

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050036	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/08/2008
NAME OF PROVIDER OR SUPPLIER BAKERSFIELD MEMORIAL HOSPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE 420 34TH STREET, BAKERSFIELD, CA 93301 KERN COUNTY		
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	<p>The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident.</p> <p>Entity Reported Incident No: CA00144287</p> <p>Representing the California Department of Public Health.</p> <p>[REDACTED]</p> <p>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY:</p> <p>Title 22 - 70435(a)(1)(A)(B)(C) - Cardiovascular Surgery Service Staff</p> <p>(a) Cardiovascular catheterization laboratory. (1) A physician shall have overall responsibility for the service. This physician shall be certified or eligible for certification in cardiology by either the American Board of Internal Medicine or the American Board of Pediatrics or have equivalent experience and training. He shall be responsible for: (A) Implementing established policies and procedures (B) Supervision and training of all personnel, including in-service training and continuing education (C) Assuring proper safety, function, maintenance and calibration of all equipment.</p> <p>The team performing an Endovascular Aneurysm</p>		<p>Title 22 - 70435(a)(1)(A)(B)(C)</p> <p>Corrective Action</p> <p>Anesthesia equipment has been standardized with identical machines placed in OR and the Cath Lab.</p> <p>A Medical Director with Board Certification in both Internal Medicine and Cardiology has responsibility for the cardiac catheterization laboratory ("Cath "Lab").</p> <p>The Section of Anesthesia is developing a rule and regulation to address Anesthesia Equipment Orientation. The rule and regulation will delineate the process for orienting new anesthesiologists to the anesthesia equipment. A competency checklist will be developed for completion by the Medical Director of Anesthesia documenting that the physician has been oriented to the equipment and is competent to utilize the machine. The Orientation checklist certifying competence will be filed in the physician's Credentials File.</p> <p>In the event new anesthesia equipment is purchased, all anesthesiologists utilizing the equipment shall be required to participate in an orientation process to ensure competency. The orientation checklist certifying competence will be filed in the physician's Credentials File.</p>	<p>2008 NOV - 7 PM 1:53</p> <p>08/25/08 ongoing</p> <p>01/1999 ongoing</p> <p>09/24/08 (Supervising Committee, MEC); 10/02/08 (Board), Ongoing</p> <p>08/25/08 Ongoing</p>

Event ID: SYXF11 10/16/2008 4:24:22PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *Jon Van Buren* TITLE *President* (X6) DATE *11/6/08*

