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
	050025	A. BUILDING _____ B. WING _____	09/18/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNIVERSITY OF CALIFORNIA, SAN DIEGO MEDICAL CENTER	**200 WEST ARBOR DRIVE, SAN DIEGO, CA 92103-8976 SAN DIEGO COUNTY**

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	The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident. Entity reported incident: CA00121965 Category: State Monitoring: Medication Error. Inspection was limited to the specific entity reported incident and does not represent the findings of a full inspection of the hospital. Representing the California Department of Public Health: [redacted], Pharmaceutical Consultant II and [redacted], Health Facilities Evaluator Nurse. 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. (c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least			

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	Continued From page 1 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 observation, interview and record review, the facility's Pharmacy and Therapeutics (P&T) Committee failed to provide oversight regarding the safe and effective administration of a high risk medication Flolan (a drug with a short half-life that opens up blood vessels in the lungs and throughout the body used for pulmonary hypertension). As a result, when the facility documented a history of errors with the drug Flolan and CADD pumps (small ambulatory infusion pumps which provided measured drug therapy in hospitals or outpatient settings), there was no evidence that the Pharmacy and Therapeutics Committee followed up on or monitored the effectiveness of the action plan. In addition, following a medication error with Flolan, a CADD pump and Patient 1, the P&T committee failed to address system wide inconsistencies and variances related to the administration of Flolan to ensure Flolan's safe and effective use. Continued implementation of the above practices by the			

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	Continued From page 2 facility was likely to place other patients with pulmonary hypertension who required the drug, Flolan, in a situation of immediate jeopardy with a potential to cause serious injury or death. Findings: On 8/2/07 an investigation was initiated due to a facility's self-reported medication error involving Patient 1 who was administered Flolan via a CADD pump. On 7/24/07 at 10:30 P.M., Patient 1 was admitted to the ICU (intensive care unit) at the Hillcrest campus, with a diagnosis of PPH (primary pulmonary hypertension: high blood pressure in the lung arteries). Record review was conducted on 8/21/07. Per a Hillcrest Intensive Care flowsheet dated 7/25/07 at 11:00 A.M., Patient 1 was administered Flolan at 2ng/kg/min via an IVAC (name brand infusion pump.) Patient 1 had one peripheral intravenous (IV) line in place. At 2:00 P.M., a PICC line (peripherally inserted dual lumen/port central catheter) was inserted which was "ok to use" by 3:00 P.M. At 7:30 P.M., "per report Dr (doctor) ..... is aware Flolan is running peripherally." On 07/26/07 at 3:30 A.M., "pt. (patient) pulled out peripheral Flolan while tossing and turning. Stopped Dopamine (increases cardiac output) gtt. (drip) flushed PICC ports. Connected Flolan and called Dr ...." The nurse documented that she was unable to restart a peripheral IV and the physician (MD 3) "ok'd" the Dopamine infusion to be			

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	Continued From page 3 discontinued so that the Flolan could be infused via the only access site which was the PICC line. The package insert for Flolan was reviewed. The package insert states: "Flolan should be administered through a central venous catheter. Temporary peripheral intravenous infusion may be used until central access is established." On 7/25/07 at 3:00 P.M., Patient 1 had a central line inserted that was ready to use but Flolan continued to be administered peripherally for 12.5 hours until the patient pulled out her peripheral IV. On 7/26/07 at 9:50 A.M., further review of the Hillcrest ICU flowsheet documented that "ambulance staff/RN at bedside. Report given. Bumex (used to decrease excessive fluid buildup) gtt (drip) arrives-to be started at Thornton as per RN transport, only have 2 IV pumps available." The Bumex could not be started until Patient 1 reached the Thornton campus since only two pumps were available on the ambulance; one was used for Flolan and the other for Dopamine. The facility staff failed to demonstrate that a back-up pump was available on the ambulance for the infusion of Flolan to Patient 1. The package insert for Flolan states: "To avoid potential interruptions in drug delivery, the patient should have access to a backup infusion pump and intravenous infusion sets." Per an interview conducted with the Thornton ICU Assistant Manager on 8/2/07 at 9:00 A.M., when Patient 1 arrived at the Thornton campus at 10:45 A.M, LN 1 switched out the Flolan infusion set-up			

