

California Department of Public Health

STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA
IDENTIFICATION NUMBER:

050230

(X2) MULTIPLE CONSTRUCTION A.

BU LD NG
B.WING

(X3) DATE SURVEY
COMPLETED

C
03/22/2007

NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

GARDEN GROVE HOSPITAL & MEDICAL CENI

12601 GARDEN GROVE SLVD
GARDEN GROVE, CA 92843

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A 0001 Initial Comment

A 000

The following reflects the findings of the Department of Public Health, formally known as the Department of Health Services, during an investigation of COMPLAINT NO. CA00093748.

Representing the Department of Public Health:



A 0121 1280.1(a) HSC Section 1280

A 012

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.

A 0141 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.

A014

DEFICIENCY CONSTITUTING IMMEDIATE
JEOPARDY

Licensing and Certification Division

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

STATE
FORM

6899

9TEN11

TITLE

(X6) DATE

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Representing the Department of Public Health:

[REDACTED]

E 474/ T22 DIV5 CH1 ART3-70263(c) Pharmaceutical | E 474
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 one physician, one pharmacist, the director
of nursing service or her representative and the
administrator or his representative.

This Statute is not met as evidenced by:

E 4751 T22 DIV5 CH1 ART3-70263(c)(1)
Pharmaceutical Service General Requirements

| E 475

(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.

Licensing and Certification Division

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E 4751 Continued From page 1

E475

This Statute is not met as evidenced by:
The above Regulation was NOT MET as
evidenced by:

The committee (pharmacy and therapeutics committee, or a committee of equivalent composition), 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 clinical record review, the hospital failed to ensure that written policies and procedures to ensure the safe and effective use of medications with black box warnings were developed and implemented. A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects **Error! Hyperlink reference not valid.** medicine%29>. It is the U.S. Food and Drug Administration's strongest required warning.

Due to the potential of serious adverse consequences, including death, droperidol (a drug used to treat nausea) has special warnings (Black Box Warnings) to ensure it is used safely. Record review revealed that one of five patients reviewed (Patient #36) received three doses of droperidol without the cardiac monitoring required

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by the Black Box Warning. Interview with the facility's pharmacy and nursing staffs revealed that they were unaware of the manufacturer's warnings and confirmed that the patients were not monitored in accordance with the manufacturer's specifications.

Findings:

On 3/20/07 at 0845 hours, a review of five medical records revealed a preprinted order sheet entitled, "Med Surg Status Post AON (Accelerated Opiate Neuronal) Procedure/Opiate Dependence" which listed droperidol (Inapsine) as a medication choice for the treatment of nausea. Droperidol (Inapsine) has a Black Box warning issued by the FDA which states:

Gases of QT prolongation and/or torsade de pointes (a potentially fatal cardiac rhythm) have been reported in patients receiving Inapsine at 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 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 inability to achieve an effective dose due to intolerable adverse effects from those drugs (see Warnings, Adverse Reactions, Contraindications, and Precautions). Cases of QT prolongation and serious arrhythmias (e.g., torsade de pointes) have been reported in patients treated with INAPSINE. Based on these reports, all patients should undergo a 12-lead EGG prior to administration of INAPSINE to determine if a prolonged QT interval (Le., QT interval greater

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than 440 msec for males or 450 msec for females) is present. If there is a prolonged QT interval, INAPSINE should NOT be administered. For patients in whom the potential benefit of INAPSINE treatment is felt to outweigh the risks of potentially serious arrhythmias, ECG monitoring should be performed prior to treatment and continued for 2 to 3 hours after completing.

There was no documentation on the preprinted order sheet that droperidol (Inapsine) was a high risk drug and there were no guidelines listed for monitoring for adverse consequences. There were no recommendations that other drugs should be used first for nausea which is not in accordance with the manufacturer's specifications/warnings. Record review revealed one of five patients (Patient #36) received three doses of droperidol 1.25 mg IV on the following dates and times; 3/18/07 at 1330 hours and 1930 hours, 3/19/07 at 1415 hours. The other four patients had orders for droperidol but did not receive the drug. During a SUNey team conference, administrator 1 stated the facility "averaged 20-22 AONR cases per month" and each having their own preprinted order sheet with I.V. droperidol as an option to treat nausea.

On 3/20/07 at 0930 hours, an interview with Nurse #1 revealed that there was no cardiac monitoring and no ECG monitoring pre or post droperidol doses for patients with droperidol orders on the sixth floor. The sixth floor is the designated floor to admit and manage patients following the AON procedure. The AON procedure preprinted order sheet was approved by the P & T committee and Medical Committee prior to implementation.

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On 3/20/07 at 0945 hours, in an interview with the clinical pharmacist who reviews orders and validates orders for sixth floor patients, she stated she was not aware of the manufacturer's Black Box warning for droperidol.

On 3/20/07 at 1600 hours, the hospital administration staff including the CEO was informed that Immediate Jeopardy (IJ) had been identified based on the hospital's failure to protect patients from potential undue adverse medication consequences from droperidol (Inapsine). Patients receiving care based on the accelerated status post opiate neuronal procedure, referred to above, with an order for droperidol (Inapsine) were not monitored for potential serious and life threatening cardiac arrhythmias (serious irregular heart beats) as required by the manufacturers Black Box warning. The hospital was asked to provide a plan of correction to address the IJ. On 3/21/07 at 0900 hours, a finalized plan of correction was submitted and accepted. The IJ was lifted on 3/21/07 at 0900 hours. The director of pharmacy stated all droperidol had been removed from the facility stock for patient use and this was documented in their plan of correction.

On 3/21/07 at around 1030 hours, two ampules of droperidol 5 mg/2 cc were found in the after hours drug supply night locker and potentially available for patient use. On interview with the pharmacy technician, she stated that she was not aware of the droperidol stocked in the after hours drug supply. The director of pharmacy stated it should have been removed and then removed the droperidol from the drug supply.

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

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