# Zuckerberg San Francisco General Hospital and Trauma Center

**Regulatory Affairs Department** 

Joint Conference Committee (JCC) Regulatory Affairs Status Report: October 2016 (reporting period September 28, 2016 – October 17, 2016)

### I. PENDING SURVEYS

- A. CMS Validation Survey (pending)
- B. California Department of Public Health (CDPH) ZSFG Re-licensing Survey unannounced
- C. Joint Commission Intra-Cycle Monitoring Consultative Survey Option 2 announced survey
- D. Joint Commission Triennial Accreditation Survey unannounced (Survey window July 1, 2016 July 28, 2017)

## II. COMPLETED SURVEYS

- A. San Francisco EMS Agency Site survey (September 27, 2016)
- B. DHCS Triennial Compliance Audit for ZSFG Psychiatry (week of October 3, 2016)

## III. PLANS OF CORRECTIONS: Reports & Updates

- A. California Board of Pharmacy Sterile Compounding (four minor deficiencies regarding documentation, plan of correction submitted 10/19)
  - Finding 1 CCR 1751.1 Sterile Injectable Recordkeeping Requirements: As discussed during the inspection, the QA report form had space for recording incubator temperatures daily for media fill and GFS tests, however, subsequent to that form's design, the incubator was placed on the hospital's Temp Trak system to ensure continuous temperature monitoring for this system. The form has been redesigned to reflect the use of Temp Trak for incubator temperature monitoring and to promote better documentation of all monitoring during the media fill and GFS tests.
  - **Finding 2 CCR 1715 Self-Assessment of a Pharmacy by the Pharmacist In Charge**: At the time of the inspection, the front page of the Self-Assessment Form that had been completed by the Pharmacist In Charge did not contain all the necessary elements. *The Pharmacy Self-Assessment Form for HPE 53667 has been completed.*
  - **Finding 3 CCR 1735.2 Compounded Limitations and Requirements:** At the time of the inspection, the front page of the Compounding Self-Assessment Form that had been completed by the Pharmacist In Charge did not contain all the necessary elements. *Compounding Self-Assessment forms for LSE 100842, LSE 100857 and LSE 100856 have been completed.*
  - **Finding 4 CCR 1735.2 Compounded Limitations and Requirements:** The master formula reviewed during the inspection did not include equipment used to compound and process to compound the product. *Master formulas have been updated to include this information.*

### IV. SITE VISITS

- A. 10/6/16 CDPH Self Report/Complaint Validation (anonymous complaint related to controlled substances, return visit; first was 9/16/16)
- B. 10/19/16 CDPH Self Report Investigation (privacy breach, retained foreign object)