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
	050077	A. BUILDING _____ B. WING _____	04/08/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SCRIPPS MERCY HOSPITAL	4077 FIFTH AVENUE, SAN DIEGO, CA 92103 SAN DIEGO COUNTY

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SEP 11 2008
LICENSING AND CERTIFICATION
SAN DIEGO DISTRICT OFFICE SOUTH

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	The following reflects the findings of the California Department of Public Health during the investigation of an entity reported adverse event. Complaint No: 142762 Category: Pharmaceutical Services Inspection was limited to the specific entity reported adverse event and does not represent the findings of a full inspection of the hospital. Representing the California Department of Public Health: [redacted] 1280.1(a)(c) Health and Safety Code Section 1280(a) 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. (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. 70263(c) (1). Pharmaceutical Service General Requirements.		Scripps Mercy Hospital acknowledges its responsibility to self-report certain patient care events. Concerns related to Patient 1's hospitalization were self-reported by the Hospital to the local CDPH office on March 4, 2008. In response to the resulting Statement of Deficiencies, the following Plan of Correction is submitted: Responsible Persons: Director of Pharmacy Administrative Director, Emergency Services Administrative Director Cardiology Manager ICU SD Campus Director ICU CV Campus STAT Orders Process: 1. One Pharmacist was designated for triaging and filling all ED orders (attachment A) 2. The default "STAT" designation for all ED orders was turned off. 3. All STAT Pharmacy orders are called in to the Pharmacy and the Nurse (RN) records on the order, the name of the pharmacy staff they spoke to and time of the call prior to scanning the order. Pharmacy staff receiving the STAT order record the time the call was received in a log book. The Pharmacy technician receiving the STAT order phone call immediately prints out the order and gives it to the Pharmacist. The hospital is piloting a bar code sticker to alleviate the need for staff to call pharmacy (ED , both sites, ICU - CV, 11th floor - SD). When the bar code is applied to the physician order on the nursing unit, and scanned to the pharmacy, it appears in red on the receiving pharmacist's computer screen (attachment B)	03/06/08 03/06/08 03/06/08

Event ID:N64L11 8/21/2008 8:23:20AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Tom Gann	CE	9-10-08

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	Continued From page 1 (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 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. Based on medical record review, staff interview, review of facility policy and procedures, and review of the automated drug delivery device reports (Pyxis), the facility's pharmacy and therapeutics committee failed to develop policies and procedures that ensured a safe and effective system for dispensing and administering 3% sodium chloride solution for hyponatremic patients. Patient 1, who had a diagnosis of severe life threatening hyponatremia (low blood sodium) was never administered a 3% sodium chloride solution when an Emergency Department Medical Doctor (ED MD 1) had written two different orders for Patient 1 to be administered 3% sodium chloride solution. Following the entity reported adverse event, the facility failed to revise and incorporate safeguards into their policy and procedures so the event would		4. A policy was developed to delineate a consistent process for: Intake and assignment of order process within the pharmacy department (assignment of responsible Pharmacist, accepting phone calls, triage of orders) attachment C 5. The IV Room phone was removed 6. The ED-assigned Pharmacist has responsibility for completing the audit log for ongoing monitoring of ED STAT medications (attachment D) Responsible Person: Wayne Lindsley, Administrative Director, Pharmacy Monitor: Monitoring of STAT medications turnaround time is an indicator on the Pharmacy QAPI Dashboard which is reviewed monthly by Pharmacy Administration and reported to the Medication Safety Committee for analysis, identification of improvement opportunities, feedback and learning. It is also reported to the Nursing Executive Council, Nursing Practice Council and through the Quality Council to the Governing Board for monitoring improvements (attachment E) 7. 3% NaCl was added to the night locker Pyxis at the Chula Vista campus to ensure timely delivery of this concentrated NaCl solution when the main Pharmacy is closed. The "high alert drug" alert is turned on from the night locker Pyxis to prompt the Operations Supervisor to perform a double check prior to removal. Monitor: Daily monitoring by the Pharmacy. Discrepancies to be reported to CV Director of Pharmacy and Nursing Administration for Operations Supervisor feedback.	03/12/08 03/12/08 03/12/08 04/24/08

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Tom Garner — TITLE: CE — (X6) DATE: 9.10.08

