| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 552608 | A. BUILDING ______ B. WING ______ | R 03/17/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| **CORNERHOUSE DIALYSIS CENTER** | **2005 NAGLEE AVENUE SAN JOSE, CA 95128** |

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| {V 000} | INITIAL COMMENTS<br><br>The following reflects the findings of the California Department of Public Health during a follow-up visit conducted on 3/16/11 and 3/17/11 as a result of a recertification survey conducted from 1/24/11 to 1/28/11.<br><br>Representing the California Department of Public Health were 10918, Health Facilities Evaluator Nurse and 14549, Health Facilities Evaluator Nurse. | {V 000} | | |
| V 120 | 494.30(a)(1)(i) IC-TRANSDUCER PROTECTORS-NOT WETTED/CHANGED<br><br>Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines' pressure monitors.<br><br>If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300-600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse.<br><br>Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients. | V 120 | | 4/18/11 |

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 120 | Continued From page 1<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview, the facility failed to ensure the external transducer protectors (two protective barriers between the external blood lines and the internal mechanism of the dialysis machine) did not become wet with blood or other fluid during each hemodialysis treatment, when two transducer protectors on separate dialysis machines were observed to be contaminated with blood. This failure increased the risk for contamination of the internal transducer and possible contamination of the internal pressure tubing set and pressure sensing port, which would then result in frequent alarms and interruptions of the treatment. Findings:<br><br>During several observations of the treatment area on 3/17/11 between 1:15 p.m. and 3:30 p.m., a total of six dialysis machines, Stations 3, 5, 6, 8, 11, and 13, were noted to have blood in the tubing connecting the venous drip chamber to the venous external transducer protector. This resulted from the drip chamber becoming too full with blood. Two transducers protectors were also noted to be wet with blood.<br><br>Upon requesting one of the patient care technicians (PTC 1) to show the back of the wet transducer at Station 3, PCT 1 stated, "Even though there's blood on this side, this type of transducer has a special divider inside it that prevents the contamination of the transducer inside the machine."" PCT 1 then looked at the transducer and stated, "The other side is okay, but I better change this." | V 120 | | |

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| V 120 | Continued From page 2 | V 120 | | |

Later, PTC 2 was asked to show the back of the wet transducer at Station 13. While she was holding the transducer for inspection, PCT 3 walked up and pointed to the transducer stating, "There's a divider inside that prevents the blood from going inside the machine. See...it's dry on this side." PCT 2 nodded and stated, "That's right." PCT 3 then proceeded to change the transducer.

There was no way of determining how long each transducer had been contaminated with blood before it was noticed during the observation.

During an interview with the facility administrator (FA) and the clinical services supervisor (CSS) at 6:15 p.m., they were informed of the transducer finding. When told what the staff had said, both the FA and the CSS stated, "That's not true. There's no divider inside the transducer. Where did they get that from?!"

Review of the facility's Policy: 1-03-11 titled: "Changing Transducer Protectors" indicated the following:

Purpose: To provide guidelines for changing transducer protectors and preventing cross-contamination.

Policy:
2. During intradialytic treatment monitoring, the arterial and venous drip chamber level should be observed and adjusted as needed.
3. External transducer protectors will be inspected for presence of blood or saline every 30 minutes during patient treatment and included as part of the monitoring process.

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| V 120 | Continued From page 3<br>4. The external transducer protector will be replaced whenever blood or saline is observed in contact with the patient side of the transducer protector.<br>7. The back of the wet external transducer protector and the delivery system pressure module leur locks will be visually inspected for blood or saline contamination prior to replacing the new sterile external transducer protector on the delivery system (dialysis machine). If blood or saline is noted on the back of the wet external transducer protector, strikethrough has occurred. Upon completion of the treatment, the delivery system is to be removed from service and labeled with the date, time, description of the problem, and the name of the teammate reporting the problem.<br>8. The internal transducer protector will be changed by the BioMed technician and the delivery system will be disinfected prior to return to use. | V 120 | | |
| {V 715} | 494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P<br><br>The medical director must-<br>(2) Ensure that-<br>(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;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, interview and record review, the facility failed to ensure staff followed facility practices for the care of one of eight (1) sampled patients. Patient 1's physician was not | {V 715} | | |

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| {V 715} | Continued From page 4 | {V 715} | | |

notified when Patient 1 was dialyzed at a lower blood flow rate than prescribed, potentially affecting the dialysis effectiveness. Findings:

Record review on 3/16/11 indicated Patient 1 was admitted to the facility for in-center hemodialysis. Her dialysis treatment orders dated 2/24/11 indicated she was scheduled for three dialysis treatments weekly with a blood flow rate (BFR) of 350 milliliter (ml) per minute to run for three hours into the right subclavian catheter (CVC). A CVC is a tube placed into a large chest vein to function as a site to perform dialysis. A discharge summary dated 3/12/11 noted Patient 1 was admitted to a hospital on 2/28/11 and discharged on 3/12/11.

The Post Treatment record dated 3/15/11 indicated at 2:53 p.m., the BFR ran at 200 ml/minute, and from 3:21 p.m. to 5:11 p.m. the BFR was at 300 ml/minute. There was no documentation indicating patient condition and the reason for why BFR was not maintained at the rate prescribed by the physician.

In an interview on 3/17/11 at 3 p.m., patient care technician 4 (PCT 4) recalled Patient 1's 3/15/11 dialysis was the first treatment since her most recent admission to the hospital. Patient 1 was not feeling well that day and he informed the charge nurse. The BFR was then lowered. He said physicians were not usually notified until the BFR was lowered to 200 to 250 ml/minute.

The policy, "Intradialytic Treatment Monitoring" dated 1/3/09 directed licensed nurses to notify the physician as needed of changes in patient status.

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| | **552608** | A. BUILDING ______<br>B. WING ______ | R<br>**03/17/2011** |

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| {V 715} | Continued From page 5<br>On 3/17/11 at 4:30 p.m., the clinical service specialist (CCS) stated staff should notify the physician or parameters should be developed in maintaining BFRs. | {V 715} | | |