

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050076</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>03/04/2016</b>
NAME OF PROVIDER OR SUPPLIER <b>Kaiser Foundation Hospital - San Francisco</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2425 Geary Blvd, San Francisco, CA 94115-3358 SAN FRANCISCO COUNTY</b>		
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit.</p> <p>Complaint Intake Number: CA00471877 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 26616, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>Health and Safety Code Section 1280.3(g): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.</p> <p>Hemodialysis is a treatment procedure which removes extra fluids and waste products from the blood which the kidneys cannot excrete when the kidneys fail. This treatment is usually done by a dialysis nurse who goes to patient bedside with the portable hemodialysis machine.</p> <p>Continuous Renal Replacement Therapy (CRRT) is a dialysis modality used to treat critically ill patients in the intensive care unit (ICU) who develop acute kidney failure. The CRRT machine and dialyzer (artificial kidney) are used to slowly and continuously remove extra fluids and waste products from the blood which the kidneys cannot excrete when the kidneys fail. This treatment is</p>		<p>The administration, staff and physicians of Kaiser Foundation Hospital (KFH) San Francisco take our responsibility for safe quality care for our patients very seriously and provide the following response to the issues identified in the Statement of Deficiencies. Documents demonstrating these actions are available on site for review and have been previously submitted to the department.</p> <p>KFH San Francisco began its investigation into this event to determine opportunities for improvement shortly after the event occurred on December 6, 2015.</p>		

Event ID:083D11

9/7/2016

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Ronald L. Goff TITLE: Senior Vice President (X6) DATE: 9/20/16

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 19

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. Except for nursing homes, the findings 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.

State-2567

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10/3/16 - Acceptable POC - ~~AK~~ Kimard, HFEM I  
10/3/16

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	<p>done by ICU nurses who have had special training on CRRT.</p> <p>Continuous Venovenous Hemofiltration (CVVH) is one of the therapy options of CRRT.</p> <p>On 1/14/16 at 4:28 PM, an Immediate Jeopardy was called based on failure to continuously monitor Patient 1's femoral catheter (dialysis access located in groin) and bloodlines during Continuous Renal Replacement Therapy (CRRT), when the access and bloodlines were covered with a blanket. One of the bloodlines became loose and was disconnected from the dialysis access causing massive blood loss and cardiac arrest on 12/6/15. The CRRT bloodlines, fluid bags and all supplies connected to the CRRT machine were discarded without further investigation if the lines were faulty and/or damaged, which had the potential for the same faulty/damaged supplies to be used for patients and cause the same incident. The CRRT machine was not removed from service after the venous line disconnection incident and continued to be used by the patient until he passed away on 12/8/15. Three trained CRRT ICU nurses (RN 1, RN 3 and RN 6) interviewed stated patients on CRRT with a femoral catheter were covered with a blanket during treatment because patients were cold and for privacy reasons. The deficient practice continued to pose a threat to patients' health and safety if the CRRT system was not monitored continuously during treatment.</p> <p>The State regulations that were violated were: Title 22: 70213(a)</p>		Response begins on page 4		

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	<p>In attendance at the Immediate Jeopardy conference were: Chief Nursing Officer Area Quality Leader Risk and Accreditation Recertification and Licensing Director Quality Consultant</p> <p>Health &amp; Safety Code 1279.1(b)(2)(B) Use of device other than as intended (b) For purposes of this section, "adverse event" includes any of the following: (2) Product or device events, including the following: (B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.</p> <p>Title 22 DIV5 CH1 ART3-70213(a) Nursing Service Policies and Procedures. (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. This RULE is not met as evidenced by:</p> <p>Based on observation, interview and record review the facility failed to ensure dialysis policies and procedures were implemented for one dialysis patient (Patient 1) when:</p>		<b>(Blank)</b>		

