

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>052048</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>05/14/2007</b>
NAME OF PROVIDER OR SUPPLIER <b>KINDRED HOSPITAL MODESTO</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>730 17TH STREET, MODESTO, CA 95354 STANISLAUS COUNTY</b>		
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	<p>Health and Safety Code 1280(a) 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>Health and Safety Code 1280(c) 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>70263. Pharmaceutical 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.</p> <p>70263. 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</p>			

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	<p><b>Continued From page 1</b></p> <p>approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.</p> <p>Based on observation, interview, and record review, the hospital failed to follow their own policies and procedures and ensure patient safety and to minimize adverse drug events as evidenced by the following:</p> <p>1. The hospital failed to protect Patient #8 from significant adverse medication effects by permitting the use of a known nephrotoxic (kidney toxic) antibiotic in the presence of compromised renal (kidney) function for which: A. the pharmacist(s) failed to adequately monitor and assess drug therapy; B. the physician continued drug therapy in the presence of a critically elevated drug level and declining renal function without apparent consideration of risk to the patient; and C. hospital staff failed to place laboratory results, critical to assessing drug therapy, in the patient's record.</p> <p>2. The hospital failed to protect patients from potentially significant adverse medication effects by permitting the use of Inapsine (droperidol) without a system for screening, monitoring, or other safeguards in effect. Droperidol is a second-line agent used to treat nausea and vomiting in patients for whom other treatments are ineffective or inappropriate. Furthermore, the manufacturer's product information contains a Black Box Warning outlining the need for cardiac monitoring prior to and following initiation of therapy. A Black Box Warning means that medical studies indicate that</p>				

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	<p><b>Continued From page 3</b></p> <p>"Inter-facility Transfer Medication Order List" (physician transfer orders) and the Medication Administration Record (MAR) from the GACH (both dated 5/05/07). The transfer medication order list included an order for, "Vancomycin 1500 mg (milligrams) daily" with no indication as to when the next dose was due (vancomycin is an antibiotic used to treat infections). The GACH MAR, dated 5/05/07, also included the entry, "Vancomycin random level at 1800 5/05/07. Further dosing when level available." (Indicating that a vancomycin drug level was to be done at 6 p.m. on 5/05/07, and based on that level, the vancomycin dosage may need to be adjusted.)</p> <p>Previously, on 5/07/07, at 10 a.m., the hospital's Director of Pharmacy (DOP) was interviewed regarding the policy and procedure for medication reconciliation. The DOP stated that a pharmacist reviews all transfer medication order information once received from the Admissions Department. The pharmacist assesses each order for accuracy and clinical appropriateness. Concerns identified by the pharmacist are entered, in writing, at the bottom of the pharmacy prepared, "Medication Reconciliation List/Admission/Transfer Orders" form for physician review. Copies of these forms are maintained in the pharmacy department with the originals placed in the patient's record. Once the original forms are signed by the physician, (indicating that he has reviewed them) they become the admission orders.</p> <p>Further medical record review on 5/10/07, at 8 a.m. revealed that Patient #8's record included two</p>			
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	<p><b>Continued From page 5</b></p> <p>* 5/08/07 written at an unspecified time: Nephrology consult (a request for a kidney specialist to consult). This order was noted at 10 p.m.</p> <p>* 5/09/07 written at 11:00 a.m.: CMP in a.m. This order was noted at 1 p.m.</p> <p>On 5/10/07, at 8:25 a.m., a review of Patient #8's record revealed that there were no results in the section of the chart labeled, "Laboratory." This observation was verified with Licensed Nurse (LN) #D.</p> <p>On 5/10/07, at 8:30 a.m., the DOP was interviewed regarding Patient #8's IV vancomycin therapy. He indicated that he was not specifically aware of Patient #8 being on IV vancomycin. He then reviewed the patient's drug profile in the pharmacy's computer data base and verified Patient #8's current orders for IV antibiotics. When asked if the pharmacy department monitored patients on IV vancomycin he indicated, "If the physician requests that the pharmacy dose vancomycin therapy then they will do so; otherwise, we just get copies of vancomycin drug levels from the lab." When asked for lab results related to Patient #8's vancomycin therapy he was unable to provide any copies. He then added, "The lab usually provides them, but sometimes we have to ask for them."</p> <p>On 5/10/07 at 8:45 a.m., the Laboratory Manager was interviewed regarding this process. The Laboratory Manager confirmed that the lab "usually" does send vancomycin levels to the</p>			

