The following reflects the findings of the California Department of Public Health during the FULL VALIDATION SURVEY conducted from 6/4/07 to 6/8/07.

Representing the Department:

1280.1(a) HSC Section 1280
If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Sections 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars ($25,000) per violation.

1280.1 (c) HSC Section 1280
For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY

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

E 4751 T22 DIV5 CH1 ART3-70263(c)(1)

Pharmaceutical Service General Requirements

(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.

The above regulations are not met as evidenced by:

Based on observations, interview and review of policies and procedures the Pharmacy and Therapeutics Committee failed to have written policies and procedures for the establishment of a safe and effective systems for the distribution, dispensing and use of drugs and biologicals for patient use. The committee failed to develop written policies and procedures:

1. To ensure staff could accurately and quickly calculate a dose of emergency medications used in pediatric emergencies. One medication,
sodium bicarbonate that was available in the crash cart in two different strengths. When asked to demonstrate the use of the facility's pediatric emergency supply, three of three staff were not able to correctly determine the dose of sodium bicarbonate. (Staff 103, 104 and 106)

2. That clearly directed staff when to use pediatric dosage forms in the cart and when to use adult dosage forms.

3. To prepare non-hazardous IV solutions in a separate hood from the hood used for hazardous compounds (cancer chemotherapeutic IV solutions as stipulated by standards of practice promulgated by the American Society for Health System Pharmacists.

These deficient practice presented an immediate threat to the health and safety of all patients treated by the facility. On 6/07/07 at 6:15 p.m., administrative staff were informed that Immediate Jeopardy existed in the area of pharmacy services.

Findings:

1. Inspection of the Unit 100/200 Crash Cart on 6/06/07 at the Hanford campus revealed it contained a Broselow Tape. This tape was color coded and is used to rapidly estimate the weight of a child by measuring the height of the child with the tape. The tape provides recommended doses for several medications based on the estimated weight classes, which are color coded on the tape. During an interview of Staff 100 on 6/06/07, he stated that the Broselow Tape was used for pediatric patients and that the hospital considered patients who were 13 years of age and younger to be pediatric patients.
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Further inspection revealed that a box containing medications used to manage heart and lung medical emergencies was placed on top of a movable red tool box that contained medical devices, and IV solutions that were used to manage emergency situations in the hospital. The medication box was sealed with a breakable plastic seal. Inspection of the contents of the medication box revealed that it contained a smaller box that also was sealed with a breakable plastic seal. A label on this smaller box identified it as containing pediatric medications. Inspection of the pediatric box revealed that it contained two 10 milliliter (ml) pre-filled syringes (PFS's) of 4.2% sodium bicarbonate with 0.5 milliequivalents/ml (mEq/ml) of solution for injection (labeled "Infant" on the front of the box. The box contained the PFS (which are used to lower acid levels in the blood), one 10 ml PFS of dextrose "Pediatric" 25% with 2.5 grams (gm)110 ml (used to raise blood sugar levels in the blood) two 5 ml PFS's of atropine, 0.1 milligrams (mg)110 ml for injection (used to increase the heart rate) . and two 5 ml PFS's of lidocaine 1% with 10 mg/ml for injection (used to treat abnormal heart rhythms).

The larger medication box also contained these drugs but the volumes and/or concentrations were greater. The larger box contained two 50 ml PFS's of sodium bicarbonate 8.4% with 1 ml Eq/ml for injection which was twice as concentrated and five times the volume of the "Infant" sodium bicarbonate in the pediatric box, one 50 ml PFS of dextrose 50% with 25 gm/50 ml which was twice as concentrated and five times the volume of the dextrose PFS in the pediatric box, two 10 ml PFS's of lidocaine 20% with 20 mg/ml for injection which was twice the concentration of the lidocaine in the pediatric box), and two 10 ml syringes of atropine.
0.1 mg/ml for injection which was twice the volume but the same concentration as the atropine in the pediatric box.

The pediatric box contained a dosing table placed on top of the pediatric medications that was color coded to the weight classes found on the Broselow Tape. It provided dosage guidelines for the atropine, sodium bicarbonate, and the lidocaine for injection found in the pediatric medication box. On 6/07/07, at 9:22 a.m. Staff 101 was interviewed in the pharmacy. She said that the medication boxes on top of the crash carts were called "Code Boxes" and all were stocked identically including the pediatric boxes found inside the code boxes. She stated that the dosing tables in the pediatric boxes were coded to the Broselow Tape and were added as a guideline to help nurses avoid dosing errors and that the Code Blue Committee as well as the Pharmacy and Therapeutics Committee had approved these dosing guidelines four to five years ago. She stated that the pediatric medication box had been created in 1996 or 1997. She stated that the same system was used at the Selma campus (a second hospital that appeared on the hospital license and therefore was considered to part of the Hanford Hospital Validation Survey) and that the policies and procedures regarding the crash carts were the same for both hospitals.