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	<p>1. Patient 1's femoral catheter (dialysis access located in groin) and bloodlines (arterial line draws blood from the patient and venous/return line returns the blood to the patient) were not monitored continuously per the facility's policy for loose connections when 1) they were covered with a blanket during Continuous Renal Replacement Therapy (CRRT), and 2) RN 2 left Patient 1's room on two occasions while Patient 1 was receiving CRRT. On 12/6/15, the return line became loose and disconnected from the femoral catheter which caused massive blood loss and cardiac arrest.</p> <p>2. The CRRT bloodlines were thrown away without examination and testing to determine if the lines were faulty per facility's policy; and the CRRT machine was not removed from service per facility's policy after Patient 1's incident on 12/6/15 and continued to be used by Patient 1 until he passed away on 12/8/15. This had the potential for the same faulty/damaged equipments to be used by Patient 1 and repeat the same incident.</p> <p>Findings:</p> <p>1. Review of the medical record indicated, Patient 1 was admitted to the facility on 12/4/15 after he had a heart attack at home. Prior to Patient 1's admission to the facility, he had placement of multiple stents in his heart to increase blood supply to his heart muscles which were done at another hospital. Patient 1 had a history of chronic kidney disease and during hospitalization, Patient 1's</p>		<p><b>Finding 1</b></p> <p><b>Corrective action taken</b></p> <ul style="list-style-type: none"> <li>On 1/14/2016, the status of all hospital inpatients were reviewed to determine if there were any CRRT or hemodialysis patients currently in the hospital. One CRRT patient was identified and</li> </ul>	1/14/2016	

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	<p>kidney function continued to decline and CRRT was initiated on 12/5/15.</p> <p>Review of the PM Nurse's Summary of Patient Progress dated 12/6/15 at 2:16 indicated, "patient alert and oriented (mentation at baseline as per daughter); continue on 2 L (liters) oxygen,.....continue CVVH (Continuous Venovenous Hemofiltration - a type of CRRT)... patient started on puree diet."</p> <p>Review of the Cardiology Progress Notes dated 12/6/15 at 7:57 PM, indicated, "Events: overnight - pressors (medication to increase blood pressure) have been weaned down - more interactive ... (this note from am rounds). Subjective: Able to tell us he (Patient 1) feels better ... continue CVVH."</p> <p>Review of the Doc (Documentation) Flowsheets from 12/5/15 and 12/6/15 for Patient 1's right femoral (groin) catheter did not indicate a section for monitoring of dialysis access and bloodlines that they were visible at all times and monitored continuously.</p> <p>In an interview on 1/15/16 at 1:00 PM, the Adult Services Director (ASD) stated there was no section in the electronic health record for monitoring of dialysis access and bloodlines. ASD stated the electronic Flowsheets for CRRT monitoring will be updated and would include a section for monitoring the dialysis access and bloodlines.</p> <p>Review of the medical records indicated the</p>		<p>KFH SF Nursing Leadership discovered that the vascular access site was covered. The RN assigned to this patient was directed to immediately uncover the site for visible monitoring.</p> <ul style="list-style-type: none"> <li>The RN assigned to the patient and the unit supervisor were immediately educated of the need to ensure that the access site is always visible and secure.</li> <li>The practice of allowing covering the site with a blanket for comfort and privacy reasons was stopped on 1/14/2016.</li> <li>All RNs who provide CRRT and Hemodialysis were immediately educated during huddles between 1/14/2016 and 2/5/2016 that "<i>All hemodialysis (including CRRT) vascular access sites should be readily visible and continuously monitored throughout the treatment of dialysis. RN must document visibility and security of access every 1 hour throughout the treatment of dialysis.</i>"</li> <li>Additional education, including a written example of appropriate hourly documentation, was provided to CRRT RNs on all shifts in Intensive Care units between 1/14/2016 and 2/5/2016. Attendance was documented with sign in sheets. Education</li> </ul>	<p>1/14/2016</p> <p>1/14/2016</p> <p>2/5/2016</p> <p>2/5/2016</p>	

