

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050121	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/12/2011
NAME OF PROVIDER OR SUPPLIER Adventist Medical Center		STREET ADDRESS, CITY, STATE, ZIP CODE 118 Mall Dr, Hayward, CA 94520-3788 KINGS 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 an inspection visit:</p> <p>Complaint Intake Number: CA00276019 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 28368, 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) (4) (A) (b) For purposes of this section, "adverse event" includes any of the following: (4) Care management events, including the following:</p>		<p>POC ACCEPTABLE YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p> <p>Reviewed By: <u>Steven Lopez</u> Name: <u>Mike Alexander</u></p> <p>Facility Notified Name: <u>Linda & Barry</u> Date: <u>12/22/11</u> Time: <u>10 AM</u> Notified By: <u>phone call</u> Name: <u>(2 539 157) - 4160</u></p>	

Event ID: B9A311 11/9/2011 2:01:39PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE
Deanne Hoyt VP Quality & Pt. Safety TITLE
12-22-2011 (X8) DATE

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	<p>Continued From page 1</p> <p>(A) A patient death or serious disability associated with a the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.</p> <p>DEFICIENCY CONSTITUTES IMMEDIATE JEOPARDY</p> <p>Title 22 Pharmacy Section 70263(c)(1) (1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.</p> <p>Based on staff interviews, reviews of clinical records, administrative documents, and professional standards of practice, the facility failed to have a safe and effective system for the distribution, dispensing and use of morphine sulfate given by Patient Controlled Analgesia (PCA). PCA is a method of providing an opioid (narcotic) for postoperative pain control by way of a programmable, self-administered intravenous (into the vein) infusion pump. Patient 1 was prescribed</p>		<p>The statements made on the plan of correction are not an admission and do not constitute agreement with the alleged deficiencies herein. This plan of correction constitutes Adventist Health Central Valley Network written credible allegation of compliance for the deficiencies noted.</p> <p>Plan of correction for findings:</p> <ol style="list-style-type: none"> 1. Facility failed to develop and implement a PCA protocol based on standards of professional practice 2. Facility failed to implement the facility's own policies and procedures 3. Facility failed to have a safe and effective system for the distribution, dispensing, and use of morphine sulfate given by PCA 	

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	<p>Continued From page 3</p> <p>7:10 p.m.</p> <p>Patient 1 was transferred to the medical-surgical floor at 8 p.m. and was found unresponsive and not breathing on 11 at 3 a.m. Bedside code blue (emergency resuscitation) was called with the emergency response team responding. Patient 1 was declared deceased at 3:47 a.m. 11.</p> <p>PCA orders were written in the PACU by CRNA (Certified Registered Nurse Anesthetist) 2 at 7:00 p.m. Morphine sulfate concentration on the PCA prescription read 1mg/ml. The self-administered dose of morphine was written at 3mg/infusion; the lock-out interval (or delay) was 10 minutes. The continuous or basal rate was 1mg/hour. The order for morphine sulfate by PCA could potentially administer 19mg per hour (3mg every 10 minutes plus 1mg/hour continuous dose)</p> <p>The PCA Computer Event log print-out was reviewed. The PCA Computer Event log compiled all data entry input into the PCA device. For example, the PCA Computer Event log documented all start and stop entries required for self-administered morphine and the continuous morphine dose. The event log documented the start of the PCA at 7:10 p.m. and showed the first self-administered dose of morphine at 7:15 p.m. of 3mg, 2nd dose at 7:27 p.m., and 3rd dose at 7:45 p.m. The last dose was self-administered on 11 at 1:27 a.m. The total number of times the event log documented self-administered dose of 3mg of morphine was 20. The total amount of morphine self-administered by the PCA was 60 mg.</p>		<p>Post Procedure</p> <p>3. A registered nurse assesses the following: vital signs, pain, sedation, and rate and quality of respirations. Additional patient education is provided prior to starting the PCA pump. The PCA pump is set up by the registered nurse with the pump programming independently verified by another registered nurse. The pump settings are documented in the patient's Medication Administration Record.</p> <p>4. A bolus of pain medication, if ordered, is administered by the registered nurse using the PCA pump. The medication administration and follow up assessments are documented in the patient's record.</p> <p>5. A registered nurse performs follow up assessments and adjustments to the PCA settings based on standard orders. Every 15 minutes x 2, every 30 min x 1, every 1 hour x 4, then every 4 hours after initiation until infusion is discontinued, the nurse determines the patient's response to the ordered pain management approach. Assessment results are documented in the patient's chart.</p> <p>6. The result of the process is safe and effective pain control.</p>	

