STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 000	INITIAL COMMENTS Surveyor: 23046 The following reflects the findings of the California Department of Public Health during a recertification survey conducted on 1/4/10. Representing the Department: Octavio Relopez, HFEN Frances Bratton, HFEN Carol Erickson, HFEN Janet Parmelle, HFEN Census: 118 Sample size: 12 Unsampled: 3 The request for addition of Home Hemodialysis services denied. Abbreviations and Acronyms: RN - Registered Nurse PCT - Patient Care Technician IDT - Interdisciplinary Team ESRD - End Stage Renal Disease FA - Facility Administrator CSS - Clinical Care Specialist PPE - Protective Personal Equipment RT - Reuse Technician	V 000		
V 101	494.20 COMPLIANCE WITH FED/STATE/LOCAL LAWS The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.	V 101		3/19/10

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 101	Continued From page 1 This STANDARD is not met as evidenced by: Surveyor: 07599 Based on record review and interview, the facility and its staff failed to operate and furnished services in compliance with state and federal laws and regulations pertaining to health and safety requirements by failing to: 1. Ensure that the facility's informed consent for the reuse of hemodialyzers included the statement that single use dialyzers are recommended by the dialyzer manufacturer for one time use only for 12 of 12 sampled patients (Patients 1-12). 2. Follow acceptable nursing standards of practice by allowing staff to administer unlabelled syringes of medications prepared by other staff to 1 of 11 sampled patients (Patient 7). Findings: On 12/29/09 during a review of the hemodialyzer reuse consent for 12 of 12 sampled patients, it was noted that the consent failed to include a statement that single use dialyzers are recommended by the dialyzer manufacturer for one time use only. An interview conducted with the Facility Administrator (FA) on 1/04/2010 at 4 PM, revealed that the facility predominately reused dialyzers for dialysis treatments however, there were times when the use of a single dialyzer was needed. A further interview with the Registered Nurse Clinical Services Specialist (RN CSS) revealed that the facility was unaware of the State Regulations pertaining to this health and safety	V 101		

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V 101	Continued From page 2 requirement. Surveyor: 26215 2. During an observation on 12/29/09 at 1:40 PM, Patient 7 was assisted into the chair at station 8. At 1:42 PM, Patient Care Technician (PCT) 2 filled two 10 cc (cubic centimeter)syringes from the normal saline bag hanging from the IV pole on the dialysis machine and placed the full unlabelled syringes back in the wrapper on the armrest table. Registered Nurse (RN) 2 was observed assisting the Nurse Manager with another patient at station 7 who was having respiratory difficulty. At 2:04 PM, RN 2 removed the caps from Patient 7's catheter, aspirated both ports, and flushed the ports with the liquid-filled unlabelled syringes. During an interview on 12/31/09 at 9:40 AM, the Nurse Manager stated that either patient care technicians or nurses filled the syringes and "It's okay for the PCT to draw up the saline and for the nurse to give it." Potter & Perry's Fundamentals of Nursing indicates "Nurses administer only the drugs they prepare. . . . The nurse never prepares medications from unmarked containers ..."	V 101		
V 110	494.30 CFC-INFECTION CONTROL This CONDITION is not met as evidenced by: Surveyor: 23046 Based on observation, interview and record review, it was determined that the facility did not meet the Condition of Participation (COP) for	V 110		3/19/10

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V 110	Continued From page 3	V 110		

infection control by failing to:

1. Provide and monitor a sanitary environment to minimize the potential transmission of infectious agents within the unit as evidenced by the dirty sink at a corner of the nurse station full of used syringe caps, red dialyzer caps, bits of paper, IV tubing and used alcohol swabs, and 2 trash cans located in the center of the treatment floor and at the entrance of facility overflowing with trash piled on the top of the container. (Refer to V111)

2. Test one of 12 sampled patients (Patient 12) for the presence of hepatitis B antibodies (anti-HBs) 1-2 months after vaccine administered, and provide one of 12 sampled patients (Patient 7) who was susceptible to hepatitis B (inflammation of the liver caused by hepatitis B virus) infection the opportunity to be vaccinated. (Refer to V112 and 126)

3. Ensure that staff were practicing appropriate hand hygiene when providing care between patients and touching dialysis machines. (Refer to V113)

4. Ensure that all staff wore appropriate protective clothing while providing services to patients in the treatment area during dialysis treatment. (Refer to V115)

5. Ensure that items taken to a patient's station were used only for that patient or disposed of following use. (Refer to V116)

6. Implement facility infection control program and precautionary practices to provide follow-up testing after 1 of 12 sample patients (Patient 9) tested positive for tuberculosis (TB) screening.

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V 110	Continued From page 4 (Refer to V142) 7. Ensure that infection control training and education of staff were up-to-date. (Refer to V142) The cumulative effect of these systemic practices had the potential to transmit infectious diseases to all 118 hemodialysis patients and staff. The facility failed to ensure compliance with Federal Regulations for the Condition of Participation: Infection Control.	V 110		
V 111	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. This STANDARD is not met as evidenced by: Surveyor: 07599 Based on observations and interview, the facility failed to provide and monitor a sanitary environment to minimize the potential transmission of infectious agents within the unit to a universe of 118 patients. Findings: On 12/28/09 at 8:30 AM, during the initial tour of the facility, observation revealed 15 patients receiving dialysis treatments. A tour of the environment revealed a sink which was full of used syringe caps, red dialyzer caps, bits of paper, IV tubing, and used alcohol swabs. An interview with the Nurse Manager on 12/28/09 at 9:30 AM, revealed the sink in question was	V 111		3/19/10

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V 111	Continued From page 5 referred to as the "dirty sink" however, should not have contained the various items which were noted.	V 111		
V 112	494.30(a) IC-CDC MMWR 2001 The facility must demonstrate that it follows standard infection control precautions by implementing- (1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009.	V 112		3/19/10

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V 112	Continued From page 6	V 112		

This STANDARD is not met as evidenced by:
Surveyor: 23046
Based on interview and record review the facility failed to ensure that standard infection control precautions were followed by failing to:

1. Follow the Center for Disease Control's (CDC) recommendations for standard infection control precautions to test 1 of 12 sampled patients (Patient 12) for the presence of hepatitis B antibodies (anti-HBs) 1-2 months after vaccine administered.

2. Vaccinate 2 of 12 sampled patients (Patient 7 and 12) who were susceptible to hepatitis B infection.

3. Monitor and implement it's infection control policies by failing to conduct annual tuberculosis screening for 5 of 12 personnel, and to provide annual Infection Control training for 3 of 12 personnel which had the potential to result in spreading tuberculosis and other infectious diseases to all patients, staff and visitors.

The facility's failure resulted in continued exposure of 5 staff and 2 patients to potential infectious diseases and had the potential to be infected and infect other patients, staff and visitors who are susceptible to tuberculosis or hepatitis B infection.

Findings:

1. During review of Patient 12's medical record on 12/29/09, it was noted that patient was admitted in the facility on 9/20/07, had been receiving hemodialysis (removal of waste from the blood) treatment and had diagnosis that included end

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V 112	Continued From page 7	V 112		

stage kidney disease, diabetes mellitus and high blood pressure (hypertension).

Review of Patient 12's Care Plan - Progress Notes dated 9/25/09 indicated that she had received the complete hepatitis B vaccine series on 9/25/08, and the test for the presence of antibodies (anti-HBs) had not been performed until 9/10/09 almost one year after receiving the vaccine risking exposure to hepatitis B infection.

The test result dated 9/10/09 indicated that Patient 12's anti-HBs level was 2 which was indicative of non-immune status and susceptible to hepatitis B infection (anti-HBs of less than 10 = susceptible; greater than 10 = immune).

During review of the facility's policy and procedure on 12/30/09, the Hepatitis Surveillance, Vaccination and Infection Control Measures (Policy: 1-05-02) under vaccination on page 5 of 7, the following were noted:

"21. Test all vaccinated patients for HBsAB (same as anti-HBs) one (1) to two (2) months after the last dose of the full vaccine series.
22. If HBsAb is <10 mIU/mL, consider the patient susceptible, revaccinate with an additional full series, and retest for HBsAb 1 to 2 months after the last dose of the second series...."

According to the recommendation by the CDC found under header "Infection Control Precautions for All Patients", on page 21 concerning Hepatitis B vaccination (Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients, dated 4/21/01/ Vol 50/ No. RR-5), the following were noted:

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V 112	Continued From page 8	V 112		

"Vaccinate all susceptible patients against hepatitis B; Test for anti-HBs 1- 2 months after last dose. If anti-HBs is less than 10 (<10) mIU/mL, consider patient susceptible, revaccinate with an additional 3 doses, and retest for anti-HBs. If anti-HBs is greater than 10 (>10), consider patient immune and retest annually."

During an interview with the Facility Administrator (FA) on 12/29/09, at 9:45 AM, he reviewed Patient 12's immunology and vaccination report and confirmed that the patient was not retested until after almost a year (on 9/10/09) and that the test result indicated Patient 12 was not immune to hepatitis B.

2a. Review of Patient 12's medical record on 12/29/09, it was noted that the patient was admitted to the facility on 9/20/07, had been receiving hemodialysis treatment and had diagnosis that included end stage kidney disease, diabetes mellitus and high blood pressure (hypertension).

Review of Patient 12's Care Plan/ Progress Notes dated 9/25/09 indicated that the pateint had received the complete hepatitis B vaccine series on 9/25/08 and test for the presence of antibodies (anti-HBs) had not been performed until 9/10/09 almost one year after receiving the vaccine.

The test result dated 9/10/09 indicated that Patient 12's anti-HBs level was 2 which was indicative of non-immune status and susceptible to hepatitis B infection (anti-HBs of less than 10 = susceptible; greater than 10 = immune).

No further documentation in medical record was

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V 112	Continued From page 9 found indicating that Patient 12 had been given the hepatitis vaccine booster after 9/10/09. During review of the facility's policy and procedure for Hepatitis Surveillance, Vaccination and Infection Control Measures (Policy: 1-05-02) under vaccination on page 5 of 7, the following were noted: "21. Test all vaccinated patients for HBsAB (same as anti-HBs) one (1) to two (2) months after the last dose of the full vaccine series. 22. If HBsAb is <10 mIU/mL, consider the patient susceptible, revaccinate with an additional full series, and retest for HBsAb 1 to 2 months after the last dose of the second series...." According to the recommendation by the CDC found under header "Infection Control Precautions for All Patients", on page 21 concerning Hepatitis B vaccination (Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients, dated 4/21/01/ Vol 50/ No. RR-5), the following were noted: "Vaccinate all susceptible patients against hepatitis B; Test for anti-HBs 1- 2 months after last dose. If anti-HBs is less than 10 (<10) mIU/mL, consider patient susceptible, revaccinate with an additional 3 doses, and retest for anti-HBs. If anti-HBs is greater than 10 (>10), consider patient immune and retest annually." During an interview with the FA on 12/29/09, at 9:45 a.m., he reviewed Patient 12's immunology and vaccination report and confirmed that the test result indicated Patient 12 was not immune to hepatitis B and had not been revaccinated with	V 112		

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V 112	Continued From page 10 booster vaccine. b. During a record review on 12/30/09 at 3:30 PM, Patient 7's Comprehensive Orders Worksheet contained physician orders dated 8/19/09 which read "Engerix 40 mcg (micrograms) intramuscular (vaccine for Hepatitis B)." Patient 7's labs on 8/22/09 indicate her Hepatitis B Antigen screen was negative (no active disease) and her Hepatitis B Antibody Screen was negative which indicated she was susceptible to Hepatitis B infection. Patient 7's care plan dated 9/4/09 indicated the plan was to "offer Hep(atitis) B and Pneumococcal Vaccine." Interview with the Nurse Manager conducted on 12/31/09 at 9:20 AM, the Nurse Manager stated Patient 7 had refused the vaccination and documentation was requested at this time. No documentation was provided which indicated the Hepatitis B vaccination had been offered and refused. Surveyor: 27011 3a. Review of personnel files conducted on 12/30/09 at 8:15 AM, revealed 5 facility staff had not completed annual tuberculosis screening for 2009. Interview conducted on 12/30/09 at 2:15 PM, the Facility Administrator confirmed 5 personnel had not completed annual tuberculosis training in 2009. Record review on December 30, 2009 at 2:30 PM, the policy titled "Tuberculosis Monitoring and	V 112		

