

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050039	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 09/10/2007
NAME OF PROVIDER OR SUPPLIER ENLOE MEDICAL CENTER - ESPLANADE		STREET ADDRESS, CITY, STATE, ZIP CODE 1531 ESPLANADE, CHICO, CA 95926-3310 BUTTE COUNTY		
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	<p>000 Initial Comments</p> <p>The following represents the findings of the California Department of Public Health during the investigation of entity reported incident 124962.</p> <p>The investigation was limited to the specific entity reported incident and does not represent the findings of a full inspection of the facility.</p> <p>Representing the Department:  RN, BSN, HFEN  PharmD, Pharmaceutical Consultant II</p> <p>Two deficiencies were written at A 0264 and A 0292. An Immediate Jeopardy was called at A 0475.</p> <p>E 475 T22 DIV5 CH1 ART3-70263(c)(1) Pharmaceutical Service General Requirements</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>This Statute is not met as evidenced by:</p>			

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	<p>Continued From page 1</p> <p>Based on record review, staff interviews, and a review of the hospital's written policies and procedures, the facility failed to ensure that the pharmacist, in consultation with appropriate hospital staff and committees, had developed guidelines, protocols or policies and procedures, in accordance with accepted standards of practice and State regulations, to ensure patient safety for the control, distribution, and use of medications in the facility. As a result the facility:</p> <ul style="list-style-type: none"> * Failed to implement corrective or preventive measures following a similarly identified deficient practice with the potential to cause serious harm, injury, impairment, or death. * Failed to implement nationally recognized patient safety goals/practices. * Failed to develop and implement a policy and procedure stipulating when independent double checks (a verification process) would be performed by licensed staff during the infusion of narcotics via Patient Controlled Analgesia (PCA) devices. * Failed to include intravenously administered Dilaudid within its "High-Risk Medication" policy and procedure. * Failed to develop and implement a policy and procedure addressing standardized intravenous (IV) fluid concentrations. <p>The cumulative effect of these systemic problems resulted in the facility's inability to ensure the</p>			
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	<p>Continued From page 2</p> <p>provision of quality health care in a safe and effective manner. The continued violation(s) has caused, or is likely to cause, serious injury or death to patient(s). As a result of these findings, at 2:35 pm, on 9/06/07, the presence of an immediate jeopardy was declared and the hospital's Chief Executive Office, Vice President of Operations, Interim Vice President of Nursing Services, and the Assistant Director of Pharmacy Services were notified.</p> <p>Findings:</p> <p>1. On 9/4/07, at approximately 9 am, a review of Patient 1's record revealed that he was a 45 year-old male with a history of pancreatic and renal transplantation, and a more recent history of developing an intermediate to high-grade (rapidly growing and spreading) non-Hodgkin lymphoma (a type of cancer of the lymphatic system) who was admitted to the facility on 8/12/07 for intractable (refractory) pain, weakness, and fluid retention.</p> <p>The admitting "History & Physical," dated 8/12/07, indicated: "Several problems leading to this hospitalization. I am guessing (these are physician entries) that the first of these is inadequate pain control. To address that I will try IV Dilaudid by continuous infusion with boluses (additional doses) as needed." The stated treatment goal was "to provide significant pain relief," and "hopefully ...being able to send him home on hospice-equivalent regimen probably IV Dilaudid by continuous infusion." (Dilaudid is an opiate [narcotic] analgesic used for the management of</p>				

