STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	012525	A. BUILDING ____ B. WING ____	07/07/2005

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FMC WEST MOBILE	**6601 WALL STREET** **MOBILE, AL 36609**

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V 139	405.2136(c)(vi) CEO: CONTRACTS The responsibilities of the chief executive officer include but are not limited to participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to the approval by the governing body of such agreements or contracts. This STANDARD is not met as evidenced by: Based on observations and interview the facility failed to ensure a policy was in place for contracted employees observed to be providing direct care services. Findings include: On 7/6/05 a contracted research employee was observed to be obtaining blood samples from three patients receiving hemodialysis treatments. An interview with the facility manager on 7/7/05 at 10:00 AM revealed the dialysis had a contract with a research company which included blood sampling. The contract did not include the employees to provide direct patient services and no policy was available for review. The facility was unable to provide a credentialing file on the contract employee when requested.	V 139		7/21/05
V 141	405.2136(c)(3)(vii) CEO: STAFF TRAINING The responsibilities of the chief executive officer include but are not limited to ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and	V 141		7/21/05

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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V 141	Continued From page 1 related development activities. This STANDARD is not met as evidenced by: Based on observations and interviews the facility failed to ensure contracted staff were provided orientation prior to performing procedures . Findings include: On 7/6/05 a contracted research employee was observed to be obtaining blood samples from three patients receiving hemodialysis treatments. An interview with the facility manager on 7/7/05 at 10:30 AM revealed the contracted employees are to provide the blood specimen tubes and the dialysis facility staff would obtain the samples. There was no documentation of this employee receiving orientation prior to performing the procedure.	V 141		
V 144	405.2136(d)(1) PERSONNEL P/P: STAFF QUALIFIED The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that ensure that all members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply. This STANDARD is not met as evidenced by: Based on observations and interviews the facility failed to ensure policies were developed to include services provided by qualified contracted employees.	V 144		7/21/05

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V 144	Continued From page 2 Findings include: On 7/6/05 a contracted research employee was observed to be obtaining blood samples from three patients receiving hemodialysis treatments. An interview with the facility manager on 7/7/05 at 10:00 AM revealed the dialysis had a contract with a research company which included blood sampling. The contract did not include the employees to obtain the blood samples and no policy regarding this procedure was available for review. The facility was unable to provide a credentialing file on the contract employee when requested.	V 144		
V 147	405.2136(d)(2) PERSONNEL P/P: HEALTH EXAMS The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that ensure that health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. This STANDARD is not met as evidenced by: Based on review of personnel records and interview the facility failed to ensure annual health examinations had been reviewed by a physician in 10 of 11 personnel records that were reviewed. Findings include: A review of 10 personnel records revealed a Employee Annual Health Re-evaluation had been	V 147		7/21/05

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V 147	Continued From page 3 completed by the employee and signed by the supervisor, however had not been signed by a physician. An interview with the facility manager on 7/7/05 at 11:00 AM confirmed the physician had not signed the forms.	V 147		
V 177	405.2136(g)(1) MEDICAL SUPERVISION: ORDERS The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medication, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge. This STANDARD is not met as evidenced by: Based on record review and interviews the facility failed to ensure physician orders were obtained prior to the initiation of medication. Findings include: 1. Medical Record # 6 was admitted for hemodialysis on 4/16/05 with a diagnosis of Polycystic Disease. A review of physician's orders revealed two late entry orders for Zemplar, dated 6/28/05. The medication orders had been implemented on 4/26/05 and 5/15/05. 2. Medical Record # 5 was admitted for hemodialysis on 2/7/05 with diagnoses including	V 177		8/1/05

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V 177	Continued From page 4 Chronic Renal Failure (CRF) and Diabetes Mellitus II. A review of physician's orders revealed late entry orders for Zemplar, dated 5/25/05. The medication orders had been implemented on 5/11/05. 3. Medical Record # 4 was admitted for hemodialysis on 4/16/04 with diagnoses including Chronic Renal Failure (CRF) and Diabetes Mellitus II. A review of physician's orders revealed late entry orders for Zemplar, dated 5/4/05. The medication orders had been implemented on 4/13/05. An interview with the facility manager on 7/6/05 at 2:30 AM revealed the orders were entered into the computer and initiated prior to the order being written and obtained from the physician.	V 177		
V 263	405.2140(a)(5)(ii) AAMI- DIALYSATE BACTERIOLOGY (AAMI 3.2.1.2) Bacteriology of the Dialysate. Total viable microbial count for the dialysate should not exceed 2000/ml. The supplier of the dialysate supply system shall be responsible for recommending a method of cleaning the equipment that will result in a device capable of meeting the requirements of this section. The user is responsible for monitoring the purity of the dialysate. This STANDARD is not met as evidenced by: Based on review of water cultures and interviews the facility failed to follow their policy for obtaining	V 263		8/1/05

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V 263	Continued From page 5 water cultures. The Technical Policy and Standards Manual, dated 12/22/04, for Bacteria and Endotoxin in Water included, "Samples for cultures will be drawn no earlier than one day before routine disinfection of any of the sample points. Additional samples may be taken immediately after completion of disinfection procedures if disinfection is performed because previous results exceeded the Action Level." A review of the disinfection log schedules and the water culture test dates from January 2005 to June 2005 revealed: Disinfection was completed on 5/31/05. Samples were obtained for presence of bacteria in dialysate on 6/1/05. Disinfection was completed on 6/27/05. Samples were obtained for presence of bacteria in water and dialysate on 6/27/05. There was no documentation the facility obtained the samples for presence of bacteria in water and dialysate before they disinfected.	V 263		
V 266	405.2140(b)(1) PE: INFECTION CONTROL There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment. Where dialysis supplies are reused, there are written policies and	V 266		7/21/05

