

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
| NAME OF PROVIDER OR SUPPLIER CORNERHOUSE DIALYSIS CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2005 NAGLEE AVENUE SAN JOSE, CA 95128 | | |
| (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 000 | INITIAL COMMENTS The following reflects the findings of the California Department of Public Health during a recertification survey conducted from 1/24/11 to 1/28/11. Representing the Department: Nikki Kratt, HFEN; Helen Ho, HFEN; Elida Huerta, HFEN; and Karen Riley, HFEN. | V 000 | | | |
| V 110 | 494.30 CFC-INFECTION CONTROL This CONDITION is not met as evidenced by: Based on observation of care delivery, interview with staff, and record review, the facility failed to comply with the Condition for Coverage for Infection Control as demonstrated by: Failure to ensure six staff (RN A, RN D, PCT A, PCT C, PCT I, and PCT H) followed facility policies for hand hygiene and glove changes for 12 patients observed (Patients 7, 8, 11, 24, 30 and the patients at stations 2, 12, 13, 15, 16, chair 13, and in the isolation room). (V113) Failure to ensure two staff (PCTs A and C) followed the policy for nondisposable items which can not be disinfected, such as rolls of tape, for three patients (Patient 3 and patients at stations 8 and 7). (V116) Failure to ensure clean areas were kept clean. One staff (RN D) placed the face shield she wore during catheter care for Patient 8, on the top of the clean supply cart, causing cross | V 110 | | 3/5/11 | |

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 110 | <p>Continued From page 1</p> <p>contamination of clean supplies. (V117)</p> <p>Failure to ensure four staff (PCTs A, B, C, and H) followed standard infection control precautions when cleaning and disinfecting contaminated equipment for five patients observed (Patients 2, 24, and the patients at station 3, chairs 1 and 13). (V122)</p> <p>Failure to ensure susceptible patients to Hepatitis B were vaccinated according to facility policy and CDC guidelines by not having a system in place to track Hepatitis B vaccination administration to assure timely completion of the ordered course for one (Patient 4) of nine sampled patient and by not revaccinating two random susceptible patients (Patients 22 and 26) with a second full Hepatitis B vaccine series. (V126)</p> <p>Failure to ensure staff used personal protective equipment when entering the isolation room while one (Patient 2, known to test positive for Hepatitis B infection) of 10 sampled patients was receiving dialysis treatment. (V130)</p> <p>Failure to follow the Centers for Disease Control (CDC) recommendation to ensure staff caring for Hepatitis B positive patients do not care for Hepatitis B susceptible patients at the same time. (V131)</p> <p>Failure to ensure four (RNs A, B, C, and D) of four staff observed followed the policy for catheter care for three (Patients 2, 7, 8) of four sampled patients and four (Patients 20, 25, 28, 29) random patients with catheters. (V147)</p> <p>The cumulative effect of these failures constituted</p> | V 110 | | | |

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| V 110 | Continued From page 2 a severe safety breach that limited the facility's ability to furnish adequate care and had the potential to cause patient harm. | V 110 | | | |
| 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: Based on observation, interview and record review, the facility failed to ensure six staff (RN A, RN D, PCT A, PCT C, PCT I, and PCT H) followed facility policies for hand hygiene and glove changes for 12 patients observed (Patients 7, 8, 11, 24, 30 and the patients at stations 2, 12, 13, 15, 16, chair 13, and in the isolation room). This failure caused cross-contamination, increasing the risk of infection for the patients and the staff. Findings: According to the Center for Disease Control (CDC), hand hygiene is the most important measure to prevent contaminant transmission. CDC recommends the use of gloves as exposure to blood and potentially contaminated items is routinely anticipated during hemodialysis. Staff should wear gloves when touching blood lines, dialyzer or machine during or after a dialysis treatment, when inserting or removing the vascular access needles, when cleaning and disinfecting machines. Gloves should be changed | V 113 | | 3/5/11 | |

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| V 113 | <p>Continued From page 3</p> <p>when soiled, when moving from an area/task where there was potential for contamination (i.e. removing lines) to a clean area or task (i.e. after touching one patient or a patient's machine and before providing care to another patient or touching another patient's machine.</p> <p>During review on 1/24/11 of the facility policy titled, "Infection Control For Dialysis Facilities" (dated September 2010), the following were noted:</p> <p>a. "Teammate Hygiene" "Hand hygiene is to be performed prior to gloving, after removing gloves, after patient and dialysis delivery system contact, and before touching clean areas such as supplies."</p> <p>b. "ChairSide Snappy Terminal and Cart (mobile computer station)" "The ChairSide Snappy cart, monitor, and keyboard are considered clean areas. Gloves are to be removed and hands washed or alcohol-based hand rubs used before and after touching the keyboard."</p> <p>1. On 1/25/11 at 8:25 a.m., PCT I was observed setting-up the dialysis machine at station 15 without first doing hand hygiene. Prior to this, he was observed performing patient-related tasks at stations 13 and 16. At one point, PCT I was observed reaching over to silence an alarm on the machine at station 16 and immediately resuming setting-up the machine at station 15.</p> <p>2. On 1/25/11 at 11:17 a.m., PCT I was observed adjusting Patient 11's television while wearing the same gloves he had worn while caring for another</p> | V 113 | | | |

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| V 113 | Continued From page 4 patient. 3. At 11:47 a.m. on 1/25/11, PCT I was observed trying to cannulate Patient 7's access. During the procedure, PCT I removed his gloves, walked to the clean nursing supplies cart and picked up another cannula (a piece of sterile flexible tubing with the needle attached at one end) from the clean supply cart without first performing hand hygiene. When he returned to Patient 7, he donned a new pair of gloves without first performing hand hygiene. 4. On 1/26/11 at 9:15 a.m., PCT C was observed pulling the sharps container (used for the disposal of used needles or other sharp instruments) out from under Patient 24's chair-side table with a gloved hand in preparation for removing the patient's first needle. She then proceeded to apply an arm clamp over the gauze covering the site. Then, without changing gloves, PCT C repositioned the sharps container with her other gloved hand. As soon as she removed the second needle, the other arm clamp fell onto the floor. After asking the patient to apply pressure to the gauze with his gloveless hand, PCT C walked over to the supply of clean clamps and retrieved another clamp without first removing her soiled gloves, and without performing hand hygiene, and donned a new pair of gloves. PCT C was interviewed regarding the sharps container observations, but she denied ever touching them with her hands. "I always use my foot to move the container." When informed she was observed touching the container with her contaminated gloves on two separate occasions, PCT C still denied what she did. | V 113 | | | |

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| V 113 | <p>Continued From page 5</p> <p>5. On 1/26/11 at 10:50 a.m., PCT C was observed stripping the used blood lines from the dialysis machine at station 2. She then took the lines and the dialyzer into the reuse room, disposed of the lines, bagged and labelled the dialyzer, and placed it in the storage refrigerator. PCT C returned to the treatment area still wearing the same contaminated gloves. She then removed the gloves and, without performing hand hygiene, proceeded to use the chair-side keyboard.</p> <p>On 1/26/11 at 11:30 a.m., the infection control manager was informed that staff was observed handling used blood lines and a patient's dialyzer, removing the gloves, and without performing hand hygiene, using the computer keyboard. The infection control manager stated, "They're supposed to wash their hands or do hand hygiene after they remove gloves. They need some education." The infection control manager stated computer keyboards were considered clean, but agreed would be contaminated if used by staff not performing hand hygiene.</p> <p>6. On 1/26/11 at 1:55 p.m., PCT C was observed using a wadded-up glove to touch the machine at station 12 and silence an alarm.</p> <p>7. On the same day at 2:05 p.m., PTC C was observed silencing an alarm on the machine at station 12 with her finger wrapped in the protective gown she was wearing.</p> <p>8. On 1/24/11 at 9:27 a.m., PCT A cleaned the dialysis machine after a patient's hemodialysis treatment and proceeded to set up new dialysis</p> | V 113 | | | |

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| V 113 | <p>Continued From page 6</p> <p>tubing at the same machine for the next patient, using the same pair of gloves.</p> <p>9. On 1/24/11 at 11:22 a.m., while in the isolation room, RN A had a glove only on her right hand and touched the dialysis machine screen. RN A took off the glove and without performing hand hygiene, proceeded to do data entry on the computer keyboard. At 11:46 a.m., RN A again took her gloves off after performing patient assessment and, without performing hand hygiene, went directly to the computer keyboard.</p> <p>10. On 1/25/11 at 3:24 p.m., using gloves, PCT H cleaned the chair number 13 and chairside equipment after a patient treatment, but did not wash or use alcohol based hand cleaner after he removed the gloves.</p> <p>11. On 1/25/11 at 3:30 p.m. PCT I removed his gloves and proceeded to get a roll of tape from another patient's chairside table. Without performing hand hygiene, PCT I put on new gloves and began to tear tape into strips for another patient.</p> <p>12. On 1/25/11 at 4:05 p.m. PCT H after the end of a hemodialysis treatment removed the reuse dialyzer and tubing from the dialysis machine and capped all open ends of the dialyzer. PCT H disposed the tubing in the biohazard container and bagged, labeled and put the dialyzer in the reuse refrigerator. PCT H took his gloves off and proceeded to enter data on the computer keyboard, without performing hand hygiene.</p> <p>12. On 1/26/11 at 12:15 p.m., PCT A was observed at station 3 where Patient 30 was undergoing dialysis. PCT A was wearing a gown</p> | V 113 | | | |