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	<p>following nursing interventions for Patient 1 on 12/6/15: At 7:00 PM - RN 1 documented on CRRT "Flowsheets" which showed all the pressures on the CRRT system were within normal limits and the Blood Flow Rate was 300 ml/min.</p> <p>At 7:14 PM - the "All Orders and Results" document indicated, RN 1 received a phone call from laboratory indicating critical results for lactate (by-product of cell metabolism when cells lacked oxygen) with a value of 7.3 (normal reference range 0.7 - 1.9 mmol/L).</p> <p>At 7:30 PM - RN 1 suctioned Patient 1 and obtained rusty and bloody secretions (from trachea) documented on the "Flowsheets."</p> <p>At 7:48 PM - the "All Orders and Results" document indicated, acknowledged electronically the physician order for dobutamine (medication for heart failure) and to draw venous blood gas (VBG - test for carbon dioxide and pH [acidity and/or alkalinity] in the blood) at 10:00 PM.</p> <p>At 8:00 PM - RN 2's Progress Notes indicated, "Returned from break early due to Patient 1 coding (cardiac arrest) care resumed from RN 1. RN 1 states Patient 1 had a bowel movement and brady down (slow heart rate) covers removed to start CPR (cardiopulmonary resuscitation) CPR started and she (RN 1) noticed the line was disconnected and blood was in the bed she was unsure if GI (gastrointestinal)/Line disconnect. Pt was coded for 45 mins (minutes) with ROSC (return of</p>		<p>continued until all appropriate staff received the education prior to administering CRRT or hemodialysis treatment.</p> <p><b>System changes made</b></p> <ul style="list-style-type: none"> <li>• Policies related to hemodialysis were reviewed.</li> <li>• The following policies were modified to state "<i>All hemodialysis (including CRRT) vascular access sites should be visible and continuously monitored throughout the treatment of dialysis. RN must document visibility and security of access every 1 hour throughout the treatment of dialysis.</i>" <ul style="list-style-type: none"> <li>○ Hemodialysis SF-PCS-22-23 (Section 1.0)</li> <li>○ Continuous Renal Replacement Therapy (CRRT) with the PrismaFlex system: nursing management SF- PCS-04-48 (Section D 13)</li> </ul> </li> <li>• These updated policies were approved by the Medical Executive Committee (MEC) on 1/20/2016</li> <li>• Changes were made to the CRRT flowsheet in the electronic medical record</li> </ul>	<p>1/20/2016</p> <p>1/20/2016</p> <p>2/3/2016</p>

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	<p>spontaneous circulation) after interventions ... 2200 (10:00 PM) Pt (patient) cleaned for BM (bowel movement) large amount of blood loss."</p> <p>At 9:28 PM - physician Progress Notes indicated, Code blue (a medical emergency in which a team of healthcare personnel work to revive an individual in a cardiac arrest) called at 2000 (8:00 PM) after patient (Patient 1) became unresponsive and bradycardic (slow heart rate) ... Pt. (patient) noted to be in PEA arrest (pulseless electrical activity - heart monitor will show heart rhythm but there was no palpable pulse) .... He was intubated (tube inserted in the trachea or windpipe to maintain open airway and assist the patient in breathing) and underwent 10 rounds of CPR ... Massive transfusion protocol was followed with transfusion of 2U (2 units of blood approximately 250 - 300 milliliters per unit) PRBC (packed red blood cell) ... He (Patient 1) was transfused and additional 4U PRBCs, 2U FFP (fresh frozen plasma - liquid part of blood indicated to stop massive bleeding) and 1 U platelets (cells in the blood that are essential for normal blood clotting) ... Family updated at bedside still wanting full interventions ... "</p> <p>PEA may be caused by many conditions, but its most frequent causes are hypovolemia (low blood volume) and hypoxemia (lack of oxygen). If your patient has lost a great deal of blood, hypovolemia should be considered as a cause of PEA. (Source: acls.com)</p> <p>Review of the physician Progress Notes, dated 12/7/15 at 12:05 AM, indicated, "Patient s/p (status</p>		<p>documentation system, to allow for accurate documentation of site visibility and security of access. The flowsheet was released and has been in use since 2/3/2016.</p> <p><b>Monitoring</b></p> <ul style="list-style-type: none"> <li>The actions have been monitored by Hospital Leadership to ensure that the actions are effective and sustained.</li> <li>The event was reported to the Risk Management Committee on January 27, 2016 and the Medical Executive Committee on February 10, 2016 for input and oversight.</li> <li>Progress on corrective actions and monitoring results is tracked by the Hospital Quality Committee to ensure sustained compliance. The Quality Committee reports to the Medical Executive Committee, which provides additional input and oversight.</li> <li>On 1/14/16, the managers of the Intensive Care Units began daily reviewing documentation in the medical record of CRRT patients once a shift for evidence of the</li> </ul>	4/14/2016	