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	<p>Continued From page 4</p> <p>Between 7:10 p.m. [redacted] 11 and 3:01 a.m. [redacted] 11 (the time the PCA was turned off) Patient 1 received 1mg/hour continuous infusion of morphine for an additional 7.8 mg of morphine. Calculation of the total amount of morphine administered to Patient 1 by way of PCA was 67.9mg.</p> <p>On 7/21/11 at 9:00 a.m. during an interview, the Director of Pharmacy (DOP) discussed the role of Pharmacy and PCA administration of morphine. The DOP stated "Pharmacy reviewed the order before approving it. We have access to Micromedics (computerized drug information data base) and they (the pharmacists) didn't use it." The DOP explained Micromedics' flags pharmacy for drug adverse effects. The DOP stated Patient 1's morphine order was at the upper end of the dosing scale and that there was no documentation opioid tolerance was considered. The DOP stated "... In my opinion, they (the Pharmacist) should have caught this; it was an unusually large dose. They (the Pharmacists) should have questioned it." The DOP agreed that the facility did not have a policy and procedure for the safe use of PCA devices.</p> <p>On 7/21/11 at 10:40 a.m., during an interview, CRNA2 stated "I was instructed by the surgeon to fill out the PCA order. He (Patient1) was a big guy and he was very anxious about not getting adequate pain control. I determined the dose based on my best clinical judgment. I believe I did the best for the patient. Education for the PCA should have been provided by Nursing. It was not done adequately..." CRNA2 confirmed he was not</p>		<p>How the correction will be accomplished, both temporarily and permanently.</p> <ol style="list-style-type: none"> Policy No.: 4000.09.18 Intravenous Patient Controlled Analgesia (PCA) Infusion developed and approved by Medical Staff Committees and Patient Care Council. Physician Order Set Patient Controlled Analgesia (PCA) Orders Opioid Naïve approved by Governing Body and Medical Staff <ol style="list-style-type: none"> PCA patient education is provided to patients prior to initiation of PCA and addresses their role in managing their pain, specific information on pump operation, safety measures, and when to alert a nurse. Education includes family members to clearly emphasize the hazards of anyone other than the patient administering a PCA dose. Determination of opioid tolerant or opioid naïvety is done by the physician immediately preceding the intended course of PCA therapy. "Patients who are considered opiate tolerant are those who have been taking, for a week or longer, at least 60 mg of morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral HYDROMORPHONE daily, 	<p>July 15, 2011 October and November 2011 August 2011</p>

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	<p>Continued From page 5</p> <p>familiar with the hospital PCA protocol. CRNA2 confirmed he did not utilize any professionally established guidelines prior to writing the PCA order.</p> <p>On 7/21/11 at 11:15 a.m., during an interview, Chief Medical Officer of Anesthesia (CMO) stated, "There was a hand off during the procedure. I'm not sure if CRNA2 was totally familiar with the patient... He (Patient1) was obese but, I wouldn't have started him on such a large dose. I would have started him low, maybe 1mg, and then titrated up if that didn't hold him." The CMO confirmed he was not aware of any hospital protocol for the safe use of PCA.</p> <p>On 8/25/11 at 2:30 p.m., during an interview, Surgeon 1 stated, "The patient did well during surgery. I told CRNA1, we need to follow this guy with a PCA on the floor. There was a hand off during the procedure, from CRNA1 to CRNA2. I don't know why. I guess they do it all the time. I do not write PCA orders... All I wrote was pain control per PCA. Anesthesia took responsibility for initiating it. I reviewed the case the next day and know the order (for PCA) would only be appropriate for someone very opiate tolerant." Surgeon 1 confirmed he was not aware of any hospital PCA protocol.</p> <p>The San Diego Patient Safety Taskforce published guidelines for the safe use of PCA devices ["Patient Controlled Analgesic (PCA) Guidelines of Care, December 2008"]. The publication (can be obtained online) read, "The use of PCA is a complex, high-risk treatment that is associated with harmful</p>		<p>or an equianalgesic dose of another opioid." (FDA) Patients who do not meet the definition of opioid tolerant, who have not had narcotics doses at least as much as those listed above for a week or more, are considered to be opiate naïve.</p> <p>c. Consistent pain assessment provides appropriate continued monitoring and evaluation of the pain management plan. Pain is assessed using a standard pain assessment scale. Minimally the patient is assessed for pain at baseline, initiation of the opioid, any change in syringe, settings, or dose change or bolus, event or deterioration.</p> <p>d. Systematic ongoing assessment for sedation using the Ramsay scale with vital signs and pain assessment occurs prior to start of PCA therapy, every 15 minutes x 2, every 30 min x 1, every 1 hour x 4, then every 4 hours after initiation until infusion is discontinued.</p> <p>e. Respiratory Assessment with ongoing sedation assessment includes respiratory rate and quality of respirations. Use of the pulse oximeter is required with all patients on PCA therapy. SpO2 and respiratory rate is assessed and documented every 1 hour for 24 hours.</p>	

