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11/3/09 SA

California Department of Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA930000002	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/03/2009
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NAME OF PROVIDER OR SUPPLIER CALIFORNIA HOSPITAL MEDICAL CENTER LA	STREET ADDRESS, CITY, STATE, ZIP CODE 1401 SOUTH GRAND AVENUE LOS ANGELES, CA 90015
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E 000	<p>Initial Comments</p> <p>The following reflects the findings of the Department of Public Health during a Complaint Investigation.</p> <p>Complaint Intake Number: CA00181940 - Substantiated.</p> <p>The inspection was limited to the specific complaint investigated and does not represent the findings of a full inspection of the facility.</p> <p>Representing the Department of Public Health:</p> <p>[REDACTED] RN-HFEN</p> <p>1280.1(c) Health & Safety Code 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 likely to cause, serious injury or death to the patient.</p> <p>Deficiency Constituting Immediate Jeopardy</p>	E-000	<p>California Hospital Medical Center considered this a very serious event and took immediate action to prevent reoccurrence as follows:</p> <p>E242:</p> <p>The hospital immediately implemented a pharmacy action plan approved by the Governing Body which states that the hospital pharmacy will immediately cease dispensing Methotrexate to Resident Physicians as follows:</p> <ol style="list-style-type: none"> <u>Resident Physicians:</u> Resident Physicians may not prescribe or administer Methotrexate. <u>Prescribing of Methotrexate:</u> Orders for Methotrexate for all OB-GYN patients must be written by the attending physician who is a member of the Medical Staff and has privileges in Obstetrics & Gynecology. Resident Physicians may not prescribe Methotrexate. The list of physicians who have privileges to prescribe Methotrexate was distributed to all pharmacy staff. <u>Processing/ Preparation of Methotrexate:</u> Pharmacy will check if Methotrexate dose is appropriate before preparation. Pharmacist will contact the physician if renal or hepatic dosing adjustment is needed or Methotrexate is contraindicated. Pharmacist looks up beta -HCG value before processing Methotrexate order. If HCG is negative (HCG <10), pharmacist will inform the physician of negative HCG and will NOT prepare/dispense Methotrexate <p>Continued on page 2</p>	3/18/2009
E 242	<p>T22 DIV5 CH1 ART3-70203(a)(2) Medical Service General Requirements</p> <p>(2) Developing, maintaining and implementing written policies and procedures in consultation with other appropriate health professionals and administration. 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 RULE: is not met as evidenced by: Based on record reviews and interviews, the facility failed to ensure that their written policy</p>	E 242		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>[Signature]</i>	TITLE <i>COO</i>	(X6) DATE <i>May 7, 2009</i>
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E 242	<p>Continued From Page 1</p> <p>and procedure for administration of Methotrexate was implemented by failing to:</p> <ol style="list-style-type: none"> Follow the criteria for receiving Methotrexate, which stipulated the "unruptured mass" is to be less than 3.5 centimeters (cm) at greatest dimension, Obtain baseline labs such as serum (blood) beta-Human Chorionic Gonadotropin (beta-hCG) prior to Methotrexate administration. The beta-hCG levels must be less than 10,000mIU/ml before giving Methotrexate. Ensure that all findings (labs and radiological studies) were reviewed by the attending OBGYN physician who must document the assessment and plan of care in the patient's record prior to administration of Methotrexate. <p>The facility's failure to follow their written policy and procedure resulted in Patient 1 being erroneously administered Methotrexate, a chemotherapeutic medication. Patient 1 did not have a positive pregnancy and did not meet the criteria as specified in the facility's Methotrexate policy for administration of this medication. Patient 1 suffered serious adverse effects following the administration of Methotrexate including immunosuppression, severe neutropenia, leukopenia, and oral, esophageal and skin ulcerations (stomatitis).</p> <p>Findings:</p> <p>On 4/2/09, an unannounced visit was made to investigate a facility reported incident involving Patient 1 who received Methotrexate medication for a possible ectopic pregnancy and suffered adverse effects. A review of Patient 1's medical record was conducted on 04/02/09. The "ED</p>	E 242	<p>4. <u>Administration of Methotrexate</u> Methotrexate for all OB-GYN patients must be administered by attending physicians who have privileges at CHMC. Resident Physicians may not prescribe or administer Methotrexate.</p> <p><u>Compliance with this action plan will be monitored by Pharmacy Director on a daily basis by reviewing Methotrexate log, and by requiring each pharmacist to review and sign policy revision and updates.</u></p> <p>In addition, the facility immediately revised and implemented the <u>Chemotherapy Administration Policy</u>, approved by the Governing Body which requires pharmacists to dispense Methotrexate for Ectopic pregnancy only to attending OB/GYN physicians and only after Pharmacist confirmation of a positive Beta-hCG level 10 or > as well as normal BUN and Creatinine and Hepatic function as follows.</p> <p><u>*Special Requirements for Methotrexate Administration to OB/GYN Patients</u> Methotrexate for OB-GYN patients <u>Prescribing of Methotrexate</u> Orders for Methotrexate for all OB-GYN patients must be written by the attending physician who is a member of the Medical Staff and has privileges in Obstetrics & Gynecology. Resident physicians may not prescribe Methotrexate.</p> <p>Continued on page 3</p>	3/18/2009
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Admitting Notes," dated 03/02/09 at 4:30 AM, revealed Patient 1 was seen in the Emergency Department (ED) with complaints of left lower quadrant abdominal pain and nausea for 2 days. Patient 1 had a history of Gastroesophageal reflux (GERD), hypertension, diabetes mellitus, hyperlipidemia, acute renal failure, and bilateral lower leg edema.

