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<tr>
<td>E000</td>
<td>Initial Comments</td>
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<td>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. The following reflects the findings of the California Department of Public Health during an investigation of an entity reported incident. Entity reported incident number: CA00176168 The inspection was limited to the specific entity reported incident and does not represent a full inspection of the facility.</td>
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<tr>
<td>E064</td>
<td>Nursing Service Policies and Procedures</td>
<td>(a)</td>
<td>Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. This Statute is not met as evidenced by:</td>
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<td>E475</td>
<td>Pharmaceutical Service General Requirements</td>
<td>(c)</td>
<td>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</td>
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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.

**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.
of nursing service or her representative and the administrator or his representative.
(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.

This Statute is not met as evidenced by:

| E 475 | Continued From page 1 |

| E 475 | E485 – Pharmaceutical Services General Requirements: |

**Immediate Actions:**
- On January 27, 2009, the Hospital conducted an immediate investigation into the events leading to the medication error.

| E 483 | T22 DIV5 CH1 ART3-70263(g) Pharmaceutical Service General Requirements |

| E 483 | (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 |

- 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.
  - Pharmacy initiated their process at 10 am on January 28, 2009 and completed it by 8 am on January 29, 2009.
  - As an independent verification, Nursing initiated their process on January 29 at 10:30 am |
and completed it by midnight of that same day.

### Temporary Actions:
- 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.
- 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.

### Permanent Actions:
**Nursing and Pharmacy Leadership:**
SUFFERING A STROKE, HEART ATTACK AND DEEP COMA. THUS, THE ABOVE VIOLATIONS CAUSED, OR LIKELY TO CAUSE, SERIOUS INJURY OR DEATH TO THE PATIENT.

Findings:

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).

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.

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.

In addition, it is the hospital policy and a professional standard (American Society of...
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."

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.

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, amlopidine 10 milligrams, and atenolol 25 milligrams (all blood

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<td>• Two policies –</td>
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<td>&quot;Medication Administration Record&quot; and &quot;Medication Management Safe Practice&quot; – were revised to reflect the new practice for medication administration as described below.</td>
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<tr>
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<td>• The policies were reviewed and approved by the Pharmacy and Therapeutics Committee on February 18, 2009.</td>
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<td>• The policies were reviewed and approved by the Medical Executive Committee on March 4, 2009</td>
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<td>• Leadership Development education for all Nursing and Pharmacy leaders</td>
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pressure medications); pantoprazole 40 milligrams (a stomach ulcer medicine); and potassium chloride 10 milliequivalents (an electrolyte).

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.

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."

In addition, the hospital policy, "MEDICATION ADMINISTRATION PROCEDURE" dated 11/06 showed that a physician's 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."

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."
Continued From page 6

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.

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, amiodipine 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.

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].

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

at the department/unit level.

Pharmacy:

- **Patient Identification:**
  - 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.

- **Medication orders that are scanned to the Pharmacy appear on a "Pyxis Connect"**
E 485  Continued From page 7
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."

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."

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 nesycynephrine 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."

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

- Medication Order Review for Clinical Appropriateness and Accuracy:
  - A Pharmacist reviews each medication order prior to it being dispensed or made available through Pyxis. It is reviewed for
Continued From page 7

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- To reconfirm their accountability for this, Pharmacists were re-educated on:
  - The process for reviewing all medication orders for clinical appropriateness at order entry. The Pharmacist shall review the patient's medication profile for therapeutic appropriateness to include:
    - Age
    - Weight and height (as appropriate)
    - Diagnoses
    - Allergies
    - Renal function
    - Other medications that the patient is taking
    - Appropriateness of drug, dose, route, frequency, time
Continued From page 7

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- Potential drug interactions, contraindications and incompatibilities
- The intervention process for unclear, inappropriate or ambiguous orders. All such clarifications and interventions must be discussed and verified directly with the prescribing or covering physician.
- This was completed on February 28, 2009

Additional Actions Taken:
- Ongoing annual competencies for Pharmacists will include expectations regarding medication order review for clinical appropriateness and accuracy, the use of two patient identifiers and opening only one patient record at a time.
- New and temporary Pharmacist training and
Continued From page 7

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Nursing:

- **RN Administration of Medications:**
  - The Hospital implemented a more comprehensive medication verification practice for all registered nurses. The verification process specifically matches the physician order against the MAR.
  - Two registered nurses verify all physician medication orders on new admissions and transfers
  - At the change of shift, registered nurses verify all new
**Continued From page 7**

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| E 485 | (generated by Pharmacy) against the existing MAR and against any new valid physician orders initiated in the last 24 hours.

- **RN Medication Administration Enhanced Training:**
  - The Hospital conducted training for all registered nurses (approximately 1400) that included:
    - The Med-Rite Program (a patient safety program that limits distractions and reduces variation in medication administration practices) that included a review of the "five rights".
    - Clinical appropriateness and assessment
    - Nurse Knowledge Exchange integration (the communication
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• Medication administration policies and procedures, performance expectations, and consequences of failure to comply.  
• Training included individual nurse medication pass observations by a qualified Nurse and/or Pharmacist for all registered nurses.  
• Training was completed by March 31, 2009.  
• For any RNs who are out on a leave of absence, training will be conducted prior to the RNs being permitted to independently
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administer medications.

- Other Actions:
  - To enhance the ability for RNs to administer medications in a safe environment, additional Pyxis units have been added to the nursing units and have been removed from most corridor locations and placed in secured rooms. This reduces interruptions and distractions thus enabling the RN to prepare medications for administration in a focused, uninterrupted manner.
  - During the 2009 annual competency review, medication administration policy and procedure review will be conducted accompanied by one-to-one med pass observations of clinical nurse competency for
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<th>(X5) COMPLETE DATE</th>
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<td><em>all registered nurses who administer medications.</em></td>
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**Accountable Parties:** Chief Nursing Officer and Inpatient Pharmacy Directors
### Monitoring:

**Pharmacy:**
- MAR audits of all admission orders are conducted by a second pharmacist to ensure accuracy of the patient, drug, dose, route, frequency and clinical appropriateness.
  - If any issues are identified during the audit, staff will be immediately educated.
  - The audit will continue for two weeks of sustained compliance at a 90 percent accuracy threshold for an appropriate order. After two weeks of sustained compliance, auditing is done on a representative sample of orders for two consecutive months of sustained compliance.
  - The results of the monitoring are reported to the Pharmacy and Therapeutics Division.
Continued From page 7

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Committee and the Medical Executive Committee.

- These Committees can require additional actions and/or monitoring as auditing results indicate.
- Pharmacy does direct observations of pharmacists while linking orders to ensure that two patient identifiers are used and that only one patient's profile is displayed at a time.
  - If any issues are identified during the audit, staff will be immediately educated.
  - The audit will continue until all Pharmacists have been observed at least once and are compliant.
- The results of the monitoring are reported to the Pharmacy and Therapeutics Committee and the Medical Executive Committee.
Continued From page 7

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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."

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 nesynephine 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."

These Committees can require additional actions and/or monitoring as auditing results indicate.

Nursing:

- Nursing and/or Pharmacy use the Med-Rite audit tool to evaluate and monitor medication passes. Every registered nurse (approximately 1400 nurses) who administers medication will be monitored through direct observation of the medication pass.
- If any issues are identified during the audit, staff will be immediately educated.
- The audit continues until all nurses have been observed.
- The results of the monitoring are reported to the Pharmacy and Therapeutics Committee and the
E 485 Continued From page 7

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