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	<p><b>Continued From page 6</b></p> <p>pharmacy for their review, but was unsure if any of Patient #8's lab results had actually been sent to the pharmacy. The Laboratory Manager was informed of the multiple lab orders dated 5/05/07, 5/06/07, 5/07/07, 5/08/07 and 5/09/07 and unavailability of their results in the patient's record or in the pharmacy. He then produced copies of all lab work done to date for this patient. When asked where the originals might be, he indicated, "They should be in the patient's chart."</p> <p>Later that morning, at 9 a.m., the Laboratory Manager confirmed that there were no lab results in Patient #8's record, and that the originals were on the nursing unit, but not filed in the record per hospital policy.</p> <p>Patient #8's lab results, provided by the Laboratory Manager, were then reviewed with the DOP. The test results revealed the following:</p> <p>* Test date/time: 5/06/07 at 9:52 a.m. A vancomycin trough level of 18.0 mcg/ml (micrograms/milliliter) with a reference range of 5.0 to 10.0 mcg/ml. (The reference range is considered the "normal" range. The trough level is a measurement of the amount of drug in the body just prior to the next scheduled dose. Elevated levels are associated with potential toxicity including damage to the kidneys.)</p> <p>* Test date/time: 5/06/07 at 9:52 a.m. A serum creatinine level of 3.4 mg/dL (milligrams/deciliter) with a reference range of 0.7 to 1.5 mg/dL. (The creatinine level is an indicator of kidney function.)</p>			

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	<p><b>Continued From page 7</b></p> <p>Elevated levels are associated with diminished kidney function.)</p> <p>* Test date/time: 5/06/07 at 1:20 p.m. A vancomycin peak level of 30.8 mcg/ml with a reference range of 20.0 to 40.0 mcg/ml. (The peak level is a measurement of the amount of drug in the body just after the administration of a dose. Elevated levels are associated with potential toxicity.)</p> <p>* Test date/time: 5/08/07 at 8:12 a.m. A serum creatinine level of 4.0 mg/dL with a reference range of 0.7 to 1.5 mg/dL.</p> <p>* Test date/time: 5/10/07 at 8:14 a.m. A serum creatinine level of 4.2 mg/dL with a reference range of 0.7 to 1.5 mg/dL.</p> <p>At this time, the DOP again verified that he had not been made aware of any of these lab results.</p> <p>On 5/10/07, at 9:30 a.m., a review of the pharmacy's policy and procedure related to medication monitoring entitled "Medication Misadventures" dated January 2007 revealed, "The Department of Pharmacy Services will conduct a prospective surveillance for high-alert medications or patients with a high risk for adverse drug reactions (ADRs)." The policy indicated that high-alert medications are drugs "likely to cause ADRs," and that they will be "identified" and "their use monitored." The policy also indicates that high-risk patients include those with "multiple organ failures, and/or renal failure."</p>			

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	<p><b>Continued From page 8</b></p> <p>Concurrent review of the manufacturer's product information for vancomycin revealed the following under each heading:</p> <p>Dosage:</p> <p>Risk-benefit should be considered when the following medical problems exist (" = major clinical significance):</p> <p>" " Renal function impairment " (because vancomycin is excreted primarily through the kidneys, patients with renal function impairment may need an adjustment in dosage.)</p> <p>Patient monitoring:</p> <p>The following may be especially important in patient monitoring (" = major clinical significance):</p> <p>" " Renal function determinations (may be required prior to, periodically during, and following treatment in patients with pre-existing renal impairment ...; daily renal function determinations may also be required in patients on high-dose or prolonged therapy, especially if renal function is changing or borderline).</p> <p>Vancomycin serum concentrations ...should not be maintained in excess of approximately 40 mcg per ml (micrograms per milliliter), and trough concentrations should not exceed approximately 10 mcg per ml."</p>			

