PoC accepted my e Ltr 1/2/08

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
	CA930000558	A. BUILDING _____ B. WING _____	09/18/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SAINT FRANCIS MEDICAL CENTER	3630 EAST IMPERIAL HIGHWAY LYNWOOD, CA 90262

(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 Department of Public Health during a Complaint Investigation. Complaint Intake Number: CA 00162393 Representing the Department of Public Health: [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	E 000		
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:	E 475		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Marshal Chen — TITLE: Chief Quality Officer & Corporate Responsibility Officer — (X6) DATE: 10/30/08

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E 475	Continued From Page 1 Based on review of facility and clinical records, and interview with staff, the facility failed to consistently implement and establish policies and procedures to ensure the safe and effective use of all drugs. The facility failed to ensure that the administration of an injectable, electrolyte replacement, potassium chloride, was monitored with blood, potassium serum levels in a timely manner for Patients 1 and 12 resulting in an adverse outcome of a critically high potassium level (hyperkalemia), and a subsequent cardiac emergency (code blue) resulting in the death of Patient 1. For Patient 1, injectable and oral potassium chloride was prescribed on July 26, 2008 at 9:30 a.m. to correct a low potassium serum level (hypokalemia) of 2.9mEq/L. A total of 200 meq of potassium chloride was administered, however a repeat potassium serum level was not obtained until the following morning of July 27, 2008 which revealed a critically high, "panic" potassium serum level of 6.9 mEq/L. Patient 1 subsequently experienced a cardiac (code blue) emergency on July 27, 2008 and expired that day at 10:34 a.m., despite resuscitation attempts. A review of facility policies on September 15 & 16, 2008, and interview with facility staff, revealed that a potassium monitoring policy was drafted after the July 27, 2008 incident involving Patient 1, but was still currently under review by hospital committees and was not implemented as yet for any units of the hospital. For Patient 12, injectable and oral potassium chloride was prescribed in the emergency room on September 16, 2008 at 1:41 a.m. for a primary admitting diagnosis of hypokalemia of 2.6mEq/L. A total of 60 meq of potassium chloride was administered but a repeat	E 475		

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E 475	Continued From Page 2 potassium serum level and/or electrical heart monitoring (EKG) were not obtained following treatment, or before discharge, on September 16, 2008 at 4:04 a.m. On September 17, 2008 at 1:00 p.m., an immediate jeopardy (IJ) was identified due to the facility's failure to establish policies and procedures for the safe and effective use of medications such as for the intravenous administration of potassium supplements that resulted in an adverse medication outcome for Patient 1 on July 27, 2008. In addition, approximately 6 weeks after the adverse medication incident involving Patient 1, the facility continued to fail to protect patients from undue adverse outcomes by the continued failure to obtain a potassium serum level for Patient 12, on September 16, 2008, after treatment, and before discharge, for a low blood potassium with intravenous and oral potassium supplementation. Findings: A review of the clinical record on September 16, 2008 for Patient 1 revealed an admission to the facility from another general acute care hospital on July 24, 2008 with a diagnosis of respiratory failure secondary to chronic obstructive pulmonary disease and aspiration pneumonia. A record review on September 16, 2008 of Patient 1 ' s laboratory values for July 26, 2008 as drawn at 7:00 a.m. noted a " critically low - LP " potassium serum level of 2.9 mEq/L when referenced to facility norms for serum potassium of 3.6 - 5.5 mEq/L. A review of Physician A's orders on July 26, 2008, at 9:30 a.m. subsequently revealed that	E 475		

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E 475	Continued From Page 3 Patient 1 was prescribed two doses of intravenous potassium chloride 40 mEq and then followed by three doses of liquid potassium chloride 40 mEq by nasal gastric tube for a total of 200 mEq of potassium chloride. The administration of the two doses of intravenous potassium chloride were completed by 4:00 p.m. on July 26, 2008. Physician A ordered the serum potassium to be rechecked with a basic metabolic panel (BMP), the following morning on July 27, 2008. A record review of Patient 1's laboratory values for July 27, 2008 as drawn at 5:50 a.m. noted a " critically high - HP " potassium serum level of 6.9 mEq/L when referenced to facility norms for serum potassium of 3.6 - 5.5 mEq/L. Further review of Patient 1 ' s record revealed that starting at 9:20 a.m., on July 27, 2008, physician orders to correct the high serum potassium with injectable calcium, insulin and glucose with oral kayexalate were initiated. However, a review of Physician B ' s dictated progress notes stated that, " at approximately 10:20 hours this morning, Patient 1 became bradycardic and unresponsive. " Despite resuscitative interventions, Patient 1 was pronounced dead at 10:34 a.m. on July 27, 2008. An interview with Pharmacy Staff One on September 15, 2008 at 11:45 a.m. revealed that a potassium monitoring policy was drafted to supplement the High-Alert Medication Safety policy and procedure #1058 after the July 27, 2008 incident involving Patient 1 to improve and provide for a timely reassessment of the serum potassium levels following intravenous administrations. However, Pharmacy Staff One stated that the changes to policy and procedure #1058 were still currently under review by hospital committees and was not implemented	E 475		

