

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050454	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/11/2008
NAME OF PROVIDER OR SUPPLIER UCSF MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 805 PARNASSUS AVENUE, SAN FRANCISCO, CA 94122-0210 SAN FRANCISCO COUNTY		
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	<p>The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident. Entity reported incident: CA00145949.</p> <p>Inspection was limited to the specific entity reported incident and does not represent the findings of a full inspection of the hospital.</p> <p>Representing the California Department of Public Health: [REDACTED] Pharmaceutical Consultant</p> <p>Title 22</p> <p>70214(a)(2) Nursing Staff Development (a) There shall be a written, organized in-service education program for all patient care personnel, including temporary staff as described in subsection 70217(m). The program shall include, but shall not be limited to, orientation and the process of competency validation as described in subsection 70213(c).</p> <p>(2) All patient care personnel, including temporary staff as described in subsection 70217(m), shall be subject to the process of competency validation for their assigned patient care unit or units. Prior to the completion of validation of the competency standards for a patient care unit, patient care assignments shall be subject to the following restrictions:</p> <p>70214(a)(A) Nursing Staff Development (a) There shall be a written, organized in-service education program for all patient care personnel, including temporary staff as described in</p>		<p>Corrective Action Flolan was added to the UCSF Medical Center's list of high risk medications, and the policy, <i>Medication Administration: High Risk Drugs</i> was revised accordingly, reviewed and approved by the Pharmacy and Therapeutics Committee on May 14, 2008.</p> <p>In the days following this incident, UCSF Medical Center began an expedited transition from use of the Alaris IV Pump to the CADD pump for all patients on Flolan or Remodulin. On April 9, 2008, CADD pumps were received and staff training began. All staff that routinely cared for patients receiving Flolan were trained on the use of the CADD pump, including rate and concentration calculations. This included staff in the 10 ICC and the 10CVT. Staff training in these areas was completed by April 11, 2008. Patients on Flolan are only admitted to 10 ICC or 10 CVT. On April 10, 2008, a memo was distributed to the entire nursing staff describing the process related to Flolan management and specifying the requirement that only competent, trained nurses care for patients on Flolan.</p> <p>In the emergency department and procedural areas, select staff were</p>	<p>5/14/08</p> <p>4/9/08</p> <p>4/11/08</p> <p>4/10/08</p>

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(X6) DATE

Steve Carraquero, RN

Director, Regulatory Affairs

1/16/09

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	<p>Continued From page 1</p> <p>subsection 70217(m). The program shall include, but shall not be limited to, orientation and the process of competency validation as described in subsection 70213(c).</p> <p>(A) Assignments shall include only those duties and responsibilities for which competency has been validated</p> <p>70263(c)(1) Pharmaceutical Service General Requirements</p> <p>(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.</p> <p>(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.</p> <p>Based on observation, staff interview and record review, the facility's Pharmacy and Therapeutics (P&T) committee failed to establish a safe and effective system for the administration of a high risk</p>		<p>trained to be Flolan competent and designated as a resource to be used should that department receive a patient on Flolan. This training was completed by April 28, 2008. If a patient on Flolan presents to an area outside of 10 ICC, 10 CVT, the emergency department or the procedural areas, the 10 ICC charge nurse is paged to come and evaluate the patient and assist with all care related to monitoring and administration of Flolan.</p> <p>CLARIFICATION SUBMITTED FEBRUARY 26, 2009</p> <p>The P&T Committee will review ISMP guidelines for updates on high risk medications on an annual basis. Recommendations for revisions to the UCSF Medical Center policy, <i>Medication Management: High Risk Drugs</i> will be made in accordance with the P&T Committee's review of the ISMP guidelines.</p> <p>Monitoring: On April 10, 2008, a memo was distributed to the entire nursing staff describing the process related to Flolan management and specifying the requirement that only competent, trained nurses care for patients on Flolan. Beginning on April</p>	<p>4/28/08</p> <p>2/26/09</p> <p>5/30/08</p>

