

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152643	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  07/19/2013
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NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE NEPHROLOGY GOSHEN	STREET ADDRESS, CITY, STATE, ZIP CODE 2257 KARISA DR SUITE I GOSHEN, IN 46526
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V000000	<p>This was an ESRD federal recertification survey.</p> <p>Survey dates: July 17 - 19, 2013</p> <p>Facility #: 012218</p> <p>Medicaid vendor #: NA</p> <p>Surveyor: Ingrid Miller, MS, BSN, RN, PHNS</p> <p>Hemodialysis incenter census: 40 patients</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN July 23, 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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V000117	<p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>Based on observations, staff interview, and review of policies and procedures, the facility failed to ensure medication vials and a syringe of medication were safely stored or discarded for 1 of 3 observations of medications creating the potential to spread infection causing agents among facility staff and all current 40 current incenter hemodialysis patients.</p>	V000117	<p>The Clinical Manager is responsible to ensure that all staff members follow the "Medication Preparation Administrative Policy &amp; Procedures."</p> <p>The Director of Operations and Operations Manager met with the facility staff on July 19 th to re-educate all staff members including employees F and K on the following policy "Medication Preparation Administration Policy", FMS-CS-IC-I-120-040A and "Medication Preparation</p>	07/19/2013			

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	<p><b>Findings</b></p> <p>1. On 7/17/13 at 2:00 PM, it was observed that an opened and empty vial of hepatitis B vaccine and a filled tubersol syringe with the name of patient #5, date of 7/10/13, and initials of Employee F, Registered Nurse (RN), were lying unattended in the corner of the nurse's station near the telephone.</p> <p>On 7/17/13 at 2:07 PM, Employee A, administrator, indicated the syringe and vial were left unattended and should have been discarded by Employee F, RN.</p> <p>2. On 7/18/13 at 9:15 AM, 5 vials of heparin (4 opened vials and 1 unopened vial) were observed unattended at the medication preparation area on the treatment floor. This observation occurred on a nontreatment day. One multidose vial of heparin 30 ml (milliliters) was dated 7/15/13 with no initials or time. A second vial of opened heparin 30 ml had a date of 5/17/13 with no initials. A third vial of heparin was marked with the initials of Employee K, PCT (patient care technician), a date of 5/17/13, and time of 9:20 AM. A 4th vial of Heparin 30 ml was not opened. A 5th vial of Heparin was dated 7/15/13 and timed with the initials of Employee K, PCT.</p>		<p>Administration Procedure", FMS-CS-IC-I-120-040C with emphasis placed on proper labeling of vials in all aspects such as; when used in its entirety, partial use, and predraws. Also discussed was proper storage and securement of medication. An in-service attendance sheet will be available in the facility for review. Clinical Manager will ensure that the "Medication Preparation and Adminstration Policy and Procedures" are adhered to by an audit tool done daily by the designated RN for 2 weeks and then weekly for 4 weeks. 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</p> <p>The Clinic Manager is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee.</p> <p>The Director of Operations is responsible to ensure that the Clinic Manager presents all data, as required and defined within the plan of correction, to the QAI Committee.</p> <p>The QAI Committee is responsible to provide oversight and ensure resolution is</p>				

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	<p>On 7/18/13 at 10:20 AM, Employee B, alternate administrator, indicated the medications had been left unattended and were not kept at the medication preparation area according to facility policy.</p> <p>3. The policy titled "Medication Preparation and Administration" with an effective date of July 4, 2012, stated, "Labeling vials When preparing medications if the vial is not used immediately in its entirety, the nurse must place the date and time the vial was opened on the medication label along with the nurse initials ... Predrawing medications - Medications may be pre-drawn up to 4 hours prior to administration - these pre - drawn medications shall be labeled and must be kept under the preparer's control or in a locked designated medication storage area ... discard single does vials after use ... Securements: the following steps must be taken for securement of medications in the facility. All medications will be kept in a locked cabinet except when in use ... When preparing medications if the vial is not used immediately in its entirety, the nurse must place the date and time the vial was opened on the medication label along with the nurse initials. Label any open multi-dose vial that is not used</p>		occurring.				

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	<p>immediately and store vial accordingly. All medications will be kept in a locked cabinet except when in use."</p>			

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V000250	<p>494.40(a) DIALYS PROPOR-TMONITOR PH/CONDUCTIVITY 5.6 Dialysate proportioning: monitor pH/conductivity It is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method before starting the treatment of the next patient.</p> <p>Based on facility document review, interview, and policy review, the dialysis failed to ensure documentation of the pH /conductivity testing was completed for 1 of 7 phoenix meters (2) with the potential to effect all of the current 40 patients receiving incenter hemodialysis.</p> <p>Findings</p> <p>1. The agency document titled "Phoenix meter log 2" with a date of July 2013 included an entry on 7/15/13 with the initials of Employee K, patient care technician, that was incomplete. There was no completion of the following columns: RO (reverse osmosis) rinsed and neg (negative), pH verify, pH post calibrate, 14 mS (milliesiemens), and 100 mS verify. There was a check in the column titled "1 % bleach disinfectant) and 10 min (minute).</p> <p>2. The agency policy titled "Bicarbonate</p>	V000250	<p>The Clinical Manager is responsible to ensure that all staff members follow the "Bicarbonate Concentrate Testing Policy".</p> <p>The Operations Manager met with the facility staff on July 19 th to re-educate all staff members including employee K on the following policy "Bicarbonate Concentrate Testing Policy", FMS-CS-IC-II-140-305A with emphasis placed on verification of the Phoenix meter prior to each day's use using the 100 mS standard solution. An in-service attendance sheet will be available in the facility for review. Clinical Manager will ensure that the "Bicarbonate Concentrate Testing Policy" is adhered to by daily monitoring by the designated RN at the start of the first shift by utilizing the Phoenix meter log. 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</p>	07/19/2013			

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	<p>Concentrate Testing" with an effective date of March 20, 2013, stated, "The calibration of the phoenix meter will be verified according to the manufacturer's IFU (instructions for use) prior to each days use using the 100 mS standard solution."</p> <p>3. On 7/19/13/ at 8:30 AM, Employee A, administrator, and Employee B, alternate administrator, indicated the documentation had not been completed for phoenix meter calibration on 7/15/13.</p>		<p>The Clinic Manager is responsible to review and analyze all monitoring data prior to the QAI Meeting and present monthly to the QAI Committee.</p> <p>The Director of Operations is responsible to ensure that the Clinic Manager presents all data, as required and defined within the plan of correction, to the QAI Committee.</p>		