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	<p>Continued From page 3</p> <p>moderate-to-severe pain.) On 8/12/07, at 1:45 pm, a physician ordered Dilaudid 2 mg/hr (milligrams per hour) by continuous IV infusion.</p> <p>Over the ensuing days, Patient 1's condition declined, such that on 8/15/07 at 9:45 am, Patient 1's code status was changed, by his physician, to Do Not Resuscitate (DNR) with comfort/supportive care. (Code status is a term used to describe what specially trained staff is to do for the patient in the case of an emergent situation). On 8/18/07 at 10:45 am, Patient 1's physician increased the Dilaudid dosage to 3 mg/hr via continuous infusion. On 8/25/07, at approximately 9 am, Patient 1's physician again increased the Dilaudid infusion rate from 3 mg/hr to 6 mg/hr continuously, with additional boluses of 3 mg IV to be given every 30 minutes, as needed (for breakthrough pain). This order was noted by nursing staff at 9:40 am. Concurrent review of Patient 1's Medication Administration Records (MARs) indicated that the change in infusion rate, from 3 mg/hr to 6 mg/hr, was done at 11 am, and that a new cassette, containing 300 mg/30 ml (milliliters) Dilaudid, was started at 12 noon by Registered Nurse 1 (RN 1). The MAR included an "addendum," on 8/25/07, at 4:35 pm, that read, "Addendum 300 mg given", followed by RN 1's initials.</p> <p>In an interview on 8/30/07 at 3 pm, RPh1 stated that he changed the concentration of the Dilaudid from 1 mg/1ml to 10mg/ml, without a physician's order. He indicated that he made the concentration change for staff convenience. RPh1 stated that on 8/25/07 at approximately 4 pm, RN 1 called him to</p>			
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	<p>Continued From page 4</p> <p>request another Dilaudid cassette. It was at this time that the medication error was discovered.</p> <p>In an interview on 8/30/07 at 4 pm, RN 1 stated that on 8/25/07 at about 4 pm, she contacted the pharmacy to request another Dilaudid cassette. RN 1 indicated that the physician was notified of the error and ordered to continue the Dilaudid at 6mg/hr. A concurrent review of the physician notification, dated 8/25/07 and timed 4:15 pm, indicated that the physician was notified of a medication error and there were "no new orders." A review of the physician's orders indicated that there were no new orders related to the medication error of 8/25/07 at or around 4-4:30 pm.</p> <p>RN 1 stated that when the medication error was discovered, she and another RN checked Patient 1's respirations. RN 1 stated that Patient 1's respirations were 24-26. There was no documented assessment in the nurses notes of Patient 1's condition from 11 am to 4:59 pm.</p> <p>A review of the nurses notes, dated 8/25/07, indicated that after the medication error was discovered, Patient 1 was assessed at 5:30 pm and at 8 pm.</p> <p>A review of the 5:30 pm nursing assessment indicated that Patient 1 had severe weakness; his respirations were regular and unlabored at a rate of 26. Lungs were coarse with diminished breath sounds. Patient 1's pulse was strong and irregular (pulse rate was not documented). Patient 1's level of consciousness was not assessed.</p>			
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	<p>Continued From page 5</p> <p>A review of the 8 pm nursing assessment indicated that Patient 1 was weak, lethargic, mildly anxious and made no purposeful movement. Respirations were labored and shallow. Lungs were coarse sounding. Patient 1 was gurgling and his skin was edematous.</p> <p>The amended "Discharge Summary," dated 8/28/07, indicated that "There was a medication error between pharmacy and nursing, and he (Patient 1) ended up getting a final concentration dose of 66.0 mg/hour from 12 noon to 4 pm on Saturday (8/25/07)." Patient 1 expired on 8/26/07 at approximately 1 am.</p> <p>Manufacturer dosing guidelines indicated that the usual 4-hour limit (standard dosing guideline) for patient controlled analgesia, in an opiate-naïve patient, was 4 to 6 mg. Patient 1, who had been receiving opioids chronically, had been receiving 12 mg over a 4-hour period continuously prior to his physician increasing the dosage on 8/25/07 to 6 mg/hr (or 24 mg over a 4-hour period). The dosage was doubled. Record review indicated that Patient 1 actually received "66 mg/hr" instead of 6 mg/hr, or 300 mg over a 4-hour time period (effectively increasing the dosage 10-fold or 1000 percent).</p> <p>In an interview with the Director of Pharmacy (DOP) on 9/04/07 at 9:50 am, he stated that there were no standardized drug concentrations for IV opiates (narcotics) and that the pharmacist may concentrate IV solutions, per physician order, nursing request, or at the pharmacist's discretion.</p>			
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	<p>Continued From page 6</p> <p>In the latter case, a pharmacist may concentrate an IV Dilaudid solution from 1 mg/ml to 5 mg/ml or even 10 mg/ml, depending upon the circumstances. The DOP also stated that the circumstances in which the pharmacist may do so are not identified by policy or procedure. The DOP further stated that for Patient 1, on 8/25/07, the pharmacist (RPh 1) had taken it upon himself-in the absence of a physician order to do so, or clear guidelines, as established by policy and procedure-to concentrate Patient 1's IV Dilaudid solution from 1 mg/ml to 10 mg/ml. The DOP indicated that RPh 1 had done so, for staff convenience, to provide nursing with a single medication cassette (a 24-hour supply) instead of multiple cassettes, each lasting up to 5 hours, which would be needed given the ordered infusion rate of 6 mg/hr. The DOP also stated that that there was no policy and procedure that required any additional warning labeling to alert the medication nurse(s) to this type of change.</p> <p>On 9/04/07, at approximately 10 am, a copy of the medication label for Patient 1's IV Dilaudid therapy, following the change in dosage on 8/25/07, was provided by the DOP. It included the name of the patient and medication; it listed the concentration of the medication (300 mg/30 ml); it did not specify the infusion rate (i.e., 6 mg/hr) or the 4-hour limit (i.e., 24 mg). In an interview with the Assistant Director of Pharmacy (ADOP), on 9/07/07 at approximately 10:45 am, he stated that the IV labeling was incorrect and that all of that information should have been included (i.e., infusion rate and 4-hour limit). He then produced the pharmacy generated "Medication Detail" form which</p>			

