CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050195	A. BUILDING _____ B. WING _____	08/24/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WASHINGTON HOSPITAL	2000 MOWRY AVENUE 1900 MOWRY AVENUE SUITE 104, FREMONT, CA 94538 ALAMEDA COUNTY

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	The following represents the findings of the California Department of Public Health during investigation of an entity reported adverse event. Entity reported intake number: CA00124329. Representing the Department: [redacted] Pharm.D., Pharmaceutical Consultant II 1280.1(a) HSC Section 1280 If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 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 an amount not to exceed twenty-five thousand dollars ($25,000) per violation. 1280.1(c) HSC Section 1280 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. DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY T22 DIV5 CH1 ART3 - 70263(c)(1) Pharmaceutical Service General Requirements (1) The committee shall develop written policies and procedures for establishment of safe and			

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	Continued From page 1 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. T22 DIV5 CH1 ART3 70263(g)(2) Pharmaceutical Service General Requirements (2) Medications and treatments shall be administered as ordered. The above regulations are not met as evidenced by: Based on observations, staff interviews and policy and record reviews, the hospital failed to implement written policies and procedures that provide for safe distribution of drugs to patients. These failures contributed to medication errors which resulted in Patient A's respiratory depression, altered level of consciousness and hypotension and transfer to the intensive care unit and placed other patients at risk for similar events. Findings: Patient A was an 87-year-old admitted from the emergency room to 3W24-02 (a designated patient room at 3 West) with the diagnoses that included heart failure, dementia, and shortness of breath.			

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	Continued From page 2 The medical record showed that Patient A did not have complaints of pain nor had a history of substance abuse. On 8/17/07 at 8:15 a.m., Patient A received methadone (a narcotic used for severe pain management or for treating persons with a history of substance abuse), Lexapro (an antidepressant), Zestril (a blood pressure-lowering drug also used to treat congestive heart failure), and desipramine (an antidepressant also used in the treatment of substance abuse disorders). According to the nurses notes dated 8/17/07 at 11:00 a.m., Patient A, "has hallucinations seeing ants crawl into her blanket, crying out loud, assist patient to relax..." The nurses notes indicated that the patient calmed down after ten minutes. The nurses notes indicate at 11:30 a.m., Patient A "appears anxious/restless," and received Valium 2.5mg one tablet by mouth. The blood pressure at 11:30 a.m. was 142/66. Medications administered to Patient A were intended for Patient B, a different patient admitted to 3 West. Further review of Patient A's record showed that the nurse gave Methadone in the absence of any pain. On November 28, 2006, the US FOOD and Drug Administration (FDA) has warned healthcare professionals regarding reports of fatal and life-threatening respiratory depression and cardiac arrhythmias in patients newly receiving oral methadone. The article showed that "methadone			

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	Continued From page 3 therapy is complex and should only be used in patients with moderate to severe pain that is not ameliorated by other nonnarcotic agents. Whereas systemic clearance of methadone can take up to 59 hours..." On 8/18/07 at 12 noon, the Nurses Notes indicated that Physician 3 was at the patient's bedside. The Progress Record dated 8/18/07, indicated that there was a medication error and the patient's altered level of consciousness and neurological changes were secondary to the medication error. The Physician's Orders dated 8/18/07 showed that Physician 3 ordered to discontinue several drugs that included desipramine, Lisinopril, Methadone and Lexapro. Physician 3 ordered intravenous fluids with 1/2 normal saline at 50 cc per hour for a total of 500 cc and then 30cc per hour. Between 12 noon and 4:30 p.m., Patient A's blood pressure remained low. Patient A remained lethargic. According to the Nurses Notes, at 4:30 p.m. Patient A's blood pressure was 66/40. A review of the medical record revealed that on 8/18/07 at 5:00 p.m., the nurse called Physician 3 and the Rapid Response Team (a multi-disciplinary emergency response team) was initiated. The team treated Patient A with Narcan and Romazicon. Narcan is a drug used as a rescue agent to reverse respiratory depression, one of the effects of a narcotic overdose. Romazicon is a rescue agent to reverse the sedating effects of benzodiazepines such as Valium. Physician 3 gave a "DNR" (Do not resuscitate)			