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	<p>post) PEA arrest ...Family collectively have come to conclusion that they do not want CPR or shocks and would want their family member to die peacefully. However, they would like to continue full medical management with continued intubation, CVVH and pressors. Code status changed to DNR [do not resuscitate] (ok for intubation, pressors)."</p> <p>Review of the physician Progress Notes dated 12/8/15 at 1:17 PM, indicated, "The family expressed concern for his (Patient 1) comfort and acknowledged that he is worse since the resuscitation (CPR) ...They also expressed concern and became very emotional when describing the resuscitation they witnessed. They reported seeing bleeding from the catheter and the patient in a large amount of blood under a blanket. They reported that he (Patient 1) was improving before this and find it difficult to accept that this 'mistake will take his life.'"</p> <p>Review of the Multidisciplinary Notes dated 12/8/15 at 3:27 PM indicated, "Charting and extubation (removal of the tube for artificial breathing) done by RT (Respiratory Therapist)."</p> <p>Review of the Certificate of Death indicated Patient 1 passed away on 12/8/15 at 3:20 PM and the Immediate Cause of Death was cardiogenic shock (The heart is not able to pump enough blood to meet the body's needs. The most common cause of cardiogenic shock is damage to the heart muscle from a severe cardiac arrest. Source: National Heart, Lung and Blood Institute website, "What is Cardiogenic Shock?").</p>		<p>hourly documentation of site visibility. Instances of non-compliant documentation were addressed immediately.</p> <ul style="list-style-type: none"> <li>After evidence of sustained practice was demonstrated by 100% compliance over a period of 90 days, random auditing of one CRRT and one hemodialysis medical record per week for two additional months occurred to ensure that the practice is sustained.</li> <li>Audit results were reported to the Quality Committee for leadership oversight and recommendations beginning in April. Final Audit results showing full compliance were reported to the Medical Executive Committee on 7/13/2016.</li> </ul> <p><b><u>Title of the person responsible for implementing the PoC</u></b></p> <p>Chief Nurse Executive</p>	<p>6/14/2016</p> <p>7/13/2016</p>	

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	<p>Review of the CRRT Machine Data History print-out and Prismaflex (CRRT machine) Operator's Manual, indicated alarms were triggered on 12/6/15 as indicated by the following:</p> <p>At 19:54:07 (7:54:07 PM) - WARNING: Return Pressure Dropping. According to operator's manual - Possible Cause(s) - Patient is moving or being moved, Possible leak in return line or catheter and Return catheter disconnected.</p> <p>At 19:54:20 (7:54:20 PM) - WARNING: Return Pressure Dropping. According to operator's manual - Possible Cause(s) - Patient is moving or being moved, Possible leak in return line or catheter. Return catheter disconnected.</p> <p>At 19:57:06 (7:57:06 PM) - WARNING: Access Extremely Negative. According to operator's manual - Possible Cause(s) - Patient is moving or coughing, or being moved or suctioned; access line clamped or kinked.</p> <p>At 19:57:15 (7:57:15 PM) - WARNING: Access Extremely Negative. According to operator's manual - Possible Cause(s) - Patient is moving or coughing, or being moved or suctioned; access line clamped or kinked.</p> <p>At 20:03:39 (8:03:39 PM) - WARNING: Access Extremely Negative. According to operator's manual - Possible Cause(s) - Patient is moving or coughing, or being moved or suctioned; access line clamped or kinked.</p>		(Blank)		

