

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050017	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/20/2016
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NAME OF PROVIDER OR SUPPLIER Mercy General Hospital	STREET ADDRESS, CITY, STATE, ZIP CODE 4001 J Street, Sacramento, CA 95819-3626 SACRAMENTO COUNTY
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	<p>The hospital notified the Patient's surrogate of the Adverse Event on 9/28/16.</p> <p>Adverse Event Notification - Informed Health and Safety Code Section 1279.1 (c), "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made."</p> <p>The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made.</p> <p>Title 22 DIV 5 CH 1 ART 3 70213 Nursing Service Policies and Procedure (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. (b) Policies and procedures shall be based on current standards of nursing practice and shall be consistent with the nursing process which includes: assessment, nursing diagnosis, planning, intervention, evaluation, and, as circumstances require, patient advocacy.</p> <p>Title 22 DIV 5 CH 1 ART 3 70263 Pharmaceutical Service General Requirements (g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other</p>		<p>Education on medication administration was provided to PACU nurses by the PACU manager during huddles beginning in October, 2016. The education covered the importance of following the physician's order including the dose, route and timing. In addition, there was education on starting with the first choice opioid agent alone. Nurses were instructed that if they had concerns about the orders they must contact the physician to discuss and enter a new order if appropriate.</p> <p>The opioid orders were modified by a team led by the Clinical Pharmacy Specialist to include maximum doses and instructions for contacting an anesthesiologist. The orders were approved in December, 2016.</p> <p>The standard order for Dilaudid for opiate naïve patients was revised to read: 0.2 mg IV push every 3 minutes prn pain. Instructions are included to notify the prescriber if the patient receives 2 mg and is still in pain. The orders were approved in December, 2016.</p> <p>(continued on the next page)</p>	<p>October, 2016</p> <p>December, 2016</p>

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	<p>than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher. Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours.</p> <p>(2) Medications and treatments shall be administered as ordered.</p> <p>On October 4, 2016 at 10:30 a.m., an unannounced visit was conducted at the facility to investigate a complaint regarding Patient 1 who had been admitted for knee surgery at the facility.</p> <p>Patient 1 was admitted on 9/28/16 for knee replacement surgery. After the surgery, Patient 1 was provided pain medication of fentanyl (an opioid used to control pain) and hydromorphone (a second opioid medication used to control pain). These medications were administered in error, causing Patient 1 to have depressed respirations and go into respiratory distress. Patient 1 became unresponsive from too many medications and died.</p> <p>Based on observations, staff interviews, medical record and hospital Policy and Procedure review, the General Acute Care Hospital (GACH) failed to ensure standards of nursing care were adhered to in the Post Anesthesia Care Unit (PACU) when medications were not administered according to physician's orders, and failed to ensure a safe and</p>		<p>The order for fentanyl for opiate naïve patients was revised to read: 25 mcg every three minutes prn pain and include instructions to hold if the patient receives 250 mcg and is still in pain. The new orders were approved in December, 2016.</p> <p>The Senior Director of Perioperative Services and the manager of the operating rooms (OR) and PACU followed the Just Culture algorithm in intervening with the PACU nurse. This was completed in October, 2016.</p> <p>Finding 2. Notification of Physician of Inability to Control Pain</p> <p>Nurses in PACU are provided with education on strategies for safe use of opioids: N-notify physician/anesthesiologist A-assessment R- re-evaluate pain C- continue monitoring S-SBAR Education was initiated in huddles October, 2016 and is provided to all new hires.</p> <p>(continued on next page)</p>	<p>October, 2016</p> <p>October, 2016</p>

