California Department of Public Heal

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| KAISER FOUNDATION HOSPITAL OAKLAND/F | 280 W MAC ARTHUR BLVD OAKLAND, CA 94611 MAY 12 2009 |

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| E 000 | Initial Comments<br><br>THIS STATE-2567 HAS BEEN AMENDED TO ADD THE STATEMENT THAT THE EVENT CONSTITUTED IMMEDIATE JEOPARDY TO THE PATIENT AND THE VIOLATIONS CAUSED OR WERE LIKELY TO CAUSE SERIOUS INJURY OR DEATH.<br><br>The following reflects the findings of the California Department of Public Health during an investigation of an entity reported incident.<br><br>Entity reported incident number: CA00176168<br><br>Representing the Department: [redacted]<br><br>The inspection was limited to the specific entity reported incident and does not represent a full inspection of the facility. | E 000 | Kaiser Foundation Hospital Oakland/Richmond presented a corrective action plan related to the entity reported event described herein to the DPH surveyor on January 29, 2009 in order to respond to the surveyor's declaration of immediate jeopardy. Attached in this plan of correction are the actions that the Hospital presented to the surveyor on January 29, 2009 in addition to a status report of where the hospital is with the actions.<br><br>**E264, E475, E483** - As presented in the Statement of Deficiencies, tags E264, E475 and E483 serve as the preamble to the findings and deficiencies as outlined in tag E485. The corrective action plan takes into account all findings cited in E485. | |
| E 264 | T22 DIV5 CH1 ART3-70213(a) Nursing Service Policies and Procedures.<br><br>(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.<br><br>This Statute is not met as evidenced by: | E 264 | | |
| E 475 | T22 DIV5 CH1 ART3-70263(c)(1) Pharmaceutical Service General Requirements<br><br>(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 | E 475 | | |

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| E 475 | Continued From page 1<br>of nursing service or her representative and the administrator or his representative.<br>(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 approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.<br><br>This Statute is not met as evidenced by: | E 475 | **E485 – Pharmaceutical Services General Requirements:**<br><br>**Immediate Actions:**<br>o On January 27, 2009, the Hospital conducted an immediate investigation into the events leading to the medication error.<br>o As a result of the Hospital's independent preliminary review, Nursing and Pharmacy began a more intensive process of reconciling all physician orders against the Medication Administration Record (MAR) for every patient. This was initiated prior to the Department of Public Health visit.<br>o Pharmacy initiated their process at 10 am on January 28, 2009 and completed it by 8 am on January 29, 2009.<br>o As an independent verification, Nursing initiated their process on January 29 at 10:30 am | 1/27/09<br><br>1/28/09<br><br>1/29/09<br><br>1/29/09 |
| E 483 | T22 DIV5 CH1 ART3-70263(g) Pharmaceutical Service General Requirements<br><br>(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 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 | E 483 | | |

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| E 483 | Continued From page 2<br>and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours.<br><br>This Statute is not met as evidenced by: | E 483 | and completed it by midnight of that same day.<br><br>**Temporary Actions:**<br>o Nursing implemented an immediate practice change that required every RN to verify the presence of a valid physician's order prior to administering any medication. This was initiated as an immediate stop-gap measure to ensure the safety of every patient in the hospital. This began at 8:00 pm on January 28, 2009 and continued through January 30, 2009.<br>o This process was put in place as a stop-gap measure until a more permanent, sustainable process could be implemented. The sustainable process is described below.<br><br>**Permanent Actions:**<br>*Nursing and Pharmacy Leadership:* | |
| E 485 | T22 DIV5 CH1 ART3-70263(g)(2) Pharmaceutical Service General Requirements<br><br>(2) Medications and treatments shall be administered as ordered.<br><br>This Statute is not met as evidenced by:<br>Based on observation, interviews and record reviews, the hospital failed to ensure policies and procedures related to the medication distribution and medication administration systems were implemented. Failure by nursing and pharmacy staff to implement policies and procedures specific to: patient identification, screening of medications for accuracy and appropriateness, ensuring a valid physician order for all medications prior to administration, and performing comprehensive patient assessments, resulted in Patient A receiving high blood pressure medicines and other medicines without a physician's order. These errors directly resulted in a heart attack, stroke and deep coma for Patient A.<br><br>THIS EVENT CONSTITUTED AN IMMEDIATE JEOPARDY (IJ), BECAUSE THE HOSPITAL'S FAILURE TO IMPLEMENT WRITTEN POLICIES AND PROCEDURES TO ENSURE SAFE MEDICATION DISTRIBUTION AND ADMINISTRATION RESULTED IN PATIENT A | E 485 | | 1/30/09 |