On 6/07/07, Staff 102 was interviewed. She stated that there were nine crash carts on the Hanford Campus and one crash cart at the Kerr Outpatient Center (associated with and part of the Hanford Hospital system).

On 6/06/07, at 3:22 p.m. Staff 103 was asked to calculate a dose of sodium bicarbonate using the Broselow tape as a dosing guide and the drugs...
found in the medication box on top of the Unit 100/200 crash cart including the pediatric box. The weight of the hypothetical child was 30 to 36 kilograms (kg) which corresponded to the largest weight class documented on the Broselow Tape. She used the pediatric dosing guidelines and stated she would give 33 mJ of the 4.2% sodium bicarbonate. The correct answer would have been 66 ml of 4.2% sodium bicarbonate (0.5 mEq/mJ times 66 ml equals 33 mEq).

On June 6, 2007, at 3:42 p.m., Staff 104 was asked to calculate a dose of sodium bicarbonate for a hypothetical pediatric patient as described above. At first she used the dosing table and said that she would give 33 ml of the 4.2% sodium bicarbonate and then noted she only had 20 ml of the 4.2% sodium bicarbonate in the pediatric box. She then calculated the dose on a piece of paper and concluded that she would give 6.6 ml of the 4.2% sodium bicarbonate to deliver the 33 mEq of sodium bicarbonate that the Broselow Tape documented should be administered to a 30 to 36 kg child if called for by the clinical situation at hand.

On 6/07/07, at 1:54 p.m. Staff 106 was interviewed in the E.D. on the Selma campus and was asked to dose sodium bicarbonate for a hypothetical pediatric patient as described above. She picked up the 4.2% sodium bicarbonate and then calculated a dose. She stated that she would give 66 ml but changed her answer to 6.6 ml. She looked at the box and said the PFS contained 50 mEq of sodium bicarbonate then changed her mind and stated it contained 5 mEq of sodium bicarbonate. Then she stated that she did not work well under pressure. Finally, she stated that she needed to terminate the interview.
On 6/06/07, at 4:45 p.m. review of the policy and procedure entitled Code Blue revealed that it made no mention of the use of either the Pediatric Advanced Life Support (PALS: provides guidelines for the selection and dosing of drugs for specified medical emergencies) or the Broselow tape and it did not provide staff with any guidelines as to when one would use the pediatric drug box and when one would use the adult medication supply in the medication box.

At this time a list was requested of every pediatric patient that had been admitted to either the Hanford or the Selma Hospital campus in the last year. Review of these lists on 6/07/07. at 7:43 a.m. revealed that 21 pediatric patients between the ages of 4 years 1 month and 13 years and 11 months had been admitted to the Hanford campus between June 2006 through May 2007 and that 19 pediatric patients between the ages of 1 year 1 month and 12 years 7 months had been admitted to the Selma campus during the same period of time. These numbers of patients did not include pediatric patients who had been seen in the emergency departments of the two campuses during that time period, but had not been admitted to the hospitals.

2. On 6/06/07, at 9:14 a.m. inspection of the pharmacy revealed that it contained one hood used to compound IV solutions in a clean environment by filtering the air through a high efficiency particulate air (HEPA) filter. It was Class II Biological Safety Cabinet (BSC) vertical flow hood (the filtered air flowed from the vented ceiling of the hood down onto the work area inside the hood and out vents in front and in the back of the hood). These cabinets are used by staff members who work with chemotherapeutic drugs used to treat various types of cancers to protect them and the surrounding environment from exposure to these substances.
Chemotherapeutic drugs are considered to be hazardous drugs. The ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs documents under "Goal U" "The preparation of hazardous drugs does not result in contamination of the health-care work environment or excessive exposure of personnel, patients, or family members to hazardous drug powders, dusts, liquids, or mists." Section 5(h) under this goal documents: "Because of its design and decontamination limitations, the BSC should be considered a contaminated environment and treated as such. The use of the SSC should be restricted to the preparation of sterile dosage forms of hazardous drugs." Therefore, this hood should not be used to compound standard (non-hazardous) IV solutions. Administrative Staff 101 stated during an interview at this time that both chemotherapeutic and non-chemotherapeutic IV solutions were compounded in the SSC.

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