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V 112	Continued From page 11 Follow-up" indicated "Follow up TB screening using TST (Tuberculin Skin Testing) will occur on an annual basis, from the date of the last TST using a one step method based." b. Record review on 12/30/09 at 8:15 AM, 12 personnel files were reviewed. Of the 12 personnel files reviewed, 3 had not completed annual Infection Control Training. During an interview on 12/30/09 at 2:15 PM, the Facility Administrator verified 3 personnel had not completed annual Infection Control Training. During a record review on 12/30/09 at 2:30 PM, the policy titled "Injury Prevention and Safety Training Inservices" indicated "Mandatory inservices include the following: (Initially and Annually) Bloodborne Pathogen Regulations, Medical Waste Management, Safety Needle Program ..."	V 112		
V 113	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. This STANDARD is not met as evidenced by: Surveyor: 27011 Based on observation, interview, and record review, the facility failed to ensure proper hand hygiene was followed. Findings:	V 113		3/19/10

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V 113	Continued From page 12 Observation on December 28, 2009 at 8:30 a.m., PCT 3 was wearing gloves during discontinuation of hemodialysis for the patient at machine #18. She pushed the footrest of the chair down with her gloved hands and returned to the patient ' s access site with the same gloves. Then she touched machine #18 with gloved hands and touched machine #21 with the same gloves. PCT 3 then discarded gloves and donned new gloves to perform site care without using hand sanitizer or washing her hands. She removed these gloves, did not use sanitizer or wash hands and touched machine #19. During an interview on December 31, 2009 at 8:45 a.m., the Nurse Manager stated his expectation was that staff performs proper hand hygiene. During a record review on December 30, 2009 at 8:15 a.m., the facility policy titled " Infection Control for Dialysis Facilities " indicated " Hand hygiene is to be performed upon entering the facility, prior to gloving, after removal of gloves, after contamination with blood or other infectious material, after patient and dialysis delivery system contact, between patients even if the contact is casual, before touching clean areas such as supplies and before leaving the patient care area. " And " Gloves should be worn when touching the blood lines, dialyzer or dialysis delivery system during or after a dialysis treatment " and " Gloves should be changed when ...after touching one patient or their dialysis delivery system and before arriving to care for another patient or touch another patient ' s dialysis delivery system. "	V 113		
V 115	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK	V 115		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100** **MONTCLAIR, CA 91763**

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V 115	Continued From page 13 Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. This STANDARD is not met as evidenced by: Surveyor: 26215 Based on observation and record review, the facility failed to ensure all staff were wearing protective cover garments in the treatment area during the initiation/termination of hemodialysis. Findings: In an observation of the treatment area on 12/28/09 at 1:40 PM, the Facility Administrator (FA) was noted to be standing next to the patient at station 12. Two visitors with the patient were wearing protective garments; however, the FA was not observed to be wearing any protective garment. The hemodialysis treatment for the patient at station 11 next to the FA was being terminated at this time which had the potential for blood splatter. The FA continued to talk to the patient at station 12 for several minutes and left the treatment area without donning a protective garment. During a record review on 12/29/09 at 4 PM, the Policy & Procedure Manual did not contain a policy for the FA ' s use of PPE.	V 115		
V 116	494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT	V 116		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100** **MONTCLAIR, CA 91763**

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V 116	Continued From page 14	V 116		

Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.
-- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.
-- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.

This STANDARD is not met as evidenced by:
Surveyor: 07599
Based on observation and interview, the facility failed ensure that items taken to a patient's station were used only for that patient or disposed of following use.

Findings:

On 12/28/09 and 12/29/09 during an environmental tour of the facility, a can of "Raid Flying Insect Spray" was noted on the counter behind Station 15. On both days, 2 non-sampled patients were noted receiving dialysis services.

An interview conducted with RN 3 on 12/29/09, at 9 a.m., failed to reveal a reason for the use of the insect spray or why it was in the area. In a further interview with the patients, neither patient was aware of the insect spray or the reason the container was located on the counter of their

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	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

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V 116	Continued From page 15 station.	V 116		
V 117	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. 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. 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. This STANDARD is not met as evidenced by: Surveyor: 27011 Based on observation and interview, the facility failed to separate clean and dirty areas which had the potential to result in cross contamination and risk of transmission of infection to all patients and staff. Findings: During a tour of the facility with RT 4 (Reuse Technician) on 12/28/09 at 9:55 AM, inside the biohazard (medical waste harmful to health)	V 117		3/19/10

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

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V 117	Continued From page 16 room, were 10 large red biohazard barrels, two clean bleach containers for disinfection of machines and 6 new clean biohazard sharps containers placed next to the red barrels. During interview with the Reuse Technician on 12/28/09, at 9:55 AM, the technician was asked if the clean items had to be stored in the biohazard room. The technician stated, "Yes, this is where we store them."	V 117		
V 126	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination Vaccinate all susceptible patients and staff members against hepatitis B. This STANDARD is not met as evidenced by: Surveyor: 26215 Based on interview, record review and facility document review, the facility failed to provide 2 of 12 sampled patients (Patients 7 and 12) with Hepatitis B vaccination which resulted in continued exposure of Patients 7 and 12 to potential hepatitis B virus infection and had the potential to be infected and infect other patients, staff and visitors who are susceptible to hepatitis B. Findings: 1. A record review of Patient 7's Comprehensive Orders Worksheet conducted on 12/30/09 at 3:30 PM contained physician orders dated 8/19/09 which read "Engerix 40 mcg (micrograms) intramuscular (an immunization for Hepatitis B)". Patient 7's labs on 8/22/09 indicate her Hepatitis B Antigen screen was negative (no active	V 126		3/19/10

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

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V 126	Continued From page 17 disease) and her Hepatitis B Antibody Screen was negative which indicated she was susceptible to Hepatitis B infection. Patient 7's care plan dated 9/4/09 indicated the plan was to "offer Hep(atitis) B and Pneumococcal Vaccine". An interview was conducted with the Nurse Manager on 12/31/09 at 9:20 AM. The NM stated Patient 7 had refused the vaccination and documentation was requested at this time. No documentation was provided which indicated the Hepatitis B vaccination had been offered and refused. Surveyor: 23046 2. During review of Patient 12's medical record on 12/29/09, it was noted that the patient was admitted in the facility on 9/20/07, had been receiving hemodialysis treatment and had diagnosis that included end stage kidney disease, diabetes mellitus and high blood pressure (hypertension). Patient 12's vaccination record indicated the anti-HBs level dated 9/12/09 was at "2" indicating non-immune status and susceptible to hepatitis B infection (anti-HBs of less than 10 = susceptible; greater than 10 = immune). Care plan documentation further indicated that the patient needed a hepatitis B booster vaccine. In an interview with the FA on 12/29/09, at 9:45 AM, the FA reviewed Patient 12's immunology and vaccination report and confirmed that the test result indicated Patient 12 was not immune to hepatitis B and failed to find documentation indicating that Patient 12 had been given the hepatitis vaccine booster after 9/10/09. During a review of the facility's policy and	V 126		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 126	Continued From page 18 procedure for Hepatitis Surveillance, Vaccination and Infection Control Measures (Policy: 1-05-02) under vaccination on page 5 of 7, the following was noted: "22. If HBsAb is <10 mIU/mL, consider the patient susceptible, revaccinate with an additional full series, and retest for HBsAb 1 to 2 months after the last dose of the second series...."	V 126		
V 142	494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P The facility must- (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; This STANDARD is not met as evidenced by: Surveyor: 26215 Based on interview and record review, the facility failed to implement its tuberculosis screening policy for 1 of 11 sampled patients (Patient 9). Findings: In a record review conducted on 12/29/09 at 11:20 AM, Patient 9's Tuberculin Skin Test record indicated the patient was administered the skin test on 5/11/09 and on 5/12/09. RN 1 documented the results as "positive 30mm x 30 mm" and "needs chest x-ray ." During a record review on 12/29/09 at 3 PM, Patient 9's Care Plan, dated 4/29/09 read the patient had missed 15 treatments in the last 60 days as the " Patient [was] in Mexico at this time." In an interview conducted on 12/31/09 at 9:20AM,	V 142		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 142	Continued From page 19 the Nurse Manager was asked the method by which the facility monitored for tuberculosis with patients traveling to and from Mexico. The Nurse Manager stated the facility had a scale to measure the tb skin test and if the patient appeared sick, he would call the doctor. During a record review on 12/30/09 at 4 PM, the facility's policy titled "Tuberculosis Infection Control Policy" read " If the patient has or has had a positive TST (Tuberculin Skin Test) or QFT-G (Quantiferon TB Gold), a physician documented medical follow-up/clearance and negative chest x-ray (completed within the last three months) will be provided and maintained in the patient ' s medical record. Chest x-rays obtained for the sole purpose of verifying correct positioning of a catheter or CVC will not be accepted. On-going annual screening will be accomplished via the TB-RAQ (TB Risk Appraisal Questionnaire) only." Patient 9's chest x-rays for 2009 were requested from the Facility Administrator on 12/29/09 at 8:25 AM, and were not received. Patient 9's chest x-rays and the Risk Appraisal Questionnaire were requested from the Clinical Services Specialist (CSS) on 12/29/09 at 10 AM, and no records were received.	V 142		
V 178	494.40(a) BACT OF H20-MAXIMUM & ACTION LEVELS 4.1.2 Bacteriology of water: max & action levels Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL	V 178		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 178	Continued From page 20	V 178		

The action level for the total viable microbial count in the product water shall be 50 CFU/mL, and the action level for the endotoxin concentration shall be 1 EU/mL. If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels.

This STANDARD is not met as evidenced by:
Surveyor: 23046
Based on record review and interview the facility failed to ensure that corrective measures were taken promptly when test results of the product water used to prepare dialysate (solution used for dialysis treatment) indicated high microbial level above the allowable limit which had the potential to result in life threatening infection to 118 patients.

Findings:

During review of the facility water culture report on 12/28/09, the culture test result of the product water on 7/9/09 indicated high microbial levels at 640 colony forming units (CFU/mL) and on 8/11/09 at 840 CFU above the maximum allowable level of lower than 200 CFU/mL. The report further indicated that the reculture test for the 8/11/09 test result was not performed until 8/21/09, 9 days later.

During an interview with the Biomedical Services (Biomed) Staff 1 on 12/28/09, at 3:10 PM, Staff 1 stated, when culture results were high the laboratory (lab) sends a message alert the following day in order that the facility could take appropriate action.

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100** **MONTCLAIR, CA 91763**

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V 178	Continued From page 21 Biomed Staff 1 further stated that the time span of retesting the product water (9 days) was too long and that the product water should have been recultured right away when the facility received the message alert the following day. In an interview with Biomed Staff 2 on 12/30/09, at 9:50 a.m., Staff 2 stated that the facility policy did not indicate a time frame as to when to reculture when microbial results were high but further stated that the time span of 9 to 10 days to reculture when microbial counts were high was too long. During a review of the facility's water culture policy and procedure (Policy: 2-06-01) on page 2 of 4, indicated the following: "... 9. Interpreting culture results: Acceptable level: Below 50 cfu/ml; Action level: 50 - 199 cfu/ml; Unacceptable level: 200 cfu/ml or greater. 10. Required responses to action or unacceptable culture results: Single site at or above the action level- Reculture of the site...." The above facility policy have no indication as to how prompt the reculturing process would take place.	V 178		
V 187	494.40(a) ENVIRONMENT-SCHEMATIC DIAGRAMS/LABELS 8 Environment: schematic diagrams/labels Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction. Additionally, piping should be labeled to indicate	V 187		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 187	Continued From page 22 the contents of the pipe and direction of flow. If water system manufacturers have not done so, users should label major water system components in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range. This STANDARD is not met as evidenced by: Surveyor: 23046 Based on observation and interview the facility failed to ensure the water treatment system included schematic diagrams that identified components, valves, sample ports, and flow direction which resulted in staff's failure to identify and follow the flow of water through the components. Findings: During an observation of the water treatment area with Reuse Technician (RT) 4 on 11/28/09, at 9:35 AM, a schematic diagram of the water treatment system could not be found posted within the water treatment room. In an interview with RT 4 conducted on 11/28/09 at 9:35 AM, the Technician was asked if there was a schematic diagram for the facility's water system. RT 4 did not have an answer. When further asked to point out where the city water enters the water system, RT 4 was reluctant and failed to point out the entry site of city water into the facility's water system.	V 187		
V 348	494.50(b)(1) VERIFY PT ID-2 PEOPLE	V 348		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 348	Continued From page 23 12.2 Verification of patient identification: 2 people Except in the case of home dialysis, two persons should check that the first and last names on the dialyzer and any other appropriate identifying information correspond to the identifying information on the patient's permanent record. If possible, one of the persons checking identification should be the patient. Completion of this step shall be recorded, along with the signature or other unique means of identifying the person verifying patient identification. NOTE-This step may be done later in the procedure but shall precede initiation of dialysis. This STANDARD is not met as evidenced by: Surveyor: 23046 Based on interview and record review, the facility failed to ensure health and safety of two (2) unsampled patients (Patients 16 and 17) by failing to check identifying information on the dialyzers and identifying the patient prior to the initiation of dialysis treatment which resulted in 2 patients being placed on dialysis using dialyzers that belonged to other patients. Findings: A review of the facility's Adverse Occurrence Log (AOR) on 12/30/09, indicated that on 6/17/09, unsampled Patient 16 was started on dialysis using another patient's dialyzer, and on 7/24/09, unsampled Patient 17 had been started on dialysis using a wrong dialyzer. Documentation in the patient progress notes dated 6/17/09 indicated that Patient 16 had been on dialysis for 5 minutes before staff discovered	V 348		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