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	Continued From page 2 not reoccur. Continued implementation of the above practices by the facility was likely to place other patients who were hyponatremic and required 3% sodium chloride, in a situation of immediate jeopardy with a potential to cause serious injury or death. Findings: The facility self reported an adverse event, dated 3/04/08, which documented that: "The hospital experienced a significant delay in providing sodium replacement for a hyponatremic patient. . . Prior to the medication being administered, the patient coded (required cardiopulmonary resuscitation) and expired (died) at 11:38 P.M." On 03/06/08 at 11:00 A.M., a survey team arrived at the facility to conduct a state complaint investigation based on the facility's self-reported adverse event. On 03/06/08 at 11:15 A.M., an interview was conducted with the ED (Emergency Department) manager. The ED manager stated that all physician orders from the Emergency Department were considered "STAT" (immediate). The physician admission orders that were scanned to the pharmacy were all coded as "STAT" orders. These STAT orders were differentiated from other orders as being a red line item (visual cue) on the pharmacy computer. The ED manager stated that there was no formal policy and procedure that reflected the differentiation between medication orders for STAT and for non-STAT.		Education 8. Face to face in-services were conducted with Pharmacy staff to describe the process changes related to processing STAT orders (attachment F) 9. Face to face in-services were conducted with all ED Physicians and hospital personnel to describe the process changes related to processing STAT orders from the ED (attachment G) 10. Hyponatremia education was completed for all Emergency Department and Intensive Care Unit nurses (attachment H)	3/12/08 3/14/08-0 7/01/08 5/15/08

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Tom Glaser | CE | 9.10.08

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	Continued From page 3 The facility's policy and procedure entitled "Medications: Orders, Administration, and Documentation" reviewed on 3/6/08, documented that "Pharmacy will process STAT orders within 15 minutes of receipt." The facility's policy and procedure entitled "IV Compounding" reviewed on 3/6/08, documented that "STAT" medications are prepared and delivered as soon as possible after label is received. On 3/06/08 at 1:00 P.M., the medical record for Patient 1 was reviewed. According to the record, Patient 1 initially presented in the ED on 2/28/08 at 1:39 P.M. Per a lab report dated on 2/28/08, Patient 1 had blood drawn at 4:00 P.M. The report documented that Patient 1's blood sodium (Na) level was 115 and marked a "C" (critical value). Normal range is 136-146 millimoles/liter (mmol/L). This critical lab result was called to an ED nurse on 2/28/08 at 5:14 P.M. The Emergency Record dated 2/28/08, and dictated by the ED MD 1 on 2/28/08 at 6:09 P.M., documented the following: "I (Emergency Room Physician) have told [redacted] (Patient 1) if [redacted] does not stay, I told [redacted] the risks, benefits, and alternatives; that [redacted] could die, have a seizure, fall, break a bone, strike [redacted] head and head trauma, and possibly die. [redacted] understands..[redacted] will sign out against medical advice." Per the ED Nurses notes on 2/28/08 at 6:15 P.M., Patient 1 left the ED via a wheelchair. On 2/29/08 at 12:00 P.M., Patient 1 re-presented in			

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	Continued From page 4 the ED. The Emergency Record dated 2/29/08, and dictated by ED MD 1 at 6:41 P.M., documented the following: "Diagnosis: 1. Severe life threatening hyponatremia (low blood sodium) 2. "Syndrome of inappropriate antidiuretic hormone (impaired water excretion by the body resulting in an abnormal blood sodium level)." On 2/29/08 at 1:15 P.M., Patient 1 had a STAT order for a blood test to check the sodium level. The blood sample was drawn at 2:20 P.M. with results at 4:00 P.M. Per the lab report dated 2/29/08; Patient 1's sodium level was 110 and marked as a critical value. A review of Patient 1's record revealed that on 2/29/08 at 6:35 P.M., ED MD 1 wrote on a Physician's Orders form the following order: "IV (intravenous) hypertonic 3% saline run at 30 ml x (for) 30 hrs." At the top right hand corner of the form was a box to mark if the order was STAT. The box was not marked as STAT. This order was scanned from the ED to the pharmacy at 7:04 P.M On 3/6/08 at 12:15 P.M., an interview was conducted with Staff S. Staff S stated that on 2/29/08 at 11:46 P.M. the order written by ED MD 1 at 6:35 P.M. was reviewed by a contract pharmacist who rerouted it to the patient's Pyxis profile. The order was never processed at that time. Further review of the clinical record revealed that			