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	<p>Continued From page 7</p> <p>created a copy of the "Label Text" and the information which was then printed on the patients' MARs. The ADOP then stated that there was "a soft-ware glitch" and that only the first two lines of label text print out on the IV label-the remainder (including the infusion rate, 4-hour dosing limit, and complete cautionary information) does not. He also stated that the IV label text should match the patients' MARs identically when the new MARs are printed for use on the next day.</p> <p>Concurrent review of Patient 1's MARs for 8/25/07, revealed that following the change in Dilaudid dosage the MARs had been altered (entries crossed-out and rewritten). RN 1 stated in an interview, on 8/30/07 at 4 pm, that she had made the hand written MAR changes, and further stated that it was not facility policy to do so.</p> <p>At 11:05 am, the Nursing Quality and Informatics nurse provided a copy of the facility's policy and procedure, "Medication: Order Processing," revised 2/06, it indicated that for changes in dosage staff was to "draw a diagonal line through the entry on the MAR ...write discontinued ...date, time, and initial, and transcribe the medication changes as a completely new order. She was unable to provide any further details as to why policy and procedure had not been followed or why the MARs had been altered.</p> <p>2. On 9/07/07, at approximately 12 noon, Pharmacy & Therapeutics Committee (P&T Committee) minutes, dated 6/22/07, were reviewed. Included in these minutes was the description of a</p>			

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	<p>Continued From page 8</p> <p>medication error involving another patient (Patient 2). Patient 2 was a 76 year-old female who had received a larger dose of IV Cardene than had been ordered by the physician (Cardene is a medication used for the management of hypertension). Specifically, the P&T Committee meeting notes indicated that Patient 2 had received the wrong medication dose, resulting in an overdose. The issues of concern were identified to include:</p> <ul style="list-style-type: none"> * Non-standard concentrations of IV solutions being used without a physician order. * Failure to follow policy for administration of IV medication (including the failure to verify IV bag labeling, its concentration and pump settings) for a total of three consecutive IV bags. * Pharmacy personnel calculated the concentration on each IV bag incorrectly. * Failure to comply with National Practice Safety Goals. <p>These meeting notes also indicated that, " ...it would appear that this incident could have been avoided had standardized concentration procedures had been followed ...;" that, "Any change in (IV solution) concentration requires an order." The Committee reportedly "chose to expedite the review of this case ..." and further indicated that the incident was being evaluated by the Medication Process Improvement Team (MIT). On 9/07/07, at approximately 12:10 pm, during an interview with the Performance Improvement Coordinator, she</p>			