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	<p><i>Continued From page 7</i></p> <p>consistent documented evidence for numerical pain assessments post-surgery for Patient 1. The AVPNS and DRM acknowledged the clinical history for Patient 1 did not include whether or not the patient was opioid naive or had history of taking narcotic type pain medications prior to surgery. The AVPNS and DRM acknowledged the documentation for neurologic and respiratory status did not follow hospital policy. The AVPNS and DRM confirmed that pain assessments for Patient 1 did not follow hospital policy. In addition the AVPNS and DRM confirmed the facility PCA Policy required patient measurements for oxygen saturation and this was not done. The AVPNS and DRM confirmed that the equipment for measuring oxygen saturation (pulse oximeter) was in the patient room, but was not connected to the patient.</p> <p>On 8/26/11 at 1:49 p.m., during an interview CNA1 stated Patient1 began sleeping and snoring very loudly when his wife left around 11 or 12 a.m. CNA1 was called to the room next to Patient1's between 1:30 and 2:00 a.m. and noted he was snoring loudly during the period of time she was in the adjacent room. At 2:30 a.m., she put ice on Patient1's foot per doctor's orders. Patient1 was snoring loudly and CNA1 did not wake him. No vital signs were taken at this time and no pain assessments were done. CNA1 acknowledged she was not familiar with the hospital PCA protocol.</p> <p>On 8/26/11 at 2 p.m., during an interview, RN1 stated, she monitored Patient 1 per the medical-surgical post-operative protocol. RN1 confirmed she was not aware of the hospital PCA protocol.</p>		<p>2. Results will be shared at Medical Staff Quality Committee and Pharmacy and Therapeutics at regularly scheduled meetings.</p> <p>FINDING 3 Facility failed to have a safe and effective system for the distribution, dispensing, and use of morphine sulfate given by PCA.</p> <p>How the correction will be accomplished both temporarily and permanently.</p> <p>1. Policy No.: 7710.12.01 requires the pharmacist to review each medication order prior to dispensing. Immediate counseling was provided to the individual pharmacist. Immediately after the event, education was provided to ensure compliance with the policy. "Opiate Dosing in High Risk Patients" was presented to pharmacy staff and Clinical Quality Review Committee.</p> <p>2. A sign was posted in surgical areas to remind staff to fax orders to the pharmacy for immediate review. The title or position of the person responsible for the correction is the Pharmacy Director.</p>	July 15, 2011

