

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050173</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>02/22/2008</b>
NAME OF PROVIDER OR SUPPLIER <b>ANAHEIM GENERAL HOSPITAL</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>3350 W. BALL ROAD, ANAHEIM, CA 92804 ORANGE COUNTY</b>		
(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
	<p>The following reflects the findings of the Department of Public Health during investigation of COMPLAINT NO: CA00152227.</p> <p>Inspection was limited to the specific complaint(s) investigated and does not reflect the findings of a full inspection of the facility.</p> <p>Representing the Department of Public Health: [REDACTED], RN, HFES: [REDACTED], Pharm D, Pharmacy Consultant.</p> <p>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.</p> <p>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>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY</p> <p>§ 70263(q)(6) Pharmaceutical Service General Requirements.</p> <p>(q) Labeling and storage of drugs shall be accomplished to meet the following requirements:</p>			

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

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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.

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	<p><b>Continued From page 1</b></p> <p>(6) Drugs shall be stored at appropriate temperatures. Refrigerator temperature shall be between 2.2 degrees C (36 degrees F) and 7.7 degrees C (46 degrees F) and room temperature shall be between 15 degrees C (59 degrees F) and 30 degrees C (86 degrees F).</p> <p>The above regulation was NOT met as evidence by:</p> <p>Based on observation, interview and document review the hospital failed to maintain the temperature in the Anaheim campus pharmacy's refrigerator in accordance with hospital policy and the manufacturer's recommendation to ensure stability, potency and safety of refrigerated medications. The violation has caused or is likely to cause serious injury or death to patients. An immediate jeopardy (IJ) was called on 2/21/08 at 1620 hours. The immediate jeopardy had not been abated at time of exit on 2/22/08 at 1800 hours.</p> <p>Findings:</p> <p>On 2/20/08 at 1046 hours, during an observation of the refrigerator located in the main pharmacy, it was found the temperature gauge displayed a temperature of 13° (degrees) centigrade (C). According to the temperature log sheet attached to the refrigerator, the acceptable temperature range should be between 2 to 8° C or 36-46° Fahrenheit (F). On review of the temperature log sheet, the documented temperatures for the last two weeks were all above the maximum acceptable temperature range. These temperatures ranged from 10 to 13° C or 50-55° F. On further review of</p>				

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	<p><b>Continued From page 2</b></p> <p>the temperature log sheets for the months of January and February, temperatures were above 8° C each day except for four days (1/25, 1/30, 1/31 and 2/4/08) when the temperatures recorded were 8° C. The temperatures on the log sheet for December 2007 were missing.</p> <p>On 2/21/08 at 0838 hours, the Pharmacy Technician counted 69 different medications stored in the pharmacy's refrigerator and most with multiple doses. Six of these medications were selected and the manufacturers were called and questioned pertaining to storage guidelines when stored at temperatures above 8 degrees C. The package insert for all six medications recommended storing in the refrigerator at temperatures between 2-8 degrees C. The six medications and the manufacturers' comments and recommendations for storing above 8 degrees C are provided below:</p> <ol style="list-style-type: none"> <li>1. Healon GV (Sodium Hyaluronate), ophthalmic medication for eye surgery, the manufacturer recommends their medication is stable outside the refrigerator range for "no more than 14 days."</li> <li>2. ATPase 2mg injection, a medication to keep blood flowing for administration of intravenous medications, the manufacturer states their product is "No longer valid out of the refrigerator range for 48 hours."</li> <li>3. Epogen injection, a medication for the treatment of anemia (low red blood cell count), the manufacturer states their "Single dose product is</li> </ol>				

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	<p><b>Continued From page 3</b></p> <p>stable outside the refrigerator range for 14 days, and 7 days for the multiple dose product."</p> <p>4. Sandostatin injection, a medication to decrease growth hormone, the manufacturer states "Their medication is stable outside the refrigerator for 14 days."</p> <p>5. Viscoat, a medication used during eye surgery, the manufacturer states "They do not stand by their product outside the refrigerator range for more than 7 days."</p> <p>6. Humulin regular insulin injection, a medication to treat patients with high blood sugars (diabetics), the manufacturer recommends not using if stored outside the refrigerator range for longer than 28 days.</p> <p>On 2/21/08 at 1405 hours, in an interview with Pharmacy Technician 1 who stated the Pharmacy Technician reads the temperature gauge each day and records the result on the temperature log sheet. The log sheet at the end of the month is reviewed by the Pharmacy Director and placed in the "refrigerator temperature binder." She stated that at the end of 2007, a call was placed to the hospital's engineering department and a message was left reporting the refrigerator's elevated temperature. According to the hospital's policy entitled, "Pharmacy Temperature Log, which states that "Engineering services is responsible for repair/maintenance of hospital refrigerators and, if the temperature can not be adjusted to be within specified range with 24 hours, the pharmacist will</p>				

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	<p><b>Continued From page 4</b></p> <p>start making arrangements for the storage of pharmaceuticals in another area that is within the correct range." This policy was not followed and medications remained in the defective refrigerator for at least 6 more weeks. In addition, there was no documentation of the call to engineering by the Pharmacy Technician, no follow up by the engineering department and no further calls by the pharmacy department.</p> <p>The hospital failed to provide safe storage of refrigerated medications which were administered to patients throughout the hospital. On 2/22/08 at 1145 hours, a list provided by the Director of Nursing showed 29 of 56 patients in the hospital's Anaheim campus received medications which had been stored in the pharmacy refrigerator.</p> <p>The violation(s) has caused, or is likely to cause, serious injury or death to the patient(s).</p>				

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