The following reflects the findings of the California Department of Public Health during an Entity Reported Incident investigation conducted on 4/2/08.

Complaint No: CA 00145575
Category: Other - Surgical Awareness

Inspection does not represent the findings of a full inspection of the facility.

Representing the California Department of Public health was [redacted], RN, HFEN.

1280 1 (a) HSC 1280

If a licensee of a health facility licensed under subdivision of (a), (b), or (f) of Sections 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction the department may assess the licensee an administrative penalty in the amount not to exceed twenty-five thousand ($25,000) per violation.

1280 1 (c) HSC Section 1280

For purposes of the 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.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY
On 4/2/08 at 2:15 p.m., Immediate Jeopardy was called as the facility failed to have a system in place to ensure that anesthesia equipment that had not been functioning correctly, was removed from service and not used for any further surgeries.

T22 DIV5 CH1 ART3-70237(a) Anesthesia Service Equipment and Supplies

(a) There shall be adequate and appropriate equipment for the delivery of anesthesia and post anesthesia recovery care.

This RULE: is not met as evidenced by:

Based on interviews and record reviews, the facility failed to have a system in place to ensure that malfunctioning anesthesia equipment was removed from service and not used for further surgeries. On 3/28/08 an Anesthesiologist expressed some question about the functionality of the anesthesia machine during a surgical procedure. This same anesthesia machine was used again on 3/31/08 for three (3) more surgical procedures. As a result, on 3/31/08 Patients’ 104, 105, and 106 each experienced various degrees of surgical awareness during their surgical procedures.

Findings:

On 4/1/08 at 2:00 p.m., the Department was informed that several patients alleged that they had experienced surgical awareness while undergoing surgery on 3/31/08. At 2:35 p.m., the Director of
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the OR [Operating Room] was interviewed. The Director said that she first learned of the patients' allegations of surgical awareness after the end of the 3rd surgical case on 3/31/08. The Director said that the anesthesia machine in Room 4 was removed from the operating room area at that time. The Director said that the Biomed department had been called down to Room 4 in the OR, twice during the 3 surgical procedures on 3/31/08. At 3:15 p.m., the Biomed technician was interviewed. The technician said that he was called to the OR several times on 3/31/08 because of the Anesthesiologist's (MD 1) concerns about the anesthesia machine in Room 4. The technician said that he checked the monitor portion of the machine, and found nothing wrong.

On 4/1/08 at 3:30 p.m., the OR circulating nurse (RN 1) who was on duty for the 3 surgical procedures on 3/31/08 was interviewed. RN 1 said that the Biomed technician did come down to the OR because of concerns about the anesthesia machine in Room 4. RN 1 said that the Anesthesiologist (MD 1) commented that Patient 105 was, "Not reacting the way she should, and her BP was giving him fits." RN 1 said that Patient 105, who was the 3rd case in Room 4 on 3/31/08, "moved both legs and her left arm" during the surgical procedure.

On 4/1/08 at 4:15 p.m., the OR nursing supervisor (RN 2) was interviewed. RN 2 was on duty on 3/31/08. RN 2 said that RN 1 had called for the Biomed technician to come down and look at the anesthesia machine in Room 4. RN 2 said that it

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.
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was her understanding from the Biomed technician that, "Appeared everything was fine." RN 2 said that at the close of the 3rd case, she learned that Patient 105 had experienced surgical awareness.

On 4/1/08 the medical record of Patient 105 was reviewed. Patient 105 was the 3rd surgical case in OR Room 4 on 3/31/08. Per the medical record, Patient 105 was admitted to the facility on 3/31/08 with diagnoses that included chronic pelvic pain, right ovarian cyst and history of excessive bleeding at the time of menses per the Operative Report. On 3/31/08 Patient 105 underwent a laparoscopy, right salpingo-oophorectomy, and removal of intrauterine device per the Operative Report. Per the PACU [post anesthesia care unit] Assessment Record, "1400 [2:00 p.m.] Pt received from OR...Alert/awake, c/o [ complained of] pain 11/10. Dilaudid titrated. Abd soft, 3 incisions clean and Band-Aid on. Pt discussing her surgery with Dr ___ [ anesthesiologist] and OR nurse [ RN 1] how she could feel four incisions and hear everything during the surgery."

On 4/1/08 at 4:40 p.m., Patient 105 was interviewed. Patient 105 told the Department that she, "Remembered the Anesthesiologist saying this will put you out...remembered hearing 'cut this side'...could feel the cutting, like it was pressure...could hear the 'click, click, click' of the speculum being inserted [into her vagina]...heard the Anesthesiologist say, 'this is unusual'...heard a nurse say, 'What should we do?....tried to tell my body to wake up, but I could not move, I could not open my eyes....remembered gagging feeling, like I..."

