California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA140000034	A. BUILDING _____ B. WING _____	C 10/14/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ALAMEDA COUNTY MEDICAL CENTER	1411 E 31ST ST OAKLAND, CA 94602

(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
E 000	Initial Comments The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident. ENTITY REPORTED INCIDENT NUMBER: CA00204680 Representing the Department: [redacted], RN, HFEN and [redacted], Pharmaceutical Consultant, II The inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the facility.	E 000	RECEIVED FEB 01 2010 Licensing & Certification East Bay District Office	
E 264	T22 DIV5 CH1 ART3-70213(a) Nursing Service Policies and Procedures. (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. This Statute is not met as evidenced by:	E 264	**E 264 T22 DIV5 CH1 ART3-70213(a) Nursing Services Policies and Procedures** **E 474 T22 DIV5 CH1 ART3-70263(c) Pharmaceutical Service General Requirements** **E 475 T22 DIV5 CH1 ART3-70263(c)(1) Pharmaceutical Service General Requirement** **E 483 T22 DIV5 CH1 ART3-70263(g) Pharmaceutical Service General Requirement** **E 485 T22 DIV5 CH1 ART3-70263(g)(2) Pharmaceutical Service General Requirements** The Hospital failed to ensure policies and procedures related to medication distribution and medication administration were implemented and the Dilantin was administered as ordered. Patient received one gram of Dilantin IVP (intravenous push) within five minutes that should have been given slowly over an hour as ordered by the physician. The medication error resulted in	
E 474	T22 DIV5 CH1 ART3-70263(c) Pharmaceutical Service 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.	E 474		

Accepted. Juliet L. Ramsey 2/8/10

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E 474	Continued From page 1 This Statute is not met as evidenced by:	E 474	the rapid deterioration and death of patient. **Corrective Action:** 1. All ICU RN staff were re-educated on the Medication Administration policy and procedures. 2. All ICU RN's were educated on Transcribing Medication physician orders. 3. All pharmacists were in-serviced to provide drug, dosage route and rate of administration when any nursing staff calls pharmacy requesting information regarding medications. 4. All ICU staff were re-educated regarding Dilantin, the indications, the route, dosage and rate of administration for a loading dose. 5. Pharmacy added Dilantin to the High Risk Medications policy and re-educated the nursing staff regarding Dilantin and High Risk medications. 6. All Dilantin was removed from ACMC pyxis machines immediately upon notification of the event.	
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 Statute is not met as evidenced by:	E 475		
E 483	T22 DIV5 CH1 ART3-70263(g) Pharmaceutical Service General Requirements (g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher. Verbal orders for drugs shall be	E 483	7. Pharmacists will now mix all Dilantin and label with drug name, dose, route, and administration rate. 8. Additional ICU competencies have been developed specifically addressing high risk alert medications and medication administration which will now require any RN working in ICU to take written cognitive test. 9. The electronic time of the scanned pharmacy orders on this patient were reviewed to identify any process and system errors. ICU orders were scanned to pharmacy at 1446 and medication was	

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E 483	Continued From page 2 given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours. This Statute is not met as evidenced by:	E 483	administered at 2155. It was identified that the order written at 1400 was not reviewed by pharmacy since Dilantin was in the Pyxis and assumed by pharmacy that Dilantin had already been administered. This has been corrected by removing all Dilantin from the Pyxis and requiring pharmacy to prepare the drug for administration. 10. Nursing and Pharmacy developed a proactive committee to review and flow the medication process to identify process/system issues that would put patients at risk for medication event. 11. ICU will implement 12 hour chart checks for nursing to check all MARs' for complete drug information which includes drug, dose, route, and rate of administration and compare the MAR to the physician's orders. 12. The RN who administered the drug was placed on Do Not Return, the registry who employees the RN was notified, the CDPH, The Joint Commission, and the California Board of Nursing was also notified of the event. **Completion Date:** 1. 10/14/09 2. 10/14/09 3. 10/14/09 4. 10/14/09 5. 10/14/09 6. 10/14/09 7. 10/14/09 8. 12/31/09 9. 10/14/09 10. 10/15/09 11. 10/14/09 12. 10/15/09	
E 485	T22 DIV5 CH1 ART3-70263(g)(2) Pharmaceutical Service General Requirements (2) Medications and treatments shall be administered as ordered. This Statute is not met as evidenced by: Based on staff interview and record reviews, the hospital failed to ensure policies and procedures related to medication distribution and medication administration were implemented and the Dilantin was administered as ordered. Patient 14 received one gram of Dilantin IVP (intravenous push) within five minutes that should have been given slowly over an hour as ordered by the physician. The medication error resulted in the rapid deterioration and death of Patient 14. Findings: The Discharge Summary dated 10/14/09 showed that the hospital admitted Patient 14 on 10/05/09 for sudden shortness of breath and chest pain. Patient 14 had a history of hypertension and end stage renal disease. Patient 14 received dialysis (process to remove chemicals and wastes from	E 485		