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	Continued From page 4 that arrived with the patient from the ambulance, with a CADD pump set-up. Facility staff did not know what type of pump set-up or pump was used on the ambulance during transport. Approximately 20 minutes after the Flolan infusion system switch, Patient 1's heart rate dropped to the 40's and her breathing became labored. MD 4 came into the room and found the CADD pump infusing Flolan at 80 cc/24 hours or 23.5 ng/kg/min and not at the prescribed rate of 34cc/24 hours or 10 ng/kg/min. Per an entry in the Physician's progress notes from 7/26/07, Patient 1 had a "bradycardia arrest." Emergent treatments and medications were initiated. Patient 1 was pronounced dead at 6:15 P.M. on 7/26/07. On 9/13/07 at 1:00 P.M., an interview was conducted with LN 1. LN1 stated that, on 07/26/07, she had not pressed the "enter" button on the CADD pump when she programmed the pump to deliver the prescribed rate of Flolan (34cc/24hours or 10ng/kg/min). Thus, the pump reverted back to the previous infusion rate (80cc/24 hours) stored in the pump. Per LN 1, it was "about 10 minutes" until the error was discovered by MD 4. LN 1 also stated that she did not prime the patient's PICC line with the prescribed higher concentration of Flolan when she switched out the infusion systems. LN 1 stated that she was unaware that the Hillcrest campus used a different infusion system for Flolan. LN 1 could not recall having to change (switch out) an entirely different Flolan infusion system before. LN 1 stated that she felt "in a hurry" because she knew the			

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	Continued From page 5 transportation personnel wanted their own infusion pumps back. LN 1 further stated that a back-up CADD pump was unavailable at the Thornton campus for Patient 1. The package insert for Flolan states: "Because Flolan is metabolized rapidly, even brief interruptions in the delivery of Flolan may result in symptoms associated with rebound pulmonary hypertension." Patient 1 had his/her Flolan infusion pumps changed (switched out) twice since being initiated on Flolan (once, upon transfer to the ambulance, and again at the Thornton campus) since different infusion pumps were used by the two campuses and the ambulance. On 09/18/07 at 10:29 A.M., an interview was conducted with the Director of Performance Improvement (DPI). The DPI stated that four action plans were made due to the 07/26/07 self-reported medication error involving Patient 1 with Flolan. During the same interview, the DPI stated (s) he was not sure if all four action plans were implemented as of this date, and would have to check with the nursing supervisors who were in charge of implementing the actions plans. On 09/18/07 at 6:20 P.M., review of the facility's Safe Medication Practices Subcommittee meeting minutes was conducted. Review of meeting minutes dated 10/03/06, documented an agenda item concerning Flolan and CADD pumps. The meeting minutes documented the following under the section entitled "Action/Recommendation, Responsible parties/Due Dates: (name) provided an			

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	Continued From page 6 update to the committee on Flolan CADD pumps. Because errors continue to occur at Hillcrest, (name), will be discussed with the critical care committee to approve a new process for these pumps where patients will be stabilized and then transferred to Thornton Hospital. Action: None." On 9/18/07 at 6:25 P.M., the Associate Chief of Pharmacy Services (Hillcrest campus) was interviewed and asked to specifically define the actions or new processes implemented by the facility, as a result of the Flolan errors referenced in the October 2006 Safe Medication Practices Subcommittee meeting. The Associate Chief of Pharmacy Services stated that the Flolan patients were "stabilized and sent to Thornton" and "that's what was done." A review of the P&T committee meeting minutes dated 10/12/06 was conducted on 09/18/07 at 6:30 P.M. and revealed no documentation or follow-up regarding the Flolan /CADD pump "new process" or plan. There was no documented evidence presented related to the Flolan and CADD pump "new" process since the 10/03/06 Safe Medication Practices Subcommittee Meeting minutes until the self-reported medication error which occurred July 2007. On 09/18/07 at 9:20 A.M., the Performance Improvement Coordinator (PIC/Pharmacist 1) also known as the "medication safety pharmacist," was asked how did (s) he ensure the safe and effective use of Flolan. Pharmacist 1 replied that Pharmacist 3 (who represented the Thornton			

