CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050043	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER: Alta Bates Summit Medical Center	STREET ADDRESS, CITY, STATE, ZIP CODE: 350 Hawthorne Ave, Oakland, CA 94609-3108 ALAMEDA COUNTY		

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00284528 - Substantiated Representing the Department of Public Health: Surveyor ID # 25304, HFEN 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. T22 DIV 5 CH1 ART 3-70263(g)(2) 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 given only by a		**The following constitutes Alta Bates Summit Medical Center's credible documentation evidencing correction of all of the alleged deficiencies cited by the California Department of Public Health in the Statement of Deficiencies Form 2567 dated May 23, 2012. Preparation and/or execution of the evidence of corrective action does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth on the Statement of Deficiencies. It has been prepared and or executed solely because it is require by State Law.** RECEIVED JUN 04 2012 Licensing & Certification East Bay District Office	

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Carol Alers	**Chief Nurse Executive**	**5/29/12**

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6/4/12 Accepted Robinson

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Continued From page 1

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.

(2) Medications and treatments shall be administered as ordered.

Based on interview and record review, the hospital failed to ensure nursing staff followed policy and procedure for the administration of a TPN solution.

(TPN: Total Parenteral Nutrition - a patient-specific mixture of essential nutrients prepared by the pharmacy for intravenous (IV) administration).

RN 1 administered an enteral feeding formula (Glucerna) through Patient 1's intravenous peripherally-inserted central catheter (PICC) resulting in the death of Patient 1.

(Enteral feeding formula - a commercially prepared nutritional supplement formula which is administered through a tube inserted into the stomach through a surgically created abdominal opening or through a tube inserted through the nose and passed into the stomach).

THIS EVENT CONSTITUTED AN IMMEDIATE JEOPARDY (IJ) WHICH PLACED THE LIFE AND SAFETY OF PATIENT 1 AT RISK WHEN NURSING STAFF FAILED TO IMPLEMENT

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	Continued From page 2 POLICIES AND PROCEDURES FOR THE ADMINISTRATION OF TPN. THIS FAILURE RESULTED IN THE DEATH OF PATIENT 1. AUTOPSY FINDINGS INDICATED PATIENT 1'S DEATH RESULTED FROM A PULMONARY EMBOLUS WHICH WAS THE DIRECT RESULT OF THE ADMINISTRATION OF THE ENTERAL FEEDING FORMULA THROUGH PATIENT 1'S PICC LINE. Findings: Medical record review, on 9/26/11, indicated Patient 1 was a 66-year' old woman who was admitted to the hospital on [redacted]11. Her multiple diagnoses included uterine and bladder cancer. Patient 1 had an intravenous peripherally-inserted central catheter (PICC) line inserted for the administration of TPN to supplement her nutritional needs because of inadequate food intake.		**Plan of Correction:** 1. On [redacted]/11, enteral feeding liter bottles were labeled with the patient's name, date of birth, tube feeding type, rate, and current date before delivery to the nursing unit. In addition, a large "not for IV use" sticker is now affixed to each liter. The labeled liter bottles for a specific patient are placed in a plastic bag with a feeding set for each liter. As of 10/7/11 instructions regarding using the Abbott Screw Cap Feeding Set were also included in each bag of liter bottles.	**Completed Date:** 10/7/11
	Review of pre-printed MD orders: 'Parenteral Nutrition', dated [redacted]11, indicated Patient 1's TPN solution contained 250 cc of 20% Lipids and Regular Insulin 80 units. The TPN solution (1750 cc IV bag) was delivered by the Pharmacy and placed in the unit refrigerator located in the Medication Room. The TPN solution was clearly labeled with Patient 1's name with a scheduled date and time of [redacted]11 at 8:00 p.m., for continuous infusion over a 12-hour period. According to hospital policy and procedure, titled, "Medication Use and Administration" dated 5/2011, "Prior to administration, a nurse will verify all High		2. Sweeps were made of the entire medical center to remove excess enteral feeding solutions from the nursing units. A series of four sweeps were made until there was a 100% removal of the product from the nursing units.	10/1/11

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	Continued From page 3 Alert Medications with another nurse." The policy listed insulin as a High Alert Medication (High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error). The policy further required verification that "...the medication selected matches the medication order and product label" and" is being administered at the proper time, in the prescribed dose, and by the correct route." Review of a policy and procedure titled "IV: Parental Nutrition (PN) -Adults", approved by the Pharmacy and Therapeutics (P&T) Committee in December 2008 and the Policy and Procedures Committee in June 200, indicated, "...the RN checks the label on the bag with the MD order before hanging the parenteral nutrition." During a telephone interview, on 10/26/11 at 8:50 a.m., certified nursing assistant (CNA 1) stated that during his 11:00 p.m. to 7:00 a.m. shift assignment, on [redacted]/11, on 2 North (2N), he entered Patient 1's room and "knew something was wrong". CNA 1 left the room to immediately tell the charge nurse (RN 2) about Patient 1. During an interviews on 9/28/11 at 8:25 a.m. and 11/17/11 at 7:45 a.m., RN 2 recalled that it was "exactly 12:30 a.m." when he responded to CNA 1's request to check on Patient 1's medical condition. RN 2 stated that when he entered the room the patient was not breathing and that a "Code Blue" was called. Review of the "Code Blue" record indicated the code team responded at 12:35 a.m. on [redacted]11 and that an attempt to resuscitate Patient 1 was unsuccessful. The code blue was		3. The Replacement RN's and ABSMC Licensed Nursing staff upon return from the strike were trained and took a post test to verify knowledge regarding the change in the organization's practice related to Enteral Feeding & TPN administration. 4. The Tube Feeding and IV Parental Nutrition Self Instructional Module (SIM) was assigned to the ABSMC Licensed Nursing staff who completed it prior to caring for a patient with TPN or Tube Feeding with 100% completion by November 11, 2011. The SIM was added to general orientation for all licensed nursing staff. An RN must take the training prior to caring for a patient receiving these services. 5. Dietary Services implemented a new system of distribution and control of the enteral tube feeding products September 30, 2011 which includes a daily removal of any enteral feeding products which have been either discontinued, were in excess for a patient, or were for a patient who was discharged. This step, and the items listed in Action Item #1, were incorporated into the Food and Nutrition Service Policy and Procedure C003 -- Preparation and Delivery of Tube Feedings.	9/30/11 11/11/11 9/30/11