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Gene A. Lannagy

Director, Regulatory Affairs

3/2/09

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	<p>Continued From page 2</p> <p>medication, Flolan (a drug with a short half-life that opens up blood vessels in the lungs and throughout the body), which resulted in Patient 1 receiving 23 times the prescribed dose of the medication on 08. The infusion device that was used for the administration of Flolan did not meet the manufacturer's specification requirements for the delivery of the medication. In addition, during the California Department of Public Health investigation on 4/10/08, it was discovered that one registered nurse (RN), with no validated competency in the operation of the Flolan Infusion device, was assigned to provide care to Patient 2, a patient on Flolan. Due to the short-life nature of Flolan and the fact that any interruption of Flolan infusion can be life-threatening, the facility's failure to ensure the safe administration of Flolan by competent staff was likely to place other patients requiring the drug, Flolan, in the situation of immediate jeopardy with the potential to cause serious injury or death.</p> <p>On 4/10/08 at 2:10 p.m., an Immediate Jeopardy (IJ) situation was declared pertaining to the unsafe administration of Flolan, a high risk medication, in the presence of the Director of Regulatory Affairs and the Licensing and Certification Coordinator of the facility.</p> <p>The IJ was abated at 5:33pm on 4/10/08 when an immediate corrective action plan was submitted by the facility and accepted by the California Department of Public Health.</p> <p>Findings:</p>		<p>10, 2008, the Nursing Supervisor monitored staff assignment to Flolan patients until May 30, 2008. The Nursing Supervisor confirmed that any staff caring for a Flolan patient had a completed and signed competency on file.</p> <p>Responsible Party: Chief Nursing Officer</p>	

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	<p>Continued From page 3</p> <p>An investigation was initiated on 4/9/2008 as a result of an incident reported by the facility involving the accidental overdose of Flolan to a patient who suffered a cardiac arrest and expired 45 minutes after the medication administration error.</p> <p>During an interview at approximately 10:25 a.m. on 4/9/08, the facility Licensing and Certification Coordinator provided a summary of the incident as follow: On 4/9/08, Patient 1 was receiving Flolan, dobutamine (a heart medication), and normal saline through intravenous therapy controlled by the same electronic infusion device, the Alaris infusion system. At approximately 7:10 p.m., RN 1 was preparing to start Patient 1 on potassium chloride by secondary infusion (piggybacking) through the normal saline infusion line at the rate of 100 ml/hr (milliliter per hour). However, RN 1 made an error and adjusted Patient 1's Flolan infusion rate from 4.2 ml/hr to 100 ml/hour. Immediately after the error was made, Patient 1 complained to RN 1 of feeling extremely tired while sitting in bed and collapsed into the bed and became unresponsive immediately after. The hospital Code Blue Team was called at once. A registered nurse responded to the code blue call noticed the mistake in the Flolan infusion rate and reset the infusion rate to 4.2 ml/hr approximately 5 minutes after the error was made. Cardiopulmonary resuscitation started at approximately 7:15 p.m. and continued until Patient 1 was pronounced dead at 7:58 p.m. on the same day.</p> <p>A review of Patient 1's clinical record showed that Patient 1 was admitted to the facility with</p>			

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	<p>Continued From page 4</p> <p>pulmonary hypertension on [REDACTED] 08. Fiolan therapy was initiated on [REDACTED] 08. On [REDACTED] /08, Patient 1 was on a stable dose of Fiolan 20 nanograms(ng) per kilogram per minute (20ng/kg/min) at the infusion rate of 4.2 ml/hr in the 10 South Unit of the facility. The Fiolan pump event log indicated that the infusion rate of Fiolan was adjusted from 4.2ml/hr to 100ml/hr at 19:16 (7:16 p.m.) on [REDACTED] 08 and was later on re-adjusted to 4.2ml/hr at 19:21 on the same day. An event note time-stamped at 1:32 p.m. on [REDACTED] 08 by an unknown provider stated, " I have reviewed the events surrounding this patient's death. Within one to two minutes before his cardiopulmonary arrest and the subsequent death, there was a misadministration of Fiolan that resulted in the patient receiving a substantially higher dose than was ordered. In addition, he had received IV Zofran for nausea and emesis. It is very likely that the Fiolan misadministration was causal given its temporal relationship to the patient's arrest. We are awaiting results of the medical examiner's evaluation to exclude other less likely potential causes, such as large pulmonary emboli or aspiration pneumonitis."</p> <p>At approximately 11:35 a.m. on 4/9/08, a team consisted of nursing managers, Director of Pharmacy (DOP), Patient Care Director, nurse specialists and Director of Regulatory Affairs demonstrated the infusion pump set-up as in Patient 1's room at the time of the incident. The Alaris Medley Medication Safety System with Point-of-Care Unit 8000 series and Pump Module 8100 Series, Version 7 was used in the incident. RN 3 explained that each infusion system</p>			
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Oak City Dist. Office