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	<p><b>Continued From page 9</b></p> <p>On 5/10/07, at 2:40 p.m., LN #D was interviewed. She stated that on 5/06/07, at 10:05 a.m., the Clinical Laboratory called the nursing unit advising her of the "critical value" related to the elevated vancomycin trough level of 18.0 mcg/ml done earlier that morning. Although not documented in Patient #8's record, LN #D indicated that she called the patient's physician and advised her of the critically elevated drug level. LN #D states that Patient #8's physician told her to "administer the vancomycin as originally ordered (the 1500 mg dose) and to obtain the peak level as ordered on 5/05/07." A review of Patient #8's IV MAR indicates that the vancomycin 1500 mg dose was given at approximately 10 a.m. on 5/06/07.</p> <p>On 5/10/07, at 2:50 p.m., a review of the physician's progress notes for Patient #8 revealed:</p> <p>* LABORATORY RESULTS: "Vancomycin peak is high at 30.8 and the trough is also high at 18. BUN nitrogen is high. Creatinine is high at 3.4 ...." (The Blood Urea Nitrogen is an indicator of kidney function.)</p> <p>* PLAN: "Continue vancomycin ...."</p> <p>* (Note: This progress note appears to have been dictated on 5/06/07 at 6:03 p.m. and transcribed on 5/07/07 at 5:02 p.m.).</p> <p>Concurrent review of Patient #8's record revealed a physician order dated 5/06/07 (time not indicated though noted by nursing at 12 midnight on 5/06/07) to decrease "vancomycin to 1 gm q 36ø and P&amp;T</p>			

