

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  04/09/2007
NAME OF PROVIDER OR SUPPLIER  ENLOE MEDICAL CENTER - ESPLANADE	STREET ADDRESS, CITY, STATE, ZIP CODE  1531 ESPLANADE, CHICO, CA 95926 BUTTE COUNTY		

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E 000 Initial Comments

The following represents the findings of the California Department of Public Health, formerly known as the Department of Health Services, during a complaint validation survey conducted 4/3/07 - 4/9/07.

Representing the Department:

 

Event ID: VS2712

8/10/2007

10:33:03AM

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

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Health and Safety Code:  
1280.1

1280.1. (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.

(b) If the licensee disputes a determination by the department regarding the alleged deficiency or the alleged failure to correct a deficiency, or regarding the reasonableness of the proposed deadline for correction or the amount of the penalty, the licensee may, within 10 days, request a hearing pursuant to Section 100171. Penalties shall be paid when appeals have been exhausted and the department's position has been upheld.

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(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.

(d) This section shall apply only to incidents occurring on or after January 1, 2007.

(e) No new regulations are required or authorized for implementation of this section.

DEFICIENCY            CONSTITUTING            IMMEDIATE  
JEOPARDY:

E 475 T22 DIV5 CHi ART3-70263(c)(1)

(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

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

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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 interview, medical record review, and document review; the hospital failed to provide safe patient care, by failing to develop written policies and procedures for the safe and effective system of dispensing and use of drugs, and by exposing patients to undue adverse. medication consequences as evidenced by:

\* Failure to monitor patients on droperidol (Inapsine) for emergence of potentially fatal arrhythmias.

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- Hospital promotion of droperidol (Inapsine) as a first line agent, and for clinical conditions not supported by manufacturer's specifications.

Findings:

Droperidol (Inapsine) has a black box warning from the manufacturer. The warning states, "Cases of QT prolongation and/or torsades de pointes have been reported in patients receiving I napsine (droperidol) with doses at or below recommended doses. Some cases have occurred in patients with no known risk factors for QT prolongation and some cases have been fatal.

Due to its potential for serious proarrhythmic effects and death, Inapsine (droperidol) should be reserved for use in the treatment of patients who fail to show an acceptable response to other adequate treatments, either because of insufficient effectiveness, or the

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inability to achieve an effective dose due to intolerable adverse effects from those drugs.

Cases of QT prolongation and serious arrhythmias (e.g., torsades de pointes) have been reported in patients treated with droperidol. Based on these reports, all patients should undergo a 12-lead ECG prior to administration of Inapsine (droperidol) to determine if a prolonged QT interval (Le., QTc greater than 440 msec for males or 450 msec for females) is present. If there is a prolonged QT interval, Inapsine (droperidol) should NOT be administered. For patients in whom the potential benefit of Inapsine (droperidol) treatment is felt to outweigh the risks of potentially serious arrhythmias, ECG monitoring should be performed prior to treatment and continued for 2-3 hours after completing treatment to monitor for arrhythmias."

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Torsades de Pointes is a cardiac arrhythmia, which may cause blackouts or sudden death.

The aT interval represents the duration of ventricular depolarization and subsequent repolarization. A delay in cardiac repolarization creates an electrophysiological environment that favors the development of cardiac arrhythmias, most clearly torsade de pointes (TdP), but possibly other ventricular tachyarrhythmias as well.

Because of its inverse relationship to heart rate, the measured aT interval is routinely corrected by means of various formulas to a less heart rate dependent value known as the aTc interval.

According to the Federal Food and Drug Administration (FDA) MedWatch Program a "Dear Health Care Professional" letter was sent out by the manufacturer of droperidol on December 4, 2001.

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The letter was to warn all health care professionals about the potential of serious and fatal arrhythmias associated with the use of the medication. The exact language of the warning sent was the language printed in the manufacturer's black box labeling information.

During medical record reviews on 4/3/07 and 4/4/07, it was noted that droperidol was one of medications listed on the 5/05, preprinted post anesthesia care unit orders. It was also noted that the preprinted orders did not include the manufacturer or FDA guidance of monitoring the electrocardiogram (EKG), prior, during, and after administration of droperidol.

On 4/5/07 beginning at 9 am, surgical staff stated that pharmacy staff stocked droperidol in all of the anesthesia kits. During an interview, a post anesthesia care unit nurse stated that she could not remember the last time she had administered, or was aware, that

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droperidol had been administered to a patient.

A request was made to review the nursing policy and procedure related to the administration of droperidol. Nursing staff stated that they did not have a policy or procedure related to the administration of droperidol.

On 4/5/07 at 10:40 am, a request was made for pharmacy staff to provide a report of droperidol use at the main campus surgery, and the outpatient surgery site. The main hospital use report showed that surgery had used droperidol 6 times out of the last 6 months. The report also showed that the use of droperidol had increased. The outpatient surgery report showed that droperidol was used 5 times out of the last 11 months, and as recently as 2/07 and 3/07.

During a concurrent interview pharmacy staff stated that they were not aware that droperidol use had

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increased. Pharmacy staff stated they were aware of the black box warning, and that it had been over two years since pharmacy assessed the use of droperidol.

On 4/5/07 at 12:45 pm, the hospital was informed that Immediate Jeopardy had been declared because of failure to ensure that written policies and procedures were developed for the safe use of drugs with known adverse medication consequences.

This violation(s) has caused or is likely to cause serious injury or death to the patient (5).

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