The following reflects the findings of the Department of Public Health during the investigation of COMPLAINT NO: CA00150933

Inspection was limited to the specific complaint(s) investigated and does not represent the findings of a full inspection of the facility.

Representing the Department of Public Health:

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY

T22 DIV5 CH1 ART 2 70283(g)(2) 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 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.

The plan of correction is prepared in compliance with federal regulations and is intended as Fountain Valley Regional Hospital and Medical Center's credible evidence of compliance. The submission of the plan of correction is not an admission by the facility that it agrees that the citations are correct or that it violated the law.

Fountain Valley Regional Hospital and Medical Center is formally requesting an informal conference with the district administrator/district manager of the California Department of Public Health.

Organization Minutes:
The confidential and privileged minutes are being retained at the facility for agency review and verification upon request.

Exhibit:
All exhibits, including revisions to Material Staff Bylaws, reviewed/revised or promulgated policies and procedures, documentation of staff and medical staff training/education are retained at the facility for agency review and verification upon request.

Policy and Procedures:
The Director of Pharmacy reviewed and revised the Medication Administration Policy PSM 5.3 to state that where the physician has provided medication administration the pharmacist will consult with the nurse to determine the most appropriate route of medication administration for that patient. The Pharmacist will print the Medication Administration Record (MAR) reflecting only one route of administration but will note that another route is available upon consultation with the pharmacist.

June 15, 2008
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hours.

(2) Medications and treatments shall be administered as ordered.

The above regulation was NOT MET as evidenced by:

Based on record review, observation and interview, the hospital staff administered Dilantin (anti-seizure medication) oral suspension intravenously to Patient A. Patient A sustained a cardiopulmonary arrest after administration of the Dilantin Oral Suspension. Patient A was administered the Dilantin medication twice by different routes: both via a G-tube and intravenously. The medication errors resulted in the patient becoming obtunded after suffering hypoxic encephalopathy (brain swelling from low blood oxygen levels) following the cardiac arrest.

Findings:

On 5/13/08, the hospital reported a medication administration adverse event. The report revealed on 5/18, a RN (registered nurse) administered an oral suspension medication intravenously. Patient A then sustained a cardiopulmonary arrest and became poorly responsive after the cardiopulmonary arrest.

On 5/28/08, Patient A’s medical record was reviewed. Patient A had a history of seizure disorder, which was well controlled by the oral medication Dilantin. Patient A was admitted on

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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting provided it is determined that other safeguards provide sufficient protection to the patient. Except for nursing homes, the findings above are disposable 30 days following the date of survey weather or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disposable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is required to continued program participation.
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4/18/08 for abdominal pain. On 4/19/08, a physician order was written for Dilantin 100 mg to be given intravenously (IV) or by gastric tube (GT) every eight hours. Patient A had two gastric surgeries on 4/18, and 4/24/08. The postoperative orders included Patient A to have nothing by mouth (NPO) and for the NG tube to be connected to continuous low-pressure suction. TPN (total parenteral nutrition) was infusing in the right upper arm via a PICC line (A peripherally inserted central catheter).

On 5/1/08, the Attending Physician's and Consultant’s Progress Notes indicated Patient A was doing well after surgery. The treatment plan was for Patient A to start clear liquids by mouth and to discontinue the NG tube. On 5/1/08, the nurse assessed Patient A in the morning and documented Patient A was confused forgetful, did not have pain, and asked the nurse to contact his family and to have some ice chips. Patient A was weak but had a full range of motion in the extremities and was cooperative with care. The NG was connected to suction and the TPN was running via the right arm PICC line.