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V 348	Continued From page 24 the error. During an interview with PCT 4 on 12/30/09, at 3:45 PM, the technician stated, "We're (PCT 4 and 5) supposed to verify identification of the dialyzer and the patient before initiating treatment and that's where we failed." During an interview with the Nurse Manager on 12/30/09, at 1:50 PM, the Nurse Manager stated that part of the corrective action that was implemented was inservice training on identification of reuse dialyzers given to all patient care staff. During a review of thre staff attendance record for the inservice titled "Verification of Patient Identification of Reprocessed Dialyzer" conducted by the FA and the Nurse Manager on 6/23 - 6/24/09 and 7/29 - 7/30/09, the Nurse Manager reviewed the inservice attendance record and failed to find documentation indicating that PCT 5 and 6 (staff involved in wrong dialyzers used on patients) had attended the inservice training. The Nurse Manager further confirmed and acknowledged that wrong dialyzers were used during dialysis treatment for unsampled Patient 16 on 6/17/09 and Patient 17 on 7/24/09 and that staff had failed to check and confirm the identity of the dialyzer and the patient before initiating dialysis. During review of the facility's Hemodialysis Policy and Procedure (Procedure: 1-03-02) revised and dated September 2009, the following was documented: "... Two teammates are to confirm and document	V 348		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 348	Continued From page 25 the identity of the patient and the reused dialyzer prior to initiating the dialysis treatment. Patients should be encouraged to identify their reused dialyzer prior to treatment initiation."	V 348		
V 400	494.60 CFC-PHYSICAL ENVIRONMENT This CONDITION is not met as evidenced by: Surveyor: 23046 Based on observation, interview and record review, it was determined that the facility failed to meet the Condition of Participation for Physical Environment by failing to: 1. Maintain an operative electrical outlet at a treatment station where patients received dialysis treatment services and ensure that trash cans within the facility were maintained clean and sanitary. (Refer to V401) 2. Ensure that sufficient space between patients was provided during dialysis treatments. (Refer to V404) 3. Maintain a comfortable temperature level and/or make reasonable accommodations for 3 unsampled patients who were not comfortable at the level of temperature of the facility. (Refer to V405) 4. Ensure that multiple patients receiving dialysis treatments had their vascular access (method used to gain access to the blood stream) sites exposed and able to be seen by staff members during dialysis treatments. (Refer to V407) The cumulative effect of these systemic practices had the potential to result in creating multiple	V 400		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

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V 400	Continued From page 26 risks to patients' health and safety. The facility failed to ensure compliance with the Condition of Participation: Physical Environment.	V 400		
V 401	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. This STANDARD is not met as evidenced by: Surveyor: 07599 Based on observation, interview and record review, the facility failed to maintain a safe and functional treatment environment for a universe of 118 patients by failing to: 1. Maintain an operative electrical outlet at a treatment station where patients received dialysis treatment services which had the potential to result in failure to use emergency equipment promptly delaying the delivery of care and further risking serious health problems or death in the event of an emergency. 2. Ensure that trash cans within the facility were maintained clean and sanitary which had the potential to result in the transmission of infectious diseases to all patients, staff and visitors. Findings: 1. On 12/28/09 at 9:00 AM during an environmental tour of the facility, a review of the emergency cart was initiated and a review of the maintenance log was conducted. According to the	V 401		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 401	Continued From page 27	V 401		

log, the cart had been checked that morning to ensure that all of the equipment was functional.

A request was made to check the function of the suction machine. The faciltiy staff then transported the cart to a wall outlet adjacent to station 2 and plugged the suction machine into the socket. The suction machine was noted to be inoperative so the the cart was taken to an outlet outside of the nursing station and across from station 2 where the suction machine was successfully checked.

An interview with the Nurse Manager at 9:30 AM, revealed the outlet was inoperative and agreed that in the event of an emergency, the patient occupying station 2 would be unable to take advantage of any emergency services which required the use of the electrical outlet.

Surveyor: 26215
2. (a) During an observation on 12/28/09 at 12:45 PM, a covered trash can with swinging lid located several feet to the left of the front door of the facility had trash overflowing out of the front of it. Styrofoam food containers and plastic bags were piled on top of the trash can. More Styrofoam food containers and a plastic bag with a container of motor oil were on the concrete in front of the trash can. When observed at 3:15 PM, the trash can had not been emptied.

(b) On 12/28/09 during an environmental tour of the facility, the 2 trash cans located in the center of the treatment floor were overflowing and in need of emptying.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

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V 401	Continued From page 28 An interview with the RN Clinical Services Specialist on 01/04/09 at 3:30 PM, revealed the trash can located at the entrance of the facility was a shared trash can and was the responsibility of the environmental services of the building to ensure that the cans were emptied on a regular basis.	V 401		
V 404	494.60(c)(1) PE-PT CARE ENVIRONMENT-SUFFICIENT SPACE The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff. This STANDARD is not met as evidenced by: Surveyor: 23046 Based on observation and interview, the facility failed to ensure that sufficient space between patients was provided during dialysis treatments which had the potential to result in cross-contamination between patients and would potentially not allow space for emergency equipment and staff to provide care in time of emergency. Findings: During treatment observation conducted from 12/28/09 to 1/4/10, multiple patients on the treatment floor were positioned very close to each other while undergoing dialysis services. Ten treatment stations with patients undergoing dialysis were observed and the space between patient's chair were approximately from 6 inches to one and one half (1 1/2) feet. The arm chairs	V 404		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING B. WING	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 404	Continued From page 29 where patient's access sites were placed could almost touch the other and space would not be enough for staff to pass through in-between the chairs. During an interview with the Nurse Manager who was on the treatment floor on 12/30/09, at 11:30 AM the Manager confirmed that multiple patients were very close to each other while on dialysis treatment and further acknowledged that multiple treatment stations did not not have sufficient space. During an interview with the FA on 12/30/09, at approximately 11:35 AMhe acknowledged that multiple patients did not have sufficient space while on dialysis treatment. According to the California Building Code supplement dated 01/01/09, the facility must "provide a minimum of 100 square feet of floor space, inclusive of aisles, per bed or station."	V 404		
V 405	494.60(c)(2) PE-COMFORTABLE TEMPERATURE The dialysis facility must: (i) Maintain a comfortable temperature within the facility; and (ii) Make reasonable accommodations for the patients who are not comfortable at this temperature. This STANDARD is not met as evidenced by: Surveyor: 07599 Based on observation, and interviews, the facility failed to maintain a comfortable termperature level and/or make reasonable accommodations for 3 of 3 unsampled patients who were not comfortable at the level of temperature of the	V 405		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

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V 405	Continued From page 30 facility. Findings: From 12/28/09 through 12/31/09 during the recertification survey of the facility, 15 of 20 stations were noted to be occupied by patients on any given day. The patients were noted to be completely covered with thick blankets or coats draped across their chests. On 12/28/09 at 9:00 AM during a tour of the facility, 3 non-sampled patients (unsampled Patients 13, 14, and 15) complained of the "temperature being cold with 1 patient stating that the only thing wrong with the facility was the "cold temperature, which was the reason he hated coming to the facility." A review of the temperature setting on the thermostat indicated 71degrees. An interview with the FA on 01/04/2010 at 4:00 p.m., revealed he was aware of the temperature as it had been cold "last week."	V 405		
V 407	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). This STANDARD is not met as evidenced by: Surveyor: 23046 Based on observation and interview, the facility failed to ensure that multiple patients receiving dialysis treatments had their vascular access (method used to gain access to the blood stream) sites exposed and able to be seen by staff	V 407		3/19/10

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	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

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V 407	Continued From page 31 members during dialysis treatments which had the potential to result in undetected accidental needle or blood line disconnection which could result in massive blood loss and death in minutes. Findings: During patient care observation on the treatment floor on 12/29/09, at 8:05 AM., unsampled Patient 15 had his vascular access site on left thigh and part of blood lines covered with blanket during dialysis treatment while 2 patient care technicians (PCT) and RN 2 were present close to Patient 15's chairside. After RN 1's attention was called, she confirmed that Patient 15's access site was covered and could not be seen by staff, then asked patient's permission and proceeded to uncover and exposed Patient 15's access site. RN 1 stated,"Sometimes when he is asleep he accidentally cover his access site," then acknowledged that access sites should always be with in view of staff during dialysis treatment. Further observation on the treatment floor on 12/30/09, at 8:30 AM, Patient 8 had her access site and blood lines covered with blanket during dialysis treatment while 2 PCTs (PCT 1 and 3) were working close at Patient 8's chairside. Patient 8's access site was observed covered for approximately 15 minutes until PCT 1's attention was called. PCT 1 confirmed that Patient 8's access site had been covered and immediately uncovered the access site.	V 407		
V 502	494.80(a)(1) PA-ASSESS CURRENT HEALTH STATUS/COMORBIDS	V 502		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING _____ B. WING _____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 502		V 502		

Continued From page 32

The patient's comprehensive assessment must include, but is not limited to, the following:

(1) Evaluation of current health status and medical condition, including co-morbid conditions.

This STANDARD is not met as evidenced by:
Surveyor: 26215
Based on observation, interview, and record review, the facility failed to assess and provide interventions for severe hypertension for 1 of 11 sampled patients (Patient 8) prior to, during, and post hemodialysis treatment.

Findings:

During a treatment observation conducted on 12/28/09 at 8:40 AM, Patient 8 was observed during dialysis treatment discontinuation. The patient complained of feeling cold and nauseous and had an emesis basin on her lap. The blood pressure was 184/128 (normal is 120/80).

Record review conducted on 12/30/09 at 4 PM, indicated Patient 8's Comprehensive Orders Worksheet contained physician orders dated 5/18/09 for Clonidine (an antihypertensive) 0.1 mg po (by mouth) prn (as needed). A review of Patient 8's Post-treatment record revealed the following:

1. On 12/16/09 at 5:38 AM, Patient 8's hemodialysis treatment was initiated with a blood pressure of 212/126. RN 1 assessed the patient at 5:50 AM and no evaluation or intervention for the hypertension was documented. At 6 AM, the blood pressure was 191/128 and no assessment

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

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V 502	Continued From page 33	V 502		

or intervention was performed. Patient 8's treatment was terminated 40 minutes early with a post treatment blood pressure of 129/100. No post treatment assessment was performed by any facility staff licensed or un-licensed.

2. On 12/18/09 at 5:35 AM, Patient 8's hemodialysis treatment was initiated with a blood pressure of 211/133. RN 1 assessed her at 6 AM and no evaluation or intervention for the hypertension was documented. No post assessment was performed when treatment was completed at 8:38 AM.
3. On 12/21/09 at 5:30 AM, Patient 8's hemodialysis treatment was initiated with a blood pressure of 209/133. RN 1 assessed her at 6 AM and no evaluation or intervention for the hypertension was documented. Patient 8's treatment was terminated at 8:25 AM with a blood pressure of 157/129. No post assessment or intervention was documented.

Review of the facility's Post Treatment Patient Assessment (Policy: 1-03-12) dated September 2007 revealed the following:

" The patient care staff will obtain and document basic data on each patient post dialysis and compare to pre dialysis findings.... Assessment data may include the following: ... cardiac status, respiratory status peripheral edema, vascular access, mental status, patient subjective statement and ambulatory status. The licensed nurse notifies the physician as needed of changes in patient's satatus. All findings, interventions and patient responses are documented in the patient's medical record."