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E 485	Continued From page 3 the blood through a machine when the kidneys no longer function) three times a week on Mondays, Wednesdays and Fridays. The Progress Notes dated 10/7/09 showed that while having hemodialysis, Patient 14 had seizures, high blood pressure and developed pulmonary edema (lung congestion) that required intubation (insertion of breathing tube and connected to a respirator). Patient 14 was transferred to the intensive care unit at 2:40 p.m. The physician's orders dated 10/7/09 at 2 p.m. included a physician's order that specifically stated to check the patient's dilantin level first and to, "give 1 gm (gram) Dilantin over 1 hr (hour). IV (into the bloodstream through a vein access), don't push quickly." A Consultation Report dated 10/7/08 at 3 p.m. indicated that Patient 14 was, "Currently hemodynamically (pertains to blood circulation) stable." Review of the Medication Record showed a handwritten transcription of the order for Dilantin as, "Dilantin 1000 mg load." Dilantin was initialed and signed by RN Z as given on 10/7/09 at 9:55 p.m.. RN Z administered the Dilantin loading dose within five minutes IVP (manually and directly into the bloodstream through a vein access). The Progress Record dated 10/7/09 at 10:40 p.m. showed that at 10:01 p.m., (six minutes after Dilantin was given), Code Blue was called in the intensive care unit because Patient 14 had bradycardia (heart rate less than 60 per minute) with PEA (pulse less electrical activity of the heart). The resuscitation efforts failed. An ultrasound of Patient 14's heart taken at the bedside confirmed that Patient 14 did not have a	E 485	**Monitoring:** 1. Nursing will review 30 charts per month to ensure that MAR's match the physician orders and have the drug, dosage, route and rate of administration for every medication. 2. Daily nursing will review, during the 12 hour chart check, all MARs for completeness with drug, dose, route, and rate of administration. 3. The Director of Pharmacy will randomly observe pharmacy providing drug information to ensure all elements, drug, dose, route, and rate of administration. **Persons Responsible:** Tina Bray, Director of Nursing Gurpreet Johal, Director of Pharmacy Linda Jenkins, CNE Bill Manns, COO Jeanette Cotanche, CQO	

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cardiac tamponade (compression of the heart resulting from the accumulation of fluid within the heart sac) and that there was no heart activity. Patient 14 died at 10:24 p.m.

Review of the hospital's written Medication Administration policy and procedure, revised on 2/09 showed that its purpose was to ensure safe administration of medications to patients. Medications are administered to patients by licensed and approved personnel that included registered nurses. The Medication Administration policy and procedure showed that all inpatient orders will be scanned to the Inpatient Pharmacy, reviewed by a pharmacist and entered into the Pharmacy Computer System that would generate a patient specific label. Pharmacy would prepare, check and match the medication with the associated label in preparation for delivery. The policy indicated that it would be the responsibility of the nurse to review the patient specific label for accuracy.

The Medication Administration procedure required that before the administration of a medication, the registered nurse who would administer the medication would verify the medication based on the medication order and product label. The registered nurse would verify and be familiar that the medication be administered at the right dose, correct route and rate of administration.

Review of a memorandum dated 10/8/09 showed that RN Z pushed one gram of Dilantin over five minutes, and the cardiac strips clearly indicate rhythm changes at that time. RN Z had said that she clarified with the pharmacist how to give the Dilantin and was told to "push" Dilantin.

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The Lexi-Comp's Drug Information Handbook, 2009- 2010 18th Edition listed that Dilantin is a drug to manage and prevent seizures. The warning and precautions with its use in IV form include hypotension and bradycardia. The adverse effects included, but not limited to hypotension, bradycardia, cardiac arrhythmias and cardiovascular collapse (especially with rapid IV use) The maximum rate of administration is 50 mg per minute. All loading doses of Dilantin should be administered in IVPB in saline.

During an interview on 10/14/09 at 10:27 a.m. RN Z said, she called the pharmacy on 10/7/09 and requested the pharmacy to mix Dilantin. According to RN Z, the pharmacist instructed her to get four ampoules of Dilantin 250 mg from the Pyxis (a medication distribution system) and give the medication IV, without any recommendation on how to give it. RN Z said, "It shouldn't have happened, I shouldn't have listened to the pharmacist, and it didn't sound right to give four vials IV push. I should have refused." RN Z failed to review and follow the physician's order to give Dilantin over an hour. RN Z failed to recognize that the maximum rate of IV administration of dilantin was 50 mg per minute.

During an interview on 10/14/09 at 12:10 p.m., Pharmacist A acknowledged she received a telephone call from RN Z and instructed RN Z to mix four ampoules of Dilantin 250 mg in a 250 ml bag of saline and use a .22 micron filter when administering the Dilantin. Pharmacist A failed to indicate the rate of administration she had instructed RN Z to give the total amount of Dilantin 1000 mg.

During an interview on 11/19/09 at 9:30 a.m., the Director of Pharmacy acknowledged that Dilantin

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E 485	Continued From page 6 order for Patient 14 was not reviewed in advance of administration as required by the current policy and procedure on Medication Administration. There was no evidence that the pharmacy received and reviewed the scanned physician's order for Dilantin written on 10/7/09 at 2 p.m.. The nurse administered Dilantin 1000 mg on 10/7/09 at 9:55 p.m. within five minutes (rather than an hour). The hospital staff had approximately over seven hours to correctly process the Dilantin order to ensure the safe administration of the drug to Patient 14 and prevent the medication error. The facility's failure to ensure its medication distribution and administration policies were followed is a deficiency that has 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).	E 485		