

Received via Fax 8/10/10 4:38pm

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050276	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/03/2010
NAME OF PROVIDER OR SUPPLIER CONTRA COSTA REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 2500 ALHAMBRA AVE., MARTINEZ, CA 94553 CONTRA COSTA 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>The following reflects the findings of the Department of Public Health during a complaint/adverse investigation visit:</p> <p>Complaint Intake Number: CA00230604 - Substantiated</p> <p>Representing the Department of Public Health: [REDACTED] Pharmaceutical Consultant II</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>T22 DIV5 CH1 ART 3-70263(g)(2) Pharmaceutical Service General Requirements (2) Medications and treatments shall be administered as ordered.</p> <p>Based on observation, staff interview, and document review, the hospital failed to ensure that medications were administered as ordered for Patient A, when RN 1 (registered nurse) did not verify the drug and the route of administration of a drug.</p> <p>Patient A received an infusion of fentanyl and bupivacaine (combination of opiate/local anesthetic medication used to ease the pain of</p>		<p style="text-align: center;">RECEIVED</p> <p style="text-align: center;">AUG 12 2010</p> <p style="text-align: center;">Licensing & Certification East Bay District Office</p>	

Event ID: IKD711 7/27/2010 8:35:38AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE
Lance S. Magaw, Chief Quality Officer
TITLE
August 10, 2010
(X6) DATE

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.

Plan of Correction reviewed & approved 8/16/10 [Signature]

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	<p>Continued From page 1</p> <p>labor) intravenously (IV) instead of Pitocin (oxytocin-medication given immediately after delivery to control uterine bleeding).</p> <p>This medication error resulted in Patient A's experiencing seizures, cardiac arrest requiring cardiopulmonary resuscitation, intubation, transfer to the Intensive Care Unit, and an increased length of hospital stay.</p> <p>THE HOSPITAL FAILED TO ENSURE MEDICATIONS WERE ADMINISTERED AS ORDERED. THESE FAILURES RESULTED IN PATIENT A SUFFERING A SUDDEN CARDIAC ARREST. THIS FAILURE CAUSED, OR WAS LIKELY TO CAUSE, SERIOUS INJURY OR DEATH TO THE PATIENT, AND THEREFORE CONSTITUTES AN IMMEDIATE JEOPARDY UNDER HEALTH AND SAFETY CODE SECTION 1280.1.</p> <p>Findings:</p> <p>Clinical record review on 6/3/10 showed Patient A was a 25 year old woman admitted to the Obstetrics Service on 5/17/10 at 12:53 p.m. for the delivery of her second baby. The "Delivery Note", dated 5/17/10, showed Patient A was admitted in active labor at 36 weeks (premature), had the membranes artificially ruptured (staff attending the labor broke the water sac) at about 3:45 p.m., and "then came to complete dilation right before the baby was delivered", at 5:30 p.m.</p>		<p>Corrective Action #1: Policy #E-A1 Labor and Delivery Policy "Intrapartum Nursing Care of Patients with Continuous Epidural Anesthesia / Patient Controlled Epidural Anesthesia (PCEA)" was reviewed and modified on 6/4/10 to reflect that the anesthesiologist will pull the epidural medication from the automated dispensing machine (ADM). Anesthesiologists were educated regarding policy change by the Department head of Anesthesia beginning 6/4/10 and all nurses were educated beginning 6/4/2010.</p> <p>Monitoring: 20 records of epidural medication removal from the ADM per month will be reviewed to ensure that we are compliant with our policy (Labor and Delivery Policy # E-A1 revised 6/4/10). Monitoring will continue until goal of 100% compliance has been achieved for four continuous months.</p> <p>Responsible Person: Department Head of Anesthesia</p>	

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	<p>Continued From page 2</p> <p>Further review showed that the physician documented on the "Discharge/Transfer Summary" (dated and not signed as of 6/3/10) that a 250 ml epidural bag containing an intravenous solution of 2 mg/ml fentanyl (opiate-pain killer) and 0.125 % bupivacaine (anesthetic), "was hung instead of the Pitocin bag and infused immediately postpartum (after delivery)." Epidural anesthesia is regional anesthesia that blocks pain in a particular region of the body. The goal of an epidural is to provide analgesia, or pain relief, rather than complete anesthesia, which is total lack of feeling. Epidurals block the nerve impulses from the lower spinal segments resulting in decreased sensation in the lower half of the body.</p> <p>The physician also documented, "Several minutes following the bolus of this medication, the patient began to have tonic-clonic seizures (generalized seizures that effect the entire brain) and became unresponsive. Code blue was called" and, "Pulse was briefly still palpable, but then was lost. CPR (cardiopulmonary resuscitation) was initiated..." Review of the summary further showed that Patient A required 6 mg of Ativan given intravenously to stop the seizures, intubation and mechanical ventilation for respiratory support, infusion of intralipid (fat emulsion) as an antidote, and was transferred to the intensive care unit.</p>		<p>Corrective Action # 2: Policy #3501 "Medication Administration" was reviewed, and found compliant with safe medication practices. Policy will be reinforced that medications not administered to a patient will be returned to pharmacy / ADM for appropriate handling. Wasted control drugs will be witnessed and documented in the ADM. All clinical staff will be educated starting 6/4/2010 by the Director of Inpatient Nursing and Chief Medical Officer that medication will not be removed from the ADM until medication is to be administered. This also includes Oxytocin.</p> <p>Monitoring: Will be performed through direct observations of clinical staff starting 6/4/10 for monitoring compliance with safe medication practice. Random observations of at least 10 per week will be conducted. Monitoring will continue until goal of 100% compliance has been achieved for four continuous months.</p> <p>Responsible Person: Director of Inpatient Nursing</p>	