In an interview conducted on 12/31/09 at 9:20

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100** **MONTCLAIR, CA 91763**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 502	Continued From page 34 AM, the Nurse Manager (NM) stated the nurse assessing a patient prior to hemodialysis is expected to contact the physician if a blood pressure was above 180 and the nurse could give Clonidine.	V 502		
V 503	494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX The patient's comprehensive assessment must include, but is not limited to, the following: (2) Evaluation of the appropriateness of the dialysis prescription, This STANDARD is not met as evidenced by: Surveyor: 07599 Based on observation, interview, and medical record review, the facility failed to maintain an evaluation of the appropriateness of the dialysis prescription for 1 of 12 sampled patients (Patient 3). Findings: On 12/28/09 at 8:30 AM, Patient 3 was observed receiving dialysis treatment. Among the parameters noted on the dialysis machine were a dialysis flow rate (DFR) of 600 and a blood flow rate (BFR) of 350. A review of the clinical record revealed the patient was admitted on 7/16/09 with orders which included a DFR of 800 and a BFR of 850 through a central venous catheter as the primary access site and an arterial-venous (AV) fistula in the left lower arm as the secondary site. In a review of the post treatment records, the following flow rates were documented:	V 503		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 503	Continued From page 35 12/28/09 - BFR 350 DFR 600 12/23/09 - BFR 275 DFR 500 12/21/09 - BFR 250 DFR 500 12/19/09 - BFR 300 DFR 500 12/16/09 - BFR 300 DFR 800 12/12/09 - BFR 200 DFR 500 12/12/09 - BFR 300 DFR 600 No documentation could be located in the medical record to indicate the reason for the fluctuations in the BFR or the DFR rates or that the physician was notified of the facility's inability to maintain the rates as prescribed. Interview with the RN clinical nurse on 12/31/09 at 9:30 AM revealed that a new AV fistula was being used and that this was the reason for the instability of the BFR and the DFR. The RN Clinical Nurse further stated that the documentation was located in the "DUCK" notes which represents documentation by the staff in the computer detailing the patients' health status. Furhter review of the computer generated notes revealed the last documentation noted was dated 12/09/09. A further review of the clinical record revealed a rounding report dated 12/31/09 which indicated physician's orders on 12/30/09 to change the access from CVC catheter to AV fistula.	V 503		
V 540	494.90 CFC-PATIENT PLAN OF CARE This CONDITION is not met as evidenced by: Surveyor: 23046 The facility failed to ensure that the Condition of Participation for Patient Plan of Care was met by failing to:	V 540		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 540	Continued From page 36 1. Develop a written comprehensive plan of care which included estimated timetables to achieve outcomes identified based on the comprehensive assessment for 12 of 12 sampled patients in a universe of 118 patients which resulted in failure to address the plan of care of 2 of 12 (Patient 12 and 2) sampled patients. (Refer to V541) 2. Re-evaluate, adjust and revise care plans of 3 of 12 sampled patients (Patients 2, 8 and 9) which resulted in a failure to achieve the specified goals. (Refer to V559) The cumulative effect of these systemic practices had the potential to result in failure to identify and meet necessary care needs of all 118 patients. The facility failed to ensure compliance with the Condition of Participation: Patient Plan of Care.	V 540		
V 541	494.90 POC-GOALS=COMMUNITY-BASED STANDARDS The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards. This STANDARD is not met as evidenced by: Surveyor: 23046	V 541		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 541	Continued From page 37	V 541		

Based on observation, interview, and clinical record review, the facility's interdisciplinary team failed to develop a written comprehensive plan of care which included estimated timetables to achieve outcomes identified based on the comprehensive assessment for 12 of 12 sampled patients which resulted in failure to address the plan of care of 3 of 12 sampled patients (Patients 2, 3, and 12) and had further potential to result in failure to identify individual problems, goals and interventions necessary in achieving patient's long term and short term goals.

Findings:

1. During record review of the 12 sampled patients (Patients 1 to12) on 12/30/09, it was noted that the patient care plans were computerized with standardized problems, goals with no estimated timetables in achieving the goals.

Further review of Patients 12 and 2's medical records on 12/30/09 revealed, the following:

a. Patient 12 was 85 years of age, receiving dialysis treatment in the facility and had diagnosis that included end stage kidney disease, diabetes and high blood pressure (Hypertension).

Review of the interdisciplinary team's (IDT) initial comprehensive assessment dated from 9/9 to 9/22/09, it indicated that Patient 12 had a history of diarrhea and had been having diarrhea (GI symptoms) for more than two weeks, had been refusing dialysis treatments and had missed treatments multiple times, had a history of a fall in the past 3 months with mild displaced fracture of the fourth proximal phalanx (a finger bone),

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 541	Continued From page 38	V 541		

and had a total fall risk assessment score of 14.

Review of the Patient Care Plan - Progress Note dated 9/25/09, no documentation was found indicating that a comprehensive plan of care of the above problems had been addressed by the IDT.

Interview with the Nurse Manager on 12/31/09, at 9:20 AM, The Nurse Manager acknowledged the above findings and stated that a plan of care should be developed to address problems based on the IDT comprehensive assessment.

b. Review of Patient 2's medical record on 12/29/09, indicated the patient was 23 years of age, admitted as in-center dialysis patient on 6/26/03 and had diagnosis that included end stage kidney disease and type 1 diabetes mellitus (insulin dependent diabetes).

Review of the IDT comprehensive assessment dated 11/12/09 and the Patient Care Plan - Progress Note dated 11/30/09, the nutritional assessment documented that Patient 2 was not diabetic, however review of the care plan indicated the patient's comorbidities (additional diseases) included diabetes mellitus type 1 and being treated with 2 units of Lantus (insulin) every day at bedtime (at hs).

Further review of the care plan, the nutritional/metabolic care plan did not address plan of care for diabetes mellitus. Documentation on Glucose/Hgb A1C (tests for blood sugar) indicated "N/A" (not applicable) and on the Plan/Intervention did not include diabetes management. No further documentation was found indicating that the IDT had developed a

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 541	Continued From page 39	V 541		

plan of care for diabetes to address potential problems.

Interview with the Nurse Manager on 12/31/09, at 9:20 AM, the Nurse Manager acknowledged that the patient's co-morbidities included diabetes mellitus type 1 and a plan of care should have been developed by the IDT to address potential problems.

Surveyor: 07599
c. A review of the medical record for Patient 3 on 12/29/09 showed the patient was admitted to the facility on 07/16/09 with diagnoses which included; end stage renal disease, hypertension, large vessel disease, and unspecified renal failure.

The primary access site for dialysis services was documented as a central venous catheter (CVC) located in the right jugular vein with a secondary access site of an arterial/venous (AV) fistula located in the left lower arm.

According to the plan of care dated 10/30/09, the goal of the facility staff was to educate the patient to the potential risks and/or complications of the continued use of the CVC and encourage the patient to exercise the left arm for development (maturation) of the AV fistula for more permanent use.

According to the post treatment records dated 12/12/09, 12/14/09, 12/19/09, 12/21/09, and 12/23/09, the patient was unable to maintain a stable dialysis flow rate (DFR) and blood flow rate (BFR) as ordered by the physician.

In an interview with the Nurse Manager on

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 541	Continued From page 40 12/31/09 at 9:30 AM, the Nurse Manager stated that the new fistula was being used which was the reason for the instability of the DFR and BFR. A further review of the plan of care developed by the IDT failed to indicate a date for which the plan was to be reviewed and/or revised to address problems or complications which may occur as a result of the patient's continued use of the CVC.	V 541		
V 559	494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must- (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section. This STANDARD is not met as evidenced by: Surveyor: 26215 Based on observation, interview, and record review, the facility failed to re-evalute, adjust and revise care plans for 3 of 12 sampled patients (Patients 8, 9, 2) which resulted in failure to acheive the specified goals. For Patient 8, the facility failed to re-evaluate and review a care plan for elevated blood pressure. For Patient 9, the facility failed to update his care plan for compliance when he missed 13	V 559		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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V 559		V 559		

Continued From page 41
treatments in 2 months.

For Patient 2, the facility failed to adjust the care plan for non-compliance to dialysis treatments resulting in multiple missed treatments and frequent hospitalization.

Findings:

Observation on 12/28/09 at 8:40 AM, Patient 8 was observed during dialysis treatment discontinuation. The patient complained of feeling cold and nauseous and had an emesis basin on her lap. Her blood pressure was 184/128 (normal is 120/80).

During a record review on 12/30/09 at 4 PM, Patient 8's Post Treatment Records read:

1. On 12/16/09 at 5:38 AM, Patient 8's hemodialysis treatment was initiated with a blood pressure of 212/126. RN 1 assessed the Patient at 5:50 AM and no evaluation or intervention for the hypertension was documented by licensed or unlicensed facility staff. At 6 AM, Patient 8's blood pressure was 191/128 and no assessment or intervention was performed. Patient 8' treatment was terminated 40 minutes early with a post treatment blood pressure of 129/100. No post treatment assessment was performed.

On 12/18/09 at 5:35 AM, Patient 8's hemodialysis treatment was initiated with a blood pressure of 211/133. RN 1 assessed her at 6 AM and no evaluation or intervention for the hypertension was documented. No post assessment was performed when treatment was completed at 8:38 AM.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 559	Continued From page 42	V 559		

Continued From page 42

2. 12/21/09 at 5:30 AM, Patient 8's hemodialysis treatment was initiated with a blood pressure of 209/133. RN 1 assessed Patient 8 at 6 AM and no evaluation or intervention for the hypertension was documented. Patient 8 ' s treatment was terminated at 8:25 AM with her blood pressure of 157/129. No post assessment or intervention was documented.

Patient 8's care plan dated 9/4/09 read " Pt ' s (Patient ' s) BP high; meds reviewed; MD aware; will continue to monitor." The blood pressure goal was 140/90; however, no re-evaluation date or revision was indicated on the care plan when this goal was not met.

Record review conducted on 12/29/09 at 8:25 AM of Patient 9's care plan dated 2/6/09, revealed the patient had missed 14 treatments for "non-compliance" in December 2008 and January 2009 and was designated as " Stable." No care plan interventions were identified by nursing. Patient 9's care plan dated 4/24/09 revealed the patient had missed 14 treatments for " Non-compliance" in March and April 2009. No care plan interventions were documented by nursing or the social worker. Patient 9's Rounding Report read he missed 13 treatments in November and December 2009. Social Worker progress notes for the fourth quarter of 2009 dated 9/7/09 read: " Pt has good compliance with his treatment. "

In an interview on 12/31/09 at 9:05 AM, the Nurse Manager stated care planning for non-compliance was performed monthly when "the social worker, dietician, and nurse discuss why Patient 9 is not coming for treatment."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 559	Continued From page 43	V 559		

Surveyor: 23046
3. During review of Patient 2's medical record on 12/29/09, it indicated that he was 23 years of age, admitted as in-center patient on 6/26/03 and had diagnosis that included end stage kidney disease and type 1 diabetes mellitus (insulin dependent diabetes).

The psychosocial 4th quarter patient progress notes dated 10/13/09, indicated that Patient 2 continued to be non-complaint with dialysis treatment and had missed several treatments. The plan of care was for social worker (MSW), facility manager, and Village Health Nurses to continue to educate the patient the consequences of missing treatments.

Further review of the Patient progress notes documented by the nurse manager on 10/31/09, indicated that patient continues to be non-compliant with treatment schedule and had been in and out of hospitalization due to non-compliance. The notes further indicated, "Will continue to educate regarding risks/ consequences of non-compliance...."

Review of the IDT comprehensive assessment dated 11/17/09 and Patient Care Plan - Progress note dated 11/30/09, documented that patient was extremely non-compliant with dialysis treatments but understands the risks of his behavior.

