

California Health and Human Services Agency
Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050211	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 03/24/2010
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NAME OF PROVIDER OR SUPPLIER ALAMEDA HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 2070 CLINTON AVE, ALAMEDA, CA 94501 ALAMEDA COUNTY
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	<p>Continued From page 1</p> <p>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>Based on interviews, clinical record reviews and Policy review the hospital failed to develop and implement written policies and procedures to ensure the safe and effective use of fentanyl patches.</p> <p>This failure exposed 7 of 7 patients reviewed, who had not been on fentanyl patches prior to admission to the hospital, to preventable adverse consequences including respiratory depression (severe trouble breathing) and death. All seven patients received fentanyl patches without a pharmacist's assessment of the appropriateness of the dose and establishing opiate tolerance prior to initiation of the patch. Two out of seven patients were elderly with respiratory depression and were initiated at the highest available size of fentanyl patches (100mcg/hr) without evaluating the appropriateness of use. In addition, one of the two patient's fentanyl patch dose was doubled two days after starting fentanyl patches.</p> <p>THE HOSPITAL'S FAILURE TO DEVELOP AND IMPLEMENT WRITTEN POLICIES AND PROCEDURES TO ENSURE SAFE MEDICATION USE HAD THE POTENTIAL TO EXPOSE PATIENTS TO IRRESVERSIBLE AND POTENTIALLY LIFE THREATENING SIDE EFFECTS, INCLUDING RESPIRATORY</p>		<p>The committee consisted of the Chief Pharmacist, Director of Quality/Risk, Patient Safety Officer, and Staff Nurse III. Effective 05/10/2010 the MERP (Medication Error Reduction Plan) Committee has been re-designed to include: medical staff membership, pharmacy staff, administration, Executive Director of Nursing, nursing staff, and ancillary staff as needed. The committee meets monthly to review all actual and/or potential medication related errors. Both internal and external sources are used (e.g. ISMP newsletters, Sentinel Events Alerts and actual error occurrences within the Hospital) to analyze current systems or processes with potential to cause error or trend analysis from internal data. All errors are categorized into each of the required eleven elements and analyzed for trends. When trends are identified with potential to cause harm, or actual harm, it is added to the MERP problem list and referred to the appropriate quality committee for development of a corrective action/implementation plan. These quality committees report back to the MERP monthly for review of evidence of effective interventions. Items are removed from the problem list by the MERP Committee after satisfactory improvements and sustainability. Aggregate data will flow from the MERP Committee to the appropriate hospital and medical staff committees as well as to the district Board of Directors in the form of an annual effectiveness report.</p>	
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9/22/2010

9.01:13AM

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	<p>Continued From page 2</p> <p>DEPRESSION AND POSSIBLY DEATH. THIS FAILURE CAUSED, OR WAS LIKELY TO CAUSE, SERIOUS INJURY OR DEATH TO THE PATIENT, AND THEREFORE CONSTITUTED AN IMMEDIATE JEOPARDY UNDER HEALTH AND SAFETY CODE SECTION 1280.1.</p> <p>Findings: According to the manufacturer package insert, the Fentanyl patch is a narcotic (opioid) pain medicine applied to the skin. It contains fentanyl, a very potent narcotic pain medicine. Fentanyl patches are only for treating persistent, moderate to severe pain in patients who are opioid-tolerant (patients who take a regular, daily, around-the-clock narcotic pain medicine). Opioid naïve patients (patient who do not take regular, daily around the clock narcotic pain medicine) have an increased risk for side effects including respiratory depression (severe trouble breathing) and death.</p> <p>Due to numerous reports of adverse events with fentanyl patches, including fatalities, caused by inappropriate prescribing, dispensing, and administration of the drug, The Food and Drug Administration (FDA) issued a public advisory containing important safety information about using Fentanyl transdermal patches. "Deaths and overdoses have occurred, and the directions for the use of this medication must be followed exactly to prevent death or serious side effects."</p> <p>Additionally, the FDA required fentanyl patch</p>		<p>Fentanyl patches were immediately removed from all automated dispensing devices and nurses were alerted regarding TDP (transdermal patch) risk (Attachment F)</p> <p>A Pharmacy Services Policy on Use of Fentanyl Patches was developed and approved (Attachment G)</p> <p>Physicians with experience in pain control were identified and informed that the pharmacist and/or physician may request a consult, according to the policy when disagreements arise surrounding appropriate Fentanyl TDP orders. (Attachment H)</p> <p>Policies/procedures/protocols for Fentanyl TDP use were developed by a sub-committee of the Pharmacy Therapeutics Committee including the: Interim Chief Pharmacist, Director of Quality/Risk, Patient Safety Officer, Staff Nurse III, Hospitalist, and Clinical Education Specialist. They include; definitions, assessments, contraindications, required monitoring with time frames, side effects with appropriate responses, administration practices, safety warnings, patient education requirements and documentation assessments.</p>	<p>02/11/2010</p> <p>02/19/2010</p> <p>03/01/2010</p>	

