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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
	050305	A. BUILDING _____ B. WING _____	12/12/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Alta Bates Summit Medical Center-Alta Bates Campus	2450 Ashby Ave, Berkeley, CA 94705-2067 ALAMEDA COUNTY

(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 Department of Public Health during an inspection visit: Complaint Intake Number: CA00368387 - Substantiated Representing the Department of Public Health: Surveyor ID # 20340, Medical Consultant The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.1(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. Health and Safety Code Section 1280.1(c): For the 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 likely to cause, serious injury or death to the patient. Title 22: 70213(d) Nursing Service Policies and Procedures Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff.			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Julie A. Petrini RN TITLE Chief Operating Officer (X6) DATE 3/13/14

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s). 1 thru 5

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

accepted K Robinson 3/19/14

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	Based on interview and record review the hospital failed to implement policies and procedures developed by the nursing staff and medical staff in order to safeguard patients during surgical procedures. Failure to do so resulted in the injection of the wrong solution into the eye of one patient (Patient 1) and potential loss of vision to that eye. THIS EVENT CONSTITUTED AN IMMEDIATE JEOPARDY (IJ) WHICH PLACED THE HEALTH AND SAFETY OF PATIENT 1 AT RISK WHEN THE OPERATING ROOM STAFF DID NOT FOLLOW ESTABLISHED PROCEDURES ON THE DELIVERY, LABELING AND VERIFICATION OF MEDICATIONS TO THE STERILE FIELD. THIS VIOLATION CAUSED OR IS LIKELY TO CAUSE THE LOSS OF VISION IN ONE EYE FOR PATIENT 1. Findings: Review of the medical record on 9/9/13 at 9 a.m. showed that Patient 1 was a healthy 71 year old male who was admitted to the hospital on [redacted]13 for a left eye cataract removal (a medical condition in which the lens of the eye becomes progressively opaque, resulting in blurred vision), and implantation of an intraocular lens (an artificial lens that is implanted into the eye of someone to replace a damaged natural lens or someone who has had a cataract removed). During an interview on 9/9/13 at 11 a.m., Surgeon 1 stated that after the patient was anesthetized she		**Plan of Correction:** 1. Immediately after the event, findings related to the medication dispensing on to the sterile field were addressed and reviewed with the O.R., I.R. and G.I. staff using the "Medication on and off the Sterile Field, Verification and Labeling" policy and procedure. Staff were required to return and demonstrate the content of the policy and verbalize the actions. 100% of the staff was required to complete prior to starting their shift. Any staff member on a leave of absence will receive training prior to returning to work.	**Completed Date:** 9/10/13

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	asked surgical technician (ST)1 for VisionBlue (trypan blue, a solution used to stain the lens capsule and approved for cataract extractions) in order to inject it into the left eye and to enhance the visualization of the lens capsule. Surgeon 1 was handed a syringe by ST 1 and injected the syringe contents into the left eye. Surgeon 1 then examined the left eye through the operating scope and found the entire area to be stained an opaque, dense blue. Surgeon 1 asked ST 1, "What did you give me?" "VisionBlue" was the reply from ST 1. Surgeon 1 then asked registered nurse (RN) 1, "What did you give the tech?" to which RN 1 replied, "methylene blue" (a long lasting tissue staining dye not intended for eye injection). Patient 1's left eye was then repeatedly irrigated with saline (a sterile salt water solution), but the eye remained opaque. Surgeon 1 stated she does not know how methylene blue came into the surgical field, "as it is not in my technique, I never use methylene blue." Surgeon 1 further stated that since she nearly always has her eye on the operating scope, she asked for the VisionBlue by name, and trusted that the operating room staff would give her the solution she requested. Surgeon 1 stated that she did not observe the solution as it was drawn into the syringe nor did she observe the placement of the label on the syringe. Patient 1 was informed of the error and the need for a transfer to another acute care specialty hospital for a possible corneal (the clear outer covering of		2. The medication carts were removed from the eye rooms and new Pyxis machines were installed during the week of September 7, 2013, and all eye medications were stored by physician's name including drug, name concentration, and amount. 3. Methylene blue was removed from all Ophthalmology preference cards. 4. The eye team was expanded and competencies were verified and validated. Competency validation will now occur annually. **Monitoring Plan:** 1. Quarterly audits of medication labeling in all procedural areas will be conducted by observation of labeling. The results of the monitoring activities will be provided to the Risk and Safety Committee on a quarterly basis. 2. As part of the ongoing education and performance improvement, results of the medication labeling audits will be presented to the staff for review and discussion using a variety of communication modalities. **Responsible Parties:** Chief Nursing Executive Director of Perioperative Services Operating Room Manager	9/13/13 11/8/13 12/31/13 Quarterly Quarterly

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	the eyeball) transplant with the final outcome uncertain. A review of the hospital policy and procedure titled, "Medications on and off the Sterile Field, Verification and Labeling" dated April 2013, showed, "Medications delivered to the sterile field in a surgical or procedural setting must be concurrently verbally and visually verified by 2 qualified personnel.", and, "All medication labels are verified both verbally and visually by two qualified individuals when the person preparing the medication is not the person administering the medication." Further, "In perioperative areas [pertaining or relating to the period of time surrounding a surgical procedure], any medication listed on the physician preference list must be verified with the physician for each procedure prior to delivery to the sterile field and/or administration." During an interview on 9/9/2013 at 10 a.m. with ST 1, she stated that she asked RN 1 for VisionBlue and in return received a syringe from RN 1. ST 1 put the VisionBlue label on the syringe and placed the syringe on the sterile field table for use during the surgery. Vision Blue is on the surgeon Preference Card, a reference guide for operating room staff regarding the supplies needed for that particular operation. In this case the Preference Card read, "Only uses Viscoat" (a brand of VisionBlue). She further states that Surgeon 1, during the course of the surgery "grabbed the syringe labeled with VisionBlue and picked it off the stand." According to ST 1, Surgeon 1 did not ask for VisionBlue and there was no verification as to			

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	the contents of the syringe labeled VisionBlue. ST 1 said, "I asked for VisionBlue and got methylene blue". During an interview on 9/9/13 at 10:30 a.m., RN 1 stated that ST 1 called her and said she needed methylene blue. RN 1 then went and found a vial of methylene blue, brought it to the table and looked for a receptacle into which she could place a few drops. RN 1 explained that on occasion some surgeons used a drop to mark the location of the incision and all that is needed is a tiny drop. Not finding a receptacle on the surgical table in order to deposit several drops of methylene blue, RN 1 drew the methylene blue into a syringe and handed it to ST 1, saying "all you need is a few drops". RN 1 then showed ST 1 a prefilled syringe of VisionBlue and told ST 1 that she, RN 1, has the VisionBlue if the surgeon requests it. When RN 1 was asked if she saw ST 1 place a label on the syringe, RN 1 answered she did not see that, nor did she observe how Surgeon 1 obtained the syringe; RN 1 said that she was charting on the computer at the time. RN 1 stated that she was asked to bring methylene blue to the table; there was never a request for VisionBlue. In a discussion with the Risk Manager, the Nurse Manager for Surgery and the Director of Perioperative Services on 9/9/12, they agreed, "there was a communication error between the RN and the tech; there was also a labeling error between the RN and the tech."			