

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>056048</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>10/17/2007</b>
NAME OF PROVIDER OR SUPPLIER <b>PACIFIC COAST MANOR</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>1935 WHARF ROAD, CAPITOLA, CA 95010 SANTA CRUZ COUNTY</b>		
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	<p>The following reflects the findings of the Department of Public Health during a Complaint Investigation visit.</p> <p>Representing the Department of Public Health: [REDACTED]</p> <p>CLASS AA CITATION -- PATIENT CARE 07-2024-0004430-F Complaint(s): CA00126633</p> <p>F329 483.25(l) Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used in excessive dose (including duplicate therapy); or for excessive duration; or without adequate monitoring; or without adequate indications for its use; or in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or any combinations of the reasons above.</p> <p>Based on a comprehensive assessment of a resident, the facility must ensure that residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.</p> <p>The facility failed to ensure one of one sampled patient (A) was free from unnecessary drugs. The facility failed to adequately monitor Patient A for serious and adverse consequences from the combined use of Morphine and Fentanyl patch. On admission, Patient A was documented as sensitive to</p>			

Event ID:T1O811

11/28/2007

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	<p><b>Continued From page 1</b></p> <p>Morphine. Three days after admission, Patient A's attending physician (MD 1), ordered Morphine injections and Fentanyl patch for Patient A. The order for Fentanyl patch was contraindicated since Patient A was opioid intolerant. Fentanyl had a "Black Box Warning" for its risk to cause a fatal overdose due to respiratory depression. Patient A expired twenty-four hours after a Fentanyl patch was applied.</p> <p>Patient A was a 71-year-old female admitted from the acute care hospital to the facility on 9/11/07, with a diagnosis of breast cancer with metastasis to the spine (spreading of the cancer beyond the primary site).</p> <p>During review on 10/10/07, the admission assessment of 9/11/07, and a psychological evaluation done on 9/04/07 at the acute care hospital, indicated sensitivity to opiates (specifically Codeine and Morphine). The nurses notes of 9/14/07 at 1:50 p.m. documented the Morphine Sulfate was given to Patient A.</p> <p>The psychological evaluation on 9/04/07 was performed to assess Patient A's competency to rule-out depression. The note described her as alert and oriented with fair reality testing. It also documented "she did not want to die, she wanted to keep fighting the cancer, and would be interested in taking medications if they were to have fewer side effects."</p> <p>A progress note written by Patient A's oncologist on 9/06/07 documented "she could have years to live even with her mets" (metastasis). The oncologist recommended physical therapy. The acute care hospital's nurses notes of 9/05/07 also documented</p>			
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	<p><b>Continued From page 2</b></p> <p>Patient A was determined to go home after a stint "at the hospital rehab" and was considering further surgery and radiation.</p> <p>On 10/11/07 the nurses notes dated 9/12/07 indicated Patient A refused all food, fluids, and her narcotic pain medications, including Methadone 2.5 milligrams (mg) and Norco 10/325 (hydrocodone bitartrate 10 mg. and acetaminophen 325 mg.).</p> <p>The nurses' notes on 9/13/07 at 9:00 p.m. documented Patient A screamed and became combative when care was provided.</p> <p>On 9/14/07 at 5:00 a.m., the nurses' notes indicated Patient A was alert, confused, and yelling, "You are all going to kill me!" An 8:00 a.m. entry in the nurses' notes documented Patient A refused medications and fluids, "pulling off oxygen and spitting at staff. Unable to calm resident." Patient A yelled, "You're killing me." "I'm not dying." The nurses' notes at 12:00 p.m. also documented the Director of Nursing (DON) called MD 1 with his "suggestions" for pain medications.</p> <p>On 9/14/07 at 1:20 p.m., MD 1 ordered the following:</p> <ol style="list-style-type: none"> <li>1) Fentanyl patch 25 mcg. (micrograms); change every three days.</li> <li>2) No CPR and No hospitalization.</li> <li>3) Haldol 1 mg. "IM" Q hrs. prn combative, refusing oral fluids.</li> <li>4) MS (morphine sulfate) 8 mg. "SC" (subcutaneous injection) q2hrs. prn (every 2 hours as needed) severe pain.</li> </ol>			