Event ID:JU111

3/18/2008

12:30:26PM

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DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>052048</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>05/14/2007</b>
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	<p><b>Continued From page 10</b></p> <p>after 3rd dose" (decrease vancomycin dosage to 1 gram, extend the dosing interval to 36 hours, with peak and trough drug levels to be done after the third scheduled dose).</p> <p>The physician's progress notes for Patient #8 dated 5/08/07 indicated:</p> <ul style="list-style-type: none"> <li>* DIAGNOSTIC INFORMATION: Laboratory data: "The patient's BUN is 33 and creatinine 4.0"</li> <li>* ASSESSMENT: "He has renal failure" (The kidneys are failing.)</li> <li>* PLAN: "Will refer the patient to the nephrologist" (kidney specialist)</li> </ul> <p>(Note: This progress note appears to have been dictated on 5/09/07 at 1:15 a.m. and transcribed on 5/09/07 at 12:14 p.m.).</p> <p>An Immediate Jeopardy was called on 5/10/07 at 5 p.m., due to: 1. Patient #8's clinical decline in renal function; 2. The administration of vancomycin in the presence of abnormal laboratory findings, without apparent consideration of risk to the patient; 3. The pharmacy department's failure to adequately assess and monitor drug therapy, or to anticipate or evaluate the potential for toxicity and adverse effects of a well-known nephrotoxic drug.</p> <p>A review of Patient #8's record on 5/11/07, at 11 a.m., indicated that on 5/10/07, at 7 p.m., the hospital's chief of medical staff ordered the IV vancomycin held pending laboratory results (a</p>			
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	<p><b>Continued From page 11</b></p> <p>vancomycin trough level and basic metabolic panel were ordered).</p> <p>Laboratory results dated 5/11/07, reported at 10:10 a.m., revealed a critically elevated vancomycin trough level of 24.8 mcg/ml, and a further increase in the serum creatinine level to 4.2 mg/dL (a 19 percent increase from the creatinine result reported 5 days previously).</p> <p>State agency monitoring remained in force until the IJ was lifted on 5/30/07 at 6:30 p.m.</p> <p>Findings (related to droperidol use):</p> <p>2. On 5/10/07, at 2:15 p.m., a review of the record for Patient #30 revealed an order for Inapsine (droperidol) dated 3/11/07 (from admission). Per hospital policy the pharmacist reviews and reconciles the admission and/or transfer orders for all patients utilizing the "Medication Reconciliation List/Admission/ Transfer Orders" form (medication reconciliation process). If the pharmacist identifies any concerns or needs related to drug therapy (for example, dosage adjustments, therapeutic drug monitoring, etc.) these are added to the end of the list for prescriber ' s review and consideration.</p> <p>The " Medication Reconciliation List/Admission/Transfer Orders " form, dated 3/17/07, for Patient #30, revealed an order for " Droperidol 1.25 mg IV every 4 hours as needed for nausea and vomiting. " There was no documented evidence that the pharmacist identified any concerns related to the use of intravenous</p>			
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	<p><b>Continued From page 12</b></p> <p>droperidol at the bottom of this form.</p> <p>Review of the MAR for Patient #30, on 5/11/07, at 1 p.m., revealed that droperidol remained on the MAR for the patient's entire stay in the hospital from 3/11/07 until 4/13/07. There was no documented evidence that Patient #30 received any droperidol.</p> <p>Inapsine (droperidol) has a Black Box Warning from the manufacturer stating that:</p> <p>* Cases of QT prolongation and/or torsades de pointes have been reported in patients receiving Inapsine (droperidol) 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. (Torsades de pointes is a potentially serious cardiac arrhythmia which can result in sudden death.)</p> <p>* Cases of QT prolongation and serious arrhythmias (e.g., torsades de pointes) have been reported in patients treated with droperidol. Based on these reports, all patients should undergo a 12-lead ECG (electrocardiogram) prior to administration of Inapsine (droperidol) to determine if a prolonged QT interval (i.e., QTc greater than 440 msec for males or 450 msec for females) is present. If there is a prolonged QT interval, Inapsine (droperidol) should NOT be administered. For patients in whom the potential benefit of Inapsine (droperidol) treatment is felt to outweigh the risks of potentially serious arrhythmias, ECG monitoring should be performed prior to treatment and</p>			

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	<p><b>Continued From page 13</b></p> <p>continued for 2-3 hours after completing treatment to monitor for arrhythmias.</p> <p>The Black Box Warning for droperidol further stipulates:</p> <p>* Due to its potential for serious proarrhythmic effects and death, Inapsine (droperidol) should be reserved for use in the treatment of patients who fail to show an acceptable response to other adequate treatments.</p> <p>Droperidol was on the "Medication Reconciliation List/Admission/Transfer Orders" form with no additional orders related to screening or monitoring before, or after its use.</p> <p>Permitting the use of droperidol without the requirement for a baseline ECG, screening for any contraindication to its use, or ECG monitoring for 2 to 3 hours after completion of therapy, represents failure to protect patients from undue adverse medication consequences by failure to monitor patients for the emergence of a life-threatening arrhythmia.</p> <p>Interview with staff pharmacists on 5/10/07, at 11 a.m., revealed no knowledge or awareness of the cardiotoxic effects associated with IV droperidol use.</p> <p>In an interview on 5/10/07, at 3:30 p.m., two of three licensed nurses admitted to not knowing the cardiotoxic risks associated with using this medication.</p>			

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	<p><b>Continued From page 14</b></p> <p>In an interview on 5/11/07, at 11 a.m., with Patient #30's physician he stated that he was not aware of the black box warning related to droperidol use; that droperidol was not a first line agent for nausea and vomiting; or that administration of droperidol requires cardiac prescreening and monitoring.</p> <p>An Immediate Jeopardy was called on 5/10/07 at 5 p.m., due to the facility ' s failure to adequately assess and monitor drug therapy, or to anticipate or evaluate the potential for toxicity and adverse effects of a well-known cardiotoxic drug.</p> <p>State agency monitoring remained in force until the IJ was lifted on 5/30/07 at 6:30 p.m.</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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