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| E 485 | Continued From page 3<br>SUFFERING A STROKE, HEART ATTACK AND DEEP COMA. THUS, THE ABOVE VIOLATIONS CAUSED, OR LIKELY TO CAUSE, SERIOUS INJURY OR DEATH TO THE PATIENT.<br><br>Findings:<br><br>Patient A was a 90 year-old brought to the Emergency Department (ED) on 1/25/09 at 2:56 p.m. from home. Patient A's diagnoses included altered mental status, signs and symptoms of dehydration, and no history of high blood pressure. Nursing admission notes showed that the patient had not taken any medications at home prior to admission to the ED. Patient A's vital signs on 1/25/09 at 8:50 p.m. showed a blood pressure of 119/55 (optimal blood pressure is 120/80).<br><br>A review of admission orders dated 1/25/09 showed the only oral medications ordered for Patient A were a vitamin tablet and Tylenol (a mild pain reliever). On 1/25/09, the medication orders were signed by the physician at 7:45 p.m. and scanned from the ED to the pharmacy at 8:35 p.m.<br><br>The hospital policy, "PATIENT IDENTIFICATION", dated 12/06, showed that "Staff is required to verify two sources of patient identification in both the inpatient and outpatient settings" when entering medication orders into the hospital electronic drug distribution system (Pyxis Connect System). Pharmacists were to verify the patient name and medical record number during the critical task of order entry into the Pyxis system.<br><br>In addition, it is the hospital policy and a professional standard (American Society of | E 485 | o Under the sponsorship and oversight of Senior Leadership (including the Hospital Chief Executive Officer and the Chief of Staff), Nursing and Pharmacy leaders collaborated in the enhancement of the existing medication safety program to address the following:<br>o Hospital policies and procedures related to medication administration, including the Medication Administration Record (MAR) verification process, were reviewed for accuracy and appropriateness. The review ensured that policies and procedures are consistent with State and Federal regulations and accrediting standards. The review and revision | |

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| E 485 | Continued From page 4<br><br>Hospital Systems Pharmacies www.ashp.org) for pharmacists to ensure that a drug is appropriate for a patient prior to releasing it for distribution and administration to the patient. The hospital policy, "KP HEALTH CONNECT MEDICATION ADMINISTRATION RECORD" dated 7/23/08 states, "All orders for medications will be screened by pharmacy for accuracy and appropriateness" and the hospital policy, "ORDERING AND TRANSCRIBING MEDICATIONS ELEMENTS OF A COMPLETE ORDER" dated 1/09 states, "Indication for the use of routine medication orders must be available in the patient's medical records..."<br><br>At the time pharmacy staff entered medication orders for Patient A, the above policies were not followed. During an interview on 1/29/09 at 11:00 a.m., Pharmacy Staff 6 said that hospital policies were not followed when medication orders were entered which resulted in Patient A being given medications ordered for Patient B. Pharmacy Staff 6 acknowledged that the medication errors would have probably been avoided if two identifiers had been checked in addition to the appropriateness of the medications for Patient A. She stated that Patient B's medication were not appropriate for Patient A. She said that all the information at the time of order entry to check the appropriateness of the medications was available and had she done so it would have prompted a call to the physician for clarification of the medications ordered for Patient A.<br><br>The hospital allowed medications to be available to Patient A without a valid physician's order. The following medications intended for Patient B were made available in the drug distribution system to Patient A: lisinopril 40 milligrams, amlodipine 10 milligrams, and atenolol 25 milligrams (all blood | E 485 | was completed by February 15, 2009.<br>▪ Two policies – "Medication Administration Record " and "Medication Management Safe Practice" – were revised to reflect the new practice for medication administration as described below.<br>▪ The policies were reviewed and approved by the Pharmacy and Therapeutics Committee on February 18, 2009.<br>▪ The policies were reviewed and approved by the Medical Executive Committee on March 4, 2009<br>o Leadership Development education for all Nursing and Pharmacy leaders | 2/15/09<br><br>2/18/09<br><br>3/4/09 |

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| E 485 | Continued From page 5<br>pressure medications); pantoprazole 40 milligrams (a stomach ulcer medicine); and potassium chloride 10 milliequivalents (an electrolyte).<br><br>A review of the medication administration record (MAR) showed that nursing staff administered to Patient A the medications ordered for Patient B. During an interview on 1/28/09 at 6:08 p.m., Registered Nurse (RN) 2 who cared for Patient A on the telemetry unit, said that the admission MAR for Patient A "got lost". She ordered a second MAR and checked orders against the Pyxis system and not against the physician's orders, as required by hospital policy.<br><br>The hospital policy, "PHYSICIANS ORDERS AND TRANSCRIPTION/NOTIFYING PROCEDURES" dated 11/06 requires nurses to review each order for accuracy and verify that the orders are appropriate for that patient. The policy shows, "A review of each transcribed order for accuracy and verification, and that the orders are appropriate for that patient."<br><br>In addition, the hospital policy, "MEDICATION ADMINISTRATION PROCEDURE" dated 11/06 showed that a physicians order is required before administration of a medication and that nurses shall make appropriate observations to rule out possible contraindications for use of medications. The policy stated, "A physician's order is required before any medication is administered."<br><br>During an interview on 1/28/09 at 6:08 p.m., staff was asked if the medication errors could have been avoided by following the above hospital policies. RN 2 said, "Absolutely" and Nurse Manager 9 said, "Exactly." | E 485 | related to managing the performance of staff and addressing failures to comply with standard policies and procedures was provided. This is intended to create a new patient safety culture. The "Just Culture" training was completed on March 19, 2009.<br>o Frontline managers, KFH leaders and Professional Staff leaders will participate in Kaiser Permanente's "Patient Safety University" program by 3rd quarter of 2009. The program introduces and reinforces patient safety principles and concepts, and then builds upon them to help participants learn and apply specific practical applications that front line leaders can use to create and sustain a culture of patient safety | 3/19/09 |