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| V 113 | Continued From page 7 and touching a dialysis machine screen at station 3 with a wadded up glove in his bare hand. Discarding the glove, he began touching Patient 30's arm close to her vascular access with his bare hands. He then donned gloves without performing hand hygiene, and began to manipulate her blood lines. He stated to Patient 30, "You're still bleeding (at the vascular access)." PCT A discarded his gloves and without performing hand hygiene, began entering data into the computer keyboard. PCT A then partially unbuttoned his gown and used his gown to touch the dialysis machine screen. PCT A went back to the keyboard and resumed entering data. PCT A donned new gloves, touched the dialysis machine, manipulated Patient 30's blood lines, then flushed the blood lines with some saline solution. Without changing his gloves or performing hand hygiene, he walked to station 12 and touched the dialysis machine screen. | V 113 | | | |
| V 116 | 13. Following observation of catheter care for Patient 8 on 1/25/11 at 3:45 p.m., RN D removed Patient 8's face mask, then removed her gloves. RN D applied alcohol gel to her hands and briefly rubbed them together. She then removed her face shield. Without performing hand hygiene, RN D donned a new pair of gloves and walked over to the patient at station 13 where she assessed the patient's access by palpating it (touching the access to feel circulation). She then removed her gloves and without performing hand hygiene, donned a new pair of gloves. She proceeded to listen to the patient's lungs and touched Patient 8's legs for edema (swelling). 494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT | V 116 | | 3/5/11 | |

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| V 116 | <p>Continued From page 8</p> <p>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.</p> <p>-- 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.</p> <p>-- 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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure two staff (PCTs A and C) followed the policy for nondisposable items which can not be disinfected, such as rolls of tape, for three patients (Patient 3 and patients at stations 8 and 7). This failure caused potential for cross-contamination, increasing the potential for infection.</p> <p>Findings:</p> <p>1. On 1/26/11 at 10:45 a.m., after terminating Patient 3's treatment, PCT C picked up an unused roll of tape from the top of the dialysis machine and returned it to the clean supply cabinet for that station.</p> <p>2. On 1/26/11 at 12:35 p.m., PCT A was observed removing contaminated post-dialysis</p> | V 116 | | | |

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| V 116 | <p>Continued From page 9</p> <p>supplies from the chair-side table at station 8. While wearing contaminated gloves, PCT A placed the used roll of adhesive tape on top of the dialysis machine. After disposing of the supplies and returning to the station, PCT A performed hand hygiene, donned clean gloves, and proceeded to disinfect the dialysis machine without discarding the tape. A few minutes later, the same roll of tape was noted missing from the top of the machine; however, it had not been observed being discarded. After observing PCT A set-up the machine for the next patient, he was asked about the roll of tape. At this time, PCT A picked up a used roll of tape from the chair-side computer stand shared between stations 7 and 8, and stated, "This is probably it."</p> <p>During review on 1/26/11 of the facility policy titled, "Infection Control For Dialysis Facilities" (dated September 2010", the following were noted:</p> <p>"a. Teammate Hygiene Hand hygiene is to be performed prior to gloving, after removing gloves, after patient and dialysis delivery system contact, and before touching clean areas such as supplies.</p> <p>b. Teammate/Patient Safety Non-disposable items that cannot be cleaned and disinfected (e.g., adhesive tape) will be dedicated for use only on a single patient. Unused supplies 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. Only teammates with clean hands may remove items from the supply cart.</p> | V 116 | | | |

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| V 116 | Continued From page 10 | V 116 | | | |
| V 117 | <p>d. ChairSide Snappy Terminal and Cart The ChairSide Snappy cart, monitor, and keyboard are considered clean areas. Gloves are to be removed and hands washed or alcohol-based hand rubs used before and after touching the keyboard."</p> <p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS</p> <p>Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure clean areas were kept clean. One staff (RN D) placed the face shield she wore during catheter care for Patient 8, on the top of the clean supply cart, causing cross</p> | V 117 | | 3/5/11 | |

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| V 117 | Continued From page 11 contamination of clean supplies. Findings: During observation of the end of catheter care for Patient 8 on 1/25/11 at 3:14 p.m., RN D discarded several blood filled syringes in the sharps container. RN D removed her gloves, then removed her face shield. Underneath her face shield, she had been wearing a face mask with her nose exposed. She placed her face shield on top of the clean supplies cart, where there were several opened boxes of supplies. On 1/26/11 at 11:30 a.m., RN C, serving also as the facility's infection control manager, was informed of the observed placement of personal face shields on the top of the clean supply cart. She stated, "The top surface of the supply cart is clean. People should not be putting face shields on top of the supply cart." | V 117 | | | |
| V 122 | 494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to ensure four staff (PCTs A, B, C, and H) followed standard infection control | V 122 | | 3/5/11 | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 122 | <p>Continued From page 12</p> <p>precautions when cleaning and disinfecting contaminated equipment for five patients observed (Patients 2, 24, and the patients at station 3, chairs 1 and 13) as evidenced by:</p> <p>PCT C retrieved wipes soaked in disinfectant solution using contaminated gloves which were previously used to provide care to Patient 24.</p> <p>PCTs B, C, and H did not fully reclined three treatment chairs (number 1 and 13 and the chair at station 3), to expose all potentially contaminated surfaces for cleaning between patients and PCT B returned the blood pressure cuff, after disinfecting it, to the contaminated basket at station 3.</p> <p>When the tubing attached to a blood pressure cuff touched a dirty sharps (used needles or other sharp instruments) container, PCT A continued to use it for Patient 2, without disinfecting it.</p> <p>These failures caused possible cross-contamination, increasing the potential for infection for patients and staff.</p> <p>Findings:</p> <p>1. On 1/26/11 at 1:10 p.m., PCT C was observed removing Patient 24's needles. Prior to removing the second needle, PTC C was observed repositioning the sharps container with her gloved hand. After removing and discarding the second needle, PTC C returned the sharps container under the chair-side table with her gloved hand. Then, without changing gloves, she walked to the supply of disinfectant wipes soaking in bleach solution, reached into the container, removed</p> | V 122 | | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 122 | <p>Continued From page 13</p> <p>several wipes, and immediately wrung out the excess fluid back into the container. PTC C then returned to station 12 and proceeded to disinfect the dialysis machine with the potentially-contaminated wipes.</p> <p>During an interview on 1/28/11 at 10:05 a.m. PCT D was asked what the proper procedure was for getting/reaching for cleaning wipes in the bleach solution. PCT D stated hands should be washed and clean gloves applied prior to reaching into the bleach solution to remove a wipe. PCT D stated used or dirty gloves should never be used to reach into the bleach disinfecting solution.</p> <p>2. On 1/27/11 at 2:30 p.m., observation showed approximately 3 inches of blood pressure cuff tubing was resting inside a dirty sharps container at Station 2. PCT A retrieved the cuff, reconnected the tubing to a blood pressure machine and wrapped the cuff around Patient 2's left arm without cleaning/disinfecting the tubing.</p> <p>3. The following observations of staff cleaning/disinfecting patient hemodialysis chairs after patients had completed their treatment, showed staff did not recline the chair to expose the area between the seat and the back of the chair and also to expose the area between the seat and the footrest of the chair:</p> <p>On 1/25/11 at 3:24 p.m. PCT H cleaned the dialysis chair number 13 with disinfecting wipes, but did not recline the chair.</p> <p>On 1/26/11 at 8:46 a.m. PCT C cleaned the dialysis chair number 1 after the dialysis treatment with disinfecting wipes, but did not recline the chair.</p> | V 122 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

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| V 122 | Continued From page 14 4. On 1/26/11 at 1:08 p.m., observation showed PCT B getting the dialysis machine ready for the next patient at station 3. He stated, "I haven't cleaned the chair yet." Prior to cleaning the chair, he removed a blood pressure cuff stuffed in a basket attached to the dialysis machine. He confirmed it had been used on the previous patient. After PCT B cleaned the blood pressure cuff and tubing using a sanitizing wipe, he placed it back in the basket, where it had previously been stored uncleaned. PCT B then proceeded to wipe down the treatment chair, which was in its most upright position. He opened the side arms of the chair to expose more chair surfaces to be cleaned. He was then informed that Patient 30, who had been sitting in the chair previously, had experienced bleeding at her site. Despite being directly informed the previous patient had experienced bleeding at her access site, PCT B did not recline the chair to more expose the back cushion to clean and ensure no blood was present. | V 122 | | | |
| 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: Based on interview and record review, the facility failed to ensure susceptible patients to Hepatitis B were vaccinated according to facility policy and CDC guidelines by: Failure to put a system in place to track Hepatitis B vaccination administration to assure timely | V 126 | | 3/5/11 | |

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| V 126 | <p>Continued From page 15</p> <p>completion of the ordered course for one (Patient 4) of nine sampled patients;</p> <p>Failure to revaccinate two random susceptible patients (Patients 22 and 26) with a second full Hepatitis B vaccine series.</p> <p>These failures increased the potential for Patients 4, 22, and 26 to contract Hepatitis B, a highly infectious disease.</p> <p>Findings:</p> <p>On 1/25/11, review of the facility policy "Hepatitis Surveillance, Vaccination and Infection Control Measures", dated December 2008, instructed, "Test all vaccinated patients for HBsAb (surface antibodies) one to two months after the last dose of the full vaccine series. If hepatitis B surface antibody is (less than) 10 mIU/ml, consider the patient susceptible, revaccinate with an additional full series, and retest for HBsAb one to two months after the last dose of the second series."</p> <p>a. During an interview on 1/26/11 beginning at 11:25 a.m., RN C stated she was assigned to be the facility infection control manager in October 2010. RN C was asked to review Patient 4's vaccination history.</p> <p>Review of Patient 4's vaccination history showed that Engerix, the Hepatitis B vaccine, was administered to Patient 4 on 5/11/09, 6/8/09, 7/31/09, and 8/17/10. RN C was asked if the fourth shot represented the fourth shot of the initial vaccination series or a booster vaccination. RN C stated it was a booster shot. RN C was asked if patients who failed to respond (develop</p> | V 126 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

