

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

HEALTH CARE FACILITIES
INSPECTION DIVISION

POC accepted by Eunice Chan 6/15/14

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050677	(X2) MULTIPLE CONSTRUCTION 2014 JUN 5 PM 3:11 RECEIVED B. WING	(X3) DATE SURVEY COMPLETED 07/23/2013
NAME OF PROVIDER OR SUPPLIER Kaiser Foundation Hospital - Woodland Hills		STREET ADDRESS, CITY, STATE, ZIP CODE 5601 De Soto Ave, Woodland Hills, CA 91367-6701 LOS ANGELES 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: CA00357973 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 28851, Pharmacy Consultant</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 CH 1 ART3 - 70263(C)(1)(q)(8) Pharmaceutical Services General Requirements (c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. (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</p>		<p>A. How the correction will be accomplished, both temporarily and permanently: 1. Affixed warning labels to PCA pumps indicating "Patient Use Only". (See Appendix A) 2. Huddled with nursing staff include the following when caring for a patient on PCA: a. Explicitly educate patient and family that PCA is for patient use only (See Appendix B) b. Provide printed PCA hand out to patient and family. Printed hand out explicitly notes "This pump is for patient use only. NOT FOR USE BY FAMILY AND/OR FRIENDS." (See Appendix C)</p> <p>B. The title or position of the person responsible for the correction: Chief Nurse Executive is responsible for correction.</p> <p>C. A description of the monitoring process to prevent recurrence: Retrospective chart review of patients on PCA pump for documentation of patient teaching on PCA use and safety. (Numerator: Total number of patients on PCA pump with documented education on PCA for patient use only. Denominator: Total number of audited patients on PCA pump.) Data on rate of compliance are reported to Risk Management & Patient Safety Subcommittee. Monitoring will continue until December 2014.</p> <p>D. The date the immediate correction of deficiency will be accomplished: Corrective actions listed above in section A1 and A2 were completed on 01/29/2014.</p>	

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *[Signature]* TITLE **DIRECTOR-RISK MGMT, PT. SAFETY, ACCREDITATION** (X6) DATE **06/02/14**

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 8

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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	<p>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>(q) Labeling and storage of drugs shall be accomplished to meet the following requirements: (8) Drugs shall be accessible only to responsible personnel designated by the hospital, or to the patient as provided in 70263 (1) above.</p> <p>Based on interview and record review, the facility failed to:</p> <ol style="list-style-type: none"> 1. Limit access to a bedside patient-controlled analgesia (pain medication) device which resulted in an unauthorized family member administering a narcotic medication to the patient. 2. Implement established policies/procedures relating to family members administering medications to patients. <p>During the course of Patient 1's surgery and the post-operative period, the patient received 19 doses of three types of narcotic medications within a six hour time period. In less than two hours after this time period, the staff found the patient unresponsive, not breathing, and in cardiac arrest. The staff called a code blue (medical emergency in which a team of medical personnel work to revive an individual in cardiac arrest). Subsequently, the patient's pulse was restored but remained unresponsive due to anoxic (caused by absence of oxygen) brain injury. Nine days later, Patient 1</p>				

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	<p>was terminally extubated (the rapid cessation of mechanical ventilation and removal of the artificial airway). Patient 1 died the next day.</p> <p>Findings</p> <p>On 7/23/13, the Department made an unannounced visit to the facility to conduct an investigation on an entity reported incident.</p> <p>Patient 1, a 66 year old female, was admitted to the facility on [REDACTED]/13. She had an admitting diagnosis of colonic constipation and was scheduled to have a surgical procedure the same day. During the course of Patient 1's stay, Patient 1 received 19 doses of three types of narcotic medications within a six hour period. The medications administered were fentanyl during surgery as an adjunct to general anesthesia, meperidine (Demerol) post-surgery for pain, and hydromorphone (Dilaudid) in a patient-controlled analgesia (PCA) device for pain.</p> <p>Fentanyl, meperidine, and hydromorphone are all defined as opioid narcotic analgesics (opium-like pain relievers with a high potential for tolerance) by Lexicomp Online and DailyMed, both nationally recognized drug information sources.</p> <p>A review of the facility's paper-based Anesthesia Intraoperative and Procedure Record indicated that, on [REDACTED] 13, Patient 1 received five doses of fentanyl, 250 micrograms (mcg) at 11 a.m. (all times approximate), 100 mcg at 12:30 p.m., 50 mcg at 1 p.m., 100 mcg at 1:30 p.m., and 50 mcg</p>				

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	<p>at 2 p.m., a cumulative total of 550 micrograms (mcg), during surgery.</p> <p>A review of the facility's computerized Medication Detail record indicated that, on [REDACTED] 13, Patient 1 received three doses of meperidine (Demerol) 25 mg at 3:10 p.m., 3:33 p.m., and 3:56 p.m., a cumulative total of 75 mg, in the post-anesthesia care unit (PACU).</p> <p>During an interview on 7/23/13 at 9:56 a.m., Pharmacist 1 stated that the meperidine dosing was typical dosing post-operatively.</p> <p>A review of the facility's Event Log Report indicated that on [REDACTED] 13, the PCA demand dose for hydromorphone (Dilaudid) was set to 0.4 mg with an 8 minute lock out period. Patient 1 received hydromorphone 0.5 mg loading dose at 4:32 pm (all times adjusted from printed record) and five 0.4 mg doses at 4:40 p.m., 4:49 p.m., 5 p.m., 5:08 p.m., and 5:16 p.m., totaling 2.5 mg, on the med-surg (medical-surgical) floor.</p> <p>A review of the facility's Event Log Report indicated that on [REDACTED] 13 at 5:23 p.m., the PCA demand dose setting for hydromorphone was changed from 0.4 mg to 1 mg. Patient 1 received five 1 mg doses at 5:28 p.m., 5:36 p.m., 5:45 p.m., 5:54 p.m., and 6:04 p.m., for a cumulative total of 7.5 mg.</p> <p>During an interview on 7/23/13 at 12:35 p.m., Pharmacist 1 stated that the surgeon ordered the PCA after surgery and that the PCA was ordered within standard dosing range</p>				