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	<p>Continued From page 1</p> <p>Repair (EVAR) on March 10, 2008 at 10:30 PM was unable to respond to an Adverse Event to Patient X during the procedure in accordance with hospital policy or established Professional Practice. This resulted in an Immediate Jeopardy that was identified on April 3, 2008 at 11 AM.</p> <p>Findings:</p> <p>On April 2, 2008 at 8:30 AM, an unannounced visit was made to Bakersfield Memorial Hospital following an entity-reported incident of Patient X suffering a hypoxic event during an emergent EVAR procedure of an Abdominal Aortic Aneurysm (AAA) in the hospital's Catheterization Laboratory Unit (Cath-Lab).</p> <p>During an interview with the Director of Peri-Operative Services and Administrator I, on April 4, 2008 at 10:30 AM, they both stated they were aware of the incident that occurred on March 10, 2008 at 10:30 PM. Patient X was taken to the cardiac catheterization laboratory for an endoscopic AAA repair on an urgent and emergent basis. The patient suffered an "Adverse Event" during the procedure when he became hypoxic while undergoing anesthesia. Patient X was then stabilized and consequentially transferred to the surgical unit to undergo an open repair of the AAA. When the Director of Peri-Operative Services was asked if the cause of the hypoxia had been determined, it was stated that a Root Cause Analysis (RCA) of the incident determined that the anesthesia machine was improperly setup prior to Patient X being induced. Due to this improper</p>		<p>Anesthesiologists shall be required to have evidence of proctoring cases for each type of anesthesia machine used.</p> <p>A safety verification checklist for the anesthesia equipment has been developed and is in use upon start-up of the machines.</p> <p>All OR staff and Cath Lab staff who work endovascular cases in the Cath Lab are oriented to the environment and procedures for endovascular cardiac cases.</p> <p>CV and Cath Lab staff oriented to team integration, coordination and team work for endovascular cardiac procedures.</p> <p>Policy & Procedure was developed for Cath Lab Endoscopic Emergent Procedures.</p> <p>Monitoring</p> <p>The Medical Staff Office will audit the anesthesia equipment orientation competency checklist to ensure completion and maintain in physician's credentials file.</p> <p>Anesthesiologists shall be required to have evidence of proctoring cases for each type of anesthesia machine used.</p> <p>Medical Staff Office prepares monthly report to the Board of Directors and MEC on physician completion of proctoring requirements.</p> <p>Director of Surgical Services to conduct monthly validation / auditing of Anesthesia Checklist and provide this report to Medical Director of Anesthesia / Surgical Supervisory Committee.</p>	<p>08/25/08 ongoing</p> <p>9/2/08</p> <p>4/18/08 ongoing</p> <p>04/08</p> <p>9/25/08</p> <p>08/25/08 Ongoing</p> <p>08/25/08 Ongoing</p> <p>08/25/08 Ongoing</p> <p>09/02/08 Ongoing</p>

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	<p>Continued From page 2</p> <p>setup, the oxygen circuit was interrupted. Consequently, the tube, feeding oxygen to Patient X, did not have any oxygen flow causing the patient to suffer a period of hypoxia. Statements by the Director of Peri-Operative Services and Administrator I indicated, the contributing factors identified were: (1) there was a breakdown of communication between the Anesthesiologist and Surgical Support staff and there was a breakdown in communication between Surgical Staff and the Cath-Lab staff. (2) Unfamiliarity with the setup and operation of the anesthesia work-station by the Anesthesiologist was also identified as a factor contributing to the event. The Director of Peri-Operative Services stated, "We have only been doing 'AAA' endoscopically for about a year now. However, those cases have only been done on an elective basis. We have a dedicated team to handle elective EVAR cases during the day. We are not setup to do them emergently. This was the first time we attempted to do this kind of procedure emergently." When asked what policy and procedures were in place that addressed EVAR procedures on urgent and emergent basis, she stated, "We have none in place at this time". Both the Director of Peri-Operative Services and Administrator I stated they were aware of the fact that there was no policy or procedure in place which would allow for this type of procedure being safely performed on an urgent and emergent basis. They stated that the usual organized process for development of new policies had not been used with regard to addressing the performance of endoscopic abdominal aortic repairs being done on an urgent and emergent basis in the cardiac</p>		<p>Completion of orientation for 100% of the staff working Endovascular cases in the Cath Lab.</p> <p>Responsible Person</p> <p>Vice President of Medical Affairs Chief of Staff Medical Director, Department of Cardiology Medical Director, Department of Anesthesia Director of Surgical Services</p>	4/18/08 ongoing
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2008 NOV -7 PM 1:54

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catheterization laboratory When the Director of Peri-Operative Services was asked whose responsibility it was to develop a policy and procedure for this type of procedure, it was stated, "the procedure is being done in the Cath-Lab. The responsibility of that department falls to the Director of the Catheterization Laboratory Conversely, we currently have no Director There is an Acting Director at this time, Staff Q. However, the problem is that my department supplies the staff that directly supports the EVAR procedures in the Cath-Lab. So, we have inter-departmental issues to consider" When asked if a written policy or procedure would help with the inter-departmental issues, she stated "yes".

During an interview with Staff A, on April 3, 2008 3:35 PM, she stated the following.