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| V 126 | <p>Continued From page 16</p> <p>adequate antibodies showing immunity) to the first vaccination series should be given a booster shot or a second full series. She stated patients should receive a booster shot. She was informed the facility policy required a second full series be given, not a booster shot. RN C stated she was not aware that a second vaccination series was required and stated she had followed a policy that called for a booster shot to be given.</p> <p>During an interview on 1/26/11 at 4:45 p.m., the clinical services specialist (CSS) reviewed the vaccination status for Patient 4 and agreed the vaccination series was not completed as outlined in the facility policy "Hepatitis Surveillance, Vaccination and Infection Control Measures." The CSS stated she recalled there was a vaccine shortage around the time Patient 4's last injection was due. The CSS was asked why the vaccination series wasn't resumed when the vaccine became available. The CSS stated the previous infection control manager was not tracking patients' immunization schedules as expected.</p> <p>b. Review of the facility's schedule showed that two Hepatitis B positive patients dialyzed on the Monday-Wednesday-Friday schedule. Further review of the schedule showed patients who were considered susceptible to hepatitis B infection were marked with an asterisk to alert staff that the patients lacked immunity to Hepatitis B virus exposure. Patients 26's and 22's names were marked with an asterisk.</p> <p>On 1/26/11, review of the facility's Vaccination Report for the Monday-Wednesday-Friday dialysis patients showed Patient 26 was given the</p> | V 126 | | | |

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| V 126 | Continued From page 17 first Engerix vaccination series in 2009 with the fourth dose completed on 10/23/09. Review of the Hepatitis B surface antibody test (measures immunity to the Hepatitis B virus) done on 12/9/09 showed Patient 26 did not develop antibodies to the first full series of the Hepatitis B vaccine. There was no evidence that Patient 26 received a second full series of the vaccine when she did not develop antibodies. On 12/1/10, Patient 26's Hepatitis B surface antibody test again showed she had not developed antibodies that would make her immune. Patient 26 then received an injection of Engerix on 12/20/10, more than one year after the first series. c. Review of Patient 22's vaccination history showed he was given the first Engerix vaccination series in 2009 with the fourth dose completed on 9/21/09. On 11/23/09, his surface antibody test result showed he had not developed antibodies. Patient 22 was not revaccinated with a full second series. On 11/26/10, his surface antibody test result showed he failed to develop sufficient antibodies. On 12/20/10, he received an injection of Engerix, more than one year later. | V 126 | | | |
| V 130 | CSS confirmed the findings on 1/26/11. 494.30(a)(1)(i) IC-HBV-ISOLATION-MACHINES/EQUIP/SUPPLIES Isolation of HBV+ Patients To isolate HBsAg positive patients, ... dedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV susceptible patients. | V 130 | | 3/5/11 | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

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| V 130 | <p>Continued From page 18</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and record review, the facility failed to ensure staff used personal protective equipment when entering the isolation room while one (Patient 2, known to test positive for Hepatitis B infection) of 10 sampled patients was receiving dialysis treatment. Also, staff failed to perform handwashing prior to exiting the isolation room.</p> <p>The facility failure increased the risk of cross-contamination and exposure to the hepatitis B virus.</p> <p>Definitions:</p> <p>Hepatitis B Virus; a virus that causes an inflammation of the liver. The virus is found in blood and body fluids and is able to live for at least seven days on surfaces. The virus is transmitted through breaks in the skin or through mucous membranes. In the hemodialysis centers/clinics where multiple patients are receiving hemodialysis at the same time, and at multiple times per week there is increased risk of exposure to direct or indirect transmission of the virus. Transmission can occur via contaminated hands of dialysis staff, contaminated equipment, supplies, and environmental surfaces.</p> <p>Personal protection equipment includes long sleeved fluid resistant gown, gloves, face shield, or mask and eye protection.</p> <p>Findings:</p> <p>Observation on 1/26/11 at 12:10 p.m. showed Patient 2, a Hepatitis B positive patient, was in</p> | V 130 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

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| V 130 | Continued From page 19 the isolation room undergoing hemodialysis. PCT A entered the isolation room, with no protective gown on, and proceeded to disconnect and reconnect the bicarbonate line from the outlet connection. At 12:12 p.m., PCT A again entered the isolation room without a gown or gloves. PCT A had a wadded glove in his right hand that he used to push on the dialysis machine screen to make changes. PCT A discarded his wadded glove and proceeded to wash his hands at the sink in the isolation room. While standing at the sink, a yellow isolation gown hanging on the wall close to the sink, brushed against his scrub pants. During an observation on 1/26/11 at 12:54 p.m. RN A, after completing Patient 2's care in the isolation room, removed her personal protection equipment and exited the isolation room without washing her hands. RN A walked across the first two rows of dialysis patients to reach the handwashing sink located at the near end of a low wall that divided the treatment room in half. Review of the facility's policy and procedure, "Infection Control And Isolation Measures For Known Or Suspected Hepatitis B Surface Antigen Positive Patients", last revised 9/2010, showed that all staff entering the isolation room were to wear long-sleeved fluid resistant/fluid impervious gowns in addition to gloves, face shield, or mask and eye protection. After removing personal protection equipment and immediately before exiting the isolation room staff were to perform hand hygiene. | V 130 | | | |
| V 131 | 494.30(a)(1)(i) IC-HBV-ISOLATION-STAFFING Isolation of HBV+ Patients | V 131 | | 3/5/11 | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
|--|---|---|---|----------------------|---|
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| V 131 | <p>Continued From page 20</p> <p>Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to follow the Centers for Disease Control (CDC) recommendation to ensure staff caring for Hepatitis B positive patients do not care for Hepatitis B susceptible patients at the same time, as evidenced by:</p> <p>Allowing staff to simultaneously care for one random patient (Patient 19) who was susceptible to the Hepatitis B virus and for Patient 2, who was a Hepatitis B positive patient. This failure put Patient 19 at increased risk for Hepatitis B infection by cross-contamination.</p> <p>Failure to develop a policy and procedure that prohibited staff members caring for hepatitis B positive patients to care for patients that were susceptible to Hepatitis B infection. This failure could cause the susceptible patients to contract the Hepatitis B virus via cross-contamination.</p> <p>Findings:</p> <p>Hepatitis B infection is caused by the Hepatitis B virus (HBV). HBV is transmitted via blood or cross-contamination. Severe HBV infection can cause prolonged illness and destruction of liver cells, cirrhosis, increased risk for liver cancer and death. (Mosby's Medical, Nursing, & Allied Health Dictionary, 8th Edition, 2009)</p> | V 131 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

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| V 131 | Continued From page 21 According to the CDC's Recommendations for "Preventing Transmission of Infections Among Chronic Hemodialysis Patients" (April 27, 2001 / Vol. 50 / No. RR-5) Hepatitis B infections "continue to occur among chronic hemodialysis patients...HBV is relatively stable in the environment and remains viable (alive) for at least 7 days on environmental surfaces at room temperature. HBsAg (virus) has been detected in dialysis centers on clamps, scissors, dialysis machine control knobs, and doorknobs . Dialysis staff members can transfer virus to patients from contaminated surfaces by their hands or gloves or through use of contaminated equipment and supplies. Most HBV infection outbreaks among hemodialysis patients were caused by cross-contamination to patients via [...] staff members who simultaneously cared for both HBV-infected and susceptible patients." CDC recommendations include assignment of staff members to HBsAg-positive patients and not to HBV susceptible patients during the same shift. According to CDC, the segregation of HBsAg-positive patients and their equipment from HBV susceptible patients resulted in 70%-80% reductions in incidence of HBV infection among hemodialysis patients. 1. Record review on 1/24/11 showed that the facility had two hepatitis B positive patients who received hemodialysis, Patient 2 being one of them. The facility had one isolation room, which had been designated station 4. The dialysis treatment room, which included the isolation room was divided into four pods. Each pod had four stations, with three shifts of dialysis patients assigned to each pod. Station 14 was in POD 4. | V 131 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
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OMB NO. 0938-0391