Further review of the ED progress notes/Nursing Assessments - under "Treatments" revealed on 03/02/09 at 10:01 AM - "Point of Care - UA (urinalysis) Pregnancy test was Negative." Patient 1 was further managed for her pain, along with tests including Chest X-Ray (CXR), Electrocardiogram (EKG), Computerized Tomography Scan (CT), and an ultrasound scan (US). The findings from the CT and US identified a large right adnexal mass (by the right ovary). It was measured at 8.12 centimeters (cm).

According to the facility's policy and procedure for "Methotrexate Treatment for Ectopic Pregnancy" with a revised date of 12/23/08, the criteria for receiving Methotrexate included treating an unruptured mass with a size is less than 3.5 cm. In addition, the facility's policy stipulated that, prior to Methotrexate administration, a baseline lab be obtained for serum beta-hCG (human chorionic gonadotropin), a blood test that can verify and check for abnormal pregnancies. There was no documentation in the medical record that a serum beta-hCG test was done for Patient 1 prior to Methotrexate administration.

The ED progress notes dated 3/2/09 at 2:06 p.m., and written by MD 1, documented MD 1, from the ED, discussed the patient with MD 4 from Internal medicine, and MD 5 from OB/GYN.

E 242

It is mandatory that every member of Obstetrics & Gynecology Call Panel who is responsible for supervising residents review the Methotrexate use in Ectopic Pregnancies policy dated 12/23/2008 which is located in CHMC call room and on the computer desktop indicating that they have read and understood both policies.

The Chemotherapy Administration Policy and the Methotrexate use in Ectopic Pregnancies policy shall be appended to the Obstetrics and Gynecology Rules and Regulations which are reviewed annually by the OB-GYN Administrative Committee. A copy of the OB-GYN Rules and Regulations are provided to all new practitioners with obstetrical privileges at the time of their appointment to the Medical Staff. Any revisions to these policies will be circulated to all practitioners with obstetrical privileges upon approval by the Executive Medical Board Compliance with this will be monitored annually By the Medical Staff Office Director