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	<p>Continued From page 5</p> <p>consisted of a Point-of Care unit which worked as the "brain" to support the delivery of up to 4 different medications at the same time by detachable modules (channels). The set-up of the system showed that the unit was supporting the infusion of Flolan and normal saline on the right side of the unit; and dobutamine and an empty channel on the left side of the unit. When asked if the system had any safeguard functions to help reduce IV medication errors, RN 3 responded that Guardrails(r) Software was installed in each infusion system which was frequently used in IV infusion therapy to alert nursing staff of dosing irregularities and provide dosing guidelines. However, the Guardrails(r) function was not utilized in the administration of Flolan in this incident. RN 3 stated that the basic infusion mode with no alert function was used in the infusion of Flolan in the incident due to the inability of the infusion system to handle Flolan dosing in the unit of ng/kg/min. When asked if Flolan met the definition of a high risk medication according to the facility's "High Risk medications" Policy and Procedure, the DOP responded, "yes". RN 3 stated that new ambulatory infusion pumps, the CADD pumps, had replaced the Alaris infusion system for the administration of Flolan as of 4/9/08.</p> <p>The manufacturer's prescribing information for Flolan documented the following information: " Flolan is administered by continuous intravenous infusion via a central venous catheter using an ambulatory infusion pump. The ambulatory infusion pump used to administer Flolan should: (1) be small and lightweight, (2) be able to adjust infusion</p>				

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	<p>Continued From page 6</p> <p>rates in 2-ng/kg/min increments."</p> <p>The Alaris infusion system that was used in the incident was not an ambulatory pump and did not have the capability of processing Flolan dose in the unit of ng/kg/min.</p> <p>Flolan (epoprostenol) is a medication for the treatment of primary pulmonary hypertension. Pulmonary hypertension is a condition of progressive narrowing of the blood vessels of the lungs, causing high blood pressure in these blood vessels and eventually leading to heart failure. Flolan works by relaxing and dilating the blood vessels in the lungs, allowing increased blood flow. Flolan lasts only for 3-5 minutes in the body and must be constantly infused intravenously directly into the bloodstream through a surgically implanted catheter inserted into the large vein leading directly into the heart by a portable, battery-operated pump. Interruption of Flolan can be life-threatening, even a brief interruption can result in a sudden reoccurrence of symptoms. Since Flolan also dilates blood vessels throughout the body, fatal occurrences of hypoxemia (low oxygen level in blood), hypotension (low blood pressure), and respiratory arrest (cessation of spontaneous breathing) have been reported following overdose of Flolan in clinical trials.</p> <p>During an interview at approximately 4:30 p.m. on 4/9/08, RN 4 of the 10 ICC unit stated that the incident prompted everyone in the unit to realize how error-prone the pump-sharing practice for Flolan administration was. RN 4 also stated that</p>			

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	<p>Continued From page 7</p> <p>the facility had stopped the pump-sharing practice for Fiolan administration shortly after the incident.</p> <p>During a review of patient clinical records and competency record of nursing staff in 10 ICC and 10 CVT (designated nursing units for patients receiving Fiolan) at approximately 11:00 a.m. on 4/10/08, it was discovered that RN 5 did not have validated competency in the operation of the new CADD pumps but was assigned to care for Patient 2, a patient on Fiolan, from 7 p.m. on 4/9/08 to 7 a.m. on 4/10/08. RN 5's competency record titled "Fiolan/Remodulin Infusion via the CADD legacy-1 Infusion Pump" dated 4/9/08 showed no validator's initials in all 17 competency areas and the record was not signed by a validator (trainer). Two concentration calculations on the competency record had not been completed. A telephone interview at approximately 12:22 p.m. with Trainer 1 & 2, who were responsible for training and validating competency in 10 ICC and 10 CVT, confirmed that competency in the operation of the CADD pump would be validated when a registered nurse was able to accurately complete the calculations and demonstrate competency in all the 17 competency areas on the form as indicated by the validator's initials. Trainer 1 & 2 stated that they could not recall RN 5 being trained or validated for competency and agreed that RN 5 did not meet the CADD pump competency requirement and should not have provided care to patients on Fiolan.</p> <p>During an interview at approximately 12:50 p.m. on 4/10/08, RN 1 stated that on the day of the incident, she adjusted the Fiolan infusion rate from</p>				

