

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050746	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/07/2009
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NAME OF PROVIDER OR SUPPLIER WESTERN MEDICAL CENTER SANTA ANA	STREET ADDRESS, CITY, STATE, ZIP CODE 1001 NORTH TUSTIN AVENUE, SANTA ANA, CA 92705 ORANGE COUNTY
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	<p>The following reflects the findings of the Department of Public Health during a complaint/adverse investigation visit:</p> <p>Complaint Intake Number: No complaints found - Substantiated</p> <p>Representing the Department of Public Health: [REDACTED], HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>Health and Safety Code Section 1280.1(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.</p> <p>Representing the California Department of Public Health: Terry Rubin, Pharm.D, Pharmaceutical Consultant II and Robert LeWinter, RPh, Pharmaceutical Consultant II</p> <p>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY</p> <p>70263(q)(6) Pharmaceutical Service General Requirements (q) Labeling and storage of drugs shall be accomplished to meet the following requirements: (6) Drugs shall be stored at appropriate temperatures. Refrigerator temperature shall be between 2.2°C (Centigrade) (36°F (Fahrenheit)) and</p>			2009 NOV 14 PM 12:12

Event ID:PQM611

3/29/2010

12:04:09PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE S. Sean Fowler Chief Operating Officer	(X6) DATE 4/14/10
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Approved 4/28/10

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	<p>Continued From page 1</p> <p>7.7°C (46°F) and room temperature shall be between 15°C (59°F) and 30°C (86°F.)</p> <p>70263 (c)(1) Pharmaceutical Service General Requirements</p> <p>(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.</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>70837(a) General Safety and Maintenance</p> <p>(a) The hospital shall be clean, sanitary and in good repair at all times. Maintenance shall include provision and surveillance of services and procedures for the safety and well-being of patients, personnel and visitors.</p> <p>The above regulations were NOT Met as evidenced by:</p> <p>Based on observation, interviews, and policy and document review, the hospital failed to maintain the</p>		<p><u>70263(C)(1) & 70837(a) – Responsible Person: Director of Pharmacy</u> 11/9/09 to 11/30/09 – All 41 Pharmacy staff were in-serviced/educated on the following:</p> <ul style="list-style-type: none"> Review of process for medication refrigerator checks in Pharmacy. 	<p style="text-align: center;">2009 APR 14 PM 12:12</p> <p>11/30/09</p>

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	<p>Continued From page 2</p> <p>temperature in the pharmacy's refrigerator in accordance with the manufacturer's recommendations, state regulations and hospital policy to ensure stability, potency and safety of refrigerated medications. Medications were stored at below freezing temperatures (as low as minus 3.7°C) from 4/1/09 to 11/9/09. This resulted in the administration of possibly defective vaccines being administered to 1636 newborn babies and 5 newborns born to mothers known to be Hepatitis B carriers or whose immune status was unknown.</p> <p>Findings:</p> <p>On 11/9/09 at 1455 hours, during a tour of the main pharmacy during a Medication Error Reduction Plan (MERP) survey, it was discovered that the pharmacy's medication refrigerator log revealed recorded temperatures for the month of November below freezing (ranging from minus 2.3° to minus 2.9°C) On further review of the temperature logs dating back to April 2009, temperatures were recorded below freezing and as low as minus 3.7°C. There was no action taken by the pharmacy staff to report these temperatures. Medications sensitive to temperature changes and known to be deactivated when frozen were administered to patients in the hospital.</p> <p>1. Stored in the refrigerator were the following vaccines: eg. Hepatitis B, Rabies, Diphtheria-Tetanus-Pertussis, Haemophilus B, Hepatitis A, Measles-Mumps-Rubella, Hepatitis B Immunoglobulin, Rota-Virus, Polio Virus, Pneumococcal, Meningococcal, and Varicella</p>		<ul style="list-style-type: none"> Defining actions to be taken when temperature is out of range. Defining process to validate the temperature. Return demonstration for checking the refrigerator temperature. <p>12/2/09 – Each medication refrigerator/freezer has a posted label that states:</p> <p style="text-align: center;">Medication Refrigerator Maintain Temperature Between 36°F to 46°F (2°C to 8°C)</p> <p style="text-align: center;">Medication Freezer Maintain Freezer 5°F or lower (-15°C or lower)</p> <p>12/09 – New policy/procedure for Patient Refrigerators, Maintenance of Medication/ Vaccine & Nourishment implemented, includes two persons checking temperature (pharmacist and pharmacy technician) twice a day.</p> <p><u>70263(c)(1) & 70837(a) – Monitoring</u></p> <p>1. 11/11/09 to present – The medication refrigerator temperature checks are validated by a pharmacist and a</p>	<p>12/2/09</p> <p>12/9/09</p>