"On March 10, 2008 at 2210 (10:10 PM), I was called in for an endo AAA for Physician B. The House Supervisor also stated that the cath lab 'Call' team was called in as well. At 2215 (10:15 PM), I called the house supervisor back to notify her that an orderly with anesthesia machine set-up experience would be needed to set up the anesthesia equipment. I specified, Staff Q, Staff R, or Staff S At 2220 (10:20 PM), again I spoke to the house supervisor and was told that she had talked to Staff R, who told her Staff S was still here and would set things up Upon arrival, we were busy retrieving items for scrub. At the time of the incident, Patient X was intubated and Physician C was complaining he couldn't get oxygen through the anesthesia machine. I checked in back of the anesthesia machine to see if the oxygen had been

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turned off. I noted the spare oxygen tank in the Cath-Lab did not have a regulator on it. Physician C now was very loudly cursing to get the machine working. Staff P was in the room trying to do so. Cath-Lab staff remained in the monitor/observation room. I told Staff T to run for an Ambu-bag (used for mechanical/manual ventilation), and I ran to CVR (Cardio-Vascular recovery room) for an oxygen tank. When I returned to the Cath-Lab with the items, one of Cath-Lab staff mentioned there was one on their crash cart. Patient X was then administered oxygen via an Ambu-bag (manually) by Physician C. I then spoke with the House Supervisor and requested that an experienced anesthesia orderly be recalled to the hospital. During this time Physician C, Physician B, and Physician H were discussing as to whether to put Patient X in the CVR room until the 'Anesthesia Orderly' arrived or to take Patient X to the operating room and proceed with the case by opening his abdomen. It was then decided to do the case open. Patient X was taken to the operating room. Patient X was in surgery at 12 midnight. When asked why staff had to run to other rooms to retrieve needed items, Staff A stated, "We were unfamiliar with where those items were located in the Cath-Lab and the Cath-Lab staff did not communicate with us." When asked who set-up the anesthesia machine initially, she stated, "Staff P was the only surgical orderly available to set-up the machine. However, he did not routinely set-up the anesthesia machine for the procedure."

During an interview with Staff P, on April 3, 2008 at 4:02 PM, he stated on March 10, 2008 he was

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	<p>Continued From page 5</p> <p>asked to help set up Cath-Lab No. 3 for a procedure. Staff P was asked if he had ever set-up the anesthesia work-station. He stated that he had "moved the work-station into the Cath-Lab and plugged it in" When asked if he had been given any kind of training or had experience to prepare and set-up the anesthesia work-station prior to that day, he stated, "No, I normally don't prepare the machines. I just move them and set them up." When asked if he was considered to be an "Anesthesia Tech", he answered "No"</p> <p>On April 3, 2008, Staff P's personnel and training record was reviewed. There was no evidence of Staff P ever being trained or oriented in the proper setup or preparation of the Anesthesia Work-station. This was discussed and confirmed with the Director of Peri-Operative Services</p> <p>During an interview with Physician C, on April 4, 2008 at 1:26 PM, he stated, "I don't normally work in the Cath-Lab. I was called in to do this procedure (EVAR)" When asked if he could explain why the Anesthesia work-station was not operating appropriately, Physician C stated, "I don't know why".</p> <p>During an interview with the Director of Peri-Operative Services and Administrator I, on April 4, 2008 at 10:30 AM, they stated, "the Root Cause Analysis determined, through two independent contractors, that the Anesthesia Machine was operating properly"</p> <p>Patient X subsequently suffered a Cerebral</p>			

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Vascular Accident (CVA) that might have been caused by the event with serious disability lasting more than seven days

The Department's review determined that the manufacturer's guidelines for the anesthesia machine had not been followed. This patient's adverse incident, which was determined by the Department to be an emergent threat to the welfare, health and safety of Patient X, resulted in the Department calling Immediate Jeopardy on April 3, 2008, at 11 AM. On April 8, 2008, at 9 AM, the Immediate Jeopardy was abated after the Department provided an acceptable Plan of Correction.

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