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| V 131 | <p>Continued From page 22</p> <p>One PCT was assigned to each pod.</p> <p>The facility patient/PCT assignment sheet, dated 1/26/11, showed that PCT A (male) was assigned to POD 3 and PCT D (female) was assigned to POD 4. The assignment sheet had several patient names with an * (asterisk) beside the name. The * (asterisk) was defined on the left lower corner of the assignment sheet as marking patients having "**Hep B Quantity<10". Patients with hepatitis B antibody levels of <10 are not considered immune to the hepatitis B virus (Center for Disease Control).</p> <p>Patient 19, who was in POD 3, was one of the patients identified on the assignment sheet as not being immune to hepatitis B. The assignment showed that on 1/26/11 Patient 19 was put on hemodialysis at 10 a.m. and was taken off at 1 p.m.</p> <p>On 1/26/11 at 12:01 p.m. PCT A stated he was taking care of Patient 2 at station 14 because Patient 2 had "issues" with female employees.</p> <p>During an observation on 1/26/11 at 12:10 p.m. PCT A entered the isolation room while Patient 2 was receiving treatment. He was not wearing a protective gown and proceeded to disconnect and reconnect the bicarbonate line from the outlet connection. At 12:12 p.m. PCT A again entered the isolation room without a protective gown or gloves. PCT A had a wadded glove in his right hand that he used to push on the dialysis machine screen to make changes.</p> <p>At 12:24 p.m. PCT A was observed at Patient 19's chairside typing on the chairside computer</p> | V 131 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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| V 131 | <p>Continued From page 23</p> <p>keyboard. At 12:26 p.m. PCT A used a wadded glove to push on Patient 19's hemodialysis machine screen.</p> <p>On 1/26/22 at 2:50 p.m. RN A was asked how long Patient 2 had being refusing to be cared for by a female PCT. RN A checked the facility records and stated that it had been at least since 3/16/10. During the interview, RN A explained that PCTs team up and work together. RN A stated, for example PCTs in POD 3 and 4 would be one team and PCTs in POD 1 and 2 would be another team. When a female PCT was assigned to POD 4, which included the isolation room, a male PCT from POD 3 would take care of Patient 2.</p> <p>During an interview on 1/28/11 at 10:08 a.m., PCT D stated that PODS 3 and 4 work as a team and would relief each other for breaks and meals. PCT D was asked when PCT A (male) went on breaks who would be the PCT who would care for Patient 2, since Patient 2 disliked females. PCT D stated PCT B (male), who was from POD 2 would provide care to Patient 2.</p> <p>On 1/28/10 the facility printed out their "Vaccination Report" as requested. Review of the report showed that Patient 19's last test on 7/28/10 for hepatitis B antibody level was <1. Patient 19 was susceptible to being infected by the hepatitis B virus.</p> <p>During an interview on 1/26/11 at 12:40 p.m., the administrative assistant (AA) stated she and the facility manager created the treatment schedules for dialyzing patients and made the staff assignments as well, assigning each patient care</p> | V 131 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
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|--|--|---|---|----------------------|---|
| NAME OF PROVIDER OR SUPPLIER CORNERHOUSE DIALYSIS CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2005 NAGLEE AVENUE SAN JOSE, CA 95128 | | |
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| V 131 | Continued From page 24 technician (PCT) to one of the four "pods" on the treatment floor. POD 4 included the isolation room where a Hepatitis B positive patient would dialyze. The AA stated the PCT assigned to POD 4 would not be taking care of susceptible patients. Susceptible patients would not be treated in POD 4 as well to decrease the chance of contracting Hepatitis B. AA stated she was unaware of the history that staff accommodated Patient 2's request and would help care for her while maintaining their own patient assignments which included susceptible patients. 2. During an interview on 1/28/11 at 10:34 a.m. the clinical services specialist (CSS) was asked about the statement in the facility policy "Infection Control and Isolation Measures for Known or Suspected Hepatitis B Surface Antigen Positive Patients" (dated September 2010) allowing staff, "In situations where a teammate will provide care for both the confirmed or suspect hepatitis B surface antigen (HBsAg) positive and HBV susceptible patients at the same time, the teammate will change gown, change gloves and wash hands between patients." The CSS stated, "That would never happen here." She stated the policy was meant for facilities that were smaller or more rural where there were fewer location options for patients to dialyze. The CSS was informed that PCT A was observed entering the isolation room of a Hepatitis B positive patient (Patient 2) and then caring for his own patients which included Patient 19, a patient identified by the facility as susceptible to the Hepatitis B virus. | V 131 | | | |
| V 147 | 494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular | V 147 | | 3/5/11 | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 147 | <p>Continued From page 25 Catheters in Adults and Children</p> <p>I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.</p> <p>II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure four (RNs A, B, C, and D) of four staff observed followed the policy for catheter care for three (Patients 2, 7, 8) of four sampled patients observed and four (Patients 20, 25, 28, 29) random patients with</p> | V 147 | | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 147 | <p>Continued From page 26</p> <p>catheters. This failure caused possible cross contamination and increased the potential for infection.</p> <p>Findings:</p> <p>Review of the facility's policy Central Venous Catheter (CVC) Cleaning and Dressing Change indicated that personal protective equipment for the staff member consisted of "face protection, including face masks, gloves, fluid resistant/fluid impervious barrier garment." Staff was directed to, "ensure patient's face is turned to side opposite CVC exit site." The rationale was, "decreases the risk of aerosolized bacteria contaminating site." Also, "Both patient and teammate (staff) will wear face masks covering nose and mouth". The rationale was, "these measures are vital to preventing the exposure of the catheter and exit site to nasal droplets and infectious bacteria."</p> <p>While performing catheter care, staff was to remove the dressing covering the access site, "remove gloves and discard. Wash hands and re-glove." The rationale was, "Hand washing protects patient and teammate from cross contamination." After exit site (the location of the catheter's exit to the skin) care was performed, staff was to, "remove gloves and discard. Wash hands and re-glove." The rationale was the same, "Hand washing protects patient and teammate from cross contamination."</p> <p>1. Observation on 1/25/11 at 3:10 p.m. showed RN D preparing to perform catheter care for Patient 8. Patient 8 had a protective face mask covering her nose and mouth. RN D wore a face</p> | V 147 | | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 147 | <p>Continued From page 27</p> <p>shield and a face mask that covered her mouth but exposed her nose completely. RN D removed the dressing over the catheter limb leads. Without changing her gloves, RN D briefly wiped the connecting ports at the end of the limb leads with povidone-iodine swabs. At the same time, RN D spoke to Patient 8, exposing Patient 8's catheter site to possible contamination through the face mask. Patient 8 murmured an answer looking directly at RN D and likewise exposing her catheter site to potential contamination through her face mask. RN D then attached syringes to the ports and removed her gloves. Without performing hand hygiene, RN D walked a few steps to the clean supply cart and with her unwashed hands, pulled some clean packaged syringes out of the cart to place on Patient 8's side table and donned a new pair of gloves. RN D then removed the old syringes from the catheter ports and attached new syringes. RN D removed her gloves without performing hand hygiene afterward. She pulled her stethoscope from around her neck and listened to Patient 8's heart and lungs. RN D then applied some alcohol gel and rubbed her hands very briefly. RN D donned a new pair of gloves, removed the syringes from the ports and connected the dialysis machine's blood lines to the ports. Her face mask still completely exposed her nose while she accessed the ports.</p> <p>At 3:25 p.m., RN D prepared to perform catheter exit site care for Patient 8. RN D's face mask was positioned so the very tip of her nose was covered. RN D began to remove the exit site dressing. The border of the dressing was taped, and RN D began to remove the exit site dressing by lifting the tape. The tape stuck on one side; in</p> | V 147 | | | |

