
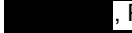



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050324 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 11/27/2007 |
| NAME OF PROVIDER OR SUPPLIER SCRIPPS MEMORIAL HOSPITAL - LA JOLLA | | STREET ADDRESS, CITY, STATE, ZIP CODE 9888 GENESEE AVENUE, LA JOLLA, CA 92037 SAN DIEGO COUNTY | | |
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| | <p>The following reflects the findings of the CA Department of Public Health during a complaint CA133082 investigation.</p> <p>Representing the California Department of Public Health:</p> <p>, Pharmaceutical Consultant , Pharmaceutical Consultant , Pharmaceutical Consultant</p> <p>HSC 1280.1(a)(c) 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 (c)(1) The committee (pharmacy and therapeutics committee, or a committee of equivalent composition) shall develop written policies and procedures for establishment of safe and effective</p> | | | |

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| | <p>Continued From page 1</p> <p>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>Based on interview, clinical record review and policy review, the hospital failed to ensure that written policies and procedures were developed and implemented to provide the safe and effective use of medications with black box warnings. A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects. It is the U.S. Food and Drug Administration's strongest required warning.</p> <p>Due to the potential of serious adverse consequences, including death, fentanyl (Duragesic) patch (a potent synthetic opiate narcotic manufactured in patch form that releases the medication in a controlled fashion and is indicated for the management of chronic pain in narcotic tolerant patients whose pain has not been manageable by other means) has special warnings (Black Box Warnings) to ensure it is used safely. Record review revealed that one patient (Patient 1) received fentanyl patch not in accordance with manufacturer's dosing guidelines and as a result required treatment with a reversal agent, naloxone (Narcan).</p> <p>Findings: On November 27, 2007 at 11:15 a.m., review of</p> | | | |

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| | <p>Continued From page 2</p> <p>Patient 1's clinical record revealed that on November 9, 2007 at 11:45 a.m., the nurse reported the patient was found in bed with labored breathing, respiratory rate = 24 and placed on oxygen at 2 liters/minute. At 11:50 a.m., the SP02 (measure of oxygen in the blood – normal ?95) fell to 80 and the oxygen was increased to 4 liters/minute. At 11:55 a.m., the SP02 decreased in to the 60's and at 12:02 p.m. the patient was found to be non responsive and a code blue (medical emergency) was called by the nursing staff. According to the patient's Discharge Summary dated 11/11/07, the patient was noted to be hypoxic and had depressed respirations when the code blue was called. She was administered naloxone (a medication to reverse the effects of an overdose of narcotic medication) and required emergency intubation (a procedure performed when a patient cannot breathe on their own and a tube is inserted through the mouth into the trachea, the airway from the mouth to the lungs) for airway protection and oxygenation, and subsequently transferred to the intensive care unit.</p> <p>The patient was admitted to the hospital on 11/7/07 to undergo a second surgery, a posterior cervical fixation and fusion, for the treatment of spondylosis (spinal arthritis) and spinal cord compression. According to the preoperative medication history located in the history and physical report, the patient was taking Vicodin (pain medication containing hydrocodone 5mg and acetaminophen) one tablet twice a day.</p> <p>During an earlier survey on 11/14/07 at 4:04 p.m. in</p> | | | |
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| | <p>Continued From page 3</p> <p>a telephone interview with Physician H, who stated the patient was taking Percocet (potent oral narcotic which contains oxycodone 5mg (milligram) and acetaminophen) one tablet 3-4 times a day up until 1 week prior to admission when the medication was changed to Vicodin. The patient could only tolerate 1 or 2 tablets of Vicodin a day because she experienced upset stomach.</p> <p>On 11/27/07 at 11:45 a.m., review of Patient 1's medication administration record revealed she received hydromorphone (Dilaudid - potent narcotic medication) 0.5mg intravenously at 8:30 pm on 11/7/07. On 11/8/07 she underwent a cervical fixation and fusion surgery. On 11/8/07 the patient received hydromorphone 1mg intravenously at 1:40 a.m., 6:10 a.m., 9:00 a.m., 11:40 a.m., 2:40 p.m., and 6:55 p.m. The patient was then started on a hydromorphone PCA pump at 9:30 p.m. and received approximately 2.6 mg during the next 14.5 hours until the code was called. A Percocet tablet was administered on 11/9/07 at 10:00 a.m.</p> <p>Fentanyl 75mcg Patch was ordered every 48 hours on 11/8/07 at 6:15 p.m. and administered at 9:40 p.m. The code blue was called on 11/9/07 at 12:02 p.m. (approximately 18 hours after the administration of the first dose of fentanyl).</p> <p>Fentanyl is a potent synthetic opioid narcotic pain medication that is available in patches that can be applied to the skin and which releases the medication through a controlled rate over 72 hours until the patch is changed. The fentanyl patch dosage form has a black boxed warning in the</p> | | | |
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| | <p>Continued From page 4</p> <p>product labeling. When a medications labeling includes a black box warning it means that medical studies indicate that the medication carries a significant risk of serious or life-threatening adverse events. The strongest warning the FDA (Food and Drug Administration) requires.</p> <p>Fentanyl patch has the following black box warning alert in the manufacturer's package insert: Fentanyl should only be used in patients who have demonstrated opioid tolerance, and who require a total daily dose at least equivalent to fentanyl 25 mcg/hr. Patients who are considered opioid tolerant are those who have been taking, for a week or longer, at least 60mg of morphine daily, or at least 30mg of oral oxycodone daily, or at least 8mg of oral hydromorphone daily or an equianalgesic dose of another opioid.</p> <p>Because serious or life-threatening hypoventilation could occur, fentanyl patch is contraindicated:</p> <ul style="list-style-type: none"> * In patients who are not opioid tolerant * In the management of acute pain or in patients who require opioid analgesia for a short period of time * In the management of post-operative pain, including use after out-patient or day surgeries * In the management of mild pain or intermittent pain <p>Patient 1 had a fentanyl patch applied to her skin following surgery for acute post operative pain which is a contraindication according to the black box warning statement above. According to the medication history report on admission, medication usage in the hospital, and interview with the</p> | | | |
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| | <p>Continued From page 5</p> <p>patient's physician H, the patient was not taking sufficient amounts of narcotic medication to be considered opioid tolerant when fentanyl was applied. On 11/14/07 at 2 p.m., pharmacist A stated there was no follow up that the physician was contacted by the pharmacist who validated the order to discuss these contraindications. On 11/16/07 at 9:49 a.m., pharmacist A stated she felt the adverse drug reaction was respiratory depression secondary to toxic effects of fentanyl patch.</p> <p>The pharmacist validated the order for fentanyl patch which allowed the nurse to obtain the medication from the PYXIS machine on the floor (automated drug dispensing system) and administer it to the patient. There were no policies or procedures and no system in place to prevent this event from occurring.</p> <p>On 11/27/07 at 2:56 p.m., the hospital administration staff including the CEO was informed that Immediate Jeopardy (IJ) had been identified based on the hospital's failure to protect patients from potential undue adverse medication consequences from fentanyl (Duragesic) patch. Patients receiving care for pain medication management, as referred to above, were administered fentanyl patch without following the contraindications to use as required in the manufacturer's black box warning. The hospital was asked to provide a plan of correction to address the IJ. On 11/27/07 at 9:05 p.m., a plan of correction was submitted and accepted.</p> <p>The violation(s) has caused or is likely to cause</p> | | | |
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