The Patient Care Plan further documented that the IDT's goal was patient to be more complaint to treatment and the intervention was to continue to educate and encourage patient to be more compliant.
The plan of care further documented that Patient

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 559	Continued From page 44 2 had missed treatment 23 times for the past 3 months from September to November 2009. No documentation in the patient's medical records was found indicating that the plan of care had been adjusted, accelerated and revised when the goal continued not to be achieved. Further review of the Patient Progress Notes indicated that Patient 2 was "no call no show" for treatment on 12/5/09 and 12/29/09. During review of the facility's policy and procedure for Patient Assessment and Plan of Care (Policy: 1-01-07), on page 4 of 5, the following were noted: "13. In addition, if the expected outcome is not achieved, the interdisciplinary team will adjust the patient's care plan to achieve the specified goal...." During an interview with the Nurse Manager on 12/31/09, at 9:20 AM, the Nurse Manager stated that if care plan goals were not met, the problem should be reassessed and the plan of care updated and revised. The Nurse Manager further acknowledged that Patient 2's plan of care for non-compliance to treatment had not been adjusted in order to meet the specified goal.	V 559		
V 625	494.110 CFC-QAPI This CONDITION is not met as evidenced by: Surveyor: 23046 Based on observation, interview and record review, the facility failed to meet the Conditions of Participation for Quality Assessment and	V 625		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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V 625	Continued From page 45 Performance Improvement (QAPI) by failing to: 1. Ensure that an effective data driven program was implemented, maintained and evaluated which resulted in an ineffective prevention, identification and monitoring of health outcomes such as the prevention and reduction of medical errors. (Refer to V626) 2. Develop an ongoing program which achieved measurable improvement in health outcomes by failing to identify or monitor trend outcomes and develop an improvement plan when needed. (Refer to V627) 3. Measure, analyze and track aspects of performance that reflects processes of care and facility operations. (Refer to V628) 4. Ensure that an effective, data driven program identify the prevalence of occurrences, commonalities and causes of medical error identification and patient safety events such as wrong dialyzer usage which resulted in 2 patients being placed on dialysis using dialyzers that belonged to other patients. (Refer to 634) 5. Ensure that QAPI program analyzed and developed action plans to minimize infection transmission, promote immunization and perform trend analysis to reduce future incidents. (Refer to V637) 6. Continuously monitor its outcome performance data, develop improvement action plans for identified issues, implement the action plan, evaluate and revise the action plan as indicated. (Refer to 638)	V 625		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

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V 625	Continued From page 46 7. Ensure that immediate corrective action took place when 2 patients were placed on dialysis using dialyzers that belonged to other patients threatening the health and safety of other patients. (Refer to V640) The cumulative effect of these systemic practices had the potential to result in creating multiple risks to patients' health and safety. The facility failed to ensure compliance with the Condition of Participation: Quality Assessment and Performance Improvement.	V 625		
V 626	494.110 QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS. This STANDARD is not met as evidenced by: Surveyor: 23046 Based on interview and record review, the facility failed to ensure that an effective data driven program was implemented, maintained and evaluated which resulted in an ineffective prevention, identification and monitoring of health	V 626		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 626		V 626		

Continued From page 47

outcomes such as the prevention and reduction of medical errors in a universe of 118 patients.

Findings:

During review of the facility's AOR log on 12/30/09, documentation indicated that on 6/17/09, unsampled Patient 16 was started on dialysis using another patient's dialyzer, and on 7/24/09, unsampled Patient 17 had been started on dialysis using a wrong dialyzer.

Documentation further indicated that Patient 16 had been on dialysis for 5 minutes before staff discovered the error.

Interview with the Nurse Manager on 12/30/09, at 1:50 PM, the Nurse Manager stated that part of the corrective action that was implemented was inservice training on identification of reuse dialyzer given to all patient care staff.

During review of staff attendance of the inservice titled "Verification of Patient Identification of Reprocessed Dialyzer" conducted by the FA and the Nurse Manager on 6/23 - 6/24/09 and 7/29 - 7/30/09, the Nurse Manager reviewed the inservice attendance and failed to find documentation indicating that PCT 5 and 6 (staff involved in wrong dialyzers used on patients) had attended the inservice training.

He further confirmed and acknowledged that wrong dialyzers were used during dialysis treatment for unsampled Patient 16 on 6/17/09 and Patient 17 on 7/24/09 and that staff had failed to check and confirm the identity of the dialyzer and the patient before initiating dialysis.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 626	Continued From page 48 On 1/4/10, the facility's Quality Improvement and Facility Management Meeting Minutes (also known as QAPI) was reviewed. The QAPI minutes dated 7/17/09, which covered the previous issues for the past 6 months (January to June 2009), under the Adverse Occurrence Reporting (AOR) section documented " 1 episode of patient on incorrect dialyzer." On the right side of the AOR section in the "Plan Needed?, Evaluation of Plan of Correction from last Meeting, and Revision to plan/New Plan sections, all areas were blank. No documentation in the QAPI minutes that an action was developed to prevent further reoccurrence of wrong dialyzers being used on patients. Review of the QAPI minutes dated 9/4/09, the AOR section of 9/4/09 minutes documented, "All July 2009 AORs were reviewed and they included 1 episode of incorrect dialyzer ...." No documentation were found indicating that a plan of correction, revision of plan or new plan had been developed to ensure that no further used of wrong dialyzer on patients will occur. During interview with the FA on 1/4/10, at 10 AM, he reviewed the QAPI minutes and failed to find documentation indicating plans of correction had been addressed and developed on the two (2) incidents of wrong dialyzers used on 2 patients. The FA further acknowledged that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes.	V 626		
V 627	494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT The program must include, but not be limited to,	V 627		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 627		V 627		

Continued From page 49
an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

This STANDARD is not met as evidenced by:
Surveyor: 23046
Based on interview and record review, the facility's QAPI program failed to develop an ongoing program which achieved measurable improvement in health outcomes by failing to identify or monitor trend outcomes and develop an improvement plan when needed in a universe of 118 patients.

Findings:

On 1/4/10, the facility's Quality Improvement and Facility Management Meeting Minutes (also known as QAPI) was reviewed. The QAPI minutes dated 7/17/09, which covered the previous issues for the past 6 months (January to June 2009), under the Adverse Occurrence Reporting (AOR) section documented " 1 episode of patient on incorrect dialyzer." On the right side of the AOR section in the "Plan Needed?, Evaluation of Plan of Correction from last Meeting, and Revision to plan/New Plan sections, all areas were blank. No documentation in the QAPI minutes that an action was developed to prevent further reoccurrence of wrong dialyzers being used on patients.

Review of the QAPI minutes dated 9/4/09, the AOR section of 9/4/09 minutes documented, "All July 2009 AORs were reviewed and they included 1 episode of incorrect dialyzer ...." No

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

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V 627	Continued From page 50 documentation were found indicating that a plan of correction, revision of plan or new plan had been developed to ensure that further occurrence of wrong dialyzer being used on patients will not happen. Review of the QAPI minutes dated 9/4/09, under the Physical Systems Review section which included water cultures, documentation under Revision to Plan/ New Plan documented, "Monthly, quarterly, semi-annually and annual audits will be performed moving forward." No documentation was found indicating that plans had been developed to address high microbial levels of the facility's product water on 8/11/09 and 7/9/09. Review of the QAPI minutes dated 9/4/09 which covered the past 7 months, under the Missed Treatment section indicated the following: Total number/percentage rate of missed (dialysis) treatments excluding vacation from January - July 2009: 1/09- 96/ 6.5 % 2/09- 101/ 7.4 % 3/09- 135/ 8.8 % 4/09- 84/ 5.5 % 5/09- 51/ 3.2 % 6/09- 108/ 6.9 % 7/09- 96/ 6/0 % The Plan section which included, "Plan Needed? and Revision to Plan/ New Plan" were blank. No documentation were found in the QAPI meeting minutes indicating that multiple missed treatments had been addressed and a plan	V 627		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100** **MONTCLAIR, CA 91763**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 627	Continued From page 51 developed by the QAPI committee members. During interview with the FA on 1/4/10, at 10 AM., he reviewed the QAPI minutes and failed to find documentation indicating plans of correction had been addressed and developed for the two incidents of wrong dialyzers being used on patients; 2 episodes of high microbial levels on the product water; and multiple patients with multiple missed dialysis treatments. The FA further acknowledged that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes.	V 627		
V 628	494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. This STANDARD is not met as evidenced by: Surveyor: 23046 Based on interview and record review, the facility's QAPI program failed to measure, analyze and track aspects of performance that reflects processes of care and facility operations in a universe of 118 patients. Findings: On 1/4/10, the facility's Quality Improvement and Facility Management Meeting Minutes (also	V 628		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 628	Continued From page 52 known as QAPI) was reviewed. 1. The QAPI minutes dated 7/17/09, which covered the previous issues for the past 6 months (January to June 2009), under the Adverse Occurrence Reporting (AOR) section documented " 1 episode of patient on incorrect dialyzer." On the right side of the AOR section in the "Plan Needed?, Evaluation of Plan of Correction from last Meeting, and Revision to plan/New Plan sections, all areas were blank. No documentation in the QAPI minutes that an action was developed to prevent further reoccurrence of wrong dialyzers being used on patients. Review of the QAPI minutes dated 9/4/09, the AOR section of 9/4/09 minutes documented, "All July 2009 AORs were reviewed and they included 1 episode of incorrect dialyzer ...." No documentation were found indicating that a plan of correction, revision of plan or new plan had been developed to ensure that further occurrence of wrong dialyzer being used on patients will not happen. During interview with the FA on 1/4/10, at 10 AM, he reviewed the QAPI minutes and failed to find documentation indicating plans of correction for the two (2) incidents of wrong dialyzers being used on patients had been addressed and developed. The FA further acknowledged that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes. 2. Review of the QAPI minutes dated 9/4/09 which covered the past 7 months, under the	V 628		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 628	Continued From page 53	V 628		

Missed Treatment section indicated the following:

Total number/percentage rate of missed (dialysis) treatments excluding vacation from January - July 2009:

1/09- 96/ 6.5 %
2/09- 101/ 7.4 %
3/09- 135/ 8.8 %
4/09- 84/ 5.5 %
5/09- 51/ 3.2 %
6/09- 108/ 6.9 %
7/09- 96/ 6/0 %

The Plan section which included, "Plan Needed? and Revision to Plan/ New Plan" were blank. No documentation were found in the QAPI meeting minutes indicating that multiple missed treatments had been addressed and a plan developed by the QAPI committee members.

During interview with the FA on 1/4/10, at 10 AM, he reviewed the QAPI minutes and failed to find documentation indicating plans of correction for the 2 episodes of high microbial levels on the product water had been addressed and developed.

The FA further acknowledged that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes.

3. Review of the QAPI minutes dated 9/4/09, under the Physical systems Review section which included water cultures, documentation under Revision to Plan/ New Plan documented, "Monthly, quarterly, semi-annually and annual audits will be performed moving forward."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 628	Continued From page 54 No documentation was found indicating that plans had been developed to address high microbial levels of the facility's product water on 8/11/09 and 7/9/09. During interview with the FA on 1/4/10, at 10 AM, he stated that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes.	V 628		
V 634	494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification. This STANDARD is not met as evidenced by: Surveyor: 23046 Based on interview and record review, the facility failed to ensure that an effective, data driven program identified the prevalence of occurrences, commonalities and causes of medical error identification and patient safety events such as wrong dialyzer usage, retesting product water when microbial levels were high and at unacceptable level in a universe of 118 patients. Findings: 1. During review of the facility's Adverse Occurrence Log (AOR) on 12/30/09, it indicated that on 6/17/09, unsampled Patient 16 was started on dialysis using another patient's dialyzer, and on 7/24/09, unsampled Patient 17 had been started on dialysis using a wrong	V 634		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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V 634	Continued From page 55	V 634		

dialyzer.

Documentation in the patient progress notes dated 6/17/09 indicated that Patient 16 had been on dialysis for 5 minutes before staff discovered the error.

The QAPI minutes dated 7/17/09, which covered the previous issues for the past 6 months (January to June 2009), under the Adverse Occurrence Reporting (AOR) section documented " 1 episode of patient on incorrect dialyzer." On the right side of the AOR section in the "Plan Needed?, Evaluation of Plan of Correction from last Meeting, and Revision to plan/New Plan sections, all areas were blank. No documentation in the QAPI minutes that an action was developed to prevent further reoccurrence of wrong dialyzers being used on patients.

The QAPI minutes dated 9/4/09, the AOR section documented, "All July 2009 AORs were reviewed and they included 1 episode of incorrect dialyzer ...." No documentation was found indicating that a plan of correction, revision of plan or new plan had been developed to ensure that no wrong dialyzer being used on patients will further occur.

During interview with the FA on 1/4/10, at 10 AM, he reviewed the QAPI minutes and failed to find documentation indicating plans of correction for the two (2) incidents of wrong dialyzers being used on patients had been addressed and developed.

The FA further acknowledged that the QAPI committee members should have developed and documented including the implementation of a

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V 634	Continued From page 56 plan of correction in the QAPI minutes. 2. During review of the facility water culture report on 12/28/09, the culture test result of the product water on 7/9/09 indicated high microbial levels at 640 colony forming units (CFU/mL) and on 8/11/09 at 840 above the maximum allowable level of lower than 200 CFU/mL. The report further indicated that the reculture test for the 8/11/09 test result was not performed until 8/21/09, 9 days after. During an interview with the Biomedical Services (Biomed) Staff 1 on 12/28/09, at 3:10 PM, he stated that when culture results were high the laboratory (lab) sends a message alert the following day in order that the facility could take appropriate action. Biomed Staff 1 further stated that the time span of retesting the product water (9 days) was too long and that the product water should have been recultured right away when the facility received the message alert the following day. Review of the QAPI minutes dated 9/4/09, under the Physical systems Review section which included water cultures, documentation under Revision to Plan/ New Plan documented, "Monthly, quarterly, semi-annually and annual audits will be performed moving forward." No documentation was found indicating that plans had been developed to address high microbial levels of the facility's product water on 8/11/09 and 7/9/09. During interview with the FA on 1/4/10, at 10 AM, he reviewed the QAPI meeting minutes and	V 634		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 634	Continued From page 57 confirmed that no documentation was found indicating that the above problem had been addressed. He further stated that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes.	V 634		
V 637	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- (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. This STANDARD is not met as evidenced by: Surveyor: 23046 Based on interview and record review, the facility failed to ensure that an effective, data driven QAPI program analyzed and developed action plans to minimize infection transmission, promote immunization and perform trend analysis to reduce future incidents in a universe of 118 patients. Findings: 1a. During review of the facility's policy and procedure on 12/30/09, the Hepatitis Surveillance, Vaccination and Infection Control Measures (Policy: 1-05-02) under vaccination on page 5 of 7, the following were noted:	V 637		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

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V 637	Continued From page 58	V 637		

Continued From page 58

"21. Test all vaccinated patients for HBsAB (same as anti-HBs) one (1) to two (2) months after the last dose of the full vaccine series.

