

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050557	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/19/2012
NAME OF PROVIDER OR SUPPLIER MEMORIAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 1700 Coffee Rd, Modesto, CA 95355-2803 STANISLAUS COUNTY		
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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: CA00293942 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 20365, 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 1280.1(c): 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>Health and Safety code Section 1279.1(c): "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made."</p> <p>The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made.</p> <p>Health and Safety Code 1279.1 (b) For purposes of this section, "adverse event" includes any of the following: (7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.</p>		<p>POG ACCEPTABLE YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p> <p>Reviewed By: <u>Stacy Lopez HFE</u> Name</p> <p>Facility Notified Name: <u>Donna Salvi</u> Date: <u>8/22/12</u> Time: <u>10:30AM</u> Notified By: <u>phone</u> Name</p>	

Event ID: 181311

7/25/2012

7:30:34AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

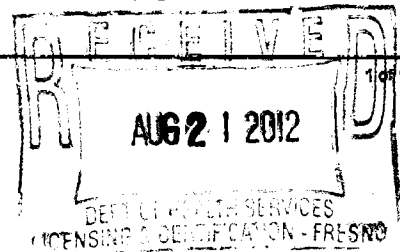
(X6) DATE

X Donna Salvi Donna Salvi

Quality Management (QA&I) Manager

8/21/12

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	<p>Continued From page 1</p> <p>Deficiency Constitutes Immediate Jeopardy</p> <p>Title 22 70231 Anesthesia Service General Requirements (a) Written policies and procedures shall be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. The policies and procedures shall include provision for at least: (3) Safety of the patient during the anesthetic period.</p> <p>Based on staff interview, clinical record and administrative document review, the hospital failed to provide for the safety of Patient 1 during the anesthetic period (the time period the patient was unconscious) in the operating room (OR) after surgery. On [REDACTED] Patient 1 underwent a routine outpatient surgical procedure (Cystolithopaxy with holmium laser - break down of bladder stones with amplified light) under general anesthesia. During the anesthetic post-operative (after surgery) period in the OR, MD 2 (Medical Doctor) delayed administration of resuscitative (life-saving) care to Patient 1 for approximately 17 minutes. This failure resulted in Patient 1 suffering from preventable anoxic brain injury (no oxygen to the brain) and Patient 1 died 11 days after surgery on [REDACTED] 11.</p> <p>Findings:</p>		<p><u>Corrective Action Accomplished for Complaint Intake #CA 00293942:</u></p> <p><u>Deficiency:</u> - Anesthesia Policies: 6/27/12</p> <p><u>A: How correction will be accomplished:</u></p> <p>Anesthesia developed and approved Anesthesia Policies in accordance with Title 22, 70233(a). These policies were approved by Anesthesia Department on 6/22/12, by Medical Executive Committee on 6/26/12 and by the Governing Board on 6/27/12.</p> <p><u>B: The title or position of the person responsible for the correction:</u></p> <p>Chair of Anesthesia, Chief of Staff, and Manager QA&I</p> <p><u>C: A description of the monitoring process to prevent recurrence of the deficiency:</u></p> <p>1) Policies are to be reviewed and approved every three (3) years. 2) The hospital has a computerized process to alert departments of renewal dates.</p> <p><u>D: The date the immediate correction of the deficiency will be accomplished:</u></p> <p>1) All required committee and Board approval completed on 6/27/12.</p>	

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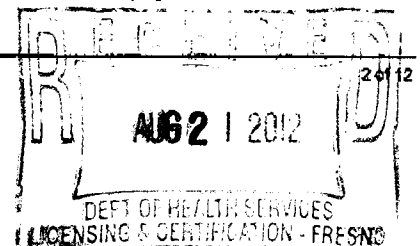


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Quality Management (QA&I) Manager