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	<p>Review of the Prismaflex outside vendor letter to the Area Clinical Technology Manager (ACTM), dated 2/23/16, regarding the Prismaflex (CRRT machine used by Patient 1) inspection and analysis, dated 2/23/16, indicated, "Analysis:... one treatment matching the description of the event was found.... December 6th at 1954 (7:54 PM): The warning alarm 'Return Pressure Dropping' was issued and cleared 13 seconds after it was issued. December 6th at 1957 (7:57 PM): A warning 'Access Extremely Negative' alarm was issued which effectively ended the treatment, no further pump movements recorded after this time. December 6th at 2004 (8:04 PM): Blood return was attempted following this alarm however due to unresolvable 'Access Extremely Negative' alarms only 11 ml (milliliters) of the filter set (dialyzer and bloodlines) volume was returned... Blood flow rate 300 ml/min... Blood loss: 1,008 ml."</p> <p>The vendor's print-out of the Prismaflex screen for Return Pressure Dropping indicated the screen had the sign, "WARNING: Return Pressure Dropping" on top of the screen in red color. On the left side of the screen was written in bold, "Possible leakage or disconnection of return line or catheter. Patient is moving or being moved. Action: 1. Make sure return catheter is securely connected to both the return line and the patient. 2. To resume treatment, press CONTINUE." The Prismaflex screen had touch screen buttons for EXAMINE ALARMS, DISCONNECT, bell icon with X (means MUTE), CONTINUE and HELP.</p>		(Blank)	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050076	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  03/04/2016	
NAME OF PROVIDER OR SUPPLIER  Kaiser Foundation Hospital - San Francisco		STREET ADDRESS, CITY, STATE, ZIP CODE 2425 Geary Blvd, San Francisco, CA 94115-3358 SAN FRANCISCO COUNTY		
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	<p>The vendor's analysis of the Prismaflex machine warning alarm, email dated 3/9/16, for "Return Pressure Dropping" and how the warning alarm was cleared after 13 seconds indicated the following: "The alarm is cleared by either pressing CONTINUE or DISCONNECT whichever action is most relevant to the current situation. Which option should be used is a clinical decision dependent on the findings while troubleshooting the alarms (actions and other possible causes is described on the screen). When using one of the two options pressing CONTINUE or DISCONNECT you are telling the machine that you want to end the treatment or continue the treatment which removes the alarm state. If you want to mute the alarm this can be done by the MUTE button which will not clear the alarm."</p> <p>During an interview on 1/12/16 at 11:06 AM, the complainant stated Patient 1 had a heart attack at home and had stents done at another hospital before transfer to the facility. The complainant stated Patient 1 was conscious and talking to his family and thought he would recover from the heart attack. The complainant stated on 12/6/15, family members were at the bedside when the dialysis machine alarmed with a "warning message about return pressure". The complainant stated RN 1 "silenced the alarm without checking Patient 1 and walked out of the room for several minutes". The complainant stated the family member called RN 1 and when RN 1 came back, Patient 1 looked like he was having seizure. The complainant stated when RN 1 pulled the blanket, there was pool of blood on the bed and the line was disconnected</p>		(Blank)	