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E 475	Continued From Page 4 as yet for any units of the hospital. An interview with Hospital Administrator One, on September 15, 2008 at 11:45 a.m., confirmed the changes to policy and procedure #1058. A random record review for Patient 12 on September 17, 22008 revealed an emergency room admission from a local skilled nursing facility on September 16, 2008 at 1:41 a.m. with a primary admitting diagnosis and chief complaint of hypokalemia of 2.6. mEq/L (normal range: 3.6 - 5.5 mEq/L.) A continued record review for Patient 12 revealed that intravenous potassium chloride 10 mEq was ordered by Physician B and administered on September 16, 2008 at 2:05 a.m. and followed by an order for 50 mEq of K-Lyte (potassium bicarbonate/citrate) that was administered by gastrostomy tube at 2:07 a.m. Patient 12 was subsequently discharged back to the local skilled nursing facility on September 16, 2008 at 4:24 a.m. However, further record review and interview with Physician C on September 17, 2008 at 11:30 a.m. revealed that a repeat potassium serum level was not obtained for Patient 12 before discharge from the emergency room. It was also stated by Physician C that, " a repeat potassium level should have been performed and is considered a standard of practice; especially after a potassium rider. " On September 17, 2008 at 1:00 p.m., an immediate jeopardy (IJ) was identified due to the facility's failure to establish policies and procedures for the safe and effective use of medications such as for the intravenous administration of potassium supplements that resulted in an adverse medication outcome for Patient 1 on July 27, 2008. In addition, approximately 6 weeks after the adverse medication incident involving Patient 1, the	E 475	Immediate Action Plan Adopt policy that 1. Requires an assessment of a serum potassium level within one hour of completing an IVPB replacement regimen of KCl (except cardiac surgery cases where specific protocol exists). 9/17/08 2. Limits the KCl IVPB dose that can be dispensed by pharmacy at one time (20mEq). 9/17/08 3. Requires a check of a patient's serum potassium level prior to dispensing KCl IVPBs. 9/17/08 4. Limits the maximum dose of KCl via IVPB that may be administered over a specific and limited time period. 9/17/08 Add a Pyxis warning reminding the RN to draw a serum potassium level post infusion and prior to administering additional doses. 9/17/08 Responsible: Director of Pharmacy All associates to be provided immediate education regarding this policy. 9/17/08 Responsible: Clinical Director of each Nursing Unit; Director of Pharmacy; VP Patient Care Services; Chief Quality Officer Additional Actions Taken: 1. Require baseline serum potassium level within previous 24 hours (prior to new order). 9/23/08 2. No more than 20meq KCl in a single IVPB, over 2 hours. 9/23/08 3. Defined replacement regimen, which may consist of several doses 9/23/08	

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E 475	Continued From Page 5 facility continued to fail to protect patients from undue adverse outcomes by the continued failure to obtain a potassium serum level for Patient 12, on September 16, 2008, after treatment and before discharge for a low blood potassium with intravenous and oral potassium supplementation. This violation involved the facility's failure to establish & implement policies and procedures for safe and accurate medication use. The facility failed to establish policies and procedures for the timely monitoring of serum potassium levels after the administration of intravenous and/or oral, potassium supplements for Patient 1 resulting in a hyperkalemic condition that was detected the following day and subsequent expiration of Patient 1 despite resuscitation efforts. In addition, for at least a period of approximately 6 weeks after the adverse potassium incident involving Patient 1 from July 27, 2008 to September 18, 2008, the facility continued to fail to protect patients from undue adverse patient outcomes by the failure to monitor the serum potassium level for Patient 12 after the administration of intravenous and oral potassium supplements and before discharge from the emergency room. This violation caused, or was likely to cause, serious injury or death to the patients who could be affected by the medication administration of intravenous and/or oral potassium supplements. The facility systemic practices involving these failures to establish facility policies and protocols also had a potential to affect all patients in the hospital.	E 475	doses not exceeding a total of 60mEq/regimen. Serum potassium level must be checked after the administration. 4. Serum potassium level to be drawn one hour following the replacement regimen. 5. Pharmacy not to release additional KCl IVPB doses without serum potassium level. 6. If K+ < 2.5mEq/L, the KCL IVPB may be infused at 20mEq/hr through a central line with continuous cardiac monitoring. Pharmacist authority to adjust KCl IVPB regimen and to order pre and post serum potassium levels within specific parameters. Revise previous administrative policy to reflect immediate action steps. Development and implementation of preprinted electrolyte replacement order form to include replacement KCl and lab requirements to support patient safety. Responsible: Director of Pharmacy, Nursing Clinical Directors, VP Patient Care Services, Chief Quality Officer Audit to ensure compliance to the policy and report to the Patient Safety Team. Responsible: Patient Safety Officer, Director of Quality Management, Chief Quality Officer.	9/23/08 9/23/08 9/23/08 9/23/08 12/31/08