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V 266	Continued From page 6 procedures covering the rinsing, cleaning, disinfection, preparation, and storage of reused items which conform to requirements for reuse in 405.2150. This STANDARD is not met as evidenced by: Based on observations and interviews the facility staff failed to follow their infection control policies for patient care and environmental cleaning. Findings include: 1. RN # 1 was observed on 7/5/05 at 1:55 PM prefilling syringes with medication. The nurse went to a patient and touched the patient's arm and then went to another patient and administered the IV medication without washing his/her hands. RN # 2 was observed on 7/6/05 at 9:15 AM prefilling numerous syringes with medication. The RN placed the syringes on a tray and went from patient to patient taking the tray and administering IV medication without washing his/her hands. An interview with the Clinical Director on 7/7/05 at 10:00 AM verified that RN #1 and 2 did not follow infection control procedures for washing their hands between patients and verified the nurses were not to take the medication tray from patient to patient. Agency Policy Bloodborne Pathogens Exposure Control Plan and Infection Control Policy Procedures. G. Housekeeping 1. ... Bleach solutions must have been made	V 266		

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V 266	Continued From page 7 within 24 hours of use in order to be appropriate for disinfection. 2. ...Clean gross contamination with cloth soaked with 1:100 dilution of household bleach. Agency Policy: Disinfection Standards for Equipment 2. Disinfection Dilution Ratio a. A 1:100 dilution of 5.25% - 6.0% standard household bleach contains at least 500 ppm free available chlorine. This concentration is obtained by adding 1/4 cup of bleach per gallon of tap water. Observations in the treatment area on 7/5/05, 7/6/05 and 7/7/05 revealed buckets containing the bleach solution. There was no documentation as to the strength and time the solution was prepared. A Patient Care Tech (PCT) on 7/6/05 at 11:00 AM was observed to pour 1 ounce of household bleach in a bucket and then placed the bucket under a running faucet. The PCT then placed another 1 ounce into another bucket and placed it under a running faucet. The amount of water in each same size bucket varied. The surveyor then asked the PCT how much bleach was placed in each bucket and the PCT stated 10%. An interview with the Clinical Director on 7/7/05 at 11:00 AM verified the PCT did not follow the correct procedure for the preparation of the bleach solution.	V 266		
V 280	405.2140(d)(2) EMERGENCY PREP: PERIODIC	V 280		8/31/05

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V 280	Continued From page 8 DRILLS All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specific role in case of an emergency. This STANDARD is not met as evidenced by: Based on interview and record review the facility failed to hold periodic drills to ensure staff preparedness for the safety of patients in case of a fire. Findings include: Agency Policy: Disaster Drills Fire Drill Procedure Purpose: To prepare the staff for a safe and orderly evacuation in the event of a fire or other disaster. 9. Fire Drills will be held quarterly on each patient shift. Review of fire drill documentation revealed no fire drills had been held since 5/27/04. Interview with facility staff on 7/7/05 at 11:00 AM confirmed there was no record of the required quarterly fire drills since 5/27/04.	V 280		
V 284	405.2140(d)(5) EMERGENCY PREP: PATIENTS INFORMED Patients are trained to handle medical and nonmedical emergencies. Patients must be fully	V 284		8/31/05

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V 284	Continued From page 9	V 284		

informed regarding what to do, where to go, and whom to contact if a medical or nonmedical emergency occurs.

This STANDARD is not met as evidenced by:

Based on record review and interviews the facility failed to ensure 4 of 4 current patients are trained for medical and nonmedical emergencies.

The Disaster Policy, dated 4/1/92, included, "Simulated fire/evacuation drills will be held on a quarterly basis on each patient and staff shift."

Findings include:

1. Medical Record # 2 was admitted for hemodialysis on 1/15/04 with diagnosis of Diabetes Mellitus II and Chronic Renal Failure.

A review of the medical record revealed no documentation of the emergency procedure being reviewed with the patient since 5/27/04.

2. MR # 3 was admitted for hemodialysis on 7/24/02 with diagnosis of Chronic Renal Failure.

A review of the medical record revealed no documentation of the emergency procedure being reviewed with the patient since 5/27/04.

3. MR # 4 was admitted for hemodialysis on 4/16/04 with diagnosis of Chronic Renal Failure.

A review of the medical record revealed no documentation of the emergency procedure being reviewed with the patient since 4/16/04.

4. MR # 3 was admitted for hemodialysis on

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V 284	Continued From page 10 2/07/05 with diagnosis of Chronic Renal Failure. A review of the medical record revealed no documentation of the emergency procedure being reviewed with the patient since 2/07/05. An interview with the facility manager on 7/6/05 at 10:00 AM confirmed the documentation for patient quarterly emergency procedures had not been completed for the above patients.	V 284		
V 432	405.2162(b)(1) ON-DUTY PERSONNEL: LICENSED PERSON Whenever patients are undergoing dialysis, one currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care. This STANDARD is not met as evidenced by: Based on observations and interview with staff the facility failed to ensure that patient care services were overseen by a professional nurse. Findings include: On 7/6/05 a contracted research employee was observed to be obtaining blood samples from three patients receiving hemodialysis treatments. An interview with the facility manager on 7/7/05 at 10:00 AM revealed she was not aware of the contracted employee obtaining blood specimens from patients during their hemodialysis treatments. She stated the lab specimen containers are delivered to the facility by the research employees and the dialysis staff obtains	V 432		7/21/05

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V 432	Continued From page 11 the samples from the patients blood lines.	V 432		