STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050024	A. BUILDING _____ B. WING _____	08/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PARADISE VALLEY HOSPITAL	2400 EAST 4TH ST NATIONAL CITY, CA 91950

(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) COMPLETION DATE
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 000		
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	**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	

OCT - 6 2015

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Gemma Rama-Banaag | TITLE: CNO | (X6) DATE: OCT 0 6 2015

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 043	Continued From page 1 functions specified in this part that pertain to the governing body ... This CONDITION is not met 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	A 043	A 043 Continued from Page 1 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	Completed 8/20/15 Start Date 8/28/15

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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	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	Start Date 8/28/15