California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDERISUPPLIERICLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA040000126		07/24/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS. CITY, STATE, ZIP CODE	ABUILDING
SAINT AGNES MEDICAL CENTER	1303 E HERNDON AVE FRESNO, CA 93710	B WING

(X4) tD 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
E 000 I Initial Comments		E000		

The following reflects the findings of the California Department of Public Health during a complaint investigation #116315.

Representing the California Department of Public Health were [redacted]

1280.1 (a) HSC Section 1280

If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Sections 1250 receives a notice of deficiency constituting an immediate jeopardy to the health and safety of a patient and is required to submit a plan or correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars ($25,000) per violation.

1280.1 (c) HSC Section 1280

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.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY

E4751 T22 DIV5 CH1 ART3-70263(c)(1) 1 E475
Pharmaceutical Service General Requirements

A.

(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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDERISUPPUERICLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA040000126	A BUILDING	07/24/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SAINT AGNES MEDICAL CENTER	1303 E HERNDON AVE FRESNO, CA 93710

B. \MNG

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FUU REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEACIENCY)	(X5) COMPLETE DATE
E 475 I	Continued From Page 1	E475		

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.

The above regulations are not met as evidenced by:

Based on observation, staff interviews, clinical record review and administrative document reviews, the hospital failed to develop written policies and procedures for the establishment of a safe and effective system for the distribution, dispensing and use of drugs to be administered by bolus intravenous (IV) infusion pumps.

Findings:

Patient A's clinical record was reviewed on June 14,2007. Patient A presented to the hospital's emergency department on April 17. 2007, and was admitted as an inpatient with complaints of shortness of breath, night chills, fevers, chest pain and coughing. She was admitted with diagnoses of chronic obstructive pulmonary disease and infection of the lungs.

The Professional Progress Record Notes documented that on April 26, 2007, at 4:45 p.m .. , Patient A was transferred to the intensive care unit (ICU) and placed on a respirator (a machine that breathes for you). The Medication Administration Records (MAR)showedthat on April 26, 2007,at 7:54 p.m .. , the patient was administered a fentanyl (a strong pain medicine)

California Deoartment of PubficnHeal[th]

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROV DERISUPPLIERICLIA IDENTIFICATION NUMBER:	(X2) MULT PLEGONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA040000126		

NAME OF PROV DER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE	
SAINT AGNES MEDICAL CENTER	1303 E HERNDON AVE FRESNO, CA 93710	07/24/2007

A.BUILD NG

B. WING

(X4) 10 PREFIX TAG	SUMMARY STATEMENT OF DEFICIENC ES (EACH DEFIC ENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENT FYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 475 I	Continued From Page 2	E475		

drip at 25 micrograms (mcg)an hour per IV pump. The fentanyl was ordered to be increased as needed until Patient A was comfortable.

The Critical Care Flow Sheet documented on May 2,2007 at 12:40 p.m .. , Patient A's respirator was discontinued. On May 2, 2007 at 9:00 am., Physician 1 ordered a fentanyl drip at 300 mcg an hour, with an additional 1 00 mcg IV bolus every 15 minutes as needed for respiratory distress.

In an interview on June 14, 2007 at 11 :00 am., Registered Nurse (RN) 1 stated she cared for Patient A in the ICU on May 2, 2007. RN 1 stated that on May 2, 2007, she received a verbal order from Physician 1 to administer a bolus of fentanyl to Patient A. RN 1 stated she responded to Physician A's verbal order to give the bolus of fentanyl by programming the IV pump to administer at a rate of "999" cc (cubic centimeters) an hour. RN 1 stated she walked away from the IV pump for an undetenTlined amount of time. Patient A's family member became aware of the continuously running fentanyl "bolus" and brought it to RN 1's attention. RN 1 stated that she then turned off the IV pump and left the room. RN 1 stated she committed a medication error which resulted in Patient A receiving an overdose of fentanyl.
RN 1 stated she should have programmed the IV pump correctly.