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	<p>Continued From page 8</p> <p>The following information was obtained from the clinical record of Patient 1: PACU Clinical Nursing Notes dated [redacted] 11 at 7 p.m. indicated "PCA set up and explained to pt. (patient) questions answered." No documentation was found for specific education as to medication precautions, adverse reactions, and side effects. No documentation was provided that showed patient and/or family were educated on PCA prior to the surgery.</p> <p>PACU Clinical Nursing Notes indicated pain assessment was done at [redacted] 11 at 7:35 p.m., "patient states pain is receding now." No numerical score was given. No other pain assessments recorded in the PACU.</p> <p>Clinical Nursing Notes indicated at 8 p.m. (patient was on the medical-surgical floor) an initial assessment was done and Patient 1 was "awake and alert". Blood pressure, pulse, and respirations were assessed at 8:28 p.m., 8:57 p.m., 10:00 p.m., 11:00 p.m., and 12:00 a.m. [redacted] 11. Pain status was assessed at 8:00 p.m. to be 6 on a scale of 1 to 10. At 12:00 a.m. pain was assessed at 5. Psycho/Social status was assessed at 8:00 p.m. as "awake and alert", at 12:00 a.m. [redacted] 11 as "sleepy easy to arouse", and at 2:00 a.m. as "sleeping and snoring; he was arousable". At 3:00 a.m., RN1 no longer heard Patient 1 snoring. RN1 entered Patient 1's room to check on him and found him unresponsive and not breathing; the emergency response team was called and PCA stopped.</p> <p>On 8/3/11 at 9 a.m., during an interview, the</p>		<p>A description of the monitoring process to prevent recurrence of the deficiency.</p> <p>Retrospective chart review for documentation of pharmacist review of PCA orders for 100% of patients on PCA from August 2011 through November 2011 was done to ensure 100% compliance with the policy, and ongoing until 100% compliance achieved followed by random chart audits for compliance monthly.</p>	

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(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 8</p> <p>pathologist reported that based on blood and tissue sampling, the death was consistent with narcotic overdose. The coroner's report Case Number 11-0191 was reviewed and under the item Immediate Cause of Death the following was listed: "Acute Opiate Toxicity".</p> <p>Review of facility Policy: Intravenous Patient Controlled Analgesia (PCA) Infusion indicated Under Policy Compliance - Key Elements: "...Oxygen saturation is a prudent supplemental assessment measurement in patients on PCA therapy ... Procedure A. Assessment 1. The patient is assessed by a registered nurse and a physician. A. The physician should determine the patient's opioid tolerance and candidacy for standard PCA orders. B. A registered nurse assesses the patient's cognitive function to determine if the patient is able to understand and participate in pain management. The nurse also reviews with the patient any education materials, including what is pain assessment and how to achieve pain relief with the PCA pump... C. Documentations 1. PCA documentation must be initiated when the infusion is started...(6) Other documentation should include: (g) patient assessment/pain management ...D. Physicians orders 1. ... f. Basal rate (should be avoided in opioid naive patient)... E. Pharmacy Distribution 2. The pharmacist will review for appropriateness based on patient demographics and dosage seen on the medication order. 3. All PCA orders that exceed the range seen on the preprinted PCA form shall be immediately discussed with the ordering physician. F. Monitoring Parameters 1. Place and</p>			

Event ID: B0A311

11/9/2011

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

TITLE

(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 those documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 080121	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/12/2011
NAME OF PROVIDER OR SUPPLIER Adventist Medical Center		STREET ADDRESS, CITY, STATE, ZIP CODE 115 Mall Dr, Hanford, CA 93230-5786 KINGS 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 10</p> <p>monitor pulse oximetry a. Notify physician of SpO2 less than 92% b. Notify physician if alertness score is 3 or greater, where (1) 6=Sleep, easy to arouse; (2) 1=Awake and alert; (3) 2=slightly drowsy, easily arousable; (4) 3=Frequently drowsy, arousable, drifts off to sleep during conversation; (5) 4=Somnolent, minimal or no response to physical stimulation; 2. Recording LOC (Level of Consciousness), vital signs, and pain assessment; a. At the initiation of therapy Prior to the start of a continuous (basal) infusion of PCA. b. Every 15 minutes X 2 hours, every 1 hour x 4 hours, then if stable every 4 hours; c. Maintenance (after therapy has been established); d. Within 1 hour of initiation or change in settings. 3. Observation hourly X 24 hours.</p> <p>Review of "Safety Issues Associated with Patient-Controlled Analgesia, (author), page 2", indicated "Patients who are candidates for post-surgical use of PCA should be trained prior to admission for their surgery. As part of the re-admission process, patients and their families must be taught the relationship between pain, pushing the button, and adequate pain relief. They should understand the benefits of PCA and how it works."</p> <p>A review of The Institute for Safe Medication Practices, Medication Safety Alert, issue July 24, 2003, page 8 indicated "Educate patients about the proper use of PCA before initiation. Start during the preoperative time so Patients are not too groggy to understand."</p>			

Event ID: B9A311 11/9/2011 2:01:39PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

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