again until 6:39 AM, a period of 44 minutes between treatment checks. The flow sheet evidenced the patient had been checked at 8:33 AM and not again until 9:31 AM, a period of 58 minutes between treatment checks.</p> <p>F. A flow sheet dated 4-10-14 evidenced the patient had been checked at 7:30 AM and not again until 9:07 AM, a period of 1 hour and 37 minutes between treatment checks.</p>			

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	<p>6. Clinical record number 5 failed to evidence the patient had been monitored every 30 minutes as required by facility policy.</p> <p>A. A hemodialysis treatment flow sheet dated 7-2-13 evidenced the patient had been checked at 10:38 AM and not again until 11:44 AM, a period of 1 hour and 6 minutes between treatment checks.</p> <p>B. A hemodialysis treatment flow sheet dated 7-6-13 evidenced the patient had been checked at 10:32 AM and not again until 11:30 AM, a period of 58 minutes between treatment checks. The flow sheet evidenced the patient as checked at 12:09 PM and not again until 1:09 AM, a period of 1 hour between treatment checks.</p> <p>C. A flow sheet dated 7-9-13 evidenced the patient had been checked at 12:03 PM and not again until 12:55 PM, a period of 52 minutes between treatment checks.</p> <p>D. A flow sheet dated 7-11-13 evidenced the patient had been checked at 10:33 AM and not again until 11:15 AM, a period of 42 minutes between treatment checks.</p> <p>E. A flow sheet dated 7-13-13 evidenced the patient had been checked at 10:21 AM and not again until 11:03 AM, a period of 42 minutes between treatment checks.</p> <p>F. A flow sheet dated 7-18-13 evidenced the patient had been checked at 10:23 AM and not again until 11:11 AM, a period of 48 minutes between treatment checks. The flow sheet evidenced the patient had been checked at 11:32 AM and not again until 12:14 PM, a period of 42 minutes between</p>						

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	<p>treatment checks.</p> <p>7. The Clinic Manager, employee M, indicated, on 4-16-14 at 10:30 AM, that the facility policy required patient checks every 30 minutes.</p>			