

PDC accepted
3/24/11

PRINTED 03/04/2011
FORM APPROVED

California Department of Public Health

De J...

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA070000139	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 01/03/2011
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NAME OF PROVIDER OR SUPPLIER DOMINICAN HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 1555 SOQUEL DRIVE SANTA CRUZ, CA 95065
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E 000 Initial Comments

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The following reflects the findings of the California Department of Public Health during investigation of an entity reported incident and complaint conducted from 12/29/10 to 01/3/11.

For Entity Reported Incident CA00247514 and Complaint CA00246476 regarding Physician Services, a State deficiency was identified (see California Code of Regulations, Title 22, Section 70263(c)(1)).

Inspection was limited to the specific entity reported incident and complaint investigated and does not represent the findings of a full inspection of the hospital.

Representing the California Department of Public Health was 28767, Health Facilities Evaluator Nurse.

Health and Safety Code, Section 12801(c)
(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.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY.

E 474 T22 DIV5 CH1 ART3-70263(c) Pharmaceutical Service General Requirements

E 474

(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.

E474
T22 DIV5 CH1 ART3-70263(c)
Pharmaceutical Service General Requirements

Discussion:
The hospital has a working Pharmacy & Therapeutics Committee (P&T) comprised of all membership outlined in T22 DIV5 CH1 ART3-70263(c) for many years. One of the responsibilities of the P&T committee is to review and approve policies related to safe medication management.

1986

Licensing and Certification Division

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

TITLE *President*

(X6) DATE

3/22/11

California Department of Public Health

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This Statute is not met as evidenced by

E 475 T22 DIV5 CH1 ART3-70263(c)(1)
Pharmaceutical Service General Requirements

(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

This Statute is not met as evidenced by:
Based on interview and record review, the pharmacist failed to implement procedures to ensure the appropriate dose and amount of a chemotherapy medication was dispensed for one of one sampled patient (1). Patient 1 received an excessive amount of a chemotherapy medication (cisplatin) which resulted in serious disability for Patient 1. Findings:

On 12/30/10, review of physician orders indicated Patient 1 was scheduled to receive outpatient chemotherapy for five consecutive days (12/30/10 to 1/10/10) for testicular cancer. Chemotherapy orders included cisplatin (medication used to treat different types of cancer) 212 milligrams (mg) given intravenously (directly into a vein); daily for

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

Deficiency: This Statute is not met as evidenced by:

Based on interview, and record review, the pharmacist failed to implement procedures to ensure the appropriate dose and amount of a chemotherapy medication was dispensed for one of one patient.

a) An administrative directive to all pharmacy staff indicating that, beginning immediately, all chemotherapy orders would require diagnosis, (type of cancer being treated), protocol name, duration of the protocol (to assess cumulative doses were consistent with established research-approved dosing guidelines, independent double check by 2 pharmacists will verify the cumulative dosing is correct to the protocol and type of cancer being treated.

Responsible Individual: Director of Pharmacy

b) The Director of Oncology Services provided immediate nursing education regarding the requirement to add the research-based chemo protocol with the MD order to use as part of the independent 2-RN double verification process at the point of administration

Responsible Individual Nursing Director of Oncology

c). The hospital policy on High Risk Medication (8610-pc-500) was revised to include the presence of the research-based chemotherapy protocols to be included from the physician when the chemo order is received. This formal written protocol will identify the protocol's approval for the type of cancer being

10/11/10

10/11/10

P&T
Committee
approval 2/10

12/13/10

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five days.

Review of the medical record indicated Patient 1 complained of ringing in the ears on day three and day four of chemotherapy, and "feeling bloated" on day four. Day five of chemotherapy was cancelled due to worsening of the patient's symptoms

On 12/30/10, review of a physician's note indicated Patient 1 called the oncology unit on [REDACTED] 10 at 1:30 a.m. with a complaint of difficulty urinating. Patient 1 was seen at the emergency department. A urinalysis test was done, followed by an insertion of a foley catheter (a tube inserted into the bladder to drain urine). Patient 1 was discharged home. The physician's note indicated a review of Patient 1's chemotherapy orders determined Patient 1 had received an excessive amount of the medication cisplatin

The on-call oncologist notes indicated Patient 1 was asked to return to the emergency department. On arrival a central line (catheter placed into a large vein used to administer medication or fluids, and to obtain blood samples) was inserted due to the "emergent nature of the situation" and Patient 1 was transferred to another hospital for possible plasmapheresis (blood purification procedure).