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	<p>effective system for the dispensing and administration of narcotic medication in the PACU including, but not limited to:</p> <ol style="list-style-type: none"> 1. Follow the physician's orders for the administration of narcotics to Patient 1; 2. Notify the physician of an inability to control pain with the use of multiple intravenous (IV) narcotics for Patient 1; and 3. Assess or evaluate Patient 1's vital signs when she was transferred from the PACU to the Acute Surgical Unit (ASU). <p>The cumulative effect of these failures resulted in an unwitnessed respiratory and cardiac arrest, which led to diffuse brain anoxia (lack of oxygen to the brain), brain swelling and subsequent death.</p> <p>Findings:</p> <p>Patient 1 was admitted to the PACU after a right total knee replacement on 9/28/16. Review of Patient 1's History and Physical dated 9/21/16, indicated Patient 1 did not have a history of any prior narcotic use.</p> <ol style="list-style-type: none"> 1. Failure to Follow Physician Order for Administration of Medication On October 5, 2016, a record review was conducted. The Physician's orders for post-operative pain written on 9/28/16 at 2:05 p.m. was for: Fentanyl "25 mcg [micrograms], IV Push, INJ [into the IV, by injection], q[every]3min Routine 		<p>The issues raised by the case were discussed with the Anesthesia committee. The Chair of Anesthesia led discussions about improving opioid orders and communication in the PACU during the November, 2016 meeting.</p> <p>Finding 3. Failure to Assess Patient's Vital Signs</p> <p>The Manager of PACU provided education to nursing staff to evaluate and document a Pasero Opioid Sedation Scale (POSS) prior to transferring patients from PACU. The Manager of PACU audits ten charts each we for documentation of POSS prior to discharge from the PACU.</p> <p>For patients arriving from PACU, the first set of vital signs should be obtained by the RN, not the CNA. Education on this change in practice was provided by the Clinical Nurse Specialist for Acute Surgical Services in October, 2016.</p> <p>(continued on next page)</p>	<p>November, 2016</p> <p>December, 2016</p> <p>October, 2016</p>

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	<p>PRN [as needed] PACU pain 1st Choice, ***PACU ONLY***. Instructions indicated to use fentanyl first for pain in the PACU. A second order, written at the same time, for hydromorphone "0.5 mg (milligrams) IV Push, INJ q 3min Routine PRN PACU pain 2nd Choice, if first choice ineffective ***PACU ONLY***.</p> <p>Review of Patient 1's electronic Medication Administration Record (eMAR), dated 9/28/16, revealed Registered Nurse (RN) 1 administered the following narcotics in error:</p> <p>A. "4:25 p.m.: hydromorphone 0.5 mg IV Push [given fast through an IV line] AND fentanyl 25 mcg IV Push." There was no documented physician's order for the two narcotic medications to be administered at the same time.</p> <p>B. "4:35 p.m. and 4:37 p.m.: fentanyl 25 mcg IV Push." Fentanyl was administered one minute too early for consecutive administrations.</p> <p>C. "4:37 p.m. and 4:38 p.m.: fentanyl 25 mcg IV Push." Fentanyl was administered two minutes too early for consecutive administrations.</p> <p>D. "4:40 p.m.: hydromorphone 0.5 mg IV Push AND fentanyl 25 mcg IV Push." There was no documented physician's order for the two narcotic medications to be administered at the same time.</p>		<p>The policy on management of post-operative patients was revised to include more frequent monitoring of patients during the first 24 hours post-op. For post-operative patients, monitoring includes:</p> <ul style="list-style-type: none"> vital signs (temperature, blood pressure, pulse, respiratory rate, oxygen saturation, and pain level) are obtained and document: i. On arrival ii. 15 minutes after arrival iii. 45 minutes after arrival iv. Every 1 hour x 3 hours, then v. Every 4 hours x 24 hours, then vi. Every 4-8 hours, per unit standard, with every change in status, or per physician (MD) order <p>The policy was revised and education was provided by the Clinical Nurse Specialist for Acute Surgical Services and the Manager of Acute Surgical Services.</p> <p>The policy was submitted for approval in October, 2106</p> <p>Education was provided in October, 2016.</p>	October, 2016