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	<p>Continued From page 3</p> <p>On 6/3/10 at 9:58 a.m., during an interview, RN 1 (a Registered Nurse on Labor and Delivery) stated that on 5/17/10 at 5:00 p.m., Patient A was tired of labor and asked for an epidural. RN 1 stated she paged the anesthesiologist and went to the automated medication dispensing machine to get the supplies. The nurse further stated that the anesthesiologist was doing an epidural in another room and would come as soon as he was done. RN 1 stated that usually she just puts the medications and supplies on the epidural cart and wheels it into the patient's room, but on 5/17/10, the epidural cart was in use, so she carried the medications and supplies into Patient A's room and set them on the bedside table. RN 1 further stated that she noticed that Patient A was acting differently, she did a vaginal exam, and she found that Patient A was completely dilated and ready to deliver the baby. RN 1 paged MD 1 and prepared to deliver the baby as it was now too late for the epidural. RN 1 also stated that the baby was delivered within 15 minutes and that the hospital policy was to give Oxytocin (Pitocin) as soon as the baby was out. RN 1 looked in the anteroom for the Oxytocin and because she could not find it, she looked back at the bedside, saw the epidural medication, thought it was the Oxytocin, and hung it on the IV "wide open" (meaning high infusion rate). RN1 stated "that's where I made the mistake, I grabbed the epidural medication thinking it was the Oxytocin and didn't check the label and just hung it." RN 1 further stated, "In the rush of things I made a</p>		<p>Corrective Action #3: Policy # 701 "Medication Administration and Documentation" was reviewed and found to be consistent with safe medication practices. All clinical staff will be educated starting 6/4/2010 regarding the six rights of safe medication administration and documentation.</p> <p>Monitoring: Will be performed through direct observations of clinical staff starting 6/4/10 for monitoring compliance with safe medication administration practice and documentation. Random observations of at least 10 medication passes per week. Monitoring will continue until goal of 100% compliance has been achieved for four continuous months.</p> <p>Responsible Person: Director of Inpatient Nursing</p>	

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	<p>Continued From page 4</p> <p>mistake. ...They (medications) don't look alike or feel alike I just didn't check." RN1 stated that about 3 minutes later, Patient A started having seizures "I know I should have read the label, I didn't", RN 1 stated during the interview</p> <p>During an interview on 6/3/10 at 2:00 p.m., Administrative Staff 1 said, "The patient got the wrong drug" and acknowledged that "leaving the medication at the bedside" may have contributed to the error and that if the nurse had looked at the label, the error wouldn't have happened.</p> <p>On 6/3/10 at 2:40 p.m. the Director of Pharmacy stated that there was an apparent tubing device compatibility issue that contributed to the medication error, where the intravenous tubing "spike was compatible with both an epidural infusion bag and an intravenous infusion bag."</p> <p>On 6/3/10 a review of the hospital policy, "Medication Administration", approved 10/2007 showed, "The individual administering the medication will verify the medication selected for administration is the correct medication based on the medication order and the medication product label." The hospital policy titled, "Medication Administration and Documentation", approved 4/10, instructed, "Prior to administering medication to the patient follow the "six rights of administering medications" right patient, right medication, right dose, right time, right route, and right</p>		Addendum: The Director of Pharmacy reported the tubing device compatibility issue to the manufacturer and the Institute of Safe Medication Practice.		

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	<p>Continued From page 5 documentation."</p> <p>In an interview with MD 2 and MD 3 on 6/3/10 at 5:40 p.m., MD 2 (Chair of Anesthesia and a physician) said he was involved in the hospital's investigation of the "medication error with fentanyl/bupivocaine" for Patient A after the fact. MD 2 indicated this case was reviewed and discussed "for education in our Anesthesia department meeting". MD 3 said, "fentanyl/bupivocaine epidurals can exert toxicity through cardiac and CNS (central nervous system) effects". MD 2 further stated, "We felt that the patient (Patient A) had both cardiac and central nervous system toxicity from the medication. (MD 3) gave lipids. Lipids are an antidote (emergency rescue medication) for bupivocaine toxicity."</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>			

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