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	<p>Continued From page 3</p> <p>Zoster. In addition to these vaccines, there were 42 other medications listed on the outside of the refrigerator, including insulin's (medications to treat high blood sugar levels in diabetes patients), that were also stored in this refrigerator.</p> <p>On 11/10/09 at 0951 hours, interviews were performed with the following six pharmacy technicians who documented temperatures on the temperature log from 4/1/09 to 11/9/09.</p> <ul style="list-style-type: none"> - Pharmacy Tech #1 has worked at the hospital for the last 26 years. She stated she didn't notice the temperature log sheet had a goal for the temperature range in Centigrade of 2 - 8° printed on it. She said she is familiar with temperature ranges in Fahrenheit (F) but not C. She refers to the Pharmacy Tech #3 (below) as the individual who collects the temperature log sheets to ensure they were completed correctly. - Pharmacy Tech #2 has worked at the hospital for the last 22 years. He thought a minus Centigrade temperature was within goal range. He admitted to not placing a minus sign next to two recordings by mistake. He referred to Pharmacy Tech #3 as the individual who reviewed all the temperature logs for errors. - Pharmacy Tech #3 has worked at the hospital for the last 4 years. She supervises Pharmacy Technicians and is in charge of their schedules. She also assists in data entry and quality control. She stated she collects the temperature logs at the end of each month but, "I have not been looking at them to check for accuracy or if follow up was needed. I expect the techs to do the follow up if 		<p>pharmacy technician. Both staff members sign the temperature log, verifying that the temperature is in range or that appropriate action is taken when the temperature is out of range. The Pharmacy Director or designee review the temperature log weekly.</p> <p>2. 12/9/09 – Department Director or designee must review temperature logs weekly and report to Pharmacy & Therapeutics Committee quarterly.</p> <p><u>70837(a) – Responsible Person – Director of Pharmacy</u></p> <p>All vaccines/medications stored in the Pharmacy refrigerator in question were taken out of storage and destroyed.</p> <p>Refrigerator in question was taken out of service and discarded.</p> <p>All medications and vaccines were reviewed to ensure they are stored per the manufacturer's recommendations for storage.</p> <p><u>70837(a) – Monitoring Process to prevent reoccurrence of deficiency:</u></p> <p>(See above Monitoring Process for 70263(c)(1) and 70837(a))</p>	<p>11/9/09</p> <p>11/15/09</p> <p>11/9/09</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">2009 DEC 11 PM 12:12</p>

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	<p>Continued From page 4</p> <p>there's a problem since it's not in the policy and procedure that I check them."</p> <ul style="list-style-type: none"> - Pharmacy Tech #4 has worked at the hospital for the last 10 years. She mainly works part-time. She stated, "I always pay attention when I record temperatures. I thought minus 2.5°C was within the normal range." She was not sure if the completed temperature logs were reviewed by another staff member. - Pharmacy Tech #5 has worked at the hospital for only the last month. She stated she did not look at the temperature readings carefully. She said since others with more seniority approved minus C numbers, she thought the numbers were within range and initialed them as being acceptable. - Pharmacy Tech #6 was interviewed twice. Her first interview occurred on 11/9/09 at 1512 hours when she stated she was too busy to check the temperature goal range and documented a freezing temperature on the temperature log. Her second interview occurred on 11/10/09 at 1226 hours when she stated no one trained her on the new temperature gauge, "So I never paid attention." She referred to Pharmacy Tech #3 as the staff member who checks the logs periodically during the month. She stated, "The Pharmacy Tech #3 checks temperature logs when she comes in," and stated the last time she saw her do this was "last week." <p>On 11/10/09 at 1116 hours, during an interview the DOP (Director of Pharmacy) stated, "No one looks at the temperature logs." They are filed and stored in the pharmacy.</p> <p>2. The manufacturer's recommendations for storing</p>			<p>2009 APR 14 PM 12:12</p>