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	<p>Continued From page 8</p> <p>4.2ml/hr to 100ml/hr by mistake when she intended to adjust the rate of the normal saline module, which was located next to the Flolan module. Both the Flolan module and the normal saline module were attached on the right side of the infusion unit. RN 1 stated that there was no "high risk medication" alert sign on the infusion unit or anywhere in Patient 7's room.</p> <p>A review of the facility's High Risk Medications Policy and Procedure (Policy 6.09.19) dated January 2007 at approximately 1:15 p.m. on 4/10/08 indicated that high risk medications was defined as "drugs that bear a heightened risk of causing significant harm when they are used in error. Mistakes may or may not be more common with these drugs but the consequences of an error with these medications can be harmful to the patient." The Policy also stated, "A medication can be given High Risk status if ongoing review of external sources, including but not limited to the Institute for Safe Medication Practices (ISMP) and the United States Pharmacopoeia (USP), identify medications that should be given High Risk status. When new High Risk medications are identified, the affected department will work with the Pharmacy and Therapeutics Committee and the Medication safety Subcommittee to review these medications and develop new process that decreases the opportunity for error." Flolan was not listed as a high risk medication in the policy.</p> <p>The Institute for Safe Medication Practices (ISMP) listed Flolan (Epoprostenol) as one of 13 high-alert specific medications. On ISMP's List of High-Alert</p>			

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NAME OF PROVIDER OR SUPPLIER UCSF MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 505 PARNASSUS AVENUE, SAN FRANCISCO, CA 94122-0210 SAN FRANCISCO COUNTY		
(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	
	<p>Continued From page 9</p> <p>Medications publication, it stated: "High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients."</p> <p>Contrary to the facility's High Risk Medication Policy and Procedures, Flolan was not identified as a high risk medication by the facility, and consequently was not reviewed for the development of processes to reduce opportunity for error.</p> <p>On 4/10/08 at 2:10 p.m., an Immediate Jeopardy (IJ) situation was declared pertaining to the unsafe administration of Flolan, a high risk medication, in the presence of the Director of Regulatory Affairs and the Licensing and Certification Coordinator of the facility.</p> <p>Due to the short-life nature of Flolan and the fact that any interruption of Flolan infusion can be life-threatening, the facility's failure to ensure the safe administration of Flolan by competent staff was likely to place other patients requiring the drug, Flolan, in the situation of immediate jeopardy with the potential to cause serious injury or death.</p> <p>The IJ was abated at 5:33pm on 4/10/08 when an immediate corrective action plan was submitted by the facility and accepted by the California Department of Public Health.</p> <p>At approximately 12:40 p.m. on 4/11/08,</p>				

Event ID:LTWW11

1/2/2009

11:28:12AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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	<p>Continued From page 10</p> <p>Pharmacist 1 demonstrated the operation of the Guardrails(r) editor software Version 7. The Guardrails(r) editor software is the authoring tool that manages how medications can be programmed on the infusion system by setting limits on the rates, volumes, and doses that are appropriate for a given patient care area to reduce IV medication errors. Pharmacist 1 stated that the Guardrails(r) safeguard functions were not used for the administration of Flolan because Flolan was not programmed into the Guardrails(r) library. Pharmacist 1 explained that in order to program Flolan into the system, it required the manual conversion of Flolan dosing unit from nanograms (ng) to micrograms (mcg) (1000ng=1mcg), which was considered an independent risk for error. Pharmacist 1 added that the facility would be upgrading the infusion pump system to a version that would be capable of processing Flolan dosing in the unit of ng/kg/min in the near future.</p> <p>At approximately 12:40 p.m. on 4/11/08, the facility Licensing and Certification Coordinator and the DOP reported that there was no record of Flolan being discussed in any P&T or Medication Safety Subcommittee meetings.</p> <p>During a telephone interview at approximately 4:35 p.m. on 4/21/08, Customer Advocacy Representative 1 at Cardinal Health (the distributor of the Alaris infusion systems) stated that the Alaris infusion system used in the incident was not recommended for the administration of Flolan due to its inability to handle Flolan dosing in the unit of ng/kg/min. Customer Advocacy Representative 1</p>			

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