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| V 147 | <p>Continued From page 28</p> <p>an effort to release the tape, RN D placed her finger directly on the exposed catheter exit site. After removing the dressing, RN D changed her gloves but did not perform hand hygiene after removing her old gloves. RN D began to cleanse the site, using successive gauzes soaked with a cleansing agent. While cleaning the exit site, RN D's face mask slipped, again completely exposing her nose.</p> <p>RN D was interviewed afterward at 3:50 p.m. She was informed she was observed wearing her face mask with her nose exposed, talking to the patient while performing catheter care, touching the site, and not consistently performing hand hygiene after removing her gloves. RN D stated she thought her nose was covered but acknowledged she talked to Patient 8 while the catheter limbs were uncovered, that she did not consistently perform hand hygiene after removing her gloves and touched the catheter site during the dressing removal, stating the dressing was difficult to remove.</p> <p>2. On 1/25/11 at 3:40 p.m., observation showed RN B performing catheter care for Patient 29 at station 9. RN B wore a face shield and a face mask that barely covered her nostrils. RN B removed the old dressing over the catheter exit site. She removed her gloves and donned a new pair of gloves without first performing hand hygiene. While the exit site was exposed, she talked to Patient 29, exposing his uncovered exit site to her exhaled breaths. RN B cleansed the exit site with several alcohol wipes, applied antibiotic ointment to the exit site and covered the site with sterile gauze. During an interview immediately following the observation, RN B was</p> | V 147 | | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 147 | <p>Continued From page 29</p> <p>informed she was observed performing catheter care with her face mask not completely covering her nose and talking directly over the exposed catheter site. RN B acknowledged her deficient practice.</p> <p>3. On 1/26/11 at approximately 12:30 p.m. RN A was observed at station 15 disconnecting Patient 25's catheter limb leads and wearing a face shield, but no face mask, exposing Patient 25's exposed limb lead ports to her exhaled breath.</p> <p>4. On 1/25/11 at 11:18 a.m., RN D was observed already in the process of connecting the limbs of Patient 20's catheter to the bloodlines in preparation for dialysis. RN D was wearing a mask, which was covered by a face shield; however, her nose was not covered by the mask. As a result, every time RN D exhaled through her nose, the face shield increased the potential for contamination of the catheter connections by funneling the exhaled air from her nose down onto her gloves, the supplies, and the equipment in the area where she was working.</p> <p>After removing her gloves and donning a new pair, without first performing hand hygiene, RN D retracted the left side of Patient 20's blouse neckline, exposing the catheter site directly below the left clavicle (collar bone). Then, without changing gloves, she placed a clean, moisture-proof, disposable towel under the catheter limbs and proceeded to remove the old dressing and tape covering the catheter site. After disposing of the dressing, RN D changed her gloves, and without performing hand hygiene, placed a sterile gauze under each limb of the catheter, and wiped around the exit site with an alcohol pad only once. RN D then applied wet 4x4</p> | V 147 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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PRINTED: 05/26/2011
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|--|---|---|---|----------------------|---|
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| V 147 | <p>Continued From page 30</p> <p>gauze squares saturated with an unknown solution around the two limbs of the catheter, wiped the exit site once with an additional saturated 4x4, applied an antibiotic ointment directly to the exit site with a sterile applicator, covered the site and catheter down to the limbs with two sterile 4x4 gauze, and changed her gloves without performing hand hygiene.</p> <p>Prior to taping the dressing in place, RN D was again observed retracting the neckline of the patient's blouse (which had migrated down and was now approximately 1" away from the catheter site) with her gloved hand. She then readjusted the dressing with the same hand and proceeded to apply the tape. When she was finished, RN D removed her gloves and, without performing hand hygiene, removed her face shield and mask.</p> <p>5. At 11:47 a.m. the same day, RN D was observed performing Patient 7's catheter care: again her nose was exposed outside the mask, she changed gloves and did not perform hand hygiene, and removed the patient's garment with a gloved hand after it migrated to within an inch of the catheter exit site.</p> <p>During an interview with RN D at 1:00 p.m. the same day, she admitted her nose was not covered by her mask while taking care of Patient's 7 and 20. She also acknowledged the potential for further contamination of her glove when she retracted the patient's neckline, contamination of the patient's clothes with a catheter-related bloodstream infection, and infection of the patient's catheter site.</p> <p>During Patient 7's catheter preparation and care,</p> | V 147 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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FORM APPROVED
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| V 147 | <p>Continued From page 31</p> <p>patient care technician (PCT) E was observed standing on the other side of Patient 7, across from RN D. It was noted she was wearing only a face shield and no face mask as required.</p> <p>When interviewed at 1:05 p.m. the same day, PCT E could not remember not wearing a mask during the preparation and care of Patient 7's catheter.</p> <p>During a review of the policies and procedures for central venous catheter (CVC) care and dressing change, the following were noted:</p> <p>"The patient and teammate will wear face masks covering the nose and mouth during a catheter procedure. Whenever removing and/or donning gloves, hands must be washed. When disinfecting the limbs of the catheter, at least 4 alcohol pads are to be used per limb. After using the germicidal moistened 4x4 gauze on the skin, the air drying time is supposed to be two minutes before proceeding."</p> <p>6. On 1/27/11 at 3:45 a.m., observation showed RN C performed catheter care for Patient 28 while wearing a face mask and shield. The mask did not cover her nose. After rubbing her hands with alcohol gel, RN C donned a pair of gloves and handed a face mask for the patient to wear. RN D removed the dressing over the right subclavian central venous catheter (CVC) site. A subclavian CVC is a tube placed into a large chest vein to function as a site to perform dialysis. At the time of dressing removal and catheter cleaning, Patient 28 did not turn his head away but was looking at his catheter site. RN C did not ask the patient to turn his head.</p> | V 147 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

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| V 147 | Continued From page 32 | V 147 | | | |
| V 253 | <p>7. During an observation on 1/26/11 at 11:22 a.m. RN A did not wear a face mask along with other PPE (Personal Protective Equipment - face shield, gloves, and fluid resistant/fluid impervious barrier garment) while she did Patient 2's central venous catheter and hemodialysis tubing connections and catheter/site care. At 2:41 p.m., RN A was again not wearing a mask when she disconnected the dialysis tubing from the central venous catheter port limbs and flushed the ports with normal saline followed by heparin (medication to keep catheter from clotting).</p> <p>On 1/26/11 at 2:50 p.m. RN A confirmed she did not have a face mask on during the time she had done catheter/site care and during the time she had accessed the catheter port limbs.</p> <p>494.40(a) MICROB MONITOR-MO DIALYS SAMPLE/COLLECT/FREQ</p> <p>7.2 Microbial monitoring methods: 7.2.1 General: Dialysate: monthly dialysate sample/collection/freq Culture ...dialysate fluid weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution.</p> <p>Dialysate samples should be collected from at least two machines monthly and from enough machines so that each machine is tested at least once per year. If testing of any dialysis machine reveals a level of contamination above the action level, an investigation should be conducted that</p> | V 253 | | 3/5/11 | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 253 | <p>Continued From page 33</p> <p>includes retesting the offending machine, reviewing compliance with disinfection and sampling procedures, and evaluating microbiological data for the previous 3 months to look for trends. The medical director also should be notified. An example of a decision tree for this process is given in Figure 1.</p> <p>7.2.2 Sample collection Dialysate samples should be collected from a dialysate port of the dialyzer ... [or] dialysate sampling ports that can be accessed using a syringe. At least 25 mL of fluid, or the volume specified by the laboratory performing the test, should be collected in sterile endotoxin-free specimen containers.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to perform the yearly culture and endotoxin test for bacteria/micro-organism on dialysate from two of the five sample dialysis machines. The facility's failure to monitor their dialysis machine had the potential to put patients at an increased risk for infections from bacteria/micro-organism and also at risk from the effects of bacterial endotoxins.</p> <p>Definitions: Dialysate - The solution used in hemodialysis. Dialysate culture - To take a dialysate sample and put it in a controlled or special medium to see if any bacteria/micro-organisms grow. Endotoxins - Are part of certain bacterial cell walls and when these bacteria are destroyed the endotoxins are released. Depending on the quantity of toxins released they can cause fever, altered resistance to bacterial infection, severe</p> | V 253 | | | |

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| V 253 | Continued From page 34 diarrhea, shock. ("endotoxin," Encyclopedia & Dictionary of Medicine, Nursing, & Allied Health. Sixth Ed., 1997, p.533.) Findings: On 11/26/11, record review of the facility's dialysis machine culture and endotoxin log showed that dialysis machines 1 and 2 were last tested on 10/23/09. On 1/26/11 at 10:20 a.m. the Biomedical Technician was asked what the facility's schedule was for testing the dialysate from each machine for the presence of micro-organism and their endotoxins. Biomedical Technician stated two dialysis machines are done monthly and every machine was done yearly. The Biomedical Technician also stated that dialysis machines 1 and 2, "got missed". | V 253 | | | |
| V 350 | 494.50(b)(1) GERMICIDE PRESENCE TEST OF EACH DIALYZER 12.3.1 Presence test of each hemodialyzer Certain germicide manufacturers require testing for the presence of germicide in each hemodialyzer before the rinsing step. These instructions should be followed. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure staff followed the policy for testing for the presence of peracetic acid (a germicide) in a reused dialyzer prior to its clinical use for one (Patient 7) of ten sampled patients. This failure increased the potential for infection. Findings: | V 350 | | 3/5/11 | |