6/1/2009

<p><u>Renal dosing adjustment:</u> Pharmacist will contact physician if renal dosing adjustment is needed or Methotrexate is contraindicated.</p>	<p>Patients with moderate renal failure (GFR 10-50 mL/min) should receive 50% of the usual dose given at the normal dosage interval and the drug should be avoided in severe renal failure (GFR less than 10 mL/min); no dosage adjustment is necessary for patients with mild renal failure (GFR greater than 50 mL/min)</p>
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E 242	<p>Continued From Page 3</p> <p>MD 1's note, dated 3/2/09, indicated the UCG (Urine Chorionic Gonadotropin or Pregnancy Test) was "verbally reported as negative but was unable to find RN documentation of it, so will re-check UCG to be sure."</p> <p>A review of the physician orders by MD 1, in the ED, written on 03/02/09, revealed another UCG (bedside) was ordered on 03/02/09 at 1:55 PM and completed by RN 1 at 2:15 PM. However, a review of the medical record revealed RN 1 made no documentation on 3/2/09 regarding the results of this second UCG test. Patient 1 was transferred to the medical floor on 03/02/09 at 3:21 PM.</p> <p>A review of the physician orders from the medical-surgical floor dated March 2, 2009 at 7 p.m., revealed an order for Patient 1 to be given Methotrexate 25 milligrams (mg) intramuscularly (IM) times one now. The medication administration record dated 3/2/09 indicated Methotrexate 25 mg was given IM to Patient 1 at 11:30 PM.</p> <p>An interview with MD 2, a 2nd year resident physician, was conducted on 04/03/09 at 10:00 AM. She stated she was reviewing Patient 1's medical record after her transfer to the medical/surgical floor. She admitted she made a mistake during her review. She stated she misread the BNP (Brain Natriuretic Peptide - used to check for cardiac problems) results, for the pregnancy test beta-hCG (Beta Human Chorionic Gonadotropin). She stated she informed the OB/GYN attending physician (MD 6), over the phone, of the BNP value as the beta-hCG of 513, and stated she thought it might be an intrauterine or ectopic pregnancy versus an ovarian tumor/mass. According to the facility's Methotrexate policy, the beta-hCG levels must</p>	E 242	<p><u>Hepatic impairment:</u> Pharmacist will contact physician if hepatic dosing adjustment is needed or Methotrexate is contraindicated.</p> <p>HCG Pharmacist will NOT prepare/dispense Methotrexate if HCG is negative (HCG <10). Pharmacist will contact physician to verify if Methotrexate is indicated</p> <p><u>Processing/ Preparation of Methotrexate</u> Pharmacy will check the Methotrexate dose to make sure it is appropriate before preparation. Pharmacy will check the list of Staff Specializing in Obstetrics & Gynecology to make sure that Methotrexate is ordered by a physician who has privileges to prescribe Methotrexate for ectopic pregnancy. The list is updated when changes in the Medical staff takes place.</p> <p>Continued on page 5</p>	<p>4/16/2009</p>
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E 242	<p>Continued From Page 4</p> <p>be less than 10,000 mIU/ml before giving Methotrexate.</p> <p>MD 2 stated it was at the end of her shift, so she reported off to MD 3, the evening 2nd year resident physician, who was coming on duty. MD 2 went to see Patient 1 to complete her assessment and discuss with the patient her condition and plan of care. Then, she documented a note in the medical record, and left the facility.</p> <p>During an interview on 04/03/09 at 10:30 AM, MD 3 stated he reviewed MD 2's note, but did not review any of the ED notes or previous labs in the computer. He then discussed the case, over the phone, with the attending physician (MD 6).</p> <p>According to MD 3, MD 6 discussed prepping the patient for the operating room (OR) to address the abdominal mass. However, since Patient 1's blood pressure was very high at the time of this evaluation, she was not medically stable to take immediately to the OR. The issue was then discussed further and it was decided to administer Methotrexate. MD 6 instructed MD 3 to order the Methotrexate and give it, after checking with the pharmacy for the dosing amounts. MD 3 wrote the order, called the pharmacy and due to Patient 1's poor renal function, a half dose was cleared by pharmacy. MD 3 stated he administered the Methotrexate to Patient 1 on 03/02/09 at 11:30 PM.</p> <p>A review of the physician progress records dated 03/02/09, did not reflect that the attending OBGYN physician (MD 6) had reviewed or documented the assessment or plan of care in the patient's medical record prior to administration of Methotrexate, as stipulated in</p>	E 242	<p>The pharmacy will only fill an order for Methotrexate for ectopic pregnancy when the order is written by a member of the Medical Staff who has privileges in Obstetrics & Gynecology.</p> <p>Resident Physicians may not prescribe Methotrexate Pharmacist responsibility for Methotrexate therapy for ectopic pregnancy</p> <p><u>Administration of Methotrexate</u> Methotrexate for all OB-GYN patients must be administered by the attending physician who has prescribed the Methotrexate. Resident Physicians will not prescribe or administer Methotrexate.</p> <p><u>Compliance with this policy will be monitored by Pharmacy Director on a daily basis by reviewing Methotrexate administration log and by requiring each pharmacist to review and sign policy revision and updates.