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	<p>and sprayed blood all over the room. The complainant stated Patient 1 had cardiac arrest and had blood transfusion. The complainant stated the family witnessed the event and made them really upset and angry. The complainant stated after the cardiac arrest, Patient 1's health declined and the died on 12/8/15.</p> <p>During an interview on 1/13/16 at 3:05 PM, Physician 1 stated on 12/6/15, he heard a commotion in the hallway and he saw staff moving rapidly to Patient 1's room. Physician 1 stated when he got in to the room, Patient 1 was in obvious distress and poorly responding. Physician 1 stated the bedsheets were pulled down and he saw a pool of blood around Patient 1's groin where his femoral catheter was, a port (bloodline) was disconnected from the CV VH machine and there was a free-flowing blood coming out from the catheter. Physician 1 stated he called a code and Patient 1 was resuscitated (CPR), massive transfusion was initiated and patient was intubated. Physician 1 stated the blood loss was approximately 1000 ml. Physician 1 stated he was told by RN 1 the disconnection of the line just occurred and there was large amount of blood per rectum. Physician 1 stated the large amount of blood per rectum was not verified by him or any of the physicians because Patient 1 was very ill to have any diagnostic tests done. When asked if blood in the stool were tested, Physician 1 stated that although Patient 1 had history of gastrointestinal bleeding, there were no tests done while patient was at the facility. Physician 1 stated Patient 1's family was on the bedside and</p>		(Blank)	

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	<p>witnessed the code which was very traumatic to the family. When asked if the incident was considered an adverse event, Physician 1 stated the incident could be classified as sentinel event (patient safety event [not primarily related to the natural course of the patient's illness or underlying condition] that reaches a patient and results in death, permanent harm and severe temporary harm) because of the line disconnection and massive blood loss.</p> <p>During an interview on 1/13/16 at 3:50 PM, RN 1 stated she was a "break nurse" on 12/6/15. RN 1 stated she relieved RN 2 at around 7:00 PM for Patient 1 who was having CRRT. RN 1 stated when a patient was on CRRT, it was a 1:1 staffing (one nurse to one patient). RN 1 stated she checked Patient 1's dialysis access, bloodlines, vital signs (blood pressure, heart rate, respirations etc.). When asked if she documented that she checked the dialysis access and the CRRT system for kinks, loose disconnections and/or air, RN 1 stated she did not document that she checked the CRRT bloodlines and dialysis access. RN 1 stated at around 7:15 PM, she stepped out of Patient 1's room because she received a phone call from the laboratory that Patient 1's lactate was at critical value and she was looking for the physician. RN 1 stated the physician came and talked to the family about the laboratory results and medications. RN 1 stated she received an order to suction the patient which she did and got a bit of bloody secretions at around 7:30 PM. RN 1 stated after she suctioned Patient 1, the family told her Patient 1 had a bowel movement and she checked the stool was colored black but looked a normal stool. RN 1 stated she</p>		(Blank)		

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	<p>told the family that she would get supplies and get help of another nurse to clean Patient 1. RN 1 stated when she got back to Patient 1's room, the patient was having violent jerking movement. RN 1 stated she uncovered the blankets and saw blood gushing out from the venous bloodline and blood was also coming from the femoral catheter. When asked how long she was away from the room, RN 1 stated she could not remember how many minutes she was away from Patient 1's room. When asked if she heard or seen an alarm on the CRRT machine before she left Patient 1's room to get cleaning supplies, RN 1 stated, she did not hear any alarm from the CRRT machine.</p> <p>During an interview on 1/14/16 at 12:55 PM, RN 6 stated she had been doing CRRT for 7 years. RN 6 stated, "We're not supposed to cover the femoral catheter per policy when a patient was having CRRT, however, patient was cold and needed privacy so the catheter and lines were covered."</p> <p>During an interview on 1/15/16 at 2:30 PM, RN 3 stated patients on CRRT had their access and bloodlines covered during treatment because the patient was cold and if the access was a femoral catheter, it's covered for privacy reasons. RN 3 stated on 12/6/15, she was part of the Rapid Response Team (facility staff that responds to medical emergency in the hospital). RN 3 stated at around 7:45 PM, she was at another floor responding to a call for a patient who was having low blood pressure. RN 3 stated when it was almost 8:00 PM, she heard on the overhead page that there was a code in ICU. RN 3 stated when</p>		(Blank)		

