

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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

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	<p>Continued From page 1</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 staff interview and medical record and document review, the hospital failed to develop and implement their policy, performing random audits, for controlled substances (CS) which lead to failure to evaluate accurate use and accurate documentation of CS, and failure to readily identify or minimize diversions. This failure to track and monitor controlled substances from receipt through administration or destruction (closed loop accountability) resulted in the followings:</p> <ol style="list-style-type: none"> 1. Patient #6 did not receive her pain medication on 05/05/07, because the facility failed to ensure that an adequate supply of Methadone (medication for severe pain) was available. 2. Patient #6 did not receive her Methadone as ordered for ninety percent of the time, and Fentanyl Transdermal (skin patches) twenty five percent of the time since her admission due to facility failure of timely detection of medication errors. 3. Due to lack of timely detection, identification or resolution of controlled substance discrepancies, there were many instances where signed out controlled substances could not be tracked to final disposition (administered to the patient or wasted). The Medication Administration Record (MAR) did not match the documentation on the Controlled Substance Record (CSR) or the automated drug dispensing device (ADDD) printout. Examples 				

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	<p>Continued From page 2</p> <p>included Methadone, Morphine, and Fentanyl for Patient #6. Similarly, although nurse's initials were seen on the MAR, indicating that medications were administered, no medications were removed from the ADDD or signed out on the CSR.</p> <p>4. The facility failed to ensure strict control for persons authorized to access controlled substances. The list of persons with authorized access was being evaluated only once every month; however, access was not terminated right at time of or shortly after employee termination or leave.</p> <p>Immediate Jeopardy (IJ) to the health and safety of patients was identified and declared by the State survey team on 05/11/07, at 5:15 p.m. This action was taken as a result of the hospital's inadequate system for the accountability of controlled substances and associated consequences. These consequences included failure to identify medication errors, possible drug diversion, impaired health care providers, and/or patient harm.</p> <p>After multiple inspections and a follow up visit on 5/30/07, the IJ was lifted on 5/30/07 at 6:30 p.m.</p> <p>Findings:</p> <p>A. On 05/07/07, at 10:00 a.m., evaluation of the pharmacy department's involvement in the detection and resolution of controlled substance discrepancies was evaluated. On interview, a hospital pharmacist indicated that there were some issues related to controlled substance</p>				

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	<p>Continued From page 3</p> <p>accountability, and that the Director of Pharmacy (DOP) was looking into it. The DOP stated on interview, later that morning, that he was looking into the controlled substance issues and that the issues resulted from "sloppiness and inaccurate documentation."</p> <p>The DOP was asked for a discrepancy report from the automated drug dispensing device (ADDD). The report covering 05/01/07 until 05/09/07 showed 32 discrepancies of which only three were resolved and had explanation for the discrepancy. There was no evidence that discrepancies were evaluated 91.7% of the time. There was no evidence that the discrepancies were analyzed or trended in attempt to identify the reasons and affect, correct, or influence the hospital practice related to controlled substances.</p> <p>These multiple discrepancies (a total of 32 discrepancies in 9 days) in accessing controlled substances, demonstrated failure of the pharmacy to evaluate controlled substance use as outlined in their policy.</p> <p>On 05/11/07 at 1:00 p.m., a review of the hospital policy for Controlled Substances, (KPS MM-20.06-A Effective Date 01/07) revealed that on a monthly basis, "routine audits of at least 3 charts at random to include the orders, dispensing, and administration patterns. Select the drugs to be assessed from a list of controlled substances with high abuse/diversion potential..." The DOP stated that he was not doing this because they were busy preparing for Joint Commission accreditation.</p>				

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	<p>Continued From page 4</p> <p>B. The hospital did not have a policy in place for the automated drug dispensing device (ADDD). In the pharmacy policy and procedure manual, there was a single sheet with "Policy KPS-MM-40.15-In Development."</p> <p>C. The pharmacy failed to evaluate controlled substances stored in areas other than the ADDDs such as medication carts. On 05/07/07, at 10:00 a.m., the hospital pharmacist indicated on interview that they have not conducted any evaluation of nurses' access to the medication carts or any evaluation for accountability of the controlled substances stored within the medication carts.</p> <p>Nurses are assigned codes for accessing controlled substance from these carts. A print out of the nurses' access to all controlled substances from the medication carts was requested on Monday 05/07/07, at 2 p.m. The pharmacist indicated that they had to call the medication cart company to obtain this information. The DOP stated on 05/09/07, that they needed to download the information into a laptop, and that they were having some technical difficulties.</p> <p>In spite of repeated request for the information, the information was never provided.</p> <p>D. On 05/11/07 at 6:00 p.m., review of the CSR for medications kept in the medication cart revealed discrepancies that occurred on 04/30/07. The CSR showed that on 04/28/07, 50 tablets of Methadone, 10 milligrams and 26 tablets of 2.5 mg were added</p>				