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	Continued From page 5 on 2/29/08 at 6:45 P.M., ED MD 1 wrote a second order for "3% NS (normal saline) 30 ml/hr" for Patient 1, on a ED Physician Documentation/Orders form. On 3/06/08 at 2:20 P.M., a review of the Pyxis with a pharmacist Staff S revealed that this 6:45 P.M. order was scanned to the pharmacy on 2/29/08 at 7:00 P.M. Staff S stated that this 6:45 P.M. order was viewed by a contract pharmacist at 11:40 P.M., on 2/29/08, but the computer system did not capture what the pharmacist did with this additional order. During the same interview Staff S could not explain why this ED order was not reviewed and processed, so the pharmacy could deliver a 3% saline solution as ordered by ED MD 1. Per the ICU (intensive care unit) flowsheet dated 2/29/08, on 2/29/08 at 9:15 P.M., Patient 1 arrived to the ICU from the ED. The ICU Licensed Nurse, LN A, who was assigned to Patient 1 for the night shift of 2/29/08 was unavailable for an interview until 3/12/08. On 03/12/08 at 12:00 P.M., LN A stated that she was aware that Patient 1 needed 3% saline to treat the patient's hyponatremia. Upon Patient 1's arrival to the ICU at 9:15 P/M., LN A asked the ED transfer nurse (LN B) if the patient was administered the 3% saline. LN B did not know anything about the 3% saline. LN A learned that the 3% saline still needed to be administered to Patient 1 so she began to call the pharmacy. Per LN A she was told the 3% saline solution was "on its way." Per LN A the solution did not arrive. LN A contacted			

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	Continued From page 6 the pharmacy two more times. After the third phone call, LN A went to the clinical record and found the 3% saline order written by ED MD 1 at 6:35 P.M. LN A stated she marked the previously unmarked STAT box, to emphasize that she needed it now, and faxed the order to the pharmacy (exact time unknown). Per LN A, the 3% saline was received at 10:45 P.M. At this point, LN A stated she wanted to take a quick break. Per LN A, she was relieved for a break by LN C "close to 11:00 P.M." LN A left the IV 3% saline bag on the bedside table and took a break. LN A stated that she had planned to administer the 3% sodium chloride when she returned. However, during her absence Patient 1 coded (emergency response required). LN A stated that she heard the code being announced while she was in the break room and she returned to the bedside. Per the Emergency Response Record dated 2/29/08, the code was initiated at 11:08 P.M. Patient 1 expired (died) at 11:38 P.M. On 3/6/08 an interview with Staff S at 2:20 P.M., revealed that the ED MD1 order on 2/29/08 at 6:35 P.M. for "IV (intravenous) hypertonic 3% saline run at 30 ml x (for) 30 hrs (hours)," that was marked as a STAT and faxed by LN A, was scanned to the pharmacy at 10:30 P.M. and processed by a pharmacist (Staff R) at 10:34 P.M. On 2/29/08 the ICU flow sheet documented that the 3% hypertonic saline arrived at 10:45 P.M. on 2/29/08.			

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	Continued From page 7 Per record review, on 2/29/08 Patient 1 had two orders for 3% sodium chloride solution written by ED MD 1 in the ED at 6:35 P.M. and at 6:45 P.M. Patient 1 arrived in the ICU from the ED at 9:15 P.M. LN A determined that the 3% sodium chloride solution was not administered to Patient 1 in the ED. LN A faxed the order to the pharmacy (exact time unknown). The 3% sodium chloride solution arrived to the ICU at 10:45 P.M. The 3% sodium chloride solution which was ordered by ED MD 1 twice, at 6:35 P.M. and at 6:45 P.M., was never administered to Patient 1. On 03/06/08 at 2:50 P.M., an Immediate Jeopardy was called related to pharmaceutical services. The COE (Chief Operating Executive), CNO (Chief Nursing Officer) and Risk Manager were present. The violations were likely to cause serious injury or death to future patients with a diagnosis of hyponatremia who required the administration of a 3% sodium chloride solution. Currently, the facility had not developed and implemented policies, procedures, or practices that would have prevented the duplication of this event. Staff present began to work on an action plan for an immediate plan of correction. On 3/17/08 at 9:49 A.M., an acceptable plan of correction was received by the facility. The Immediate Jeopardy was abated.			

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