8/21/12

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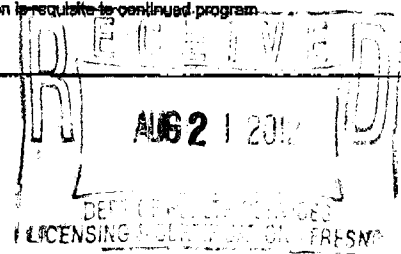
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	<p>Continued From page 2</p> <p>The entity reported incident faxed to the Department on 12/22/11 at 4:22 p.m. indicated the following "... patient ... had a cystoscopy (direct visualization of the bladder with a scope), ureteroscopy (direct visualization of the ureters with a scope) procedure at (the hospital) on [REDACTED] 11. The procedure was completed without complications ...upon extubation (removal of the breathing tube) the patient became combative and suffered a respiratory arrest that lead to a cardiopulmonary arrest. The patient was re-intubated, given medications, and stabilized in the OR. The patient remains in-house in our ICU (intensive care unit) with a diagnosis of an anoxic brain injury..."</p> <p>On 3/15/12 at 8:30 a.m., the clinical record for Patient 1 was reviewed. Patient 1 was a 65 year old male with bladder and ureter stones. Patient 1 underwent elective outpatient surgery on [REDACTED] 11. The surgical procedure performed was a Cystolithopaxy with Holmium laser. MD 1 was the primary surgeon and the procedure started at 3:51 p.m. and ended at 6:35 p.m. Eight bladder stones were removed and MD 1 left the operating room after an uncomplicated surgery.</p> <p>On 3/15/12 at 12 p.m., during a concurrent interview, the clinical record for Patient 1 was reviewed with MD 2, MD 2 stated he was the anesthesiologist for Patient 1 on [REDACTED] 11 and performed endotracheal general anesthesia (anesthesia resulting in total paralysis with a tube placed in the patient's throat and the patient</p>			

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 X: *Donna Salvi* Donna Salvi TITLE Quality Management (QA&I) Manager (X6) DATE 8/21/12

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	Continued From page 8 connected to a breathing machine). MD 2 stated Patient 1 was extubated (breathing tube taken out) at 8:38 p.m. while still in the OR after the surgery. MD 2 stated the monitors were taken off to move Patient 1 to the gurney (specialized hospital bed with wheels). Patient 1 was to be placed on the gurney in order to move Patient 1 out of the OR. Patient 1 became agitated. MD 2 stated three other staff (RN 1, RN 2 and Staff B), moved Patient 1 to the gurney and held the patient in place because of his thrashing. At this time MD 2 stated he administered propofol (also known as diprivan which is a strong anesthetic medication) 60 milligrams (unit of measure) in order to calm Patient 1. MD 2 stated Patient 1 immediately calmed down after the propofol was administered. MD 2 stated he noticed Patient 1 had stopped breathing about 60 seconds after the diprivan was administered. MD 2 stated he lowered the head of the bed and inserted an oral airway (an apparatus inserted into the mouth to prevent the tongue from blocking the ability to breathe) and nasal (through the nose) airway. MD 2 stated he placed the pulse oximeter on Patient 1 and "there was no oxygenation." (The pulse oximeter is a device placed on the finger to measure oxygen saturation. Oxygen saturation is a measure of how well the lungs are moving oxygen into the blood stream.) MD 2 stated he started administering oxygen by mask while the OR staff checked whether the monitors were working appropriately. MD 2 stated Patient 1 continued to not breathe on his own while he was administering oxygen by mask. MD 2 stated the OR staff brought into the OR the CPR (cardiopulmonary resuscitation) emergency cart at		<u>Deficiency:</u> Equipment Malfunction: <u>A: How correction will be accomplished:</u> 1) Equipment Malfunction P&P was reviewed for accuracy and shared with staff. 2) Bio-Med maintains preventive maintenance checks on all OR equipment. Bio-Med has a computerized system that automatically generates a work order when equipment is due for preventive maintenance check. <u>B: The title or position of the person responsible for the correction:</u> Manager of Surgical Services, Assistant Manager of OR, Bio-Med Manager, and Manager QA&I <u>C: Description of the monitoring process to prevent recurrence of the deficiency:</u> 1) In service to 100% of OR staff on Equipment Malfunction P&P, sign in sheets validated by Quality Management. 2) Environmental tracers have been in process for several years, Bio-Med preventive maintenance is part of this tracer, demonstrated 100% compliance times forty-eight (48) months. <u>D: The date the immediate correction of the deficiency will be accomplished:</u> 1) Equipment malfunction policy-77% of staff in-serviced on 4/27/12, remaining staff were in-serviced by 6/28/12. 2) OR Bio-Med preventative maintenance checks have been 100% compliant for more than 4 years.	6/28/12

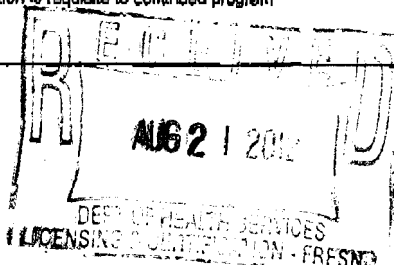
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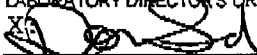