A printed Medication Administration Record (MAR) for the administration period from 5/1/08 at 0700 hours through 5/2/08 at 0659 hours, listed Dilantin 100mg/4ml oral suspension by GT every eight hours. On the bottom of the MAR, there was a statement, "IV or GT, do not give both." Another page of the MAR showed "Dilantin 100 mg / two (2) ml IV every 8 hours, infuse through 0.2-micron filter for IVPB." The bottom line showed "IV or GT do

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<tr>
<th>Responsible Person(s):</th>
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<tr>
<td>Chief Nursing Officer</td>
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<td>Director of Pharmacy</td>
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<th>Additional Corrective Actions:</th>
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| The Chief Nursing Officer identified the nurse involved in this case as a registry nurse. The hospital received a copy of the Registry RN’s competencies, required training, and licensure prior to acceptance by the hospital of the assignment of this nurse. The nurse indicated in these documents that she had frequent experience with the administration of Dilantin. All orientation at the facility was completed as required. As a result of this event the Staffing Office Coordinator designated the registry nurse as "Do Not Return", and the Chief Nursing Officer reported the details of this event to California Board of Registered Nurses.
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not give both.

A pharmacy record showed on 5/1/08 at 1728 hours, a registered nurse removed a Dilantin 100mg/4 ml oral suspension syringe from the Pyxis (an automatic medication dispensing device). At 1735 hours, the nurse initiated the MAR on the "GT" order and administered the medication; the nurse documented on the Patient Care flowsheet at 1740 hours, Patient A complained the lights were hurting his eyes after he received Dilantin. The family was at the bedside.

The hospital investigation, revealed on the CPR (cardiopulmonary resuscitation) Record, the educator nurse asked the nurse for the medication she gave to the patient. The nurse stated she administered Dilantin IV, but she did not have the medication syringes any more. The nurse could not recall how many or what kind of syringe(s) she was using. During interview, the nurse stated on the MAR, there were two printed orders for administering Dilantin. She interpreted the orders to mean the Dilantin was to be given by two different routes, GT and IV. The MAR showed Patient A had two Dilantin orders for 1400 hours. She gave Patient A the Dilantin IVPB at 1400 hours. The patient refused the oral Dilantin. She rechecked the patient at 1720 hours, and administered another Dilantin intravenously. She recalled Patient A was complaining of his arm burning and eyes hurting after medication. She went out of the room and reported it to the charge nurse. When she went back to the patient's room, Patient A was unresponsive. Cardiopulmonary resuscitation was...
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A CPR Record documented on 5/1/08 at 1749 hours, the code blue team arrived, and Patient A was unconscious. The ECG (electrocardiogram) showed the patient had no heart beat and was pulseless. Patient A was intubated (a tube inserted to assist with breathing), shocked for cardioversion and was injected with multiple medications to resuscitate him. The code blue was stopped at 1826 hours, and Patient A was transferred to the intensive care unit for ventilator management and further medical care.

The Physician's Progress Notes on 5/2/08, documented Patient A was poorly responsive, on the ventilator, had a fever and hypoxic encephalopathy. The plan of care was continued ventilator support.

On 5/28/08 at 1115 hours, during an interview, the Manager of Quality Resource stated in her interview with the licensed nurse 5/8/08, the nurse admitted she administered the Dilantin oral suspension intravenously. The nurse could not recall the detail of the administration process, but once she noted the patient developed discomfort after receiving the medication, she reported it.

On 5/28/08 at 1645 hours, during a pharmacy tour with the hospital pharmacist and the Manager of Quality Resource Management, a Dilantin oral suspension syringe was observed. It was orange in color.
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The manufacturer’s reference showed Dilantin oral suspension was 100 mg/4ml in an orange suspension, with an orange-vanilla flavor, with an alcohol content of 0.35 percent. It was supplied in an oral syringe.

On 5/28/08 at 0920 hours, interview with the patient’s family revealed on 5/1/08 the registered nurse went into the room at approximately 1735 hours, with two syringes in her hand. One syringe was an orange color and the other was clear. The nurse first pushed the orange colored medication into the IV. Patient A started to complain of his arm burning. The nurse stopped, switched to the clear syringe and then went back to the orange medication. She pushed in all of the orange medication. A couple of minutes later Patient A told the family he felt he was having a seizure attack and became unresponsive. His heart stopped and the emergency team came.

On 5/28/08 review of the hospital P&P titled Medication Administration revealed the policy stated the healthcare provider needed to perform a verification that the medication selected for administration was correct, based on the medication order and product label.

The violation(s) has caused or is likely to cause, serious injury or death to the patient(s).