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| E 485 | Continued From page 6<br><br>During an interview on 1/28/09 at 5:08 p.m., the Pharmacy Director said, "It is hospital policy and a professional standard for pharmacist and nurses to ensure patients are identified and drugs are appropriate for the patient prior to the administration of each medication to the patient." The director said that multiple policy failures were identified which contributed to medication errors for Patient A.<br><br>Review of Patient A's MAR showed that on 1/26/09 at 9:44 a.m., RN 1 administered the following medicines to Patient A: lisinopril 40 milligrams, amlodipine 10 milligrams, pantoprazole 40 milligrams (a medicine to treat stomach ulcers), potassium chloride 10 milliequivalents, and a multivitamin. RN 1 administered medications without a physician order to Patient A. During an interview with RN 1, she said, "The meds matched the MAR. The patient matched the MAR. The patient matched the Pyxis." RN 1 said, "I did not do anything wrong." RN 1 indicated that if RN 2 had compared the MAR to the physician admission orders, the medication errors could have been avoided.<br><br>On 1/29/09 a review of the Rapid Response record dated 1/26/09 at 9:05 p.m., showed vital signs indicating a low blood pressure reading of 66/47 (normal- 120/80), a low heart rate of 47 (normal- 60-100), and a low respiratory rate of 2-3 breaths per minute (normal- 12-20), [LexiComp 2009 online].<br><br>During an interview on 1/29/09 at 11:29 a.m., Physician 3 said that he arrived to Patient A during a Rapid Response on 1/26/09 at 9:05 p.m. The physician said that Patient A was in severe respiratory distress, "breathing 4-6 breaths per | E 485 | at the department/unit level.<br><br>*Pharmacy:*<br>o *Patient Identification:*<br>o Pharmacists were re-educated on the policy that requires them to use two unique, patient specific identifiers (patient name and medical record number) when linking patient medication orders in "Pyxis Connect". This re-education started at 4:00 pm on 1/28/09 and continued until all pharmacists receive the re-education. As Pharmacy staff came into the hospital, they received this education prior to the start of their shift. This was completed on February 28, 2009.<br>o Medication orders that are scanned to the Pharmacy appear on a "Pyxis Connect" | 1/28/09<br><br>2/28/09 |

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| E 485 | Continued From page 7<br>minute" and had a labile (spastically fluctuating) blood pressure. Physician 3 described how Patient A was immediately intubated (a plastic tube inserted into the airway to deliver life sustaining oxygen). Physician 3 said he could not rule out that the blood pressure medications (antihypertensive medications) administered in error caused the severe change in Patient A. He said, "The antihypertensives certainly may have played a role. The medications certainly, we thought, were playing a role."<br><br>On 1/29/09 a review of Patient A's "Progress Note" dated 1/28/09 at 4:10 p.m. and signed by Physician 4 showed, "...patient is dying". A later entry dated 1/28/09 at 9:45 a.m. showed, "Patient has taken a turn for the worse" ... "have not done formal brain death testing" ... and "appears to have had large M.I. (heart attack) and CVA (stroke)." The same note showed, "System error pharmacy for printing incorrect meds on MAR and nurse not double checking MD orders."<br><br>On 1/28/09 at 6:36 p.m., Patient A was observed in the Intensive Care Unit lying still in bed, on a ventilator and receiving intravenous neosynephrine and norepinephrine (life-saving medications used to support blood pressure). In an interview, RN 10 said that Patient A's "...brain was not responding... he's receiving maximum blood pressure support with medicines... the ventilator (breathing machine) is keeping him alive." | E 485 | computer monitor and must be electronically linked to the patient's KP HealthConnect (electronic medical record) profile. Pharmacists are being re-educated to only open one patient's KP HealthConnect profile at any given time. This education began on 1/29/2009. As Pharmacy staff came into the hospital, they received this education prior to the start of their shift. This was completed on February 28, 2009<br>o *Medication Order Review for Clinical Appropriateness and Accuracy:*<br>o A Pharmacist reviews each medication order prior to it being dispensed or made available through Pyxis. It is reviewed for | 1/29/09<br><br>2/28/09 |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | CA14000000188 | A. BUILDING _____ B. WING _____ | C 01/29/2009 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| KAISER FOUNDATION HOSPITAL OAKLAND/F | 280 W MAC ARTHUR BLVD OAKLAND, CA 94611 |

| (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 |
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