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	<p>Continued From page 5</p> <p>of vaccines is as follows:</p> <ul style="list-style-type: none"> - Hepatitis B Vaccine (Engerix-B(r)) - "Store refrigerated between 2-8°C (36-46°F). Do not freeze; discard if product has been frozen." - Hepatitis B Immune Globulin (HyperHEP B(r)) - "Store at 2-8°C (36-46°F). Do not freeze." - Tetanus Toxoid (T-Tox(r)) - "Refrigerate 2°C to 8°C (36-46° F). Do not freeze." <p>These vaccines were stored in the pharmacy refrigerator and dispensed to patients in the hospital and administered.</p> <p>There were 1636 newborns inoculated with the above Hepatitis B Vaccine from 4/1/09 to 11/9/09. In addition there were 5 newborn babies inoculated with Hepatitis B Vaccine and Hepatitis B Immune Globulin and 1 adult inoculated with Tetanus Toxoid during this same time period. The 5 newborn babies required inoculation with both Hepatitis B Vaccine and Hepatitis B Immune Globulin when their mother tested positive for the Hepatitis B Antigen in her blood. These 5 newborn babies (Patients) are listed below:</p> <ul style="list-style-type: none"> - Patient #1 was born on 7/31/09 to a mother whose immune status to Hepatitis B was unknown or for whom the Hepatitis B surface antigen had not been tested. Patient #1 received Hepatitis B immune globulin at 0849 hours on 7/31/09 and Hepatitis B vaccine at 0159 hours on 7/31/09. The biologicals administered to Patient #1 had been stored at temperatures, below freezing, in violation of the manufacturer's recommendation, possibly resulting in ineffective immunization response for 		<p><u>70837(a) – Responsible Person – Director of Pharmacy</u></p> <ol style="list-style-type: none"> 1. 11/11/09 – 11/16/09 – Western Medical Center Santa Ana sent out 1636 letters to the parents of Newborns that received Hepatitis B Vaccines from 4/1/09 through 11/9/09. 2. 11/11/09 – 11/20/09 – 41 physicians were identified as caring for the 1636 newborns. Each of the 41 pediatricians was notified in writing, as well as by phone. 3. 11/12/09 – Four (4) positive Hepatitis B mothers and five (5) babies were notified. Three (3) of the mothers were actively being followed by the Orange County Public Health Department – Perinatal Hepatitis B Prevention Program. One (1) mother was being followed by the Riverside Public Health Department – Perinatal Hepatitis B Prevention Program. 	<p>11/16/09</p> <p>11/20/09</p> <p>11/12/09</p>

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	<p>Continued From page 6</p> <p>the patient.</p> <p>- Patient #2 was born on 8/02/09 to a mother who had tested positive for Hepatitis B. In keeping with public health guidelines, Patient #2 was administered Hepatitis B vaccine and Hepatitis B immune globulin within 12 hours of birth. The biologicals administered to Patient #2 had been stored at temperatures, below freezing, in violation of the manufacturer's recommendation, possibly resulting in ineffective immunization response for the patient.</p> <p>- Patient #3, Twin A, was born on 10/19/09 to a mother who had tested positive for Hepatitis B. Twin A was administered Hepatitis B vaccine at 0340 hours, and Hepatitis B immune globulin at 0450 hours on 10/19/09. The biologicals administered to Patient #3 had been stored at temperatures, below freezing, in violation of the manufacturer's recommendation, possibly resulting in ineffective immunization response for the patient.</p> <p>- Patient #4, Twin B was born on 10/19/09. Patient #4 was administered Hepatitis B vaccine at 0340 hours on 10/19/09 and Hepatitis B immune globulin at 0500 hours on 10/19/09. The biologicals administered to Patient #4 had been stored at temperatures, below freezing, in violation of the manufacturer's recommendation, possibly resulting in ineffective immunization response for the patient.</p> <p>- Patient #5 was born on 5/15/09. Patient #5 was administered Hepatitis B vaccine 0845 hours on 5/15/09 and Hepatitis B immune globulin at 1045 hours on 5/15/09. The biologicals administered to Patient #5 had been stored at temperatures, below freezing, in violation of the manufacturer's recommendation, possibly resulting in ineffective</p>		<p>4. 11/12/09 – Department of Pediatrics meeting convened to discuss findings and action plan.</p> <p>5. 11/13/09 – Vaccine Information Hotline was established. Registered Nurse was put in place to answer/return phone calls. 168 calls were made to the Vaccine Information Hotline.</p> <p>6. 11/17/09 – 11/18/09 – 661 patients that received the Tetanus vaccine were sent letters notifying them of the storage issue.</p> <p>7. 11/17/09 – A Tetanus re-vaccination clinic was established in the Emergency Room for patients wishing to return for re-vaccination.</p> <p>8. 12/4/09 – Western Medical Center Santa Ana contacted City Council for advice on which Spanish language newspaper would reach the most residents.</p> <p>9. 12/10/09 – 12/17/09 – Ad placed in <u>Meniondas</u> newspaper.</p>	<p>11/12/09</p> <p>11/13/09</p> <p>11/18/09</p> <p>11/17/09</p> <p>12/4/09</p> <p>12/17/09</p>