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| V 350 | <p>Continued From page 35</p> <p>The facility policy titled "Priming a Reprocessed Dialyzer Free of Peracetic Acid utilizing Althin 1000/TINA Dialysis Delivery Systems", dated September 2009, was reviewed on 1/27/11. The policy instructed the staff to, "Perform peracetic acid presence test per procedure prior to starting the priming procedure."</p> <p>1. During an observation of station 15 on 1/27/11 at 11:15 a.m., the following was noted:</p> <p>The hemodialysis machine was already set-up with Patient 7's reused dialyzer, which was currently being rinsed of the germicide left in the dialyzer during the reuse process.</p> <p>At the completion of the rinse, PCT G proceeded to begin priming (circulating normal saline solution through) the entire system. At this time, the two test strips used to test for the presence of the germicide, both prior to and after the rinse of the dialyzer, were not visible anywhere on the machine. When asked about the tests for the presence of the germicide, PCT G could not produce the test strip and stated, "I must not have done it."</p> <p>During an interview with one of the re-use technicians (RT K) later the same day, RT K stated, "The first test strip only tests for the presence of [germicide] in the dialyzer, while the second strip tests for the presence of remaining [germicide] after the rinsing of the dialyzer."</p> <p>During an interview on 1/28/11 at 9:50 a.m. PCT B was asked what the significance was when reused dialyzers were tested for the presence of</p> | V 350 | | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 350 | Continued From page 36 peracetic acid, PCT B stated the test was done after the dialyzer was taken out of storage and prior to use to check that Renalin had been present and in sufficient concentration in the dialyzer to kill bacteria. PCT B stated and then demonstrated how the white pad of the test strip turned dark/black when the germicide was present in sufficient concentration. | V 350 | | | |
| V 403 | 494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This STANDARD is not met as evidenced by: Based on observation, interview and record review, the facility failed to ensure that the medication refrigerator temperature was maintained between 36° - 46° F range and that the Phoenix pH meters were maintained per facility policy and procedure. The facility's failure to keep the medication refrigerator temperature within range had the potential to affect the potency and efficacy of medication. The facility's failure to maintain the Phoenix pH meter according to the facility's policy and procedure had the potential that the meters could give false reading when used to do the pre-treatment check of pH and conductivity of the dialysate on each patient's dialysis machine. | V 403 | | 3/5/11 | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
|--|---|---|---|----------------------|---|
| NAME OF PROVIDER OR SUPPLIER CORNERHOUSE DIALYSIS CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2005 NAGLEE AVENUE SAN JOSE, CA 95128 | | |
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| V 403 | <p>Continued From page 37</p> <p>Incorrect conductivity has the potential to reduce the effectiveness of the dialysis treatment and to affect the patient's electrolyte balance. Incorrect pH readings have the potential to put patients' pH levels into unsafe levels.</p> <p>Definitions:</p> <p>Dialysate - Dialysis solution which has levels of electrolytes/minerals, such as Potassium and calcium. The levels of the electrolytes in the solution are determined by the physician's order.</p> <p>pH - Measures the degree to which a solution is acidic or alkaline. A pH of 7 is considered neutral. A pH of less than 7 indicates acidity and a pH of more than 7 indicates alkalinity. A pH above 7.8 or below 6.8 is generally fatal. ("pH," Encyclopedia & Dictionary of Medicine, Nursing, & Allied Health. Sixth Ed., 1997, p.1232.)</p> <p>Electrolytes and Conductivity - Electrolytes are chemical substance, when dissolved in water decompose into electrically charge particles, and thus are capable of conducting an electric current. Electrolytes are essential to the normal function of human body cells. Common electrolytes are sodium, potassium, chloride and bicarbonate. ("electrolyte" Encyclopedia & Dictionary of Medicine, Nursing, & Allied Health. Sixth Ed., 1997, p.513)</p> <p>Findings:</p> <p>1. Observation of the interior of the medication refrigerator on 1/24/11 at approximately 9:30 a.m. noted several boxes containing vials of the medication Epogen (medication that stimulates</p> | V 403 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 403 | <p>Continued From page 38</p> <p>the bone marrow to make red blood cell). Review of the manufacturers medication information insert showed, "Store Epogen in the refrigerator between 36°F and 46°F (2°C to 8°C)."</p> <p>The medication refrigerator had a digital monitor magnetically attached to the front door. It was noted that the set temperature range on the monitor had 33°F as minimum low and 47°F as the maximum.</p> <p>Review of the "Medication Refrigerator Temperature Log" on 1/24/11 at 9:41 a.m. showed that on 1/14/11 at 5 p.m. and on 1/15/11 at 5:15 p.m. the refrigerator's recorded temperature was 33°F. The next refrigerator temperature logged was on 1/17/11 at 5 a.m. and it was 39°F.</p> <p>On 1/24/11 at 10:52 a.m. the log book was reviewed with FA (Facility Administrator), who stated the biomedical technician was in charge of the refrigerator temperature maintenance.</p> <p>A second observation on 1/28/11 at 10:46 a.m. , in the presence of Biomedical Technician, showed that the medication refrigerator digital monitor still had 33°F as the low minimum setting for the temperature range. Biomedical Technician stated he had nothing do with setting the temperature range and that if the refrigerator temperature was either below or higher than the set range, nurses were to adjust the inside temperature control nob.</p> <p>During an interview on 1/28/11 at 10:51 a.m. RN A stated the digital monitor had fallen on the floor on 1/10/11 and since then the minimum low</p> | V 403 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
|--|--|---|---|----------------------|---|
| NAME OF PROVIDER OR SUPPLIER CORNERHOUSE DIALYSIS CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2005 NAGLEE AVENUE SAN JOSE, CA 95128 | | |
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| V 403 | <p>Continued From page 39</p> <p>temperature setting had been 33°F. RN A stated she had asked the Biomedical Technician to check the monitor and remembered that he had adjusted the inside temperature control dial. RN A was asked if the monitor would alarm if the temperature fell below or above the temperature range setting, RN A stated, "No." RN A stated the minimum and maximum temperature range settings were for staff reference as to what was an acceptable refrigerator temperature.</p> <p>2. Record review on 1/26/11 at 3:40 p.m. of the "Phoenix Meter Log" showed that the facility had three meters. The log instructed staff to verify the meter's calibration prior to the first use each day or if inaccurate readings were suspected. If the meter was not within parameters, Biomedical Services staff were to recalibrate the meter before it could be used. The meters were used to test the dialysis machines' conductivity and pH (safety checks).</p> <p>The January 2011 log for meter #2 had no entries for 1/1-1/10 and on 1/11 documentation read, "Broke". There was no documentation to show the meter was repaired. The next entry on the log for meter #2 was on 1/20 and 1/21, which showed it had been used. From 1/22 to 1/26/11, there were no entries. On observation, meter #2 was found to be in use on 1/26/11, but the log did not show the meter was checked prior to being used on the treatment area.</p> <p>a. Review of the facility's policy and procedure for "Phoenix Meter Level I And II Calibration", last revised 3/10, showed that, "Calibration is completed by Biomed Services on a monthly basis..." The monthly calibrations were to ensure</p> | V 403 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
|--|--|---|---|----------------------|---|
| NAME OF PROVIDER OR SUPPLIER CORNERHOUSE DIALYSIS CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2005 NAGLEE AVENUE SAN JOSE, CA 95128 | | |
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| V 403 | Continued From page 40 that the pH meter was functioning properly. Any pH meters that could not be calibrated or needed repair were to be returned to the manufacturer. On 1/28/11 at 9 a.m. the Biomedical Technician was asked for the "Monthly Phoenix Meter Calibration Log". Biomedical Technician was unable to provide information to show that the monthly calibration of the Phoenix meters had been done. b. During an interview on 1/28/11 at 9:30 a.m. PCT B was asked what the routine care of the Phoenix pH meter was. PCT B stated at the end of the work day the meters were disinfected with a bleach solution, rinsed, then stores with Neo-Care (cleans mineral deposits in the syringe) solution drawn into the syringes. PCT B stated Neo-Care solution provided lubrication for the syringe so that the plunger would not stick. PCT B was asked to show where the Neo-Care was kept and he was unable to locate it. PCT B went to the Biomedical room and asked the Biomedical Technician for the location of the Neo-Care supply. Biomedical Technician stated there was no supply of Neo-Care in the facility. | V 403 | | | |
| 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: Based on observation, interview, and record review, the facility failed to ensure that the vascular access sites were visible throughout the patients' dialysis treatment for one (Patient 2) of | V 407 | | 3/5/11 | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
|--|--|---|---|----------------------|---|
| NAME OF PROVIDER OR SUPPLIER CORNERHOUSE DIALYSIS CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2005 NAGLEE AVENUE SAN JOSE, CA 95128 | | |
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| V 407 | <p>Continued From page 41</p> <p>ten sampled patients and seven random patients (Patients 12, 13,14,15,16, 17, and 27).</p> <p>The facility's failure to have the patients' vascular access sites exposed and visible had the potential for rapid, fatal exsanguination (massive blood loss) if patients' cannulating needles became dislodged from the access or the tubing accidentally disconnected while hidden from view.</p> <p>Definitions:</p> <p>Vascular access: In hemodialysis, a vascular access provides a way to remove and then return blood from and to the body.</p> <p>There are three kinds of vascular access sites; a fistula, which is made when an artery and a vein are joined under the skin, a graft, where the artery and vein are joined by a plastic tube also under the skin, and a catheter, which is inserted into a vein in the neck or below the collarbone and which is meant for short term use.</p> <p>Findings:</p> <p>1. During an observation on the initial tour of the facility on 1/24/11 at 9 a.m. Patient 12 had his left arm vascular access covered.</p> <p>Between each dialysis chair station there was a portable unit with a computer screen and keyboard. At 9:05 a.m. PCT I was at the chairside computer which was on the same side Patient 12's arm with the covered access was. At 9:11 a.m. RN E approached Patient 12 and checked his dialysis machine, at 9:20 a.m. PCT I was at Patient 12's chair station, and at 9:35 a.m. PCT I walked in front of Patient 12's chair station.</p> | V 407 | | | |