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	Continued From page 4 order at 5:45 p.m. Nurses notes on 8/19/07 indicate Patient A was transferred to the intensive care unit on 8/18/07 at 6:30 p.m. because of low blood pressure and lethargy. Dobutamine drip was started intravenously to increase the blood pressure. Patient A's blood pressure did not improve despite receiving the maximum dose of Dobutamine and died on 8/19/07 at 7:49 a.m. According to the facility's investigation, the errors were introduced into the order processing system when RN 1 - recopied by hand - orders dated 8/16/07 for all Patient B's medications - onto an unlabeled blank Medication Reconciliation Form (a type of physicians orders defined by the facility). Later, this form was accidentally labeled with Patient A's name. RN 1 explained to administration that the "original was messy" and that was the reason for recopying the medications. The orders intended for Patient B were faxed to pharmacy with a sticker affixed identifying Patient A. Pharmacy entered these medication orders on the medication profile of Patient A. The administrative and clinical pharmacy staff members were interviewed on 8/24/07 about the drug dispensing procedure. At 6:20 p.m., PM 1 (Pharmacy Manager) said that it was the expectation of pharmacy management that all clinical staff pharmacists ensure appropriateness of medications prior to dispensing by contacting the physician for clarification for any unclear orders (such as missing indications of prescribed drugs)			

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	Continued From page 5 as outlined in their "Pharmacists Duties & Responsibilities, Policy number: 2:02.02, effective 3-25-05." PM 1 said that all pharmacists have access through the pharmacy medication management software system to extensive patient-specific medical information including: patient history and physical and diagnoses, demographic information, clinical labs, medication profile, dispensing records and medical records from previous admissions. On 8/24/07 at 6:35 p.m., CSP 1 (Clinical Staff Pharmacist) said that a drug evaluation is conducted by a pharmacist for all orders prior to processing and dispensing medications. SP 1 stated "I first check to see if it is a new patient. I check the reason for admission, allergies, the medication profile for drug interactions and duplicate orders." When asked, do you always check for an indication?" CSP 1 said, "Absolutely." When asked, " What do you do if you can' t find it? CSP 1 said, "If I don't know, I'll call the physician. "There was no documentation present by the hospital that the pharmacist who processed the orders for Patient A called the physician to clarify the Methadone order in the absence of a supporting diagnosis for Patient A of either severe pain or history of narcotic addiction in the medical record. When PM 1 was asked if implementation of the policy, checking for indications and calling the physician for verification would have prevented the error, PM 1 responded, "Yes, I see your point." During the interview, PM 1 indicated that CSP 1			

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	Continued From page 6 was responsible for processing the medication orders for Patient A. As of 8/24/07, PM 1 confirmed that CSP 1 or any pharmacy staff has not been counseled for failure to complete all steps in the drug evaluation process in accordance with the facility's policy, including the step of ensuring methadone is appropriate for a patient prior to dispensing it for administration. PM 1 stated when processing orders they "always use two identifiers ...the patient's name and the patient's room number." The pharmacy's procedure for identifying patients by room number is not a reliable system to ensure safe distribution and dispensing of drugs. According to the Joint Commission, National Patient Safety Goals, to improve the accuracy of patient identification it is recommended to: "Use at least two patient identifiers." Also, according the Joint Commission, it is the standard of practice that the "room number or physical location is not used as an identifier." According to Pathways for Medication Safety, a Partnership between the American Hospital Association, Health Research and Educational Trust, and the Institute for Safe Medication Practices, 2002, it was stated that patient room should not be used for identification: "(I) improvement in the accuracy of patient identification. "One of JCAHO's recommendations is for providers to "use at least two patient identifiers (neither to be the patient's room number)			

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	Continued From page 7 whenever taking blood samples or administering medications or blood products. Acceptable identifiers may be the patient's name, an assigned identification number, telephone number, or other patient specific identifier. " The hospital failed to: a. implement written policies and procedures for safely processing orders. Specifically, the pharmacy policies and procedures require the pharmacist "to ensure appropriateness of medications for the patient". By pharmacy staff dispensing methadone for Patient A, in the absence of a diagnosis or supporting medical history, the hospital failed to prevent serious medication errors for Patient A. The medical records for Patient A were available to the pharmacist who processed the order. The standard of practice and the manufacturer's labeling places limits on the prescribing of methadone. Methadone prescriptions are restricted to patients who have diagnoses of either severe pain or a history of narcotic use. b. implement written policies and procedures for clarifying medication orders for dangerous drugs. Specifically, the pharmacist failed to contact the physician or intervene when a review of the medical record did not support that a drug is appropriate for a patient. c. evaluate the pharmaceutical services provided and make recommendations to the pharmacy and therapeutics committee which ensure medication is			

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	Continued From page 8 administered as ordered. Specifically, the hospital failed to develop an immediate correction plan that would prevent a recurrence of a similar series of medication errors. The hospital failed to develop a procedure for safe distribution and accurate dispensing of medications by employing unreliable "room numbers" as part of the patient identification system. The use of room numbers, which change throughout a patient stay, is not a reliable identification system and is not the standard of care. The identified violations and system failures contributed to Patient A's respiratory depression, altered level of consciousness and hypotension as a result of medication errors and potentially placed other patients at risk for serious complications related to medication errors. The identified violations and system failures resulted in the facility's inability to ensure the safe distribution of drugs as ordered by the physician.			

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