A 000 INITIAL COMMENTS

The following represents the findings of the California Department of Public Health during a Federal Complaint Validation Survey.

Federal Complaint #: 455011

The facility was comprised of two campuses, Hospital A and Hospital B. Hospital A was the main campus.

Representing the California Department of Public Health:

21053, District Administrator
22930, HFES
21899, HFES
29499, HFEN
29626, LSC
29359, Pharmaceutical Consultant II
27194, Pharmaceutical Consultant.

The census on the day of entry was 167.

Findings in this document may predate authorization by CMS to conduct a survey for compliance with Conditions of Participation for Governing Body, QAPI, Infection Control, and Pharmaceutical Services, as the hospital was being surveyed under State Authority beginning on 8/17/15.

A 043 482.12 GOVERNING BODY

There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the

A 043 The Facility's Governing Body is responsible for the conduct of the Hospital. The Administrator, a member of the Governing Board, met with the entire

Continued on Page 2
A 043 Continued From page 1
functions specified in this part that pertain to the
governing body...

This CONDITION is not as evidenced by:
Based on interview and record review, the
hospital did not have an effective governing body
that carried out the functions required by a
governing body when:

1. The Hospital failed to ensure that an effective
quality assessment and performance
improvement program (QAPI) was implemented
when the hospital failed to ensure monitoring of the sterile (germ free) intravenous (IV, directly
into a vein) compounding (mixing) program to
identify competency issues in the pharmacy IV
compounding area. The pharmacy identified that
eight technicians failed an initial gloved fingertip
competency test. The hospital did not analyze the
test data and create a corrective action. The eight
technicians continued to compound IVs. These
failures resulted in the potential, from 1/1/15 to
8/18/15, for 7,301 patients to be exposed to
preventable infections from 4,322 contaminated
IV medications (A 273 #1)

2. The hospital failed to ensure the intravenous
(IV, directly into a vein) sterile (germ free)
compounding (mixing) area was free of dust,
stains, and foreign (black & brown) material.
Dust, stains, and foreign material, were present
on surfaces in the ante (area to prepare for
mixing IVs) and buffer (area for mixing IVs)
rooms. These failures resulted in the potential,
from 1/1/15 to 8/18/15, for 7,301 patients to be
exposed to preventable infections from 4,322
contaminated medications. (A 501 #2)

3. The hospital failed to ensure an air pressure
gauge was installed between the buffer (area to

Leadership Team to discuss Code of
Conduct and leader expectations and
responsibilities. As department leaders,
each one must comply with the hospital's
Policies and Procedures, the State
Regulations, and National Standards.
Leaders are primarily responsible for the
compliance of their departments.

A 043 Item 1

a) The Pharmacy director was re-
educated on the Performance
Improvement program the process of
Plan, Do, Check, Act as the structure of the
continuous Performance
Improvement to ensure that outcomes
are assessed and analyzed to increase
quality and ensure continuous
improvement. Findings must be reported
and discussed with P&T & Infection
Control Committee and Performance
Improvement Committee to assist in
resolving or rectifying the identified
issue. USP <797> standards were
reviewed with the pharmacist in charge.
Fingertip glove testing must be
completed for technicians or staff
performing IV compounding.

b&c) The Pharmacy Technicians were all
re-educated in the appropriate way of
donning sterile glove to maintain
sterility. A competency check will be
completed and validated by another

Continued on Page 3
A 043 Continued From page 2

mix sterile (germ free) intravenous (IV, directly into a vein) medications and the ante-area (area to prepare for mixing IVs). The hospital did not install an air pressure gauge to monitor the pressure differential (difference) between the buffer and the ante-area. This failure resulted in the potential, from 1/1/15 to 8/18/15, for 7,301 patients to be exposed to preventable infections from 4,322 contaminated medications. (A 501 #3)

4. The hospital failed to ensure air pressure differentials (differences) between the buffer room (area to mix sterile (germ free) intravenous (IV, directly into a vein), ante-room (area to prepare to mix IVs), and general pharmacy, were documented on a log at least every work shift. The hospital did not maintain a log of air pressure differentials between the buffer room, ante-room, and general pharmacy. These failures resulted in the potential, from 1/1/15 to 8/18/15, for 7,301 patients to be exposed to preventable infections from 4,322 contaminated medications. (A 501 #4)

5. Duplicate or incomplete medication orders, which had the potential to result in increased variability and risk of harm to patients from a medication error or adverse reaction, were not clarified by nurses. (A 405 #s 1, 2, 3)

6. The hospital failed to ensure medication orders with the same pain scale were reviewed for therapeutic duplication. This failure had the potential to place the patient at risk for overdose on narcotic pain medications. (A 500)

7. The hospital failed to ensure safe and proper use of a single dose medication vial. This failure

A 043 Continued from Page 2

A 043 Item 1 Continued

fingertip glove testing. For new hires, fingertip testing will be completed within 90 days of hire then annually thereafter. A process was created for future similar issues: the TPN and Medium Risk IV compounding will be outsourced until technicians responsible for compounding has met the standards. Existing contract through Corporate with CAPs will be utilized for outsourced compounded IV medications, who meets standards, will also be able to assist on an emergency basis.

d) Monitoring
Pharmacy Technicians responsible for maintaining sterility of gloves when preparing to compound medications is monitored: (a) New hire: training will be given during initial hire and 90 days after hire; competency validation will be completed through "fingertip glove" test which will be performed after initial competency check or within 90 days of hire then annually; (b) For current employees: initial competency re-education and competency validation will be completed through "fingertip glove" test. Will continue to comply and monitor results of: Microbial Analysis by Environmental Purity and Sterility Test by and the End-Product Sterility Test for potential contamination. A Root Cause Analysis

Continued on Page 4