for approval by Edmond Yee 12/17/08

PRINTED: 10/16/2008
FORM APPROVED

California Department of Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA93000015	A. BUILDING _____ B. WING _____	09/16/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BROTMAN MEDICAL CENTER	3828 DELMAS TERRACE CULVER CITY, CA 90231

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E 000	Initial Comments	E000	Complaint Intake No: CA 00163007 CMS 2567 receipt date at Brotman Medical Center: 10/16/08	
	The following reflects the findings of the Department of Public Health during a Complaint Investigation. Complaint Intake Number: CA00163007 Representing the Department of Public Health: [redacted], Pharmacy Consultant [redacted], R.N., HFEN 1280.1(c) Health & Safety Code 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	E475	A) A procedure has been implemented whereas High Alert Medications (HYDROmorphone, MorPHINE, Meperidine vials and carpujects) are labeled with High Alert stickers prior to being placed into inventory. High Alert medications are checked by a Technician and a Pharmacist for High Alert stickers prior to dispensing. Daily rounds are performed by a Pharmacy Technician to verify all High Alert medications stocked in the MedDispense system have been labeled with High Alert stickers. Adherence to this process is overseen by the Director of Pharmacy.	9/15/08
E 475	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 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. This RULE: is not met as evidenced by:		B) The hospital policy titled, "Medication Safety – Look-Alike and Sound Alike Medications" was revised to reflect the changes needed to properly procure, store, and dispense High Alert Medications. These revisions include the following: (1) On-going staff education regarding the potential for hydromorphone and morphine mix-up. Education includes staff inservice and the posting of signage for awareness. (2) Hydromorphone and morphine shall include a double-check of at least the following: (a) Correct Patient (b) Correct Drug & Concentration (c) Correct Dosage (d) Correct Route (e) Correct Time (3) Any time a nurse prepares a dose of hydromorphone or morphine, a second nurse must double check the accuracy of dose preparation. Both nurses will verify the "5 Rights of Medication	9/15/08

TORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Mary R Donnelly	VP Pt Care Services	10/20/08

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E 475	Continued From Page 1 Based on review of facility and clinical records, inspection of the facility and interview with staff, the facility failed to consistently implement policies and procedures to ensure the safe and effective use of all drugs. The facility failed to ensure that an injectable, opiate pain medication, Dilaudid (hydromorphone) was administered as prescribed for Patient 1 resulting in an adverse outcome of anoxic encephalopathy (oxygen depletion with subsequent brain function deterioration) and coma. The facility also failed to ensure that a policy and procedure regarding the labeling of the high-alert medications, Dilaudid and a newly approved policy and procedure for verification by a second nurse prior to the administration of Dilaudid and morphine were consistently followed. For Patient 1, an opiate pain drug, Dilaudid 4mg was prescribed to be administered subcutaneously every 3 hours as needed for severe pain. However, on July 24, 2008, Registered Nurse 1, administered the injectable Dilaudid 4 milligrams (mg) directly into a vein by intravenous push rather than subcutaneously as prescribed. Patient 1 subsequently experienced a cardiac (code blue) emergency approximately 30 minutes later, at 1:45 p.m. and was resuscitated but experienced anoxic encephalopathy with repeated seizures resulting in a comatose condition requiring continued mechanical ventilation for breathing. A review of facility policies on September 15, 2008 revealed an approved procedure whereby the facility identified, high-alert medications, such as Dilaudid injection, would be individually labeled with a pink-high alert sticker prior to dispensing by the pharmacy. In addition, a new procedure was implemented whereby the administration of Dilaudid and morphine by	E 475	Administration" have been reviewed prior to administration of the medication and document verification on the patient's Medication Administration Record. Monitoring for compliance is conducted by the Charge Nurse of each nursing unit on a daily basis. (4) A PCA protocol has been instituted which includes a double check of the correct drug and concentration, correct dosage, and correct pump settings, if applicable. This policy revision was approved at the Pharmacy and Therapeutics Committee on 10/16/08. The policy will be presented to the Medical Executive Committee on 10/21/08 and to the Governing Board on 10/22/08 for approvals. Adherence to this policy is overseen by the Director of Pharmacy and the VP, Patient Care Services. C) The IV Guideline Protocols were updated to reflect current formulary and re-formatted per the DPH Pharmacy Consultant's request. The guidelines include areas of administration, routes of administration, authorized personnel to administer medications and customary frequency dosing. These guidelines have been placed in applicable nursing units. Adherence to these protocols are overseen by the Director of Pharmacy and the VP, Patient Care Services. D) A New Graduate Nursing Program was instituted in the facility on 10/10/08. The 6-week course requires mandatory attendance by all new graduates and includes an increased focus on medication administration and safety. This process is overseen by the Clinical Nurse Educator and the VP, Patient Care Services. E) A Nurse Preceptor Training Program was instituted in the facility with the first course held on 9/18/08. This is a one-day, intensive training program to prepare bedside nurses as preceptors to fulfill their role of acclimating	9/30/08 10/10/08 9/18/08