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|--|--|---|---|----------------------|---|
| NAME OF PROVIDER OR SUPPLIER CORNERHOUSE DIALYSIS CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2005 NAGLEE AVENUE SAN JOSE, CA 95128 | | |
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| V 407 | <p>Continued From page 42</p> <p>Each time staff had failed to look at Patient 12's access site.</p> <p>2. An observation on 1/24/11 at 12:47 p.m. showed Patient 2 was in the isolation room, seated in a recliner chair that faced the door. Patient 2's right chest vascular access site was covered by clothing, which included a long sleeve dark brown light fabric jacket/shirt. RN A and PCT I had been in the room to verify the dialysis, but neither had checked and exposed the site. Continued observation from 1 p.m. to 1:30 p.m. showed that the catheter access site remained covered.</p> <p>3. Observation on 1/25/11 at 8:04 a.m. showed Patients 13,14, and 15 had their vascular access sites covered. All three patients had their bodies covered up to their chin with blankets.</p> <p>At 8:11 a.m., PCT H was at Patient 13's chairside and failed to see that the access site remained covered.</p> <p>At 8:21 a.m. PCT F was a Patient 14's chairside and failed to check the access site.</p> <p>At 8:10 a.m., PCT H at 8:10 a.m. was at Patient 15's chairside but failed to see that the access site was covered. At 8:22 a.m. and 8:29 a.m. PCT F was at Patient 15's chairside. Each time PCT F failed to see that the access site was covered. Patient 15's access site remained covered at 8:45 a.m.</p> <p>4. On 1/26/11 at 11:46 a.m. Patient 2's right chest vascular access site was covered while on hemodialysis. At 12:10 p.m. PCT A entered the</p> | V 407 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
|--|--|---|---|----------------------|---|
| NAME OF PROVIDER OR SUPPLIER CORNERHOUSE DIALYSIS CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2005 NAGLEE AVENUE SAN JOSE, CA 95128 | | |
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| V 407 | <p>Continued From page 43</p> <p>isolation room to adjust the bicarbonate wall connection, but did not exposed the patient's access site. RN A at 12:54 p.m. administered Patient 2's medication through the dialysis tubing. RN A did and exposed the access site. The access site was observed covered between 11:46 a.m. until 1: 00 p.m. and again between 2:20 p.m. and 2:41 p.m.</p> <p>5. During an observation on 1/27/11 at 7:50 a.m. RN B walked in front of Patients 14's and 15's chair stations and failed to notice that the access sites were covered. At 8:10 a.m. PCT H was observed looking at Patient 15's dialysis machine, then entering data in the chair-side computer. Further observations at 8:16 a.m. showed PCT H was at the computer keyboard which was located between Patient 14's chair and another patient's chair, and at 8:24 a.m., PCT F was at Patient 15's dialysis machine. Each time staff failed to look at the access site and thus the access site remained covered.</p> <p>6. On 1/27/11 at 10 a.m. , Patient 17's vascular access site was covered. At 10:10 a.m. the access site was still covered. It was only at 10:20 a.m. that RN B uncovered Patient 17's right chest and revealed the catheter access site.</p> <p>During an interview on 1/27/11 at 10:21 a.m., PCT F stated the vascular access sites were to be exposed at all times for visualization. PCT F acknowledged the potential for a needle to become dislodged from the vascular access site or for blood tubing to come apart and result in the patient quickly bleeding to death.</p> <p>On 1/27/11, review of the facility policy "AV</p> | V 407 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
|--|---|---|---|----------------------|---|
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| V 407 | Continued From page 44 Fistula or Graft Cannulation with Safety Fistula Needles and Administration of Heparin", dated July 2009, showed, "Access sites are to remain visible at all times during treatment." 7. On 1/25/11, between 8:05 a.m. and 8:35 a.m., PCT I was observed working at his assigned stations 13, 15, and 16, often walking up to or past a patient, talking to a patient, or documenting treatment information on the chair-side computer without assessing the patients access sites which were not in view being covered by blankets. 8. Observation at 8:05 a.m. on 1/25/11 showed Patient 27 at station 13 was asleep and covered by a large blue blanket up to her chin, hiding her vascular access. At 8:08 a.m., PCT I walked right by Patient 27 without assessing whether her access was visible or not. At 8:14 a.m., PCT I walked over to Patient 27 then began entering data on the adjacent computer keyboard. He glanced toward Patient 27 whose access was still completely covered, but he did not tell her to uncover the access. Observation at 8:20 a.m. and 8:30 a.m. showed Patient 27's access was still completely covered. At 8:35 a.m., observation showed PCT I was close to Patient 27. He was asked where Patient 27's vascular access was located. PCT I looked down at Patient 27 for a few moments and then pulled back her blanket to reveal her access located on her left forearm. | V 407 | | | |
| V 416 | 494.60(d)(4)(iii) PE-CONTACT LOCAL EOC ANNUALLY | V 416 | | 3/5/11 | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
|--|--|---|---|----------------------|---|
| NAME OF PROVIDER OR SUPPLIER CORNERHOUSE DIALYSIS CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2005 NAGLEE AVENUE SAN JOSE, CA 95128 | | |
| (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 416 | Continued From page 45 The facility must- (iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to initiate contact with the local disaster management agency. This failure could result in the local disaster management agency not being aware of the facility's needs during a disaster or emergency. Findings: On 1/26/11, review of the facility's emergency preparedness binders did not indicate the facility had contacted the local disaster management agency. The clinical services specialist present during the review, confirmed no contact had been made, and confirmed the importance of notifying the disaster agency so it would be aware of the facility's needs. On 1/26/11 at 9:20 p.m., the CSS stated she had discussed with the facility administrator the necessity of contacting the local disaster management agency and "I even gave them the template (of the contact letter)." | V 416 | | | |
| V 460 | 494.70(a)(9) PR-INFORMED OF REUSE & OPTIONS The patient has the right to- (9) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers; | V 460 | | 3/5/11 | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
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OMB NO. 0938-0391

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| V 460 | Continued From page 46 This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure that one (Patient 8) of 10 sampled patients, had consented to the use of reused dialyzers prior to their use. Reused dialyzers were used for Patient 8 for the first two weeks of her dialysis, contrary to her responsible party's refusal for dialyzer reuse. Findings: On 1/25/11, review of Patient 8's medical record indicated she was admitted to the facility on 12/26/10 for in-center hemodialysis. Review of Outpatient Hemodialysis Physician Standings Orders 2010, dated 12/23/10, showed the physician ordered reuse dialyzers to be used for Patient 8's dialysis treatments. Review of consents signed during the admission process showed a family member signed consents as the responsible party (RP) for Patient 8. Review showed RP signed Patient's Rights dated 12/30/10 which included, "If you require hemodialysis and dialyzer reuse is practiced in the facility, you are entitled to the following: To give or refuse permission to participate in the reuse program and to request to change from one to the other at any time either verbally or in writing. Refusal to participate in reuse will still allow the patient to dialyze in this facility and receive other services; however, failure to agree to reuse will minimally restrict the choice of a dialyzer." Review showed RP signed Reuse Information and Consent Form dated 12/30/10 as well. RP checked the following, "I do not wish to participate in the reuse procedure at this time." | V 460 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

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|--|---|---|---|----------------------|---|
| NAME OF PROVIDER OR SUPPLIER CORNERHOUSE DIALYSIS CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2005 NAGLEE AVENUE SAN JOSE, CA 95128 | | |
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| V 460 | Continued From page 47 Review of Patient 8's treatment sheets showed she did not begin dialysis until 12/30/10, the date Patient 8's RP signed refusal for reuse. Review of the 12/30/10 treatment sheet showed Patient 8 was dialyzed with a new dialyzer. Review of 1/6/11 treatment run showed Patient 8's dialyzer was reused. Review of 1/8/11 treatment run showed Patient 8 was again dialyzed with a new dialyzer. Review of 1/11/11 and 1/13/11 treatment runs showed Patient 8's dialyzer was reused. On 1/15/11, Patient 8's treatment sheet showed Patient 8 was dialyzed with a non-reuse dialyzer. The re-use technician was interviewed on 1/25/11 at 1:35 p.m. He confirmed Patient 8 had undergone dialysis with reused dialyzers, and stated, "Her doctor made the change." The facility manager (FA) was interviewed on 1/25/11 at 1:55 p.m. The FA confirmed Patient 8 should not have been dialyzed with reused dialyzers. She stated, "The nurse should look at the consent form. While doing admission, the nurse should notify the physician of patient refusal (to use reuse). I found it (consent signed by RP on 12/30/10). We notified the physician." The FA stated she did not notify Patient 8's RP that reused dialyzers were used for Patient 8, contrary to the RP's wishes. | V 460 | | | |
| V 560 | 494.90(b)(4) POC-PTS SEEN BY MED STAFF 1X/MO The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assistant providing ESRD care at least monthly, | V 560 | | 3/5/11 | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 560 | <p>Continued From page 48</p> <p>as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure three (Patients 1, 2, and 4) of ten sampled patients were seen by a healthcare provider at least monthly as evidence by a monthly progress note placed in the medical record. This failure placed the patients at risk of not having all their needs addressed.</p> <p>Findings:</p> <p>1. Record review on 1/24/11 indicated Patient 4 was hospitalized for the treatment of an infection from 8/26 to 9/3/10. There were no physician progress notes filed in the record since Patient 4 returned to the facility.</p> <p>In an interview on 1/24/11 at 3 p.m., Patient 4 stated her doctor did not come to the facility but did see her in the office.</p> <p>On 1/25/11 at 11:30 a.m., the clinical service specialist (CSS) stated physician progress notes, "should be in" the record. She said, "That's a problem. We always have to call" to get the records.</p> <p>On 1/26/11 at 9 a.m., the administrative assistant (AA) stated Patient 4's physician, "Doesn't come to the clinic." The staff members contacts the physician and received progress notes or responses by fax.</p> | V 560 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552608 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 01/28/2011 |
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| V 560 | Continued From page 49 On 1/27/11 at 5 p.m., the CSS stated the facility has 38 physicians. Physicians "should round on each patient once a month and document." She said she had "no idea" if the facility kept track of physician visits. | V 560 | | | |
| V 637 | 2. Review of Patient 2's physicians' progress notes on 1/24/11 showed that the last progress note was dated 8/11/10 and the progress notes prior to 8/11/10 were dated 4/27/10. On 1/24/11 at 3:10 p.m. the AA (Administrative Assistant) stated Patient 2's physician usually did not come to the dialysis center but instead saw patients in his office. The AA stated that the physician's office would then fax a copy of the progress notes to the center. AA was unable to find any other physician progress notes in Patient 2's record. 3. Review of Patient 1's physicians' progress notes on 1/25/11 showed progress notes dated 3/23/09, 6/23/10, 8/8/10, 9/3/10, 9/17/10, and 11/10. The progress notes did not reflect consistent monthly physician visits. | V 637 | | 3/5/11 | |
| | 494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT | | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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| V 637 | <p>Continued From page 50</p> <p>The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must-</p> <p>(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to identify, analyze, and develop recommendations and a plan of action when the infection rate associated with central venous catheter use increased more than twice the facility's goal. This failure increased the potential for further catheter related infections.</p> <p>Findings:</p> <p>The facility's quality assurance/performance improvement program was reviewed with the clinical services specialist (CSS) on 1/28/11 at approximately 10 a.m. The infection rate associated with central venous catheter (CVC) use for the year 2010 was illustrated by the use of a line graph indicating the monthly catheter infection rate. A large increase was noted for May 2010, with an infection rate of 12% and June 2010, with an infection rate of 11%. There was no documentation showing the facility identified the infection spike for May and June as a problem and consequently there was no documentation</p> | V 637 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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| V 637 | Continued From page 51 showing the facility developed an action plan to reduce the infection rate. According to the CSS, "Our (facility's) goal is less than 5%. I would have expected them to identify the problem. If you're not achieving goals you have to have a plan." | V 637 | | | |
| 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 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: Based on interview and record review, staff failed to follow facility practices for the care of two (Patients 4 and 9) of 10 sampled patients and one (Patient 21) random patient, as evidenced by: Patient 9 was not administered a medication as ordered, nor was his physician notified for an unclear medication order, increasing the potential for adverse outcome, Patient 4's physician was not notified when Patient 4 dialyzed at a lower blood flow rate than prescribed, potentially affecting the dialysis effectiveness. Medications that were to be stored at room temperature, were drawn up into syringes and refrigerated, potentially reducing their efficacy. Staff did not clean and disinfected Patient 21's | V 715 | | 4/18/11 | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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FORM APPROVED
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| V 715 | <p>Continued From page 52</p> <p>arm in accordance with facility policy prior to cannulation, placing Patient 21 at risk for infection.</p> <p>Findings:</p> <p>1. Record review on 1/26/11 indicated Patient 9 was admitted to the facility for three treatments on 9/21/10, 9/23/10, and 9/25/10. Patient 9's usual dialysis facility was located hundreds of miles away and his dialysis care administered by another provider. Review of the sending facility's Hemodialysis Standing Orders, dated 9/3/10 and faxed to the facility on 9/13/10, showed Patient 9's physician ordered Zemplar 6 micrograms to be administered three times a week during Patient 9's dialysis treatments. Zemplar is a form of Vitamin D used to reduce bone loss of calcium and resultant high blood calcium levels caused by hyperparathyroidism frequently occurring in end stage renal disease. Patient 9 also had an order for Hectoral 100 milligrams IV (intravenous-injected into a medication port during dialysis) every two weeks. Hectoral is a form of Vitamin D with similar actions to Zemplar. The use of both Hectoral and Zemplar is not common.</p> <p>Review of the treatment runs dated 9/21/10, 9/23/10, and 9/25/10 showed neither Zemplar nor the facility's equivalent medication, Hectoral was administered to Patient 9.</p> <p>The clinical services specialist (CSS) on 1/26/11 at 2:40 p.m. reviewed the orders for Hectoral 100 mg. and stated "That's not right. They (sending facility) probably thought it was iron (an iron supplement, for example Venofer)." The CSS</p> | V 715 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
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OMB NO. 0938-0391

