The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number: CA00283942 - Substantiated

Representing the Department of Public Health:
Surveyor # 20365, HFEN

The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.

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.

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."

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.

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.

Event ID: 181311  7/26/2012  7:30:34 AM

Laboratory Directors or Provider/Supplier Representative's Signature: Donna Salvi  Quality Management (QA&I) Manager  8/21/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be exempted from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosed 30 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 disclosed 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is required to continued program participation.
Continued From page 1

Deficiency Constitutes Immediate Jeopardy

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:

1) Safety of the patient during the anesthetic period.

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 Patient 1 underwent a routine outpatient surgical procedure (Cystolithotomy 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 May 11.

Findings:

Corrective Action Accomplished for Complaint Intake #CA 00293942:

Deficiency: - Anesthesia Policies: 6/27/12

A. How correction will be accomplished:

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.

B. The title or position of the person responsible for the correction:

Chair of Anesthesia, Chief of Staff, and Manager QA&I

C. A description of the monitoring process to prevent recurrence of the deficiency:

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.

D. The date the immediate correction of the deficiency will be accomplished:

1) All required committee and Board approval completed on 6/27/12.
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 _______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 anoxic brain injury."

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 _______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.

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 _______11 and performed endotracheal general anesthesia (anesthesia resulting in total paralysis with a tube placed in the patient's throat and the patient..."
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<th>Event ID: 181311</th>
<th>7/29/2012</th>
<th>7:30:34AM</th>
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<tr>
<td>LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE</td>
<td>Donna Salvi</td>
<td>Quality Management (QA&amp;E) Manager 8/21/12</td>
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## Statement of Deficiencies and Plan of Correction

### Deficiency: Equipment Malfunction - 6/28/12

#### How correction will be accomplished:

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.

#### The title or position of the person responsible for the correction:

Manager of Surgical Services, Assistant Manager of OR, Bio-Med Manager, and Manager QA&E

#### Description of the monitoring process to prevent recurrence of the deficiency:

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.

#### The date the immediate correction of the deficiency will be accomplished:

1. Equipment malfunction policy - 77% of staff in-serviced on 4/27/12, remaining staff in-serviced by 6/28/12.
2. OR Bio-Med preventative maintenance checks have been 100% compliant for more than 4 years.
Continued From page 4

this time. The CPR emergency cart monitor was connected to Patient 1. MD 2 stated the CPR monitor did not indicate Patient 1 was breathing and Patient 1 did not have a heart rate. (The CPR monitor has the capability of measuring blood pressure, pulse rate and respiratory rate.) MD 2 stated that while he was administering oxygen by mask, the patient was not breathing and the pulse oximeter continued to read zero. MD 2 stated around this time he performed LMA (laryngeal mask airway - an apparatus that holds the tongue down and keeps the airway open while administering oxygen). MD 2 stated Patient 1 had not started to breathe while performing LMA. At some point MD 2 stated another anesthesiologist (MD 3) came into the OR and suggested re-intubation. MD 2 stated he then re-intubated and mechanically ventilated Patient 1. MD 2 stated that CPR was started once Patient 1 was re-intubated. MD 2 stated the monitor was recording a heart rate and a respiratory rate once Patient 1 was re-intubated.

During the interview, MD 2 stated the clinical record did not document that a Code Blue was called. MD 2 stated no one was assigned to document the events in the OR while Patient 1 was not breathing. MD 2 stated he did not call a Code Blue. MD 2 stated he did not press the Code Blue button on the wall of the OR. MD 2 stated a Code Blue should have been called. The term Code Blue is used to indicate a patient requiring resuscitation or otherwise in need of immediate medical attention due to respiratory arrest (not breathing) or cardiac arrest (no heart rate). MD 2 was asked how much

Deficiency: Code Blue Record Keeping 2/1/12

A: How correction will be accomplished:
1) 100% OR Code Blue events will be entered into the computerized risk event database.
2) All OR Code Blue events will be analyzed by OR Assistant Manager, Risk Coordinator, and Anesthesia on clinical outcome.
3) Clarification of roles during an OR Code Blue is now part of the Mock Code Blue training.
4) After every OR Code Blue, the room will be sequestered by taping off the entrance to the room and no equipment will be turned off. The Charge RN is responsible for ensuring all monitor stripes have been collected.

B: The title or position of the person responsible for the correction:
Chair of Anesthesia, OR Assistant Manager, OR Charge Nurse, and Manager QA&I

C: A description of the monitoring process to prevent recurrence of the deficiency:
1) An intensive analysis is conducted after each OR Code Blue event, ensuring all equipment and documentation is present along with BHR completion, six(6) month 100% compliance, then all OR Code Blue events will be reviewed at Code Blue Committee and evaluated for clinical outcomes and potential process improvement.
2) If an area of opportunity is identified, team members are interviewed and improvement in processes, communication, or documentation may be implemented.

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

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X) DATE

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

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Continued From page 5

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."

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 parallel 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.

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 2/11. 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 2/11. 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.

Deficiency: Code Blue Record Keeping
(Continued)
D. The date the immediate correction of the deficiency will be accomplished:
1) 100% compliance with entering a risk event after a code blue starting 2/2/12 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.