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	Continued From page 4 terminated at 12:53 a.m. and Patient 1 was pronounced dead at 1:03 a.m. on [redacted]11. During a telephone interview, on 10/18/11 at 11:25 a.m., RN 10 confirmed that she had been assigned as a Code Blue responder on the 7:00 p.m. to 7:00 a.m. shift on [redacted]11. RN 10 recalled that during the code she heard the IV pump machine alarming near the Patient 1's bed and the IV pump message screen indicated there was an "occlusion" in the system. RN 10 stated that she saw an "opaque, tan/beige" enteral feeding solution running through the IV tubing/pump and into Patient 1's PICC infusion port. She immediately disconnected the tubing from the PICC infusion port. RN 10 recalled that she informed MD 1 about the enteral feeding solution being connected to the PICC and that MD 1 acknowledged it and continued with the code blue resuscitation efforts. RN 10 recalled that she spoke with RN 1 in the patient's room after the code blue ended. She had asked RN 1 what IV fluids she administered into Patient 1's PICC prior to the Code Blue and RN 1 responded, "Just the TPN". RN 10 recalled that she was touching the bottle of enteral feeding solution that was still hanging on the IV pole when she asked RN 1, "Is this your TPN?" RN 1 replied, "Yes". RN 10 stated that RN 1 got a "deer in the headlights look" when she told RN 1 that the solution was not TPN but an enteral feeding formula (Glucerna). She stated that RN 1 "...immediately took the bottle of feeding formula [Glucerna] and the tubing off the pump and threw it in the trash."		6. The Food and Nutrition Sub-Committee policy and procedure D001 - Committee Concerned with Nutrition Care, was revised to reflect that all changes in the use of eternal feeding will be reviewed by the Sub-Committee and approved by the Chief Nurse Executives prior to being sent to the P&T Committee for approval. 7. The Chair of the Food and Nutrition Sub-Committee, the Pharmacy and Therapeutics Committee (P&T Committee), the Chief Nurse Executives and the Clinical Nutrition Manager unanimously agreed that the Director of Materials Management contact the manufacturer (Abbott) to replace the tubing with the screw cap tubing. The Director of Materials Management worked with the Director, Clinical Support Services to develop an education huddle tool which was implemented for 100% of staff. 8. The new tubing was placed into distribution. Education on how to use the tubing is in every bag set-up. Training using the education huddle tool was completed on 10/7/11. A representative from Abbott assisted with the formalized training for RN's.	11/1/11 10/1/11 10/7/11

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	Continued From page 5 During an interview on 11/17/11 at 7:54 a.m., RN 2 stated that Patient 1's TPN solution was discovered unused and in the medication room refrigerator on the nursing unit (2N) after Patient 1 coded and died.		9. The TPN policy and procedure was revised and approved to include, the practice of 2 RN's double checking the TPN against the order prior to administration.	10/31/11
	On December 5, 2011, at 12:00 PM, Officer (B) informed the Department by telephone that the coroner's autopsy finding results had determined the death of Patient 1. Patient 1's death resulted from a pulmonary embolus which was a direct result of the administration of the enteral feeding formula [Glucerna] through Patient 1's intravenous PICC line.		10. The Enteral Feeding Policy and Procedure was revised to include the practice of 2 nurses double checking the enteral feeding against the order prior to administration.	10/31/11
			11. Education on how to use the new Abbott Screw Cap Feeding Set tubing is included in every bag of liter bottles.	10/31/11
	This facility failed to prevent the deficiency(ies) as described above that 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).		12. The length and scope of the Orientation Program was expanded to 8-12 hours for all future replacement workers and was in place for the strike which occurred on 12/22-23/11. The Orientation Program will include clinical competencies and key high risk topics including: the 5 Rights of Medication Administration, Chain of Command, Accessing Policies and Procedure Online, and high risk policies and procedures.	12/23/11
			13. ACES, the replacement worker vendor, incorporated ABSMC's generic orientation booklet into their online orientation program. Once accepted, all replacement worker candidates will be required to complete the accompanying post test and present it at the time of hotel check-in. Anyone who has not completed this, will not be transported to ABSMC until this step is done.	12/23/11

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			Monitoring Plan: 1. Food and Nutrition manager will conduct random observational audits daily to assure compliance with tube feeding packaging for delivery. 90 observational audits will be recorded quarterly for 1 year and the findings reported to the Risk Management/Patient Safety Sub-Committee.	Daily
			2. 100% of enteral tube feedings sent to nursing units are packaged correctly by [redacted]11. All bags of enteral tube feeding liter bottles contain instructions for the use of the Abbott Screw Cap Feeding Set as of 10/7/11.	Daily
			3. 100% of excess product was removed from the nursing units by 9/27/11. For a period of three months, weekly sweeps will be conducted to assure the new procedures are working.	Weekly

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