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	<p><b>Continued From page 3</b></p> <p>5) MS 4 mg."SC" q2hrs. prn moderate pain.</p> <p>6) MS 2 mg. "SC" q2hrs. prn mild pain.</p> <p>7) D/C Methadone and D/C Norco.</p> <p>The Medication Administration Record (MAR) documented the Fentanyl patch was placed on Patient A the morning of 9/15/07.</p> <p>During review on 10/11/07, Patient A's clinical record did not include a care plan for monitoring the adverse consequences of Morphine and Fentanyl patch use. Signs and symptoms of Fentanyl toxicity include shallow breathing, sleepiness or sedation, the inability to think or talk normally, and confusion. Morphine's adverse side effects include respiratory depression.</p> <p>Patient A continued to have no fluid intake on 9/15/07 according to the nurses' notes. The 2:00 p.m. entry in the nurses' notes documented, "when she did awaken" she yelled repeatedly, "I'm dying!" When asked if she was in pain, Patient A yelled "No Pain!" However, she continued to receive the Morphine injections.</p> <p>On 9/16/07 at 9:00 a.m., Licensed Nurse 3 (LN 3) documented Patient A as comatose and responsive to "pain only", in the nurses' notes flow sheet. Patient A received oxygen via nasal cannula at 2 LPM (liters per minute); her oxygen saturation was 77%. (Normal parameters of oxygen saturation are equal to or greater than 95% on room air.) The nurses notes documented Patient A received Morphine Sulfate (MS) 4 mg. "SQ" at 9:40 a.m., and MS 8 mg. "SQ" at 11:40</p>			
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	<p><b>Continued From page 4</b></p> <p>a.m., although the DON documented her as "responsive to deep pain only" in his 10:45 a.m. entry.</p> <p>During a telephone interview with LN 3 on 10/17/07 at 10:10 a.m., the evaluator asked why she gave Morphine injections twice (4 mg. and 8 mg.) when she had documented Patient A as comatose and responsive to pain only. LN 3 stated "because of her elevated heart rate and respiratory rate." LN 3 stated she was aware of Patient A's sensitivity to Morphine and she wanted to call MD 1 for a change in medications, but the DON told her "not to call" and to "just keep her comfortable."</p> <p>On 9/16/07 at 2:00 p.m., Patient A's documented vital signs were: BP unable to be palpated; T=103.7 (ax); P=100; respiratory rate=16. At 3:35 p.m. the nurses notes documented her oxygen saturation at 82% with decreased respirations and no response to stimuli. Patient A expired on 9/16/07 at 3:55 p.m.</p> <p>During a telephone interview with the consultant pharmacist for the facility on 10/17/07 at 1:20 p.m., he stated he was not informed of Patient A's opioid status. The evaluator asked if he was knowledgeable of her sensitivity to opiates, specifically Morphine and Codeine, which she had refused during her hospitalization. The pharmacist stated he was "routinely only informed of their (patients) drug allergies."</p> <p>During a telephone interview on 10/17/07 at 11:15 a.m., MD 1 was asked by the evaluator why he ordered a Fentanyl patch when Patient A was opiate naive (opiate intolerant or on less than 60 mg. of Morphine Sulfate or 30 mg. of Oxycodone per day for one week). MD 1 answered, "Was she?" The evaluator</p>			
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	<p><b>Continued From page 5</b></p> <p>mentioned the medications Patient A received while she was in the acute care hospital. She was on Methadone (a narcotic pain medication), Toradol "IV" (non-narcotic, non-steroidal anti-inflammatory medication used to treat pain), and a Scopolamine patch (for nausea). MD 1 initially had no response, then stated he would call back later.</p> <p>Fentanyl transdermal patch (Duragesic from Janssen Pharmaceutica, Inc.) contains a high concentration of a potent opioid, Fentanyl, which is 50-100 times as potent as Morphine. Fentanyl is one of several opioid medications with a high potential for abuse and associated risk of fatal overdose due to respiratory depression (Black Box warning). Special emphasis added by the manufacturer: the Fentanyl transdermal patch is contraindicated; 1) in patients who are not opioid tolerant and, 2) in the management of acute pain or in patients who require opioid analgesia for a short period of time. (Reference: Manufacturer's prescribing information June, 2005.) Serum Fentanyl concentration may increase by approximately one-third for patients with a body temp of 40 degrees Centigrade (104 degrees F.) secondary to a temperature-dependent increase in Fentanyl release from the patch and increased skin permeability (Geriatric Dosage Handbook, Lexi-Comp, 12 ed., pp. 595 - 602).</p> <p>The most important factor to be considered in determining the appropriate dose of the Fentanyl patch is the extent of the pre-existing opioid tolerance. Based upon daily oral Morphine dose in the 45-134 mg./day range, the Fentanyl 25 mcg. patch is recommended. The most common reactions experienced by adults are confusion, tremors, restlessness, anxiety, and paranoia. (Physicians</p>			
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	<p><b>Continued From page 6</b></p> <p>Desk Reference, 2005, 59th ed., pp. 1734). Since Patient A had been on Methadone 2.5 mg. tablets twice a day since her admission to the facility, and on Toradol (a non-narcotic anti-inflammatory) and Methadone during her hospitalization, she was essentially considered opiate naive or intolerant.</p> <p>The facility failed to adequately monitor Patient A for the adverse side effects of Morphine Sulfate injections and Fentanyl transdermal patch use when she was opioid intolerant. The end result was a rapid decline in Patient A's condition. Patient A expired in the facility 24 hours after the Fentanyl patch was applied.</p> <p>This violation presented an imminent danger to the patient and was a direct proximate cause of the death of the patient.</p>			

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