Deficiency: Code Blue Communication

6/28/12

a. How correction will be accomplished:
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 "#" 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 RN - record/scribe on Code Blue record with interventions and times, complete Code Blue evaluation form after code.

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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. RN 1 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."

On 3/8/12 at 10:05 a.m. during an interview, Staff 8 (Anesthesia Technician) discussed her role in the care of Patient 1 on [redacted]. 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

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**Deficiency: Code Blue Communication (Continued)**

6) 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.

7) Anesthesia Tech (if available) - Bring point of care machine and line cart.

8) RN to MD 2 (any staff member) - Charge Nurse - retrieve supplies as requested, retrieve blood as needed.

9) At end of code, place yellow "Do Not Enter" tape on door reviewed.

10) Chain of Command with emphasis on immediate escalation.

11) Anesthesiologist involvement with OR staff in OR Mock Code Blue training.

B: The title or position of the person responsible for the correction:

Chair of Anesthesia, OR Nurse Manager, OR Educator, and Manager QA.

C: A description of the monitoring process to prevent recurrence of the deficiency:

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 90% of staff received training.

2) Ongoing mock codes that include all OR staff and Anesthesiologist will be done on a rotating basis. Quality will monitor and validate sign in sheets to ensure 100% ongoing training.
Continued from page 7

Patient 1. Staff 6 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.

On 3/14/12 at 2:50 p.m., during an interview, RN 2 discussed her role in the care of Patient 1 on shift. 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, groaning 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.

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(MD 2) put in a nasal airway, but it was not helping. Then he put in an LMA and hooked up the anesthesia monitor and was ventilating the patient. There was no pulse oximeter reading... RN 2 stated that once MD 3 arrived in the OR, he had to mention to MD 2 more than once to re-intubate Patient 1. RN 2 stated that at no time was a Code Blue called.

On 3/14/12 at 3:11 p.m., during an interview, RN 3 discussed her role in the care of Patient 1 on 3/11. RN 3 stated she was the assigned nurse for Patient 1. RN 3 stated she was also the assigned circulating nurse for Patient 1's procedure. RN 3 stated she was relieved for a break by RN 1. RN 3 stated by the time she returned from break, Patient 1 was on the gurney and not breathing and MD 3 was in the OR. RN 3 stated she assessed Patient 1's pulse by feeling the wrist and determined the pulse was "thready". RN 3 stated that at this time the pulse oximeter read zero. RN 3 stated that at no time was a Code Blue called.

On 3/16/12 at 9:30 a.m., during an interview, MD 4 (Chairman of the Department of Anesthesiology) discussed the events that occurred on 3/11 regarding Patient 1. MD 4 stated he reviewed the events that occurred with Patient 1 on 3/11. MD 4 stated that his review of the clinical record for Patient 1 showed that after being extubated Patient 1 became agitated and Patient 1 stopped breathing after being given propofol. MD 4 stated "... It was recognized that the patient (Patient 1) was not breathing. The pulse oxygen saturation sensor..."
AUG. 21. 2012 3:54PM MHA QUALITY MANAGEMENT

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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From the anesthesia machine was tried again with no reading ... (MD 2) could have asked for help, and should have pushed the code blue button ... There was no official/assigned code blue record keeper. Yes, there were opportunities for improvement and there were delayed responses.

On 5/2/12 at 4:18 p.m., during an interview, MD 3 discussed his role in the care of Patient 1 on 5/1/12. MD 3 stated he was called into the OR by an OR staff member. When MD 3 walked into the room he stated the patient had not been intubated, although "the patient had an LMA". When asked if he thought the patient was stable, he stated, "No." MD 3 explained that once he walked into the OR, he assessed the situation as an emergency and encouraged the attending anesthesiologist to intubate Patient 1. MD 3 stated that once Patient 1 was intubated then the patient became hemodynamically stable (blood pressure, heart rate and oxygenation were stable); He did not remember how long he was in the room. MD 3 stated he stayed in the room long enough to see the patient stable and he personally placed an arterial line (tube placed in an artery) for better monitoring. He did not leave the room until the patient was stable and he asked if there was need for further assistance prior to exiting the OR. He stated he was not aware of how long the patient had been unstable or not intubated. MD 3 stated he did not know the length of time the patient was not breathing.

On 3/15/12, a review of the clinical record for Patient 1 with the Risk Manager indicated the

Event ID: 161911 7/25/2012 7:30:34AM

LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVES SIGNATURE
Donna Salvi  Quality Management (QA&I) Manager 8/21/12

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following timelines for the events on Event 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 8:50 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.

The discharge physician note on Event 11 indicated the following "... (Patient 1) was pronounced dead at 1 p.m. and was taken off ventilator ..."

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."

On 3/15/12, the following policy and current procedure titled "Code Blue Team Duties," undated, indicated under "Anesthetist/ Nurse - Code team leader - Maintain patient airway/ventilation - Manage drugs and fluids - Utilizes ACLS protocol if relevant - Monitors hemodynamics. Tips to Running..."
Continued From page 11

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...

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]. 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] while being cared for in the hospital.

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.

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).