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	<p>E. "4:55 p.m. and 4:56 p.m.: fentanyl 25 mcg IV Push." Fentanyl was administered two minutes too early for consecutive administrations.</p> <p>Review of the hospital's Policy and Procedure titled, "Medication Management" dated 1/28/16 indicated: A. "Administration of Medications: 70. Use all of the components of the eight rights for every medication administered. a. Right Patient, b. Right Medication, c. Right Dose, d. Right Route, e. Right Time, f. Right Documentation, g. Right Reason, h. Right Response".</p> <p>In an interview with the PACU Director on 10/10/16, at 2:30 p.m., the PACU Director confirmed RN 1 did not follow physician's orders regarding the time interval between fentanyl administrations and acknowledged fentanyl and hydromorphone should not have been administered together.</p> <p>In an interview with the Pharmacy Director (PD) at the facility on 10/13/16 at 2 p.m., the PD acknowledged fentanyl and hydromorphone should not have been administered at the same time and confirmed fentanyl had been administered too early for consecutive administrations.</p> <p>2. Notification of Physician of Inability to Control Pain On October 5, 2016 a review of the medical record for Patient 1, indicated there was no documented evidence RN 1 notified the surgeon of an inability to relieve pain with the prescribed narcotic medication</p>		<p>For post-operative patients, centralized monitoring of continuous pulse oximetry is provided for at least six hours after arrival from PACU.</p> <p>The policy was revised and education was provided by the Clinical Nurse Specialist for Acute Surgical Services and the Manager of Acute Surgical Services in October, 2016.</p>	October, 2016

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	<p>in the immediate post-operative period in the PACU.</p> <p>A review of the electronic medical record (EMR) on October 5, 2016 found that a total of 225 mcg of IV fentanyl and 5.5 mg of IV hydromorphone were administered over one hour and 11 minutes to a 74 year old patient with no history of narcotic use. There was no documented evidence of ongoing pain assessments to determine the level of pain or the effectiveness of the opioid pain medication administered.</p> <p>In an interview with RN 1 in the PACU on 10/4/16, at 3:20 p.m., RN 1 stated Patient 1 was in severe pain, rated 8/10, and described her respiratory status as "Lamaze breathing" or "hyperventilating" and thought her pain was anxiety related. RN 1 stated the amount of pain medication used for any patient was dependent on the patient's tolerance to pain and past history of narcotic use. RN 1 stated she administered a total of 5 mg of hydromorphone in 0.5 mg increments and 200 mcg of fentanyl in 25 mcg increments to Patient 1 during her stay in PACU prior to transfer to ASU.</p> <p>In an interview with RN 4 on 10/10/16, at 2 p.m., RN 4 stated she relieved RN 1 for a break around 5:10 p.m. and described Patient 1's respiratory status as "lamaze breathing". RN 4 stated she waited for 10 minutes then medicated Patient 1. RN 4 stated Patient 1 continued to moan in pain and lamaze breathe. RN 4 stated she discussed the amount of pain medication Patient 1 had received with RN 1, and they had agreed together that no more pain medication would be given prior to transfer. RN 4</p>			

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	<p>stated she left to take a break. There was no documented evidence RN 4 contacted the physician regarding the amount of pain medication Patient 1 had received or the "lamaze breathing" respiratory status.</p> <p>In an interview with a PACU RN (RN 3) on 10/13/16, at 12:25 p.m., RN 3 stated if a patient did not obtain pain relief with multiple doses of narcotics, she would notify the physician and stated physicians were immediately available to nursing staff if there were any issues with inadequate pain control.</p> <p>In an interview with the PACU Director on 10/10/16, at 2:30 p.m., he stated if pain medication did not relieve Patient 1's pain, RN 1 should have notified the physician so he could re-evaluate other pain control measures available.</p> <p>In an interview with the Director of Quality Management (DQM) on 10/10/16, at 10:30 a.m., the DQM confirmed RN 1 did not notify the physician of Patient 1's "Lamaze breathing", unrelieved pain or the increased use of narcotic medication. The DQM stated RN 1 did not notify the physician of her assessment of "anxiety" rather than pain.</p> <p>3. Failure to Assess Patient's Vital Signs Review of RN 4's nursing note dated 9/28/16 at 5:30 p.m. indicated, "Oxygenation: needs [oxygen] to maintain [oxygen saturations greater than] 90%".</p> <p>A review of the EMR found that the last documented vital signs in the PACU 9/28/16 at 5:45 p.m. were: 8/P (blood pressure) 109/41; HR (heart rate) 62; RR</p>			