22. If HBsAb is <10 mIU/mL, consider the patient susceptible, revaccinate with an additional full series, and retest for HBsAb 1 to 2 months after the last dose of the second series...."

Review of Patient 12's medical record on 12/29/09, the Patient Care Plan - Progress Notes dated 9/25/09 indicated that she had received the complete hepatitis B vaccine series on 9/25/08, and the test for the presence of antibodies (anti-HBs) had not been performed until 9/10/09 almost one year after receiving the vaccine risking exposure to hepatitis B infection.

The test result dated 9/10/09 indicated that Patient 12's anti-HBs level was 2 which was indicative of non-immune status and susceptible to hepatitis B infection (anti-HBs of less than 10 = susceptible; greater than 10 = immune). No further documentation in medical record was found indicating that Patient 12 had been given the hepatitis vaccine booster after 9/10/09.

During an interview with the Facility Administrator (FA) on 12/29/09, at 9:45 AM, he reviewed Patient 12's immunology and vaccination report and confirmed that the patient was not retested until after almost a year (on 9/10/09) and that the test result indicated Patient 12 was not immune to hepatitis B.

The FA further confirmed that Patient 12 had not been revaccinated with hepatitis B booster vaccine.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING _____ B. WING _____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 637	Continued From page 59	V 637		

b. During a record review on 12/30/09 at 3:30 PM, Patient 7's Comprehensive Orders Worksheet contained physician orders dated 8/19/09 "Engerix 40 mcg intramuscular (vaccine for Hepatitis B)." Patient 7's labs on 8/22/09 indicate her Hepatitis B Antigen screen was negative (no active disease) and her Hepatitis B Antibody Screen was negative which indicated she was susceptible to Hepatitis B infection. Patient 7's care plan dated 9/4/09 indicated the plan was to "offer Hep(atitis) B and Pneumococcal Vaccine."

During an interview with the Nurse Manager on 12/31/09 at 9:20 AM, he stated Patient 7 had refused the vaccination and documentation was requested at this time. No documentation was provided which indicated the Hepatitis B vaccination had been offered and refused.

2. During a record review on 12/30/09 at 2:30 PM, the policy titled "Tuberculosis Monitoring and Follow-up" indicated that follow up TB screening using TST (Tuberculin Skin Testing) will occur on an annual basis, from the date of the last TST using a one step method based.

The policy titled "Injury Prevention and Safety Training Inservices" indicated that mandatory inservices for staff included the following: (Initially and Annually) Bloodborne Pathogen Regulations, Medical Waste Management, Safety Needle Program.

During a record review on 12/30/09 at 8:15 AM, 12 personnel files were reviewed. Of the 12 personnel files reviewed, 5 had not completed annual tuberculosis screening for 2009, and 3 had not completed annual Infection Control

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 637	Continued From page 60 Training. During an interview on 12/30/09 at 2:15 PM, 12/30/09 at 2:15 PM, the FA verified 5 personnel had not completed annual tuberculosis training in 2009 and 3 personnel had not completed annual Infection Control Training.	V 637		
V 638	494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. This STANDARD is not met as evidenced by: Surveyor: 23046 Based on interview and record review, the facility's QAPI program failed to continuously monitor its outcome performance data, develop improvement action plans for identified issues, implement the action plan, evaluate and revise the action plan as indicated. Findings: On 1/4/10, the facility's Quality Improvement and Facility Management Meeting Minutes (also known as QAPI) was reviewed. 1. The QAPI minutes dated 7/17/09, which covered the previous issues for the past 6 months (January to June 2009), under the Adverse Occurrence Reporting (AOR) section documented "1 episode of patient on incorrect dialyzer."	V 638		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 638	Continued From page 61	V 638		

On the right side of the AOR section in the "Plan Needed ?, Evaluation of Plan of Correction from last Meeting, and Revision to plan/New Plan" sections, all areas were blank. No documentation in the QAPI minutes that an action was developed to prevent further reoccurrence of wrong dialyzers being used on patients.

Review of the QAPI minutes dated 9/4/09, the AOR section of 9/4/09 minutes documented, "All July 2009 AORs were reviewed and they included 1 episode of incorrect dialyzer ...." No documentation were found indicating that a plan of correction, revision of plan or new plan had been developed to ensure that further occurrence of wrong dialyzer being used on patients will not happen.

During review of the facility's AOR log on 12/30/09, documentation confirmed that on 6/17/09, unsampled Patient 16 was started on dialysis using another patient's dialyzer, and on 7/24/09, unsampled Patient 17 had been started on dialysis using a wrong dialyzer. Documentation further indicated that Patient 16 had been on dialysis for 5 minutes before staff discovered the error.

2. The QAPI minutes dated 9/4/09, under the Physical systems Review section which included water cultures, documentation under Revision to Plan/ New Plan documented, "Monthly, quarterly, semi-annually and annual audits will be performed moving forward."

No documentation was found indicating that plans had been developed to address high microbial levels of the facility's product water on 8/11/09 and 7/9/09.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 638	Continued From page 62	V 638		

During interview with the FA on 1/4/10, at 10 AM, he stated that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes.

3. The QAPI minutes dated 9/4/09 which covered the past 7 months, under the Missed Treatment section indicated the following:

Total number/percentage rate of missed (dialysis) treatments excluding vacation from January - July 2009:

1/09- 96/ 6.5 %
2/09- 101/ 7.4 %
3/09- 135/ 8.8 %
4/09- 84/ 5.5 %
5/09- 51/ 3.2 %
6/09- 108/ 6.9 %
7/09- 96/ 6/0 %

The Plan section which included, "Plan Needed? and Revision to Plan/ New Plan" were blank. No documentation were found in the QAPI meeting minutes indicating that multiple missed treatments had been addressed and a plan developed by the QAPI committee members.

During interview with the FA on 1/4/10, at 10 AM, he reviewed the QAPI minutes and failed to find documentation indicating plans of correction had been addressed and developed for the following: Two (2) incidents of wrong dialyzers being used on patients; 2 episodes of high microbial levels on the product water; and multiple patients with multiple missed dialysis treatments.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

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V 638	Continued From page 63 The FA further acknowledged that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes. During an interview with the Medical director on 1/4/09, at 11:30 AM, he stated that he was aware of the 2 incidents of wrong dialyzer being used on patients. He further stated that he had not participated in providing training and education for staff and had been relying on the FA and Nurse Manager in providing training and education for staff.	V 638		
V 640	494.110(c) QAPI-QAPI-IMMEDIATELY CORRECT ANY IJ ISSUES The facility must immediately correct any identified problems that threaten the health and safety of patients. This STANDARD is not met as evidenced by: Surveyor: 23046 Based on interview and record review, the facility's QAPI program failed to ensure that immediate corrective action took place when 2 patients were placed on dialysis using dialyzers that belonged to other patients threatening the health and safety of other patients. Findings: During review of the facility's AOR log on 12/30/09, documentation confirmed that on 6/17/09, unsampled Patient 16 was started on dialysis using another patient's dialyzer, and on 7/24/09, unsampled Patient 17 had been started on dialysis using a wrong dialyzer. Documentation further indicated that Patient 16 had been on dialysis for 5 minutes before staff discovered the	V 640		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

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V 640	Continued From page 64 error. During interview with the Nurse Manager on 12/30/09, at 1:50 PM, the Nurse Manager stated that part of the corrective action that was implemented was inservice training on identification of reuse dialyzer given to all patient care staff. During review of staff attendance of the inservice titled "Verification of Patient Identification of Reprocessed Dialyzer" conducted by the FA and the Nurse Manager on 6/23 - 6/24/09 and 7/29 - 7/30/09, the Nurse Manager reviewed the inservice attendance and failed to find documentation indicating that PCT 5 and 6 (staff involved in wrong dialyzers used on patients) had attended the inservice training. On 1/4/10, the facility's Quality Improvement and Facility Management Meeting Minutes (also known as QAPI) was reviewed. The QAPI minutes dated 7/17/09, which covered the previous issues for the past 6 months (January to June 2009), under the Adverse Occurrence Reporting (AOR) section documented " 1 episode of patient on incorrect dialyzer." The QAPI minutes dated 9/4/09, under the AOR section documented, "All July 2009 AORs were reviewed and they included 1 episode of incorrect dialyzer ...." No documentation were found indicating that a plan of correction, revision of plan or new plan had been addressed and developed to ensure that no further occurrence of wrong dialyzer being used on patients will happen. In the Plan section, the "Plan Needed ?,	V 640		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

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V 640	Continued From page 65 Evaluation of Plan of Correction from last Meeting, and Revision to plan/New Plan" sections were all noted blank. No documentation were found indicating that a plan of correction, revision of plan or new plan had been addressed and developed to ensure that no further occurrence of wrong dialyzer being used on patients will happen. During interview with the FA on 1/4/10, at 10 AM, he reviewed the QAPI minutes and failed to find documentation indicating plans of correction for the 2 incidents of wrong dialyzers being used on patients had been addressed and developed. The FA further acknowledged that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes.	V 640		
V 710	494.150 CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR This CONDITION is not met as evidenced by: Surveyor: 23046 The facility failed to ensure that the Condition of Participation for Responsibilities of the Medical Director was met by failing to ensure that the oversight regarding the delivery of quality patient care was met as follows: 1. The facility's Medical Director failed to ensure that Hepatitis B vaccination, monitoring and follow-up for patients had been followed and implemented according to facility guidelines. In addition, the Medical Director failed to ensure that the facility was maintained clean, comfortable, safe and sanitary for a universe of 118 patients. (Refer to V711)	V 710		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

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V 710	Continued From page 66 2. The Medical Director failed to ensure that the operational responsibility for the Quality Assessment and Performance Improvement (QAPI) program was met by failing to ensure that the QAPI program was data driven and trends related to improved health outcomes monitored. (Refer to 712) 3. The Medical Director failed to ensure that facility staff received appropriate education and training in infection control. (Refer to V713) 4. The Medical Director failed to ensure that facility staff who provided care in the facility adhered to the facility's policy and procedure regarding implementation of infection control program, patient assessment and plan of care, and the QAPI program. (Refer to V715) The cumulative effect of these systemic practices resulted in failure to ensure compliance with federal regulations for the Condition of Participation: Responsibilities of the Medical Director.	V 710		
V 711	494.150 MD RESP-MED DIR QUAL/ACCOUNTABLE TO GOV BODY The dialysis facility must have a medical director who meets the qualifications of §494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients. This STANDARD is not met as evidenced by: Surveyor: 23046	V 711		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

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V 711		V 711		

Continued From page 67

Based on interview and record review, the facility's Medical Director failed to:

1. Ensure that Hepatitis B vaccination, monitoring and follow-up for patients had been followed and implemented according to facility guidelines.

2. Ensure that the facility was maintained clean, comfortable, safe and sanitary for a universe of 118 patients.

Findings:

1a. During record review on 12/29/09, Patient 12's Care Plan - Progress Notes dated 9/25/09 indicated that she had received the complete hepatitis B vaccine series on 9/25/08, and the test for the presence of antibodies (anti-HBs) had not been performed until 9/10/09 almost one year after receiving the vaccine risking exposure to hepatitis B infection.

Patient 12's vaccination record in the care plan indicated that her anti-HBs level dated 9/10/09 was at "2" (2 mIU/mL) indicating non-immune status and susceptible to hepatitis B infection (anti-HBs of less than 10 = susceptible; greater than 10 = immune). Care plan documentation further indicated that patient needed hepatitis B booster vaccine.

During review of the facility's policy and procedure for Hepatitis Surveillance, Vaccination and Infection Control Measures (Policy: 1-05-02) under vaccination on page 5 of 7, the following were noted:

"21. Test all vaccinated patients for HBsAB (same as anti-HBs) one (1) to two (2) months after the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 711	Continued From page 68	V 711		

last dose of the full vaccine series.