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	<p>A review of the undated Event Timeline for PCA-related Injury indicated that on [REDACTED] 3 at 1720 (5:20 p.m.), "Patient complaining of unrelieved pain. Will call [physician] regarding patient's request to increase pain medication dose ...[family member] remained at bedside."</p> <p>A review of the facility's undated Event Timeline under [REDACTED] PCA Pump History indicated that on [REDACTED] 3 at 1723 (5:23 p.m.), PCA demand dose setting for hydromorphone was changed from 0.4 mg to 1 mg.</p> <p>A review of the undated Event Timeline for PCA-related Injury indicated that on [REDACTED] 13 at 1728 (5:28 p.m.), "PCA settings changed per [physician's] orders (demand dose from 0.4 mg to 1 mg Dilaudid (hydromorphone) with eight minute lockout [between doses]. Patient alert and oriented and verbalized understanding of new dose. Pain = 8 (out of 10 on pain scale). RN observed patient pressing PCA button."</p> <p>Based on the drug reference DailyMed, the PCA demand dose standard dosing range for hydromorphone is 0.05-0.4 mg.</p> <p>Based on record review of the facility's PCA Pump Orders, Hydromorphone (Dilaudid) 0.2 mg/ml PCA IV, the recommended demand dose is 0.1-0.5 mg and the recommended lockout interval is 5-15 minutes.</p> <p>Based on record reviews of the medication</p>			

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	<p>administration records dated [REDACTED] 13, the locations, time frames, and total amounts of narcotics administered to Patient 1 are summarized as follows:</p> <p>Surgery: 11 a.m. to 2 p.m. (times approximate), Fentanyl 550 mcg PACU: 3:10 p.m. to 3:56 p.m., Meperidine 75 mg Med-Surg: 4:32 p.m. to 6:04 p.m., Dilaudid (hydromorphone) by PCA, 7.5 mg</p> <p>A review of the Event Timeline of the PCA related injury report stated, on [REDACTED] 13 at 1800 (6:00 p.m.), "Patient sleeping comfortably, arousable and stating that abdomen still hurts. Reassured patient and spouse that pain medication is working. Will continue to monitor patient 's pain level."</p> <p>A review of Patient 1's Code Blue record progress note, dated [REDACTED] 13 at 6:16 p.m., indicated, "...According to [family member], the patient was awake and alert and speaking to him around 6pm and [Patient 1 ' s] pain was finally better controlled. Then [Patient 1] had fallen asleep and the [family member] states he was happy ' the pain was finally controlled ' . The [family member] states he pressed the PCA button 1-2 times more, even when [Patient 1] was asleep, since he saw it was working. " At 8:21 p.m., the progress note addendum indicated, " ...When the nurse walked into the room, she found the patient non-responsive and the code blue was called. "</p> <p>A review of the PCA Event Log Report, dated [REDACTED] 13, indicated that the last demand dose of Hydromorphone 1 mg was administered at 6:04</p>			

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	<p>p.m. (daylight savings time adjusted from 5:04 p.m. on the printed record) while Patient 1 was asleep.</p> <p>During an interview on 7/23/13 at 10:55 a.m., Administrator 1 stated that the hospital policies and procedures do not allow family members to administer medications.</p> <p>A review of the policy titled "PCA (Patient Controlled Analgesia" , last revised "1/13" , stipulated "...family members and health care professionals shall not administer the patient demand dose by activating the PCA (" PCA by proxy ")."</p> <p>A review of the procedure titled "PCA (Patient Controlled Analgesia", last revised "1/13", under the subheading "Interventions ...Nursing Measures and Patient Teaching," stipulated "Caution patients, family members and visitors that no one except the patient should press the PCA button to deliver a dose."</p> <p>A review of Patient 1's Certificate of Death, dated [REDACTED]/13, indicated the immediate cause of death as "anoxic encephalopathy" (disorder of the brain caused by absence of oxygen) and the conditions leading to death as "cardiopulmonary arrest" (complete cessation of heart activity) and "probable hydromorphone intoxication." The death certificate indicated the injury occurred as a result of "administration of hydromorphone."</p> <p>The cumulative effects from the three narcotic analgesics and the extra dose of hydromorphone</p>				

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	<p>administered to Patient 1 by an unauthorized family member resulted in probable hydromorphone intoxication, respiratory depression, cardiac arrest, unresponsiveness, and death.</p> <p>Therefore, the facility failed to limit access to a bedside patient-controlled analgesia device which resulted in an unauthorized family member administering a narcotic medication to the patient.</p> <p>The facility's failure to implement its policy/procedure relating to family members not administering narcotic medication to a patient, via a patient controlled analgesic device, is a deficiency that has caused or is likely to cause serious injury or death to a patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Section 1280.1.</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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