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	<p>Continued From page 3</p> <p>manufacturers to place the following warning on the labeling: "Fentanyl should ONLY be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a total daily dose at least equivalent to Fentanyl patch 25 mcg/hr. Patients who are considered opioid-tolerant are those who have been taking, for a week or longer, at least 60 mg of morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid. Because serious or life-threatening hypoventilation could occur, fentanyl patch is contraindicated: In patients who are not opioid-tolerant".</p> <p>On 2/12/10, record reviews and staff interviews were initiated for seven patients (2, 3, 4, 5, 6, and 8) who had not been on fentanyl patches prior to admission to the hospital. During interview on 3/24/10, the interim director of pharmacy (Pharm 2) stated there was no documented pharmacist assessment or interventions regarding the use of fentanyl patches for patients 2, 3,4,5,6,7 and 8. Record reviews and staff interviews showed the hospital had used Fentanyl patches without assessing the indication for its use and the dose ordered as follows:</p> <p>1. Patient 2 was admitted to the hospital on [REDACTED] 09 from a skilled nursing facility when [REDACTED] was found in respiratory distress (difficult and labored breathing). He was [REDACTED] years old with an admission assessment that included respiratory failure secondary to pneumonia, heart failure, hypotension, and sepsis (blood infection). Patient 2</p>		<p>These policies/procedures/protocols specifically include:</p> <ol style="list-style-type: none"> 1) Fentanyl TDP Physician Order Set (Attachment I) 2) Fentanyl TDP Nursing Protocol which includes a documentation flow sheet, a teaching protocol and patient education documents (Attachement J, K, L, M) 3) A Nursing Medication Administration Procedure was also revised to include TDP's (Attachment N) <p>All were approved at a special session of the Medical Executive Committee (MEC). Full implementation of these efforts began 03/15/2010.</p> <p>The Department of Nursing Pain Management Protocol [Attachment O] and Pain Management Flow Sheets [Attachment P] reflect requirements for effectiveness/response to pain medications. The Fentanyl TDP protocol, Fentanyl TDP flow sheet, and Fentanyl TDP Teaching Protocol indicate the specific requirements for Fentanyl TDP.</p> <p>Fentanyl TDP was added to the High Alert Medication list [Attachment Q].</p> <p>MRI Screening Tool updated to include potential concerns for patients with Fentanyl TDP's [Attachment R].</p>	<p>02/19/2010</p> <p>02/19/10</p> <p>02/19/2010</p> <p>02/22/2010</p>
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	<p>Continued From page 4</p> <p>required the placement of tube through the mouth and into the trachea (windpipe) to provide a means of mechanical ventilation for breathing (intubation), antibiotics treatment for infection, medications to assist the beating of the heart, fluids, sedatives and pain medications. After extubation (removal of the breathing tube), Patient 2 was not able to breathe easily and suffered from respiratory distress. The family decided to stop life prolonging treatments and provide the patient with comfort care only.</p> <p>On [REDACTED] 10, Patient 2 received 4 mg of IV morphine.</p> <p>On [REDACTED]/10, Patient 2 received the following pain medications:</p> <p>Fentanyl patch 100mcg/hr (applied at 2:30 p.m.) Morphine 5mg intravenous (IV) (administered at 2:50 p.m.) Morphine 5mg/hr continuous infusion IV (started at 3:30 p.m., stopped at 8:15 p.m.)</p> <p>Patient 2 did not have any documented pain nor had [REDACTED] received any opiate pain medications on [REDACTED] 09 or [REDACTED]/09 prior to application of the fentanyl patch application.</p> <p>Prior to admission to the hospital, Patient 2's opiate pain medication while in the skilled nursing facility was vicodin (a mild to moderate oral pain combination medication) 1-2 tablets every four hours as needed for moderate to severe pain. Patient's record did not indicate the frequency, quantity and duration of vicodin use. Patient 2 did not meet the definition of opiate tolerant.</p>		<p>Education for Fentanyl TDP usage was completed for:</p> <ul style="list-style-type: none"> • Pharmacists [Attachment S] • Nursing Staff, including self study modules for new hires [Attachment T] • Medical Staff [Attachment U] <p>Chief Pharmacist will monitor 100% of all Fentanyl TDP orders for 12 months beginning 2/10 (concurrent review) [Attachment V]</p> <p>Staff Nurse III will monitor Fentanyl TDP usage for 12 months beginning 2/10 (retrospective review) [Attachment W].</p>	<p>02/27/2010</p> <p>03/09/2010</p> <p>03/11/2010</p> <p>02/2011</p> <p>02/2011</p>