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	<p>Continued From page 5</p> <p>(stocked) into the cart. On 04/30/07, the CSR showed that 44 tablets of 10 mg and 26 tablets of 2.5 milligrams were returned to pharmacy (removed from cart). According to the CSR, there was one entry on the CSR indicating that only two tablets had been removed; therefore, forty eight (10 mg tablets) should be returned to the pharmacy. There was no evidence that the discrepancy involving the four 10 milligram tablets was ever reconciled.</p> <p>Review of the "Controlled Substances" policy "KPS-MM 20.06-A" on 05/11/07 revealed that pharmacy staff would review the controlled substance administration record for discrepancies or omissions. The policy was not implemented as evidenced by the presence of the unresolved discrepancy for Methadone for Patient #6 since 4/30/07.</p> <p>Failure of the facility to implement their policies for controlled substances (CS) by failing to perform random audits and consequently failing to evaluate accurate use and accurate documentation, and failing to readily identify or minimize diversions, resulted in the following:</p> <ul style="list-style-type: none"> * Patient #6 not receiving her pain medication on 05/05/07. * Patient #6 not receiving her Methadone as ordered for ninety percent of the time, and Fentanyl Transdermal (skin patches) twenty five percent of the time. * The Medication Administration Record (MAR) for 				

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	<p>Continued From page 6</p> <p>Patient #6 did not match the documentation on the CSR or the ADDD printout; medication examples included Methadone, Morphine, and Fentanyl. Similarly, although nurse initials were seen on the MAR, indicating that medications were administered, no medications were removed from the ADDD or signed out on the CSR.</p> <p>Additionally, the facility failed to ensure strict control for persons authorized to access controlled substances as the list of authorized access was evaluated only once every month and that access was not terminated right at time of or shortly after employee termination.</p> <p>1. On 05/11/07, at 9:00 a.m., the medical record for Patient #6 was reviewed. Patient #6 was admitted on 04/28/07 for management of severe pain related to neurosarcoidosis (inflammation and abnormal deposits in the tissues of the nervous system resulting in severe pain), myelodysplasia (bone marrow disorder), and decubitus ulcers (bed sores) due to her relative lack of mobility.</p> <p>Patient #6 had multiple pain medication orders including Fentanyl Transdermal 200 micrograms/hour every 72 hours (a topical patch); morphine 9 milligrams (mg) IV (intravenous) injection every 2 hours as needed; Lortab 5/500 (a combination of hydrocodone and Tylenol) one or two tablets every 6 hours as needed; and Methadone 75 mg four times every day.</p> <p>On 05/07/07, at 9:00 a.m., Patient #6 told a State Surveyor that this past Saturday (meaning</p>				

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	<p>Continued From page 7</p> <p>05/05/07) she was not given her Methadone (a controlled substance for the treatment of severe pain). The patient indicated that the night nurse told her that the pharmacy was closed, that they did not dispense enough Methadone, and that the nurse did not have access to the pharmacy.</p> <p>Patient #6 had an order to receive Methadone four times a day or every 6 hours.</p> <p>Review of the Methadone supply records revealed that there was an insufficient quantity of Methadone available for administration between 5:00 p.m. on Friday, 05/04/07, and 10:21 a.m. on Saturday, 05/05/07, at which time the pharmacy dispensed additional Methadone. Consequently, Patient #6 did not receive one dose of Methadone to treat her severe pain.</p> <p>2. To ensure the accountability of controlled substances and accuracy of medication administration, a closed-loop system must be present. (Tracking of each dose of medication; i.e., from initial sign-out to disposition, including the verification of a valid physician order, is termed, closed-loop accountability.)</p> <p>On 05/11/07, comparisons of what medications were removed (via documented access) for administration with those that were actually documented on the MAR for Patient #6 was performed. Documented access for controlled substance was obtained from the CSR and the ADDD access reports. The comparison revealed multiple medication errors including wrong doses and omissions (not administering the medication at</p>				