The hospital's Controlled Substance Administration and Audit Record dated May 2, 2007, documented that RN 1 began the administration of fentanyl for Patient A at 12:30 p.m .. In interview on July 6,2007, at 1:10 p.m., the hospital's PhanTIacy Clinical Coordinator stated Patient A's last bag of fentanyl contained 2500 mcg in a 250 ml bag of solution.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDERISUPPLIERICLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA040000126	B BUILDING	07/24/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE	C WING
SAINT AGNES MEDICAL CENTER	1303 E HERNDON AVE FRESNO, CA 93710	

(X4) 10 PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	10 PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 475	Continued From Page 3	E475		

According to the Physician 1 orders dated May 2, 2007, Patient A was to receive a maximum amount of 700 mcg of fentanyl in one hour by IV pump administration. However, according to the Controlled Substance Administration and Audit Record and the Critical Care Flow Sheet on May 2, 2007, between 12:30 p.m. and 1 :35 p.m., Patient A received 1800 mcg of fentanyl within 65 minutes. In interview on July 6, 2007 at 1 :40 p.m., the Pharmacy Clinical Coordinator stated Patient A received 1800 mcg of fentanyl between 12:30 p.m. and 1:35 p.m ..

On July 6,2007, at 1:40 p.m., the Pharmacy Clinical Coordinator stated there were no hospital written policies and procedures regarding the administration of medication boluses with IV infusion pumps.

On July 6, 2007 at *4:30* p.m., both the Director of Risk Management and Nursing Director of the Critical Care Unit stated there was no hospital written policy and procedure regarding the administration of medication boluses via IV infusion pumps.

2. On July 24,2007, at 12:40 p.m., both the Director of Risk Management and the Nursing Director of the Critical Care Unit stated there were no hospital written policies and procedures regarding the administration of medication boluses via IV infusion pumps.

Three ICU registered nurses were interviewed on July 24,2007, regarding the use of the hospital IV infusion pump and were asked to demonstrate the administration of a medication bolus on the pump.

On July 24. 2007, at 1 *:05* p.m., RN 2 stated that

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDERISUPPLIERICLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA040000126	ABUILDING	07/24/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS. CITY. STATE. ZIP CODE
SAINT AGNES MEDICAL CENTER	1303 E HERNDON AVE FRESNO, CA 93710

8. WING

(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
E 475 I	Continued From Page 4	E475		

the hospital pumps did not have a "bolus mechanism on them." However, in the case of a fentanyl bolus, RN 2 stated that she would program the pump and the pump "does the calculating for you."

RN 3 stated in interview on July 24, 2007, at 1 :30 p.m., that if she received an order for a fentanyl bolus, she would prefer to give the bolus via a syringe, because it was "more accurate" and she was more "comfortable" doing it this way. But, RN 3 stated she could give the fentanyl via the pump "if [she] had to." When asked if she would find it helpful to have IV infusion pump written resources, policies and procedures or manufacturer's instructions available in the event RN 3 had a problem and needed to troubleshoot, RN 3 answered, "yes."

In an interview on July 24, 2007, at 2:05 p.m., RN 4 stated the only IV "bolus" medication she administered via the IV infusion pump was amiodarone (a cardiac anti-arrythmic medication). RN 4 explained she usually administered this medication using the IV pump over 10 minutes. But if the ordered medication "bolus" was Versed, diprivan, Ativan or fentanyl, RN 4 stated she would "push it through the line" after obtaining the appropriate syringe from the drug supply. RN 4 explained further, she "could bolus ... there's 1000mcg in a 200 ml bag" and stated she could withdraw the medication from the IV solution bag from above in order to bolus.

In summary, the nurses' knowledge on how to administer IV medication boluses was inconsistent. There was a lack of uniformity in the responses regarding the administration of potentially dangerous IV medication boluses in the ICU setting.

California Deoartment of~ublicHealth

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDERISUPPIIERICLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA040000126	ABUILD NG	07/24/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY. STATE, Z P CODE	B.WING
SAINT AGNES MEDICAL CENTER	1303 E HERNDON AVE FRESNO, CA93710	

(X4) 10 PREFIX TAG	SUMMARY STATEMENT OF DEFIC ENC ES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC DENTIFYING INFORMATION)	10 PREFIX TAG	PROV DER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFIC ENCY)	(X5) COMPLETE DATE
E 475 I	Continued From Page 5	E475		

The violation(s) has caused or is likely to cause serious injury or death to a patient(s).