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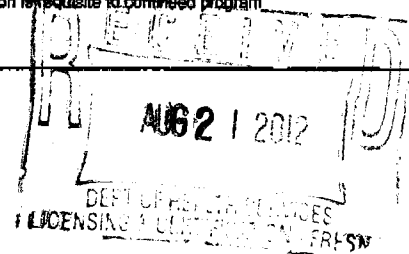
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 Donna Salvi
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	<p>Continued From page 5</p> <p>time elapsed while Patient 1 was not breathing and responded "I do not know. The patient was not breathing until CPR was started." When asked about the reason for the delay in administering resuscitative measures and calling a code blue for Patient 1, MD 2 responded with the following statement: "I zoned out."</p> <p>During the interview, MD 2 described how he prepared for the anesthesia for the surgery on Patient 1. MD 2 stated on 12/19/11 before Patient 1's case, he performed his usual routine which was checking the anesthesia machine, checking that the oxygen was running, and that there was a good seal on the CO2 (carbon dioxide) machine and that it was not loose. MD 2 stated "I check the anesthesia machine before each case. I log off the machine after each case and print up a report. The surgeon usually leaves after surgery ends as the surgeon did in this case. I reverse the paralysis of the anesthetic agent and turn off all but the oxygen." MD 2 stated that all of the checks performed prior to Patient 1's surgery stated the equipment was functional and ready for surgery.</p> <p>On 2/6/12 at 1:35 p.m., during an interview, RN (registered nurse) 1 described his role in the care of Patient 1 on [redacted] 11. RN 1 stated he was the relief circulating nurse (in relief of RN 3) for Patient 1's surgical procedure and started his shift at 6:07 p.m. on [redacted] 11. RN 1 stated Patient 1 became agitated after MD 2 extubated him. RN 1 stated MD 2 immediately administered a medication that calmed Patient 1. RN 1 stated MD 2 did not call out the name of the medication given to Patient 1.</p>		<p><u>Deficiency: Code Blue Record Keeping (Continued)</u> <u>D: The date the immediate correction of the deficiency will be accomplished:</u></p> <p>1) 100% compliance with entering a risk event after a code blue starting 2/1/12 and is ongoing times 6 months with 100% compliance, then bi-annual random check with 100% compliance. 2) Starting 2/1/12, 100% review of all OR Code Blue events have been reviewed against standard of care measures. Starting 9/12, all OR Code Blue events will be reviewed at the Code Blue Committee. This is an ongoing measure.</p> <p><u>Deficiency: Code Blue Communication</u> 6/28/12</p> <p><u>A: How correction will be accomplished:</u> 1) "Tips on Running a Code Blue in the OR" was reviewed and updated with clear identification of roles and responsibilities. New title is "Operating Room Code Blue Team Roles". Functions are as follows: a) Anesthesiologist - code team leader, directs code b) Circulator #1 - push Code Blue Button, if team members identify non-responsiveness from Anesthesiologist and patient is deteriorating, IMMEDIATELY escalate to code situation and push Code Blue Button, after hours call "88" to activate hospital wide code team c) Surgeon - begin chest compressions, manage wound closure, initiate more IV access d) Scrub Tech/Nurse - Chest compressions if surgeon not available e) Circulator #2/Charge Nurse on PM - record/scribe on Code Blue record with interventions and times, complete Code Blue evaluation form after code</p>	