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

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could not breathe...heard the doctor say, 'She is
dropping'...heard the doctor say, 'we are done'
...then heard the Anesthesiologist say, "I am going
to wake you up." Patient 105 said that she
immediately woke up, and that she told the
Anesthesiologist, "I felt every .....[expletive
deleted]......thing you did. I was awake the whole
time."

On 4/1/08 the medical record of Patient 104 was
reviewed. Patient 104 was the 1st surgical case in
OR Room 4 on 3/31/08. Per the medical record,
Patient 104 was admitted to the facility on 3/31/08
with diagnoses that included chronic pain,
menorrhagia (excessive bleeding at the time of
menses) and adenomyosis (benign invasive growth
of the endometrium into the muscular layer of the
uterus) per the Operative Report. On 3/31/08
Patient 104 underwent a total abdominal
hysterectomy and bilateral salpingo-oophorectomy
/removal of uterus, tubes and ovaries/ per the
Operative Report. A progress note written by the
Anesthesiologist noted, "Patient had intraoperative
recall."

On 4/1/08 at 5:00 p.m., Patient 104 was
interviewed. Patient 104 told the Department that
she, "Woke up in the middle of her surgery
[3/31/08], felt cutting, smelled burning, felt intense
pulling down and towards her right side, I could feel
the tears coming down my cheek...why didn't they
see my tears, I tried to talk...the pain was
horrendous...heard the surgeon saying she had a
lot of scar tissue...remembered them taking the
tube out." [being extubated] Patient 104 cried
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during the interview, and said that she was still having a lot of pain. Patient 104 said that she was afraid to go to sleep.

On 4/2/08 the medical record of Patient 106 was reviewed. Patient 106 was the 2nd surgical case in OR Room 4 on 3/31/08. Per the medical record, Patient 106 was admitted to the facility on 3/31/08 with diagnoses that included left adnexal mass, pelvic pain and dysfunctional uterine bleeding per the Operative Report. On 3/31/08 Patient 106 underwent an exploratory laparotomy and left ovarian cystectomy per the Operative Report. On 4/2/08 at 10:00 a.m., Patient 106 was interviewed. A family member was present with Patient 106 at the time of the interview. During the interview, Patient 106 said that she," Remembered waking up and felt horrible pain between her legs...felt like something being forced in...like being raped." Patient 106 said that later she learned a urinary catheter had been inserted. Further review of Patient 106's medical record confirmed that a "16 Fr [french] 2-way Foley urinary catheter" was inserted during the surgical procedure on 3/31/08.

On 4/2/08 at 1:45 p.m., the Associate Chief Nursing Officer informed the Department that an Anesthesiologist (MD 2) had mentioned that he questioned the functioning of the anesthesia machine in OR Room 4 during a surgical procedure three days prior, on 3/28/08.

On 4/2/08 at 2:15 p.m., Immediate Jeopardy was called as the facility failed to have a system in
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place to ensure that anesthesia equipment that had not been functioning correctly, was removed from service and not used for any further surgeries.

On 4/2/08 at 3:50 p.m., MD 2 was interviewed by telephone. MD 2 said that he was using the anesthesia machine in OR Room 4 on 3/28/08 when he questioned whether the vaporizer of the machine was delivering the anesthetic inhalant in the correct amount. MD 2 said that he switched to another anesthetic inhalant to complete the surgical case, and the machine appeared to function appropriately after that. MD 2 said that he mentioned to RN 1 on 3/28/08, that he questioned the functioning of the anesthesia machine in Room 4. MD 2 said that he was in the OR on 3/31/08 and spoke briefly with MD 1 after concerns were raised about the functioning of the anesthesia machine in Room 4. MD 2 said that RN 1 acknowledged that he had mentioned this issue to RN 1, and that she said, "Yes, you told me."

On 4/2/08 at 4:15 p.m., RN 1 was re-interviewed. The Director of the OR was present during this interview. RN 1 denied that MD 2 told her about the "vaporizer" on 3/28/08. RN 1 then said that, "Maybe they talked about it on Sunday" (3/30/08). At the conclusion of the interview, it was unclear as to content of the conversation[s] between RN 1 and MD 2 on 3/28, 3/30 and 3/31.

Concerns about the functionality of the anesthesia machine in Room 4 of the OR were raised on Friday 3/28/08 by MD 2. The anesthesia machine was not removed from use until after the 3rd case.
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on 3/31/08. Licensed staff had some knowledge that the anesthesia machine was not functioning properly prior to 3/31/08. The machine was not removed from use until after Patient 105 immediately aroused after surgery and told the surgical team, "I felt every .....[expletive deleted]......thing you did. I was awake the whole time."

On 4/2/08 at 7:45 p.m., the Immediate Jeopardy was abated, after the facility provided an acceptable plan of correction.