</u></p> <p>On 4/16/2009, Medical staff policy relating to Resident oversight by attending physicians was revised to include the changes in the Methotrexate policies as follows:</p> <p><u>Supervision of Residents in California Hospital Orientation of Residents:</u> An orientation process is mandatory for all residents doing to California Hospital for a clinical rotation. There is a 29 slide PowerPoint presentation that all the residents must review. Below is an extract from this presentation that addresses supervision of residents.</p> <p>See attached for PowerPoint slides</p> <p>There is a California Hospital Residency Meeting that occurs every other week in which residency issues including supervision are discussed and action plans generated.</p> <p>Continued on page 6</p>	4/16/2009
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E 242	<p>Continued From Page 5</p> <p>the facility's policy and procedure for Methotrexate Treatment for Ectopic Pregnancy with a revision date of 12/23/08.</p> <p>Methotrexate is a chemotherapy drug commonly used for the treatment of certain female cancers and can be used for the treatment of an early ectopic pregnancy that has not ruptured. Methotrexate is given as an injection, and acts by destroying any pregnancy-related tissue in the body. Serious adverse effects included leukopenia, thrombocytopenia, anemia, nausea, vomiting and stomatitis, acute liver toxicity, kidney damage, skin rash or psoriatic lesions (webmd.com/baby/methotrexate, 4/8/09).</p> <p>A review of the physician's notes revealed Patient 1 did develop immunosuppression, severe neutropenia, leukopenia, renal function decline and oral, esophageal and skin ulcerations over the next 8 days following the administration of the Methotrexate. According to the consulting physician's notes, starting with 03/11/09, medical staff suspected serious side effects from Methotrexate. On 03/15/09 the primary physician (MD 4) documented, "Methotrexate poisoning." Patient 1 had already been placed on reverse isolation on 03/11/09 and required advanced medical management and extended hospital care in the Intensive Care Unit. On 03/17/09, Nursing Staff documented on the physician's order sheet that Patient 1's white blood count had dropped to a critical low of 00.3 (normal range is 4.3 - 10.8 cells per cubic millimeter of blood).</p> <p>According to an interview with Admin 1 on 4/3/09 at 12:45 PM, the facility had revised the Methotrexate Protocol after an adverse event occurred in December 2006, when another physician gave Methotrexate to a female patient</p>	E 242	<p><u>Methotrexate Protocol</u> In 2007 a methotrexate protocol was developed. The policy listed: The criteria for receiving methotrexate, The contraindications to receiving methotrexate Also stated that "All labs & radiological studies must be reviewed by the attending who must document the assessment and plan, along with the informed consent in the chart." <u>2009 Specific Protocol updates:</u> 1: The Methotrexate protocol was redistributed 2: From now on residents will not prescribe or administer methotrexate any longer. The Attending will be required to prescribe and administer Methotrexate. 3: The pharmacy will not dispense Methotrexate for ectopic pregnancy management unless they independently verify a positive BHCg result</p> <p><u>Residency Program Monitoring:</u> The program director will survey residents once monthly on supervision. Any issues will be conveyed to the Chair of the department of OB/GYN in California Hospital. Residents will attend California Hospital Residency Meeting on a regular basis to have input The Residency Program Director, the Associate Program Director & the Residency Program Director in CA will meet regularly to review the rotation The Associate Program Director with help from Other faculty will provide on-site monitoring and support of the residents in California Hospital.</p> <p>Continued on page 7</p>	4/16/2009

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E 242	<p>Continued From Page 6</p> <p>who had a positive Intrauterine pregnancy, not an ectopic pregnancy and the patient lost the fetus. She stated the new protocol still allowed the Resident Physician's to order and administer Methotrexate. Admin 1 stated the facility, however, did not provide any extra training or certification for the administration of Methotrexate to the physicians.</p> <p>According to Pharmacist 1, during an interview on 3/20/09 at 1:15 p.m., there was a list in the pharmacy for certified and specially trained Registered Nurses who can administer Methotrexate. However, there was no list developed for residents and attending physicians.</p> <p>This policy and procedure failure, relating to the use of chemotherapeutic medication on a patient who was not pregnant, resulted in Patient 1 being erroneously administered Methotrexate and subjected the patient to serious complications and harm.</p>	E 242	<p><u>Residency oversight and policy changes/updates will be monitored for compliance by Residency Program Director and all current and new residents are mandated to review and sign the Methotrexate policy.</u></p> <p>In addition, the polices were distributed to the Residency Affiliation Agencies for education and review each month.</p>	
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