22. If HBsAb is <10 mIU/mL, consider the patient susceptible, revaccinate with an additional full series, and retest for HBsAb 1 to 2 months after the last dose of the second series...."

During an interview with the FA on 12/29/09, at 9:45 AM, he reviewed Patient 12's immunology and vaccination report and confirmed that the test result indicated Patient 12 was not immune to hepatitis B and failed to find documentation indicating that Patient 12 had been given the hepatitis vaccine booster after 9/10/09.

b. During a record review on 12/30/09 at 3:30 PM, Patient 7's Comprehensive Orders Worksheet contained physician orders dated 8/19/09 read "Engerix 40 mcg intramuscular (an immunization for Hepatitis B)." Patient 7's lab tests on 8/22/09 indicated her Hepatitis B Antigen screen was negative (no active disease) and her Hepatitis B Antibody Screen was negative which indicated she was susceptible to Hepatitis B infection. Patient 7's care plan dated 9/4/09 indicated the plan was to "offer Hep(atitis) B and Pneumococcal Vaccine."

During an interview with the Nurse Manager on 12/31/09 at 9:20 AM, he stated Patient 7 had refused the vaccination and documentation was requested at this time. No documentation was provided which indicated the Hepatitis B vaccination had been offered and refused.

2a. During an environmental tour of the facility on 12/28/09, a request was made to check the functioning of the suction machine of the emergency cart to a wall outlet adjacent to station

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

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V 711	Continued From page 69 2 and plugged into the socket. The suction machine was noted to be inoperative so the the cart was taken to an outlet outside of the nursing station and across from station 2 where the suction machine was successfully checked. An interview with the Nurse Manager, revealed the outlet was inoperative and acknowledged that in the event of an emergency, the patient occupying station 2 would be unable to take advantage of any emergency services which required the use of the electrical outlet. b. During an observation on 12/28/09 at 12:45 PM, 2 trash cans located in the center of the floor were overflowing and in need of emptying. Another covered trash can with swinging lid located several feet to the left of the front door of the facility had trash overflowing out of the front of it. Styrofoam food containers and plastic bags were piled on top of the trash can. More Styrofoam food containers and a plastic bag with a container of motor oil were on the concrete in front of the trash can. When observed at 3:15 PM, the trash can had not been emptied. During interview with the RN Clinical Services Specialist on 1/04/09 revealed that the trash can located at the entrance of the facility was a shared trash can and was the responsibility of the environmental services of the building to ensure that the cans were emptied on a regular basis. c. During observation from 12/28/09 to 1/4/10, multiple patients in the treatment floor were positioned very close to each other while undergoing dialysis treatment.	V 711		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100** **MONTCLAIR, CA 91763**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 711	Continued From page 70	V 711		

Ten treatment stations with patients undergoing dialysis were observed and the space between patient's chair were approximately from 6 inches to one and one half (1 1/2) feet. The arm chairs where patient's access sites were placed could almost touch the other and space would not be enough for staff to pass through in-between the chairs.

During an interview with the Nurse Manager who was on the treatment floor on 12/30/09, at 11:30 AM, he confirmed that multiple patients were very close to each other while on dialysis treatment and further acknowledged that multiple treatment stations did not not have sufficient space.

During an interview with the facility administrator on 12/30/09, at approximately 11:35 AM, he acknowledged that multiple patients did not have sufficient space while on dialysis treatment.

d. On 12/28/09 at 9:00 AM during a tour of the facility, the patients were noted to be completely covered with thick blankets or coats draped across their chests. Three (3) non-sampled patients (unsampled Patients 13, 14 and 15) complained of the "temperature being cold with 1 patient stating that the only thing wrong with the facility was the "cold temperature, which was the reason he hated coming to the facility."

A review of the temperature setting on the thermostat indicated 71 degrees. An interview with the Administrator on 1/04/2010 revealed he was aware of the temperature as it had been cold "last week" and new vents had been installed.

e. During patient care observation on the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100** **MONTCLAIR, CA 91763**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 711	Continued From page 71 treatment floor on 12/29/09 and 12/30/09 unsampled Patient 15 and sampled Patient 8 had their vascular access sites and part of blood lines covered with blankets during dialysis treatment while patient care technicians (PCT) and staff RN were present close to Patient's chairside. On 12/29/09, at 8:05 AM, RN 1's attention was called regarding Patient 15's access site and part of blood lines being covered. RN 1 confirmed that patient's access site and blood lines were covered and could not be seen by staff, then asked patient's permission and proceeded to uncover and exposed unsampled Patient 15's access site. RN 1 acknowledged that access sites should always be with in view of staff during dialysis treatment. On 12/30/09, at 8:30 AM, Patient 8's access site was observed covered for approximately 15 minutes until PCT 1's attention was called. PCT 1 confirmed that Patient 8's access site had been covered and immediately uncovered access site.	V 711		
V 712	494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program. This STANDARD is not met as evidenced by: Surveyor: 23046 Based on interview and record review, the facility's Medical Director failed to ensure that the operational responsibility of the QAPI program was met by failing to ensure that an effective data driven program was implemented maintained and	V 712		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100** **MONTCLAIR, CA 91763**

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V 712	Continued From page 72 valuated which resulted in an ineffective prevention, identification and monitoring of health outcomes such as the prevention and reduction of medical errors. Findings: On 1/4/10, the facility's Quality Improvement and Facility Management Meeting Minutes (also known as QAPI) was reviewed. 1. The QAPI minutes dated 7/17/09, which covered the previous issues for the past 6 months (January to June 2009), under the Adverse Occurrence Reporting (AOR) section documented " 1 episode of patient on incorrect dialyzer." On the right side of the AOR section in the "Plan Needed?, Evaluation of Plan of Correction from last Meeting, and Revision to plan/New Plan sections, all areas were blank. No documentation in the QAPI minutes that an action was developed to prevent further reoccurrence of wrong dialyzers being used on patients. During review of the facility's AOR log on 12/30/09, documentation confirmed that on 6/17/09, unsampled Patient 16 was started on dialysis using another patient's dialyzer, and on 7/24/09, unsampled Patient 17 had been started on dialysis using a wrong dialyzer. Documentation further indicated that Patient 16 had been on dialysis for 5 minutes before staff discovered the error. Review of the QAPI minutes dated 9/4/09, the AOR section of 9/4/09 minutes documented, "All July 2009 AORs were reviewed and they included 1 episode of incorrect dialyzer ...." No documentation were found indicating that a plan	V 712		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 712		V 712		

Continued From page 73
of correction, revision of plan or new plan had been developed to ensure that further occurrence of wrong dialyzer being used on patients will not happen.

2. During review of the QAPI minutes dated 9/4/09, under the Physical systems Review section which included water cultures, documentation under Revision to Plan/ New Plan documented, "Monthly, quarterly, semi-annually and annual audits will be performed moving forward."

No documentation was found indicating that plans had been developed to address high microbial levels of the facility's product water on 8/11/09 and 7/9/09.

During interview with the FA on 1/4/10, at 10 AM, he stated that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes.

3. Review of the QAPI minutes dated 9/4/09 which covered the past 7 months, under the Missed Treatment section indicated the following:

Total number/percentage rate of missed (dialysis) treatments excluding vacation from January - July 2009:

1/09- 96/ 6.5 %
2/09- 101/ 7.4 %
3/09- 135/ 8.8 %
4/09- 84/ 5.5 %
5/09- 51/ 3.2 %
6/09- 108/ 6.9 %
7/09- 96/ 6/0 %

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

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V 712	Continued From page 74 The Plan section which included, "Plan Needed? and Revision to Plan/ New Plan" were blank. No documentation were found in the QAPI meeting minutes indicating that multiple missed treatments had been addressed and a plan developed by the QAPI committee members. During interview with the FA on 1/4/10, at 10 AM, he reviewed the QAPI minutes and failed to find documentation indicating plans of correction had been addressed and developed for the two incidents of wrong dialyzers being used on patients; 2 episodes of high microbial levels on the product water; and multiple patients with multiple missed dialysis treatments. The FA further acknowledged that the QAPI committee members should have developed and documented including the implementation of a plan of correction in the QAPI minutes. During an interview with the Medical director on 1/4/09, at 11:30 AM, he stated that he was aware of the 2 incidents of wrong dialyzer being used on patients. He further stated that he had not participated in providing training and education for staff and had been relying on the FA and Nurse Manager in providing training and education for staff.	V 712		
V 713	494.150(b) MD RESP-STAFF ED, TRAINING & PERFORM Medical director responsibilities include, but are not limited to, the following: (b) Staff education, training, and performance. This STANDARD is not met as evidenced by: Surveyor: 23046	V 713		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 713	Continued From page 75 Based on interview and record review, the facility's Medical Director failed to ensure that all staff had completed annual Infection Control Training. Findings: During a record review on 12/30/09 at 8:15 AM, 12 personnel files were reviewed. Of the 12 personnel files reviewed, 3 had not completed annual Infection Control Training. During an interview on 12/30/09 at 2:15 PM, the Facility Administrator verified 3 personnel had not completed annual Infection Control Training. During a record review on 12/30/09 at 2:30 PM, the policy titled "Injury Prevention and Safety Training Inservices" indicated "Mandatory inservices include the following: (Initially and Annually) Bloodborne Pathogen Regulations, Medical Waste Management, Safety Needle Program ... " During an interview with the Medical director on 1/4/09, at 11:30 AM, he was asked if he had participated in staff training and education. the Medical Director stated that he had not participated in providing training and education for staff and had been relying on the FA and Nurse Manager in providing training and education for staff.	V 713		
V 715	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and	V 715		3/19/10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 715	Continued From page 76	V 715		

safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers;

This STANDARD is not met as evidenced by:
Surveyor: 23046
Based on observation, interview and record review, the facility's Medical Director failed to ensure that that staff who provided care to patients in the facility adhered to the facility's policies and procedure and guidelines regarding the implementation of infection control program, physical environment, comprehensive assessments and plan of care and the QAPI program.

The Medical Director's failure to oversee and ensure that facility policies and procedures were implemented by all staff created multiple risks to staff and patients' health and safety.

Findings:

1. During review of the facility's Infection Control Policy and Procedure dated and revised 2008 on 12/30/09, the following were noted:

a. During an observation on 12/28/09 at 8:30 AM, PCT 3 was wearing gloves during discontinuation of hemodialysis for the patient at machine #18. She pushed the footrest of the chair down with her gloved hands and returned to the patient's access site with the same gloves. Then she touched machine #18 with gloved hands and touched machine #21 with the same gloves. PCT 3 then discarded gloves and donned new gloves to perform site care without using hand sanitizer or washing her hands. She removed these

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ____ B. WING ____	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 715	Continued From page 77	V 715		

gloves, did not use sanitizer or wash hands and touched machine #19.

During an interview on 12/31/09 at 8:45 AM, the Nurse Manager stated his expectation was that staff performs proper hand hygiene.

During a record review on 12/30/09 at 8:15 AM, the facility policy titled "Infection Control for Dialysis Facilities" (Policy 1-05-01) dated and revised September 2009, indicated the following:

"1. Hand hygiene is to be performed upon entering the facility, prior to gloving, after removal of gloves, after contamination with blood or other infectious material, after patient and dialysis delivery system contact, between patients even if the contact is casual, before touching clean areas such as supplies and before leaving the patient care area." And, "9 Gloves should be worn when touching the blood lines, dialyzer or dialysis delivery system during or after a dialysis treatment," and "10. Gloves should be changed when ...after touching one patient or their dialysis delivery system and before arriving to care for another patient or touch another patient's dialysis delivery system."
b. During review of the policy and procedure for Hepatitis Surveillance, Vaccination and Infection Control Measures (Policy: 1-05-02) under vaccination on page 5 of 7, the following were documented:

"21. Test all vaccinated patients for HBsAB (same as anti-HBs) one (1) to two (2) months after the last dose of the full vaccine series.

22. If HBsAb is <10 mIU/mL, consider the patient susceptible, revaccinate with an additional full

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100** **MONTCLAIR, CA 91763**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 715	Continued From page 78	V 715		

series, and retest for HBsAb 1 to 2 months after the last dose of the second series...."

During review of Patient 12's Care Plan - Progress Notes dated 9/25/09, it indicated that she had received the complete hepatitis B vaccine series on 9/25/08, and the test for the presence of antibodies (anti-HBs) had not been performed until 9/10/09 almost one year after receiving the vaccine risking exposure to hepatitis B infection.

The test result dated 9/10/09 indicated that Patient 12's anti-HBs level was 2 which was indicative of non-immune status and susceptible to hepatitis B infection (anti-HBs of less than 10 = susceptible; greater than 10 = immune).