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E 475	Continued From Page 2 nursing staff would be verified by a second nurse. However, 32 of 36 Dilaudid syringes inspected on the P-5 unit and 8 of 20 Dilaudid syringes inspected on the P-2 unit on September 16, 2008 at 1:20 p.m. were unlabeled with the pink-high alert sticker. Also, random record reviews revealed that injectable administrations of morphine on the P-5 unit for Patient 2 and Dilaudid on the P-2 unit for Patient 3 on September 16, 2008 that were not verified by a second nurse. When questioned, the assigned nurses for the respective patients were unaware of the second nurse verification requirement. On September 15, 2008 at 2:20 p.m., an immediate jeopardy (IJ) was identified due to the facility's failure to consistently implement policies and procedures for the safe and effective use of medications such as for the opiate, pain medication, Dilaudid, that resulted in an adverse medication outcome for Patient 1 on July 24, 2008. In addition, approximately 7 weeks after the adverse medication incident involving Patient 1, the facility continued to fail to protect patients from undue adverse outcomes by the incomplete implementation of labeling policies and procedures for high-alert medications and administration verification of Dilaudid and morphine by a second nurse . Findings: A review of the clinical record on September 15, 2008 for Patient 1 revealed an admission to the facility's medical-surgical unit on July 23, 2008. The admission was for a surgical procedure involving a colon resection and closure of the colostomy stoma. It was noted that progress notes dated July 23, 2008 at 10:00 a.m. by Licensed Nursing Staff A stated that, "Received patient sitting in bed; vital signs are stable;	E 475	new graduate nurses to the rigors of a high intensity, acute-care hospital environment. This process is overseen by the Clinical Nurse Educator and the VP, Patient Care Services.	

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denies having pain. Observed (patient) walking, gait is steady." On the following day, progress notes dated July 24, 2008 at 11:45 a.m. by Licensed Nursing Staff B after Patient 1 returned from the surgical procedure stated that, "Received patient from recovery room status post colon resection and closure of colostomy. Up on arrival, patient is drowsy but verbally responsive. Breathing easy and regular."

A review of Physician A's post surgical transfer orders as dictated on July 24, 2008, at 12:40 and 2:03 p.m., and transcribed by Licensed Nurse B indicated for Patient A to receive Dilaudid (hydromorphone) 4 mg every 3 hours as needed for severe pain. The physician's order also stipulated for Dilaudid to be administered by subcutaneous (beneath the skin surface) injection.

A review of Licensed Nurse B's progress notes, dated July 24, at 1:15 p.m., revealed that Patient 1 complained of severe sharp abdominal pain with a pain scale rating of 7 out of 10. Licensed Nurse B's notes further revealed at 1:30 p.m., Patient 1 was administered Dilaudid 4 mg for pain. During an interview with Hospital Administrator One and Two on September 15, 2008 at 12:30 p.m. , it was stated that Licensed Nurse B was supervising Licensed Nurse A on July 24, 2008. Licensed Nurse A was a newly hired nurse who recently graduated from a nursing program. A review of documents on September 15, 2008 of Licensed Nurse A's performance appraisal summary, dated June 25, 2008, and Medication Safety: Avoiding Medication Errors Class, dated June 08, 2008, revealed that Licensed Nurse A had passed his medication safety class and met his position qualifications.

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However, a continued interview with Hospital Administrator One and Two on September 15, 2008 at 12:30 p.m. and review of documents revealed that contrary to Physician A's orders, the Dilaudid was administered to Patient 1, directly into a vein by intravenous push by Licensed Nurse A rather than subcutaneously as prescribed. It was further stated by Hospital Administrator One and Two that supervising, Licensed Nurse B was not with Licensed Nurse A at the time of administration of Dilaudid for Patient 1 and had left the room to attend to another patient.