A consultation note dated [REDACTED] 10 from Patient 1's primary oncologist stated, "I discovered that I had transposed 2 numbers in calculating his chemotherapy doses, and thus, the patient had received 100 mg per meter squared per day of cisplatin instead of 20 mg per meter squared per day of cisplatin for the 4 days he was administered the chemotherapy." The primary oncologist contacted the pharmacy department

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treated, and will follow the order through the pharmacy and nursing processes of medication preparation and administration.

d) A clinical pharmacist was re-deployed provide full time service to the Oncology Service. This pharmacist works on the clinical unit and reviews 100% of chemotherapy orders for accuracy, completeness and appropriateness against the research-based protocol and other reference material, e.g., Facts and Comparisons, NCCN and other references are used. The written protocol is required for the chemotherapy order to be considered "complete". Any deviations from protocol, or if the order is incomplete are clarified by the clinical pharmacist with the prescriber until all discrepancies are resolved. The order is not forwarded to the Pharmacy Department for preparation until the order is complete.

Monitoring:

Monitoring to insure compliance with the new administrative directive/policy has been undertaken. 100% of all chemotherapy orders. Findings will be presented to Pharmacy & Therapeutics Committee. Expected performance is 100%. Monitoring will be continued as part of ongoing medication safety. Performance in February 2011 was 100%

12/15
Ongoing

California Department of Public Health

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and it was confirmed Patient 1 received the above ordered dose of cisplatin for 4 days

During a telephone interview on 01/03/11 at 9:20 a.m. with the primary pharmacist (PH 1) who received the cisplatin order, PH 1 stated he received the order that included the patient's diagnosis of testicular cancer. PH 1 stated he referenced the medication and realized the medication dose ordered was high and further research indicated the dosage ordered by the physician was an appropriate dose for one day of treatment. PH 1 stated he did not realize the frequency was incorrect. PH 1 processed the medication order which was then verified by a second pharmacist (PH 2).

During a telephone interview with PH 2 on 12/30/10 at 1:20 p.m., PH 2 discussed the policies and procedures to be followed when the pharmacy received a chemotherapy order from a physician. The order was scanned into the pharmacy computer system and a label for the medication printed. Two pharmacists checked the label for appropriate dosage and accuracy. The medication dosage was checked by two pharmacists who calculated the patient's body surface area (BSA) (total area of skin on the human body) to ensure correct medication dosage was ordered for the patient. In addition to calculating the patient's BSA for dosage appropriateness, the patient's cancer diagnosis was reviewed to ensure the medication dosage ordered was appropriate to treat the specific type of cancer for which it was ordered. PH 2 stated the medication order for Patient 1 was correct and appropriate for a one-time "single" dose. PH 2 stated the pharmacy overlooked the part of the order where it stated the patient was to receive the medication for five consecutive days.

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E 475	<p>Continued From page 4</p> <p>Review of the hospital's policy and procedures for "High-Risk Medication Administration" dated 5/21/10 indicated, Under Section 3. Chemotherapy Agents: Two pharmacists double check order and dosage</p> <p>According to online literature (www.lexi.com) an appropriate cisplatin dose for testicular cancer can range from "10-20 mg/m2/day for 5 days repeated every 3 weeks." An average cisplatin dose for ovarian cancer may range from "75-100 mg/m2 [once] every 4 weeks."</p> <p>Patient 1's discharge (DC) summary from the hospital where he was transferred for treatment of cisplatin toxicity and plasmapheresis was reviewed. The DC summary indicated Patient 1 was admitted on [REDACTED] 10 to the intensive care unit with acute renal (kidney) failure due to cisplatin overdose and cisplatin ototoxicity (damage to the hearing or balance functions of the ear by drugs or chemicals). Patient 1 received daily plasmapheresis and was started on dialysis. Patient 1 was in the intensive care unit for 17 days. On [REDACTED] 10, the patient was discharged from the hospital. He was scheduled to continue dialysis and was referred to a nephrologist (kidney doctor) for outpatient care. In addition to the above referral, Patient 1 was scheduled to follow-up with an audiologist for loss of hearing</p> <p>The pharmacists' failure to implement the hospital policies and procedures to verify the appropriate dose and frequency of Patient 1's chemotherapy medication resulted in Patient 1 receiving an excessive amount of the medication which caused, or is likely to cause, serious injury or death to the patient therefore constituting an immediate jeopardy within the California Health</p>	E 475		
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E 475	Continued From page 5 and Safety Code, Section 1280.1(c)	E 475		
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