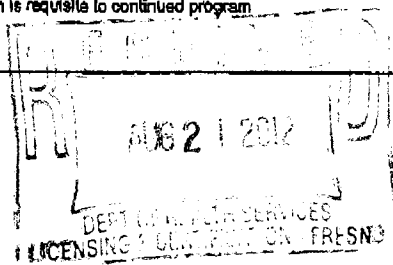
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	<p>Continued From page 6</p> <p>RN 2 stated he became aware MD 2 was bagging (administering oxygen manually by mask) Patient 1 "longer than usual". RN 1 stated that at this time he asked MD 2 if he (RN 1) could help with Patient 1. MD 2 responded that he could not get a pulse oximeter reading. RN 1 then brought another pulse oximeter and attached it to Patient 1's finger. This new pulse oximeter read zero. RN 2 then placed the pulse oximeter onto Patient 1's ear lobe and the reading remained zero. RN 1 was asked how much time elapsed while Patient 1 was not breathing and had a pulse oximeter reading of zero, and he responded "I do not know; minutes were lost." RN 2 stated no Code Blue was called and the Code Blue button mounted on the OR was not pushed. RN 1 stated the expectation was for MD 2 to call the Code Blue. When asked about the reason for the delay in calling Code Blue, RN 2 stated "MD 2's job was to be the captain of the ship and maintain the patient's airway and monitor the patient's vital signs and assess the patient...(MD 2) did not do his job. We reacted when we saw time was being lost and something needed to be done."</p> <p>On 3/6/12 at 10:05 a.m. during an interview, Staff 8 (Anesthesia Technician) discussed her role in the care of Patient 1 on 3/6/11. Staff 8 stated she was not assigned to the procedure for Patient 1. Staff 8 stated she became involved with Patient 1 when RN 2 (staff RN on duty) opened the OR door of Patient 1's procedure suite and said "Grab the crash cart and ask for another anesthesiologist." Staff 8 stated she located the emergency crash cart, brought it into the OR where Patient 1 was located, and hooked up the crash cart monitor to</p>		<p><u>Deficiency:</u> Code Blue Communication (Continued)</p> <p>f) Charge Nurse - Notify another Anesthesiologist immediately to report to code blue room, traffic control, remain at door and notify house supervisor. Request further help if necessary.</p> <p>g) Anesthesia Tech (if available) - Bring point of care machine and lins cart</p> <p>h) Runner (any staff member)/Charge Nurse - retrieve supplies as requested, retrieve blood as needed.</p> <p>i) At end of code, place yellow "Do Not Enter" tape on door reviewed.</p> <p>2) Chain of Command with an emphasis on immediate escalation.</p> <p>3) Anesthesiologist involvement with OR staff in OR Mock Code Blue training.</p> <p><u>B: The title or position of the person responsible for the correction:</u></p> <p>Chair of Anesthesia, OR Nurse Manager, OR Educator, and Manager QA&I</p> <p><u>C: A description of the monitoring process to prevent recurrence of the deficiency:</u></p> <p>1) 100% of all OR staff and Anesthesiologist have completed Mock Code Blue training utilizing a simulator mannequin with an emphasis on verbal communication and roles during a code. Quality to monitor and validate sign in sheets to ensure 100% of staff received training.</p> <p>2) Ongoing mock codes that include all OR staff and Anesthesia will be done on a rotating basis. Quality will monitor and validate sign in sheets to ensure 100% ongoing training.</p>	

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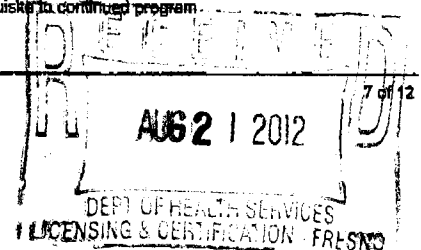
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Quality Management (QA&I) Manager

8/21/12

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050557	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/19/2012
NAME OF PROVIDER OR SUPPLIER MEMORIAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 1700 Coffee Rd, Modesto, CA 95355-2803 STANISLAUS COUNTY		
(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) COMPLETE DATE
	<p>Continued From page 7</p> <p>Patient 1. Staff 8 also stated that she called another anesthesiologist (MD 3) to go into the OR where Patient 1 was located. Staff 8 stated that once the cardiac monitor was hooked up to Patient 1, the pulse oximeter continued to read zero. Staff 8 stated that MD 3 had suggested to MD 2 to re-intubate Patient 1. Staff 8 stated that the suggestion to re-intubate was repeated three times before MD 2 elected to re-intubate. Staff 8 stated that no Code Blue was called. Staff 8 stated during the time Patient 1 was not breathing and the pulse oximeter reading was zero, there was no direction given by MD 2 to perform resuscitative care. Staff 8 commented that during this time, staff in the OR asked MD 2 more than once: "Do you want to call a code (code blue)?" and MD 2 did not respond.</p> <p>On 3/14/12 at 2:50 p.m., during an interview, RN 2 discussed her role in the care of Patient 1 on 11. RN 2 stated she was the registered nurse on-duty which meant she coordinated the operating room procedures. RN 2 stated she became involved with Patient 1's care once she was called into the room to help. The first thing she noticed was Patient 1 was on the gurney "sort of awake, gasping for air." RN 2 stated she helped hold the patient and then the patient stopped struggling. (RN 2 stated she did not know at the time MD 2 had administered propofol.) RN 2 stated at some point she noted Patient 1 had stopped breathing. RN 2 stated she asked Staff 8 to bring into the OR the crash cart and to call another anesthesiologist (MD 3). Regarding Patient 1 not breathing, RN 2 stated she had mentioned to MD 2 "... you have to do something.</p>		<p><u>Deficiency: Code Blue Communication (Continued)</u></p> <p><u>D: The date the immediate correction of the deficiency will be accomplished:</u></p> <p>1) 100% of OR Staff have reviewed "Tips on Running a Code Blue in the OR" and escalation policy, 72% staff attended OR Staff Meeting on 2/2/12, remaining staff completed by 6/28/12.</p> <p>2) 72% of all staff completed mock code blue training on 2/24/12, remaining staff/MD were completed by 6/28/12.</p> <p>3) Ongoing monitoring and validation by Quality Management will commence on Q3.12 times two (2) quarters, if 100% compliance, one (1) quarter random selection, if 100% compliance, then annual random sample times two (2) years.</p>	