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	<p>Continued From page 8</p> <p>During interview on 3/24/10 at approximately 12:45 p.m., the interim director of pharmacy (Pharm 2) stated that a per diem pharmacist had approved the order to increase Patient 2's fentanyl patches from 100mcg to 200mcg on [REDACTED]/09. According to Pharm 2, there was no documentation of any pharmacist interventions or assessments regarding the dose increase. Pharm 2 stated that he could not find any literature or documentation regarding the use of fentanyl patches to relieve respiratory distress.</p> <p>On 3/24/10, the intensive care registered nurse (RN 2) who had applied Patient 2's fentanyl patch on [REDACTED] 09 was interviewed with the telemetry unit nurse manager (RN 3) present. RN 2 stated that she had assumed that the patch was used to control pain. RN 2 and RN 3 reviewed Patient 2's record and could not find any indication that Patient 2 needed additional pain control that required the use of fentanyl patches. RN 3 stated that there was no indication for fentanyl patches. RN 2 and RN 3 were not aware that MD1 had prescribed fentanyl patches to relieve Patient 2's respiratory distress nor that fentanyl patches were used to relieve respiratory distress for comfort care patients.</p> <p>Based on patient 2's advanced [REDACTED], respiratory status lack of opiate tolerance, and the lack of an indication, the initiation of fentanyl 100mcg/hr patch with a subsequent increase to fentanyl 200mch/hr patch in less than 48 hours were not appropriate and were likely to cause Patient 2 serious harm.</p> <p>2. Patient 3 was admitted to the hospital on</p>			
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	<p>Continued From page 12</p> <p>During interview on 3/24/10 at 2:00 p.m., Pharm 2 stated there was no documented pharmacist assessment or interventions regarding the appropriateness of fentanyl 25mcg/hr patch for Patient 4</p> <p>4. Patient 5 was admitted to the hospital on 12/3/09 for abdominal pain and shortness of breath with a history of a gastrointestinal tumor and multiple abdominal surgical procedures. According to the medical record, Patient 5's pain/opiate medications, prior to hospitalization, was oxycodone 5mg every 3 hours as needed and did not indicate frequency or duration of use. The hospital treatment plan included keeping Patient 5 comfortable, treatment with morphine for pain and starting a fentanyl patch. On 12/3/09, Patient 5 received a fentanyl patch 25mcg/hr at 9:00 a.m.</p> <p>Patient 5's medical record did not include any documentation demonstrating Patient 5's opiate tolerance or risk/benefit analysis justifying the use of fentanyl patches. According to the manufacturer's instructions and the boxed warning, Patient 5 would have to have used oral 30 to 67mg of oxycodone or morphine 60mg daily or the equivalent for at least a week in order to receive a fentanyl 25mcg/hr patch.</p> <p>During interview on 3/24/10 at 3:00 p.m., Pharm 2 Stated there was no documented pharmacist assessment or interventions regarding the appropriateness of fentanyl 25mcg/hr patch for Patient 5.</p>			
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	<p>Continued From page 13</p> <p>5. Patient 6 was admitted to the hospital on 10/6/09 for fever with a history of a metastatic breast cancer, lung and spinal cord cancer. Patient 6's pain/opiate medication, prior to hospitalization was hydromorphone 4mg, 1-2 tablets by mouth, every 4-6 hours as needed for pain. Patient 6's medical record did not include frequency or duration of use. Patient 6 received fentanyl patch 100mcg/hr on 10/7/09.</p> <p>Patient 6's medical record did not include any documentation demonstrating that she had been receiving the equivalent opiate dose to 100mcg/hr fentanyl patch. According to the manufacturer's instructions and the boxed warning, Patient 6 would have to have used oral 40 to 50mg of hydromorphone daily for at least a week in order to receive a fentanyl 100mcg/hr patch.</p> <p>During interview on 3/24/10 at 2:45 p.m., Pharm 2 Stated there was no documented pharmacist assessment or interventions regarding the appropriateness of fentanyl 100mcg/hr patch for Patient 6.</p> <p>6. Patient 7 was admitted to the hospital on 12/29/09 for left foot gangrene. Patient 7 was not on any opiate pain medication prior to hospitalization. Patient 7 was not verbally communicating and had pain as evidenced by moaning (no documented pain level). Patient 7 had a do not resuscitate order and was on comfort care/hospice.</p> <p>Patient 7 received the following opiate pain</p>			
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	<p>Continued From page 14</p> <p>medications while hospitalized,</p> <p>12/29/09: 6mg of IV morphine 12/30/09: 10mg of IV morphine and a morphine drip was started 12/31/09: the morphine drip was discontinued and a fentanyl patch 25mcg/hr applied at 12:02 p.m., then Patient 7 was discharged.</p> <p>Patient 7's medical record did not include any documentation demonstrating Patient 7's opiate tolerance or risk/benefit analysis justifying the use of fentanyl patches. According to the manufacturer's instructions and the boxed warning, Patient 7 would have to have used IV morphine 10-22mg daily or the equivalent for at least a week in order to receive a fentanyl 25mcg/hr patch.</p> <p>During interview on 3/24/10 at 2:55 p.m., Pharm 2 stated there was no documented pharmacist assessment or interventions regarding the appropriateness of fentanyl 25mcg/hr patch for Patient 7.</p> <p>7. Patient 8 was admitted to the hospital on 10/31/09 for acute pancreatitis and pancreatic cyst and was not on any opiate/pain medication prior to hospitalization. Patient 8's opiate/pain medication upon admission was hydromorphone 1mg IV every 2 hours as needed for pain.</p> <p>Patient 8 received the following opiate pain medications while hospitalized:</p> <p>10/30/09: 3.5mg of IV hydromorphone</p>			
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