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	Continued From page 7 campus) was present at the root cause analysis (RCA), would be the pharmacist to ask since the PIC had agreed with the RCA that it was a "nursing issue and not a pharmacy issue." On 09/18/07 at 9:20 A.M., Pharmacist 3 stated that the root cause analysis was correct, in that it was a nursing issue and not a pharmacy issue. Pharmacist 3 indicated (s) he was not familiar with any event/circumstances that happened in the Hillcrest campus or the ambulance ride to Thornton for Patient 1. On 09/18/07 at 9:42 AM, a group interview was conducted with pharmacy representatives from both campuses. Pharmacy staff present included: Pharmacist in Chief, Hillcrest Director of Pharmacy, Thornton Director of Pharmacy, Pharmacy Performance Improvement Coordinator, Clinical Coordinator - Pharmacy, Hillcrest coronary care unit pharmacist, and Thornton campus-pharmacists. The group was asked who in the pharmacy was responsible for, and how did the pharmacy ensure, the safe and effective use of medications being delivered via drug delivery devices such as intravenous pumps and CADD pumps. During the same interview, pharmacy staff could not provide documented evidence that they had assessed for safety and ensured the safety and effectiveness of automatic drug delivery devices, such as intravenous pumps in the Thornton and the Hillcrest campuses, including the pumps used in the intra-facility transportation of patients via ambulances.			

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	Continued From page 8 On 8/2/07 at 9:00 A.M., the Thornton campus Director of Nurses (DON) stated that primary pulmonary hypertension (PPH) patients were treated primarily at the Thornton campus because the physician and nursing expertise was at the Thornton campus. Pulmonary Hypertension Specialist Nurses with expertise on Flolan and CADD pumps were also located only at the Thornton campus. It was further explained that the PPH patient volume was so low at the Hillcrest campus that it was difficult for the nurses to maintain competency requirements related to Flolan administration with the CADD pump. An IVAC infusion pump was utilized at the Hillcrest campus to infuse Flolan since all the nurses were competent with the use of an IVAC pump, while the Thornton campus used a CADD pump. On 8/21/07 at 10:00 A.M., the Director of Performance Improvement (DPI), stated that the Thornton campus utilized the CADD pump to infuse Flolan because this pump was capable of infusing the drug at higher concentrations and lower rates. Also, Flolan required continuous delivery. Once patients were started on Flolan they never went off of the drug, so the patients were discharged with the same ambulatory CADD pump infusion system initiated in the hospital, for home delivery purposes. The Thornton campus' additional plan of care for Flolan patients included Flolan specific Guidelines of Care, dosing/rate administration sheets, Flolan specialty nurses, and mandatory Flolan specific competency requirements for the nurses. On 09/18/07, a review of the facility's practices for			

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	Continued From page 9 Flolan use revealed that the facility's staff and the Pharmacy and Therapeutics Committee failed to assess system-wide variances in different infusion pumps and tubing for Flolan. This necessitated restarting and resetting the administration of Flolan. There was no assessment pertaining to the system-wide variances with Flolan guidelines, protocols, and staff competency requirements. There was no assessment as to whether the medical transportation personnel or nurses were trained or met Flolan competency requirements. In addition, there was no assessment pertaining to the fact that Flolan was infused peripherally to Patient 1 at the Hillcrest campus, despite the presence of a viable central access site. On 9/18/07 at 7:10 P.M., an Immediate Jeopardy was called related to pharmaceutical services. The Director of Regulatory Affairs (DRA), Thornton DON, and the Thornton Pharmacy Manager were present. The violations were likely to cause serious injury or death to future patients with a diagnosis of pulmonary hypertension who required the administration of Flolan. The facility's quality assurance process, including appropriate committees and personnel failed to identify and analyze system-wide issues and inconsistent practices, to ensure the safe and effective use of Flolan, a drug that the facility had deemed as a "high risk medication." In addition, the facility had not developed and implemented policies, procedures, or practices that would have prevented the duplication of this event. On 9/18/07 at 10:55 P.M., a plan of action was			

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