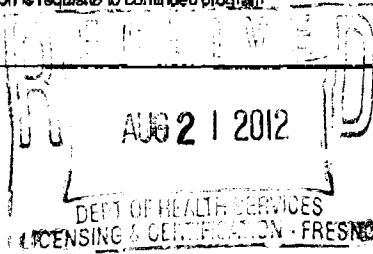
Event ID: 181311

7/25/2012

7:30:34AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE
 Donna Salvi
 TITLE
 Quality Management (QA&I) Manager
 (X6) DATE
 8/21/12

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	<p>Continued From page 10</p> <p>following timelines for the events on [redacted] 11: 1) surgery ended at 6:35 p.m.; 2) Patient was extubated at 6:38 p.m.; 3) documented heart rate (prior to not breathing) at 6:39 p.m.; 4) re-intubation occurred at 6:50 p.m.; 5) CPR started at 6:56 p.m. According to the time lines, the patient was not breathing and without oxygen for approximately 17 minutes. The Risk Manager stated that all documentation of the times of the events regarding Patient 1 occurred "after the fact". The Risk Manager stated there was no assigned staff to record the events "real time" and all times were estimated and documented after the events had occurred.</p> <p>The discharge physician note on [redacted] 11 indicated the following "... (Patient 1) was pronounced dead at 1 p.m. and was taken off ventilator ..."</p> <p>On 3/15/12, the following policy and procedure titled "Medical Staff Bylaws: Department of Anesthesia Rules and Regulations," dated 10/18/11, indicated under "... 1. Pre-Anesthetic Care ... f. To ensure the safety of the patient during the anesthesia period, the Department recommends that the following requirements be met ...d. Monitor and handle any complications from anesthesia."</p> <p>On 3/15/12, the following policy and current procedure titled "Code Blue Team Duties", undated, indicated under "Anesthesiologist - Code team leader - Maintain patient airway/Ventilation - Manage drugs and fluids - Utilizes ACLS protocol if relevant -Monitors hemodynamics. Tips to Running</p>			

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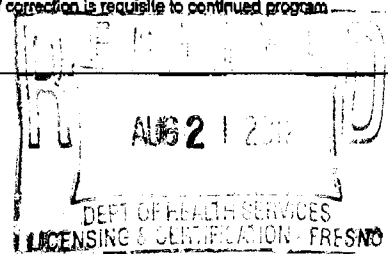


Donna Salvi

Quality Management (QA&I) Manager

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	<p>Continued From page 11</p> <p>a Code Blue 1. Anesthesia runs the code - They are the code team leaders. 2. Activation of Code Blue button - Button will be activated by the closest team member. It is essential to activate this button because it notifies the charge nurse, anesthesia techs, equipment techs, and leadership team..."</p> <p>The hospital failed to provide for the safety of Patient 1 during the anesthetic period in the OR following a routine outpatient surgery on [REDACTED] 11. Patient 1 suffered a 17 minute period of not breathing after being extubated and MD 2 delayed administration of resuscitative care. This failure directly led to Patient 1 suffering irreversible anoxic brain injury. The patient died on [REDACTED] 11 while being cared for in the hospital.</p> <p>The failure to provide for the safety of patients during the anesthetic period directly led to the licensee's noncompliance with one or more requirements of licensure and caused, or is likely to cause, serious injury or death to the patient. The above facility failures may result in an Administrative Penalty.</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 1280.1(c).</p>			

Event ID:181311 7/25/2012 7:30:34AM

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Donna Salvi Donna Salvi TITLE Quality Management (QA&I) Manager (X6) DATE 8/21/12

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