A review of Licensed Nurse B's progress notes dated July 24, 1:40 p.m. revealed that ten minutes after the administration of Dilaudid 4mg by intravenous push, Patient 1 was, "noted unresponsive, no pulse, no blood pressure; patient cyanotic and unconscious - code blue pronounced." A review of Physician B's progress note, dated July 24, 2008 at 1:45 p.m., revealed that Patient 1 was resuscitated during the code blue and was intubated to protect her airway. Patient 1 was subsequently transferred to the intensive care unit (ICU), where Patient 1 remained for sixteen days until discharged on August 15, 2008.

A review of Licensed Nurse C's progress notes, dated July 25, 2008 from 1:30 - 4:00 p.m., revealed that, "Patient (1) is having seizures result of hypoxia and that is unknown when/if patient will awaken from the current state. Patient remains comatose; not following commands."

A review of Physician C's hospital discharge summary dated August 15, 2008., revealed that Patient 1 was transferred/discharged to General Acute Care Hospital Two in a comatose state,

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ventilator dependent and diagnosed with "anoxic encephalopathy", due to lack of sufficient oxygen to the brain.

It was stated by Physician D in a progress note from General Acute Care Hospital Two that was dated August 18, 2008 at 10:15 a.m. that, "Given Dilaudid and noted seizures with apnea. Patient intubated and resuscitated with continued seizures. Patient has been uncommunicative since with an assessment of anoxic encephalopathy."

A review of the facility policy entitled, "Preparation and Administration of Medications: TX98-NPSG6" revealed a procedure whereby, "Any medications administered to a patient must have an order from a licensed individual." In addition, "medications are administered in accordance with the six rights that includes ...right route."

An interview with Pharmacy Staff One and Two on September 16, 2008 at 1:00 p.m. and review of facility documents revealed a policy entitled, "High Alert Medication Safety Profile: TX04-NPSG6" whereby facility identified, high-alert medications, such as Dilaudid injection, would be individually labeled with a pink-high alert sticker prior to dispensing by the pharmacy. In addition, a new procedure was implemented, effective September 16, 2008 whereby, "In an effort to improve patient safety...anytime a nurse prepares a dose of hydromorphone or morphine, a second nurse must double check the accuracy of the dose preparation by verifying the 5 rights prior to the administration and document verification on the MAR (medication administration record.) There shall be no exception."

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However, an inspection on September 15, 2008 at 1:20 p.m. of Dilaudid floor stock in units P-5 and P-2 revealed that 32 of 38 Dilaudid syringes inspected on the P-5 unit and 8 of 20 Dilaudid syringes inspected on the P-2 unit were unlabeled with the pink-high alert sticker as stipulated in policy TX04-NPSG8.

In addition, random record reviews on two hospital units revealed injectable administrations of morphine on the P-5 unit for Patient 2 and Dilaudid on the P-2 unit for Patient 3 on September 15, 2008. However, a review of the respective medication administration records for Patients 2 & 3 revealed that the administration of the morphine and Dilaudid were not verified by a second nurse. During interviews with Licensed Nurses D & E on September 15, 2008 at 1:35 p.m. and 1:50 p.m., they both stated that they were unaware of the second nurse verification requirement or intravenous push guideline restrictions.

On September 15, 2008 at 2:20 p.m., an immediate jeopardy (IJ) was identified due to the facility's failure to consistently implement policies and procedures for the safe and effective use of medications such as for the opiate, pain medication, Dilaudid, that resulted in an adverse medication outcome for Patient 1 on July 24, 2008. In addition, approximately 7 weeks after the adverse medication incident involving Patient 1, the facility continued to fail to protect patients from undue adverse outcomes by the incomplete implementation of labeling policies and procedures for high-alert medications and administration verification of Dilaudid and morphine by a second nurse.

This violation involved the facility's failure to implement policies and procedures for safe and

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E 475	Continued From Page 7 accurate medication use. The facility failed to consistently implement policies and procedures for the accurate administration of medications as prescribed for Patient 1 resulting in the administration of an opiate pain medication, Dilaudid, by the wrong route and subsequent anoxic encephalopathy and coma. In addition, for at least a period of approximately 7 weeks after the medication error involving Patient 1, from July 24, 2008 to September 15, 2008, the facility continued to fail to protect patients from undue adverse patient outcomes by the inconsistent enforcement of the labeling of high-alert medication such as Dilaudid as well as the newly implemented policy of second nurse identification and verification for Dilaudid. This violation caused, or was likely to cause, serious injury or death to the patients and staff who could be affected by errors with medication administration. The facility systemic practices involving these failures to enforce facility policies and protocols also had a potential to affect all patients in the hospital.	E 475		