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| V 715 | <p>Continued From page 53</p> <p>stated Hectoral was used by the facility instead of Zemplar and Hectoral 100 mg. was an incorrect dose. She stated, "They (facility's nursing staff) should have verified the order (with the sending facility)." The CSS reviewed the treatment runs and confirmed that neither Hectoral or Zemplar was administered. The CSS stated the nursing staff was responsible for inputting the physician orders. After reviewing the orders that were input into the facility's electronic order system, the CSS confirmed the nurses did not even enter the order for Zemplar or Hectoral, contrary to facility practice.</p> <p>Review on 1/26/11 of the facility's "Job Description: Registered Nurse-Chronic (Outpatient in-center hemodialysis)" indicated that among "essential duties and responsibilities" registered nurses were to "administer medications, fluid therapy or other appropriate treatments per physician orders."</p> <p>2. Review of Patient 4's record on 1/24/10 indicated she was admitted to the facility for in-center hemodialysis. Her dialysis treatment orders indicated she was scheduled for three dialysis treatments weekly with a blood flow rate of 350 milliliter (ml) per minute to run for three hours into the right subclavian central venous catheter (CVC). A subclavian CVC is a tube placed into a large chest vein to function as a site to perform dialysis.</p> <p>Observation on 1/24/11 at 3 p.m. showed Patient 4 undergoing dialysis treatment. The blood flow rate (BFR) was running at 200 ml/hour.</p> <p>The Post Treatment record dated 1/17/11 indicated at 2:27 p.m., the BFR ran at 200</p> | V 715 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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| V 715 | <p>Continued From page 54</p> <p>ml/hour, and from 3:04 p.m. to 4:33 p.m., the BFR was at 320 ml/ hour. On 1/19/11, the Post Treatment record showed the BFR at 200 ml/hour at 2:27 p.m., the BFR at 280 ml/hr from 3:08 p.m. to 3:38 p.m., and BFR at 300 ml/hour from 4:08 p.m. to 5:08 p.m.</p> <p>In an interview on 1/25/11 at 1:25 p.m., RN B, who reviewed the 1/17/11 and 1/19/11 Post Treatment records, stated a physician was to be notified when BFRs were not at the rate ordered by a physician. She confirmed Patient 4's physician was not notified.</p> <p>On 1/28/11 at 9:45 a.m., the CSS in an interview stated if BFRs were not meeting prescribed orders, licensed nurses were to make a list of those patients and call the physician. She said she did not know if there was a policy addressing this practice but she will search.</p> <p>At the end of the survey on 1/28/11, a policy for notifying physicians when prescribed BFRs was not achieved was not available.</p> <p>3. During the initial tour on 1/24/11 at 9:52 a.m. inspection of the medication refrigerator showed</p> | V 715 | | | |

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| V 715 | <p>Continued From page 55</p> <p>numerous syringes labeled with patients' names that contained various drawn up medications. Four of the 10 ml (milliliter) syringes contained a dark fluid. The dark fluid was identified as Venofer, an intravenous iron supplement. Ten 3 ml syringes contained a clear fluid identified as Hectorol, an intravenous vitamin D supplement. The labels indicated both medications were drawn up on 1/24/11, The labels did not indicate the time the medications were drawn into syringes.</p> <p>Further observation showed no additional Venofer or Hectorol were stored in the refrigerator, but in a cupboard at room temperature. The manufacturer's medication information inserts in each box with the vials of Venofer and Hectorol indicated, "Store in original carton at 25 degrees C (77 degrees F). Excursions (temporarily out of range) permitted to 15-30 degrees C (59-86 degrees F)." After the FA (Facility Administrator) had reviewed the manufacturer's medication information inserts, she acknowledge that Venofer and Hectorol should not be refrigerated.</p> <p>Review of the "Medication Refrigerator Temperature Log" on 1/24/11 at 9:41 a.m. showed that on 1/14/11 at 5 p.m. and on 1/15/11 at 5:15 p.m., the refrigerator temperatures were 33°F, below the manufacturer's recommended storage temperatures for Venofer and Hectorol.</p> <p>4. During an observation on 1/25/11 at 3:30 p.m. PCT I used a povidone iodine pad to clean Patient 21's left forearm/arm access site and immediately wiped off the iodine with a dry gauze.</p> <p>PCT I stated he had immediately wiped off the iodine from Patient 21's arm because Patient 21 had complained in past visits that the iodine</p> | V 715 | | | |

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CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/26/2011
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| V 715 | Continued From page 56 made him "scratch". Review of the facility's policy and procedure "AV Fistula Or Graft Cannulation With Safety Fistula Needle (SFN) And Administration of Heparin", dated July 2009, showed that in order for povidone iodine to be effective it needed 60 seconds of contact time and need to three minutes to air dry. The policy indicated that for patients who were allergic to iodine, alcohol 70% pads could be used in place of iodine. During an interview on 1/26/11 at 11:44 a.m., RN C, who also served as the infection control manager, confirmed wiping off Betadine (povidone iodine) immediately after application on the skin was not adequate cleaning. RN C added, they're (staff) supposed to disinfect with alcohol first." She was informed alcohol was not used first, only the hurriedly wiped Betadine. | 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: Based on interview and record review, the facility | V 726 | | 3/5/11 | |

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| V 726 | <p>Continued From page 57</p> <p>failed to maintain complete and accurate medical records for two (Patients 3, 6) of 10 sampled patients.</p> <p>For Patient 3, the facility failed to document on the medical record front cover that Patient 3 had a medication allergy. This failure placed Patient 3 at risk for receiving that medication in error and having an allergic reaction.</p> <p>For Patient 6, the facility failed to document the staff's name and signature who had explained the facility dialyzer re-use program to the patient and if Patient 6 consented or not to participate in the re-use program.</p> <p>Findings:</p> <p>1. Review on 1/25/11 of facility "Reuse Information And Consent Form", dated 12/11/09, showed the form enumerated the eleven patients' rights related to the facility's dialyzer reuse program. The form instructed the patient to check one of the options: consent to reuse, or do not wish to participate in the reuse procedure. The form read, "The facility's reuse program and process was explained to me by" and had two lines for staff to print their names and to sign. The same form also contained a box for the patient's signature, as an attestation that the patient received the information.</p> <p>Patient 6's re-use consent, dated 12/12/10, showed Patient 6's signature and his printed name documented on the lines for staff. Also, the form did not have a checked mark in front of the written statements to indicate whether Patient 6 had consented or refused the reuse program.</p> | V 726 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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| V 726 | Continued From page 58 During an interview on 1/25/11 at 7:46 a.m. Patient 6 stated he was aware and had agreed to be part of the facility's reuse dialyzer program. 2. During a review of Patient 7's medical record on 1/25/11, there was a blank allergy sticker on top of the record. Further review showed Patient 7 had a well documented (in the physician's admitting orders, admission assessments, and hospital discharge records) allergy to penicillin. During an interview with the facility administrator (FA) on 1/25/11, upon being shown the allergy to penicillin documented in the record and the blank allergy sticker, she stated, "Yes...it should be filled out." | V 726 | | | |