No further documentation in medical record was found indicating that Patient 12 had been given the hepatitis vaccine booster after 9/10/09.

During an interview with the FA on 12/29/09, at 9:45 AM, he reviewed Patient 12's immunology and vaccination report and confirmed that the test result indicated Patient 12 was not immune to hepatitis B and had not been revaccinated with booster vaccine.

b. Review of the policy titled "Tuberculosis Monitoring and Follow-up" indicated that follow up of TB screening using TST (Tuberculin Skin Testing) will occur on an annual basis, from the date of the last TST using a one step method based.

During review of staff personnel files on 12/30/09, 5 of 12 personnel files had not completed annual tuberculosis screening for 2009.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 715	Continued From page 79 During an interview on 12/30/09 at 2:15 PM, the Facility Administrator verified that 5 personnel had not completed annual tuberculosis training in 2009. c. During review of the facility 's policy titled Tuberculosis Infection Control Policy (Policy 1-05-03), with revised date December 2008, on 12/30/09 at 4 PM, the following were noted: "If the patient has or has had a positive TST (Tuberculin Skin Test) or QFT-G (Quantiferon TB Gold) a physician documented medical follow-up/clearance and negative chest x-ray (completed within the last three months) will be provided and maintained in the patient ' s medical record. Chest x-rays obtained for the sole purpose of verifying correct positioning of a catheter or CVC will not be accepted. On-going annual screening will be accomplished via the TB-RAQ (TB Risk Appraisal Questionnaire) only. " During a record review on 12/29/09 at 11:20 AM, Patient 9's Tuberculin Skin Test Record indicated he was administered the skin test on 5/11/09 and on 5/13/09, RN 1 documented the results as "positive 30mm x 30 mm" and "needs chest x-ray." During a record review on 12/29/09 at 3 PM, Patient 9's Patient Care Plan dated 4/24/09 read he had missed 15 treatments in the last 60 days and "Pt in Mexico at this time." During an interview on 12/31/09 at 9:20 AM, when asked how the facility monitored for tuberculosis with patients traveling to and from Mexico, the	V 715		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MONTCLAIR DIALYSIS CENTER	**5050 PALO VERDE STREET, SUITE 100 MONTCLAIR, CA 91763**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 715	Continued From page 80 Nurse Manager stated the facility had a scale to measure the tb skin test and if the patient appeared sick, he would call the doctor. Patient 9's chest x-rays for 2009 were requested from the Facility Administrator on 12/29/09 at 8:25 AM and were not received. Patient 9's chest x-rays and the Risk Appraisal Questionnaire were requested from the Clinical Services Specialist (CSS) on 12/31/09 at 10 AM and no records were received. d. Review of the policy titled "Injury Prevention and Safety Training Inservices" (Policy 4-01-02), it indicated that mandatory inservices for staff included the following: (Initially and Annually) Bloodborne Pathogen Regulations, Medical Waste Management, Safety Needle Program ... " During review of staff personnel files on 12/30/09, 3 of 12 staff had not completed annual Infection Control Training. During an interview on December 30, 2009 at 2:15 p.m., the Facility Administrator verified that 3 personnel had not completed annual Infection Control Training. e. During an observation on December 28, 2009 at 1:40 PM, the Facility Administrator (FA) was standing next to the patient at station 12. The two visitors with the patient at station 12 were wearing protective garments; however, the FA was not wearing any protective garment. The hemodialysis treatment for the patient at station 11 next to the FA was being terminated at this time which had the potential for blood splatter. The FA continued to talk to the patient at station 12 for several minutes and left the treatment area	V 715		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052804	A. BUILDING ______ B. WING ______	01/04/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 715	Continued From page 81	V 715		

without donning a protective garment.

During a record review on 12/30/09 at 4:00 PM, the Infection Control Policy & Procedure (Policy 1-05-01) dated and revised 9/09, the following were noted:

"13. ... Appropriate lab coats or gowns will be worn at all times when on the treatment floor."

f. During a tour of the facility with RT 4 on 12/28/09 at 9:55 AM, inside the biohazard (medical waste harmful to health) room were 10 large red biohazard barrels, two clean bleach containers for disinfection of machines and 6 new clean biohazard sharps containers placed next to the red biohazard barrels.

During interview with RT 4 on 12/28/09, at 9:55 AM, she was asked if the clean items had to be stored in the biohazard room. RT 4 stated, "Yes, this is where we store them."

During a record review on 12/30/09 at 4:00 PM, the Infection Control Policy & Procedure (Policy 1-05-01) dated and revised 9/09, the following were noted:

"43. ... Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. ... Teammates will not ... store clean supplies in the same or adjacent area to that where used equipment ... are handled."

2. During review of the facility's Adverse Occurrence Log (AOR) on 12/30/09, it indicated that on 6/17/09, unsampled Patient 16 was started on dialysis using another patient's

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V 715	Continued From page 82	V 715		

dialyzer, and on 7/24/09, unsampled Patient 17 had been started on dialysis using a wrong dialyzer.

Documentation in the patient progress notes dated 6/17/09 indicated that Patient 16 had been on dialysis for 5 minutes before staff discovered the error.

During interview with the Nurse Manager on 12/30/09, at 1:50 PM, he confirmed and acknowledged that wrong dialyzers were used during dialysis treatment for unsampled Patient 16 on 6/17/09 and Patient 17 on 7/24/09. He further stated that staff had failed to check and confirm the identity of the dialyzer and the patient before initiating dialysis.

During interview with the PCT 4 on 12/30/09, at 3:45 PM, she stated, "We're (PCT 4 and 5) supposed to verify identification of the dialyzer and the patient before initiating treatment and that's where we failed."

During review of the facility's Hemodialysis Policy and Procedure (Procedure: 1-03-02) revised and dated September 2009, the following were documented:

"... Two teammates are to confirm and document the identity of the patient and the reused dialyzer prior to initiating the dialysis treatment. Patients should be encouraged to identify their reused dialyzer prior to treatment initiation."

3. During review of the facility's Post Treatment Patient Assessment (Policy: 1-03-12) dated September 2007, the following were documented:

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V 715	Continued From page 83	V 715		

"The patient care staff will obtain and document basic data on each patient post dialysis and compare to pre dialysis findings.... Assessment data may include the following: ... cardiac status, respiratory status peripheral edema, vascular access, mental status, patient subjective statement and ambulatory status. The licensed nurse notifies the physician as needed of changes in patient's status. All findings, interventions and patient responses are documented in the patient's medical record."

During an observation on 12/28/09 at 8:40 AM, Patient 8 was observed during dialysis treatment discontinuation. She complained of feeling cold and nauseous and had an emesis basin on her lap. Her blood pressure was 184/128 (normal is 120/80).

During a record review on 12/28/09 at 4 PM, Patient 8's Comprehensive Orders Worksheet contained physician orders dated 5/18/09 for Clonidine (medicine for high blood pressure) 0.1 mg po (by mouth) prn (as needed). Her Post Treatment Records indicated the following:

On 12/16/09 at 5:38 AM, Patient 8's hemodialysis treatment was initiated with a blood pressure of 212/126. RN 1 assessed her at 5:50 AM and no evaluation or intervention for the hypertension was documented. At 6 AM, her blood pressure was 191/128 and no assessment or intervention was performed. Patient 8's treatment was terminated 40 minutes early with a post treatment blood pressure of 129/100. No post treatment assessment was performed.

On 12/18/09 at 5:35 AM, Patient 8's hemodialysis treatment was initiated with a blood pressure of

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V 715	Continued From page 84 211/133. RN 1 assessed her at 6 AM and no evaluation or intervention for the hypertension was documented. No post assessment was performed when treatment was completed at 8:38 AM. On 12/21/09 at 5:30 AM, Patient 8's hemodialysis treatment was initiated with a blood pressure of 209/133. RN 1 assessed her at 6 AM and no evaluation or intervention for the hypertension was documented. Patient 8's treatment was terminated at 8:25 AM with a blood pressure of 157/129. No post assessment or intervention was documented. During an interview on 12/31/09 at 9:20 AM, the Nurse Manager (NM) stated he would expect the nurse assessing a patient prior to hemodialysis to contact the physician if a blood pressure was above 180 and the nurse could give Clonidine.	V 715		
V 726	494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility. This STANDARD is not met as evidenced by: Surveyor: 07599 Based on clinical record review and staff interviews, the facility failed to maintain complete and accurate records for 2 of 12 sampled patients (Patients 4, and 9) and 15 non-sampled patients. Findings:	V 726		3/19/10

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V 726	Continued From page 85 On 12/29/09 a review of the clinical record for Patients 4 and 9 revealed physician's progress notes, an indication of the patients' health status, were completely illegible. Facility staff from the RN clinical manager to the Dietician were asked to interpret the physician's notes without success. A further review revealed the physician provided care for 17 of the facility's 118 patients. An interview with the Clinical Services Specialist revealed that the nephrologist did not read each other's records and the nurses make rounds with the doctors on such a regular basis that they know the orders and the information that is relayed to the physician and have no need to read the progress notes. A further interview with the Medical Director of the facility on 1/04/09 at 11:30 AM, confirmed that nephrologist do not read each other's records however he was not made aware of the patients illegible records until recently.	V 726		
V 727	494.170(a) MR-PROTECT PT RECORDS FM LOSS/CONFIDENTIAL The dialysis facility must- (1)Safeguard patient records against loss, destruction, or unauthorized use; and (2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following: (i) The transfer of the patient to another facility. (ii) Certain exceptions provided for in the law. (iii) Provisions allowed under third party payment contracts. (iv) Approval by the patient. (v) Inspection by authorized agents of the Secretary, as required for the administration of	V 727		3/19/10

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V 727	Continued From page 86 the dialysis program. This STANDARD is not met as evidenced by: Surveyor: 26215 Based on interview and record review, the facility failed to provide state surveyors with complete medical records during inspection of the facility in a timely manner. Findings: 1. During a record review on 12/29/09 at 8:25 AM, no current dialysis orders were present in the medical record for Patient 9. During an interview at this time with the Nurse Manager, he was unable to find current orders and stated "They must have been thinned. They are not supposed to thin those." On 12/29/09 at 11:45 AM, current care plans for 7 sampled patients (Patients 1, 2, 5, 7, 8, 9, 10) were requested from the Facility Administrator. At 2:20 PM, these records had not been received. On 12/30/09 at 3:45 PM, the complete orders for prn (as needed) medications were requested from the Clinical Services Specialist. On 12/31/09 at 8:30 AM, the Clinical Services Specialist stated, "I contacted IT and prn medication indications and frequency won't print out. You can only see them on the computer." □ Surveyor: 23046 2. During record review on 12/29/09, at approximately 11:30 AM, multiple patient care plans were found not updated or could not be found in the patients' medical record. Current	V 727		

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V 727	Continued From page 87 care plans for the 7 sampled patients (Patients 1, 2, 5, 7, 8, 9, 10) were then requested from the Facility Administrator (FA) and at approximately 3 PM, the requested records had not been received and reason not known until after the interview of the facility's social worker. During an interview with the facility's social worker on 12/29/09, at 3:05 PM, she stated that patient care plans were not kept in the patient's medical record but in a separate binder and kept in the nurse manager's office. The social worker further stated that the nurse manager's room would be locked past normal day time office hours and the patient care plans would not be accessible to staff during that time. The nurse manager's office was a separate room located away from the treatment floor and the medical records storage area. During interview with the Clinical Care Specialist (CCS) on 12/29/09, at 4 PM, she stated that the care plan binder will be moved from the nurse manager's office to the medical records storage cabinet in order to be accessible to all staff.	V 727		
V 729	494.170(b)(1) MR-COMPLETE RECORDS PROMPTLY (1) Current medical records and those of discharged patients must be completed promptly. This STANDARD is not met as evidenced by: Surveyor: 07599 Based on interview and clinical record review, the facility failed to complete the discharge record for 1 of 1 patient (Patient 4). Findings:	V 729		3/19/10

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V 729	Continued From page 88	V 729		

On 12/30/09 a review of the clinical record for Patient 4 revealed the patient was admitted on 9/30/09 with diagnoses which included; end stage renal disease and type 2 diabetes. Patient 2 expired on 12/3/09. A review of the clinical record from 09/30/09 failed to include the following documentation:

a. the rounding report which includes the physician's orders, lab results, nutrition/metabolic assessment, dialysis adequacy, and treatment assessment.
b. any nursing documentation of concerns relating to the treatment of the patient and communication with the physician.
c. a plan of care developed by the interdisciplinary team (IDT)

An interview with the Clinical Nurse Specialist (CSS) on 1/4/2010 at 4:15 PM, revealed the documentation noted above was stored in the computer and not printed and placed in the patient's closed record.