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	<p>she got into Patient 1's room, she could not get in the room right away because blood was everywhere. RN 3 stated the blood looked like it was sprayed all over the room that it even reached the board on the wall where staff write patient instructions and name of assigned staff. RN 3 stated there was blood on the equipment, bed and floor. RN 3 stated CRRT machine was not connected to the patient and she noticed the blood on the CRRT system was not returned to the patient which was approximately 200 ml. RN 3 stated the blood clotted and the bloodlines and dialyzer were discarded. RN 3 stated the CRRT machine did not have emergency supplies like clamps and fluid spike needed to return the blood to Patient 1. RN 3 stated the emergency supplies should be on the CRRT machine so the blood could be return during an emergency. RN 3 stated Patient 1 had blood from the abdomen to the groin area. RN 3 stated after the code was finished, she stayed to help clean the patient. When asked if she saw a large bloody stool, RN 3 stated, the stool looked normal, it didn't look like melena (black tarry stool associated with upper gastrointestinal bleeding) and it didn't look like the blood was coming from the rectum when she helped cleaned Patient 1.</p> <p>During an interview on 3/3/16 at 2:45 PM, RN 2 stated she was the nurse assigned to Patient 1 on 12/6/15. RN 2 stated RN 1 relieved her for a 30 minute break. RN 2 stated she was coming back from break when she heard the code was called and pushed the crash cart to Patient 1's room. RN 2 stated when she got to Patient 1's room, the</p>		(Blank)		

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	<p>code was on-going and Patient 1 was being intubated. RN 2 stated she knew the CRRT return line was disconnected because the room looked like the blood was sprayed on the walls of the room and there was lots of blood underneath the Patient 1. RN 2 stated blood transfusion was initiated. RN 2 stated family members were present and witnessed the code. When asked if she witnessed bleeding from the rectum, RN 2 stated she could not tell if the blood was coming from the rectum or from the return line but Patient 1 did not have rectal bleeding after the incident.</p> <p>Review of the Prismaflex Operator's Manual indicated, "Chapter 4: Alarm System - The operator is notified of an alarm condition via a red or yellow status light, an audible alarm and an alarm screen on the display. Each alarm screen has instructions for how to respond to the alarm ... page 23 ... WARNINGS: The control unit may not be able to detect disconnections of the set from the blood access and return connections, which can result in blood loss. Ensure the patient's blood access and return connections are firmly secured ... Carefully observe the set and all operation while using the Prismaflex System for a patient treatment."</p> <p>Review of the facility's policy and procedure entitled Continuous Extracorporeal Blood Therapy (which include CRRT) with the Prismaflex System revised 1/12, indicated, "13. Continuously monitor the system for kinks, loose connections, air and the presence of blood in the ultrafiltrate (pink tinge). 23. Stopping Treatment: a. If therapy needs to be held, return blood to the patient and follow the</p>		(Blank)		