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	<p>(respiratory rate) 15; O2 Sats (oxygen saturations, normal 92-100%) 99% on room air.</p> <p>Patient 1 was transferred and admitted to the ASU on 9/28/16, at 6 p.m., during shift a change.</p> <p>The Certified Nursing Assistant 1 (CNA 1) obtained vital signs on 9/28/16 at 6:20 p.m.</p> <p>A review of the medical record showed the 9/28/16, 6:20 p.m. vital signs were documented as follows: B/P 144/64; HR 61; RR 19; O2 Sats 91% on room air.</p> <p>In an interview with CNA 1 on 10/10/16, at 1:40 p.m., CNA 1 stated after taking Patient 1's vital signs, RN 2 entered the room, to quickly check on Patient 1, since she was in the process of discharging another patient. CNA 1 stated she showed RN 2 Patient 1's vital signs and RN 2 responded they "Looked perfect". CNA 1 documented the vital signs in the EMR for RN 2.</p> <p>In an interview with RN 2 on 10/10/16, at 10:15 a.m., RN 2 stated when she entered Patient 1's room, CNA 1 was in the process of obtaining vital signs. RN 2 left the room to obtain IV fluid, equipment and order Stat (immediate) labs. The phlebotomist arrived at 6:32 p.m. to draw lab work at the same time RN 2 stated she hung IV fluids. RN 2 stated she was not aware of any abnormal values regarding Patient 1's B/P or O2 Sats. RN 2 stated if she had known of Patient 1's increased B/P and decreased O2 Sats, she would have given Patient 1 oxygen and an incentive spirometer (a device used to help</p>			

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	<p>patients deep breathe). RN 2 described Patient 1 as being "drowsy and nodding off during conversations", requested the overhead light be turned off and the window shades drawn. RN 2 stated she was not informed during transfer report by RN 1 the last time, dosage or amount of narcotic medication that had been administered to Patient 1 while in the PACU. RN 2 did not acknowledge she said the vital signs were "perfect".</p> <p>Review of the hospital's Policy and Procedure titled, "Patient Assessment/Reassessment and Care Planning", dated 6/23/16, indicated: "Attachment A: Adult Admission History Form... This baseline assessment will be started upon arrival to the unit and completed within 12 hours. A list of medications the patient is taking is documented by the RN immediately upon arrival, these include medication details and compliance. If home medications are documented by the pre admission nurse, the compliance, including last dose must be updated at time of patient's arrival... Last Charted Values ... The last charted values must be verified for accuracy by the clinician before signing the chart and/or changed to reflect the correct assessment."</p> <p>Included in the manufacturer warnings and precautions for hydromorphone were the following: 1. Serious, life-threatening respiratory depression has been reported with the use of opioids, even when used as recommended. Monitor patients closely for respiratory depression, especially within the first 24-72 hours of initiating therapy 2. Profound sedation, respiratory depression, coma,</p>			