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	<p>Continued From page 9</p> <p>stated that the MIT team meets monthly; members included representatives from pharmacy, nursing, and quality care. The stated goal of this team being that of improving patient safety, as related to medication use. Meeting minutes were maintained for these meetings. The Performance Improvement Coordinator was unable to provide any documentation that there had been further discussion or follow-up to the medication error, involving Patient 2, as described in the aforementioned P&T Committee meeting minutes. The Nursing Quality and Informatics nurse also verified these findings.</p> <p>The Joint Commission (formerly The Joint Commission on Accreditation of Healthcare Organizations) each year publishes its National Patient Safety Goals (NPSGs). Goal 3 for 2007 is "to improve the safety of using medications." Within this stated goal is the requirement "to standardize and limit the number of drug concentrations it (the facility) uses." This requirement applies to drugs compounded in the hospital, typically IV solutions. The Joint Commission is most concerned "that hospitals limit the number of concentrations of 'high-alert' medications, which are those that have the highest risk of causing injury when misused. This includes-but isn't limited to-narcotics (opiates)"</p> <p>The Institute of Safe Medication Practices (ISMP), in an article dated April 1, 2006, "Patient-Controlled Analgesia: Making It Safer for Patients," indicates that, "Lack of familiarity with nonstandard concentrations was identified as another potential</p>			

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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: 050039	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 09/10/2007
NAME OF PROVIDER OR SUPPLIER ENLOE MEDICAL CENTER - ESPLANADE		STREET ADDRESS, CITY, STATE, ZIP CODE 1531 ESPLANADE, CHICO, CA 95926-3310 BUTTE 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 10</p> <p>root cause of prescribing and administration errors. Sometimes, for a reason such as fluid restriction, a more concentrated form of a drug may be requested. These nonstandard concentrations are a set up for failures unless every single clinician that may change the order, adjust the pump, or prepare and dispense the drug is knowledgeable about them."</p> <p>One of the 12 interventions that the Institute for Healthcare Improvement (IHI) recommends for its 5 Million Lives Campaign-which has set a target of reducing five million incidents of harm from December 2006 to December 2008-is to "Prevent Harm from High-Alert medications ...starting with a focus on ...narcotics (opiates)" Specific recommendations to improve safety with the use of narcotics included (that) "patient-controlled analgesia should be independently double-checked on the unit."</p> <p>"High-Alert Medications: Safeguarding against Errors," published by the American Pharmaceutical Association in 1999, concluded that a majority of medication errors resulting in death or serious harm involved a small number of specific medications. The study conducted by the ISMP termed medications having the highest risk of causing injury as "high alert medications." Opiates and narcotics were identified by the ISMP study are among the top-five high-alert medications, indicating that they have a particularly high risk of causing patient harm, including serious harm and death.</p>			

Event ID:ZL2G11

3/18/2008

12:23:34PM

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

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	<p>Continued From page 11</p> <p>The cumulative effect of these systemic problems resulted in the hospital's inability to ensure the provision of quality health care in a safe and effective manner. The violation(s) has caused or is likely to cause serious injury or death to patient(s). As a result of these findings, at 2:35 pm, on 9/06/07, the presence of an Immediate Jeopardy was declared.</p> <p>On 9/10/07, at approximately 12 noon, a Plan of Correction (POC) was provided that included revised policies and procedures for the infusion of narcotics; double checks of high-risk medications; high-risk medication use; and a new policy and procedure for standardized IV medication concentrations. The POC was accepted, and on 9/10/07, at 1:05 pm, the Immediate Jeopardy was abated.</p>			

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