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	<p>recirculation procedure ... b. If therapy needs to be discontinued, follow the end of treatment procedure, returning patient blood whenever possible. c. Keep a 250 ml. bag of NS (normal saline) with an adapter spike available at the bedside to return blood to the patient when the treatment is discontinued or held ... 25. In a Code Blue situation, return blood to the patient if possible, stop treatment and clamp lines."</p> <p>2. During an interview on 1/14/16 at 12:25 PM, the Risk Manager stated the machine was sent to Biomed for testing and maintenance to verify RN 1's report that the CRRT machine did not alarm when the venous line was disconnected. The Risk Manager stated Patient 1 continued to use the same CRRT machine after the line disconnection incident on 12/6/15 until 12/8/15. The Risk Manager stated the CRRT machine was sent to Biomed on 12/9/15 after Patient 1 discontinued the treatment, however, only the CRRT machine was sent and not the dialyzer and all lines connected to the CRRT machine. The Risk Manager stated Patient 1's incident happened on a weekend and all the equipment and supplies connected to the CRRT machine were discarded.</p> <p>During an interview and record review on 1/14/15 at 2:35 PM, the Area Clinical Technology Manager (ACTM) stated the CRRT machine used by Patient 1 was serviced on 12/10/15. ACTM verified the report on the document Clinical Technology - Service Report dated 12/10/15 which indicated, "Ran functional checks per ACTM request. Was told no equipment do not need to be sequestered. There were multiple pressure alarm event observed</p>		<p><b><u>Finding 2</u></b></p> <p><b><u>Corrective action taken</u></b></p> <p>All RNs were immediately educated during huddles between 1/14/2016 and 1/23/2016 on sequestering equipment after an event with the message: "Staff are responsible for sequestering suspect medications, medical equipment and supplies involved in any event not primarily related to the natural course of the patient's illness or underlying condition, which reaches a patient and results in death, permanent harm, severe temporary harm, and other defined events."</p> <p><b><u>System changes made</u></b></p> <p>Beginning in 2017 annual education module on managing issues related to equipment and supplies will be enhanced to include more</p>	1/23/2016	3/30/2017

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	<p>on the history screen. Ran pressure calibrations, functional performance checks. Unit is working normally." ACTM stated the CRRT machine was not sequestered because on 12/10/15, it was found out the machine was working properly so the CRRT machine was put back to service. ACTM stated after Patient 1's event on 12/6/15, all consumables were supposed to be saved like the CRRT machine and all lines connected to the machine for investigation of faulty or defective equipment.</p> <p>Review of the facility's Sentinel, Significant, and Other Event Management policy and procedure, reviewed 4/15, indicated, "4.1 Event Categories 4.1.1. (Level 1) Sentinel Events: A patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, permanent harm, severe temporary harm, and other defined events ...5. Medical Center: Intervention and Communication Following an Event ... 5.2. Situation Stabilization: Immediate actions are to be taken to reduce the likelihood of further occurrences. Such actions may include discontinuing use of and removing faulty or suspect equipment ..."5.3. Preservation of Evidence: Preservation of evidence, such as documents or supplies, is necessary to ensure an effective analysis and record of the occurrence. Appropriate actions may include obtaining statements from witnesses, securing medical records and/or biological specimens, and sequestering suspect medications and medical equipment (such equipment shall be referred to clinical engineering or other appropriate department for examination and</p>		<p>information on sequestering suspect medications, medical equipment and supplies involved in any patient adverse event.</p> <p><b>Monitoring</b></p> <ul style="list-style-type: none"> <li>The actions have been monitored by Hospital Leadership to ensure that the actions are effective and sustained.</li> <li>The event was reported to the Risk Management Committee on January 27, 2016 and the Medical Executive Committee on February 10, 2016 for input and oversight.</li> <li>Progress on corrective actions and monitoring results is tracked by the Hospital Quality Committee to ensure sustained compliance. The Quality Committee reports to the Medical Executive Committee, which provides additional input and oversight.</li> <li>Beginning on 4/4/2016 and continuing for a period of 60 days, during rounds, managers randomly questioned staff members to test their knowledge of the policy for sequestering equipment or supply involved in a patient</li> </ul>	6/4/2016

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	<p>testing to determine if the equipment is faulty)."</p> <p>This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.3(g).</p>		<p>safety event. An audit tool was utilized for data collection.</p> <ul style="list-style-type: none"> <li>Audit results have been reported to the Quality Committee for leadership oversight and recommendations beginning in April. Final Audit results showing full compliance were reported to the Medical Executive Committee on 7/13/2016.</li> </ul> <p><b><u>Title of the person responsible for implementing the PoC</u></b></p> <p>Chief Nurse Executive</p>	7/13/2016	

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