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	<p>and death may result from the concomitant use (to use at the same time) with other central nervous system (CNS) depressants. Because of these risks, reserve concomitant prescribing of this drug as for use in patients for whom alternative treatment options are inadequate. Because of similar pharmacological properties, it is reasonable to expect similar risk with the concomitant use of other CNS depressant drugs with opioid analgesics.</p> <p>3. Due to additive pharmacologic effect, the concomitant use of CNS depressants including alcohol, an increase the risk of hypotension, respiratory depression profound sedation, coma, and death; and</p> <p>Included in the manufacturer warnings and precautions for fentanyl were the following:</p> <ol style="list-style-type: none"> 1. Serious, life-threatening respiratory depression has been reported with the use of opioids, even when used as recommended. 2. Profound sedation, respiratory depression, coma, and death may result from the concomitant use with other CNS depressants. 3. As postoperative analgesia, concomitant use of fentanyl can increase the risk of hypotension, respiratory depression, profound sedation, coma, and death. <p>Review of nursing progress notes dated 9/28/16, at 7 p.m. revealed, "[7 p.m.] came into the [patient] room with day shift RN to receive report on [patient]. [Patient] found unresponsive. Code blue [emergency due to absent heartbeat or breathing] called and initiated. MD present at the bedside, [Patient] transferred to [intensive care unit]".</p>			

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	<p>Review of RN 2's progress notes dated 9/28/16 at 8:03 p.m., indicated, "Upon bedside report at [6:50 p.m.] patient was unresponsive. Code blue was initiated and code blue team arrived shortly after".</p> <p>Review of the critical care management physician consult dated 9/28/16 at 8:11 p.m. indicated: a. "History of Present Illness: Obstructive Apnea (patient quits breathing while asleep). ... She was recovered in the PACU, there she received 300 mcg of IV fentanyl between (4-5 p.m.) and 5.5 mg of IV [hydromorphone] between [4-5:30 p.m.]"; and b. "Assessment and Plan: unfortunately unknown down time prior to recognition of pulselessness. Received 300 mcg IV fentanyl and 5.5 mg of IV [hydromorphone] within 90-minute window in PACU last charted dose less than 1 hour before last seen normal. Worrisome for possible medication effect with central sedation leading to respiratory arrest and subsequent code blue. Outpatient medication list does not reveal significant chronic opioid use".</p> <p>In an interview with the PACU Director on 10/10/16, at 2:30 p.m., the PACU Director confirmed RN 1 did not follow physician's orders regarding the time interval between fentanyl administration and acknowledged fentanyl and hydromorphone should not have been administered together.</p> <p>In an interview with the Pharmacy Director (PD) on 10/13/16 at 2 p.m., the PD acknowledged fentanyl and hydromorphone should not have been administered together and confirmed fentanyl had</p>			

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3/28/2018

10:24:30AM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050017	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/20/2016
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NAME OF PROVIDER OR SUPPLIER Mercy General Hospital	STREET ADDRESS, CITY, STATE, ZIP CODE 4001 J Street, Sacramento, CA 95819-3626 SACRAMENTO COUNTY
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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>been administered too early for consecutive administrations.</p> <p>Review of the hospital's Policy and Procedure titled, "Medication Management" dated 1/28/16 had no guidance for the administration of narcotic medication in the PACU when the physician ordered "first choice and second choice" pain medication.</p> <p>The PACU Director stated the use of first and second choice narcotic pain medication was an "individual nursing decision" and staff relied on "previous practice experience" to decide whether to administer "first or second line narcotics".</p> <p>In a concurrent observation of the computerized physician computer order entry (CPOE) and interview with Anesthesiologist 1 (A 1) on 10/13/16 at 12:35 p.m., A 1 demonstrated how he could modify the standardized PACU pain medication order set to include specific medication dosage limits and time. A 1 stated the pain medication selected should be dependent on the patient's tolerance to narcotics, age and frailty. A 1 stated the first choice narcotics should be administered first a couple of times, then administer the second choice medication. A 1 stated staff should use common sense and come to A 1 for instructions if the staff were not sure what to do.</p> <p>Review of a diagnostic test of Patient 1's brain dated 10/1/16 at 12:07 p.m. and 10/3/16 at 10:20 a.m. indicated, "Diffuse brain edema [swelling] with anoxic (without oxygen) encephalopathy [abnormal brain function], diffuse anoxic injury and small focal</p>			

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	<p>right acute/subacute infarct [tissue death]...."</p> <p>Patient 1 had artificial life support withdrawn and expired 10/5/16 at 6 p.m.</p> <p>This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.3(g).</p>			

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