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(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
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	<p>Continued From page 8</p> <p>nutrition" which stated if temperatures remain out of range after 30 minutes to contact engineering immediately. If no response with a 15 minute period, contact the clinical manager immediately. Move medications to another refrigerator. Document the action taken. Pharmacy to replace medications.</p> <p>The engineering department failed to follow their policy and procedure entitled, "Equipment Evaluation Point System." If this P&P was followed, the refrigerator would have been inspected every 3 months and the below freezing temperatures discovered.</p> <p>The facility failed to provide safe storage of refrigerated vaccines which were administered to newborn patients in the hospital from 4/1/09 to 11/9/09. The hospital sent out 1,636 letters on 11/11/09 to the parents of these newborn patients notifying them that the vaccine administered to their child was stored at temperatures outside the manufacturer's recommendation and possibly resulted in an ineffective immunization response of their child. Storing vaccines in a refrigerator that is not in compliance with the manufacturer's recommendations, the facility cannot guarantee their potency and safety.</p> <p>The facility failed to maintain and periodically inspect, by qualified staff, the pharmacy medication refrigerator in accordance with the facilities policy, manufacturer's recommendations, and regulatory requirements to ensure that medications were safely and properly stored. As a result, vaccines</p>		<p>The medication refrigerator inventory was corrected to include all medication refrigerators.</p> <p><u>70837(a) – Monitoring</u></p> <ol style="list-style-type: none"> 1. An appropriate maintenance procedure in writing is assigned every three (3) months to all medication refrigerators and the temperature probes "PM" requires calibration annually. "PM" completion is validated every month by the Facilities Manager and the Director of Facilities. The Environment of Care conducts environmental tours every six (6) months, and the medication refrigerators are inspected during these tours. 2. As of 11/17/09 the pharmacy refrigerators and freezers have been assigned their own classification, Reg-Rx and Frez-Rx. This process allows for a more detailed scrutiny of the scheduled work, inventory and most recently completed maintenance. Maintenance is scheduled to be completed every three (3) months by maintenance, and Biomedical Engineering now validates the temperature monitoring devices accuracy every twelve (12) months with a NIST calibrated electronic thermometer. 	12/3/09
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2010 APR 14 PM 12:12

Event ID: PQM611	3/29/2010	10:52:10AM	
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE	

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050746	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/07/2009
NAME OF PROVIDER OR SUPPLIER WESTERN MEDICAL CENTER SANTA ANA		STREET ADDRESS, CITY, STATE, ZIP CODE 1001 NORTH TUSTIN AVENUE, SANTA ANA, CA 92705 ORANGE COUNTY		
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	<p>Continued From page 9</p> <p>and other refrigerated medications were stored outside the required temperature range, in below freezing temperatures, where potency could not be guaranteed. These vaccines and medications were then administered to patients in the hospital.</p> <p>This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).</p>		<p>3. Facilities maintenance of all medication/vaccine refrigerators is reported to Quality Council quarterly.</p> <p>4. 11/9/09 to present - The medication refrigerator temperature checks are validated by a pharmacist and pharmacy tech. Both staff members sign the temperature log, verifying that the temperature is in range or that appropriate action is taken when the temperature is out of range.</p>	<p>2010 APR 14 PM 12:12</p>

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