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	<p>Continued From page 8</p> <p>all.)</p> <p>* According to the MAR and medication access records, the wrong Methadone dose was administered to Patient #6 from admission, 04/28/07 until 5/08/07. Of 40 doses, four were administered correctly; that meant ninety percent of the time the wrong dose of Methadone was administered. On admission, Patient #6 had a physician order for Methadone 75 mg to be given four times every day; however, review of the MAR revealed that only 70 mg was administered each time.</p> <p>* Patient #6 had an order for Fentanyl (also a medication for severe chronic pain) 200 micrograms to be applied to the skin every 72 hours. The hospital failed to administer this pain medication for Patient #6 one out of four times since her admission. This means twenty five percent of the time the Fentanyl dose was omitted. Patient #6 received her first Fentanyl dose in the hospital on 05/01/07 and the subsequent dose on 05/04/07. The third dose was due on 05/07/07; however, there was no documented evidence that the dose was applied, as there was no ADDD access or CSR sign out for Fentanyl.</p> <p>According to the ADDD, the next documented removal for Fentanyl patches was on 05/09/07 at 1:29 a.m. This was five days after the last Fentanyl dose was applied.</p> <p>* On 05/11/07, a review of Patient #6's MARs, for 04/28/07 and 04/29/07, revealed initials indicating</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	
	<p>Continued From page 10</p> <p>of the 14 Methadone tablets, a total of 140 mgs.</p> <p>* Discrepancies between the MAR and the ADDD access report for controlled substances were seen with other medications. Patient #6 had a physician order to receive morphine 9 milligrams (injectable) every 2 hours as needed for break through pain. A review of the pain assessment flow sheet which span Patient #6's hospital stay, from 04/28/07 to 05/11/07, revealed documentation of only three morphine administrations (a total 27 mg). According to the ADDD access record, morphine was removed 13 times, for a total of 117 milligrams. The MAR documentation did not match all the morphine accessed from the ADDD either. Morphine removed on 05/02/07, 05/03/07, and 05/05/07 were not reconciled. That meant twenty three percent of the time (three out of thirteen) documented morphine removal was not accounted for.</p> <p>* Although initials were seen on the MAR indicating that medications were administered; there were no evidence that medications were removed from the ADDD or signed out on the CSR.</p> <p>The presence of initials on the MAR did not always mean that Patient #6 received her medications. Review of the MAR, on 05/11/07, for 04/28/07 and 04/29/07, revealed initials indicating that Methadone was administered 5 times. However, there was no documentation of medication sign out on the CSR or the ADDD access report.</p> <p>Similarly, on 04/30/07, there were four initials on</p>				

Event ID:VB4J11

3/18/2008

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

TITLE

(X6) DATE

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	<p>Continued From page 11</p> <p>the MAR, indicating that four doses of methadone, 75 mg each, 300 mg total, were administered. However, documented access for Methadone on 04/30/07 showed that two tablets, 10 milligrams each, were signed out on the CSR and 8 tablets were removed according to the ADDD access report. A combined total of 10 tablets (100 mg total). It is impossible to administer 300 mg if only 100 mg were removed. There was no explanation for the discrepancy by facility staff.</p> <p>4. On 05/07/07 at 10:00 a.m., a facility pharmacist indicated that the list of employees with access to controlled substances from the automated drug-dispensing device (ADDD) is evaluated on a monthly basis and that access to controlled substances by nurses that are no longer employed by the facility are removed. Because access is not removed upon termination, a "terminated" employee could continue to have access to controlled substances up to a month after termination. The facility pharmacist stated on interview that the names of terminated employees are not communicated to the pharmacy in a timely manner to facilitate the timely termination of their access to controlled substance.</p> <p>The facility's failure to implement their policies for controlled substances by failing to perform random audits and consequently failing to evaluate accurate use and accurate documentation, and failing to readily identify or minimize diversions and associated consequences such as failure to identify medication errors, possible drug diversion, impaired health care providers, and/or patient harm</p>				

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	<p>Continued From page 12</p> <p>presented a system failure that contributed to Patient 6 not receive her pain medications.</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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