

Regulatory Affairs Department

Joint Conference Committee Regulatory Affairs Status Report for August 2018 (July 18, 2018 – August 20, 2018)

I. PENDING SURVEYS

A. Urgent Care Center Licensing of new location in B5 (September 10, 2018)

II. COMPLETED SURVEYS / SITE VISITS

- A. CDPH site visit re: two self-reported hospital acquired pressure injuries and two complaints (discharge services and quality of care) (July 24, 2018)
- **B. CDPH** site visit re: Vaccines for Children inspection (July 24, 2018)
- C. CDPH site visit re: two complaints (patient flow and falls data) (August 6, 2018)
- **D. Baby Friendly Hospital Recertification** (August 7th & 8th, 2018)

III. PLANS OF CORRECTIONS: Reports & Updates

A. Office-Based Opiate Treatment (OBOT) (June 7-8, 2018) - two findings:

Deficiency/Finding	Regulation	Plan of Correction
The treatment plan dated October 2017 and December 2017 did not contain the type and frequency of counselling the patient was to receive.	9 CCR 10305(f)(2) Patient Treatment Plans	Reviewed and re-trained counsellors and treatment plan reviewers on treatment plan requirements, emphasizing the need to include the type and frequency of counselling the patient is to receive. Supervising counsellor/treatment plan reviewer will perform a review of all treatment plans to ensure the type and frequency of counselling is included before the treatment plan is submitted to the MD for final signature and completion.
2. The patient record did not contain documentation that the physician reviewed the patient's deviation of Take Home medications during August 2017.	9 CCR 10355 (c) (2) Medication Dosage Levels	Reviewed procedures with all OBOT physicians and OBOT nurses regarding the need to document that the program physician has reviewed and approved all medication orders (including take home orders, dose adjustments and step level changes) by means of a signed order by the physician.

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B. Board of Pharmacy- Annual Survey for Compounding (Only) (July 11, 2018) - three findings:

Deficiency	Regulation	Plan of Correction
1. The order of protective equipment placement was not in a compliant sequence. Staff were washing hands prior to donning shoe covers. The current process/room configuration indicated that staff would be stepping down with shoe covered feet onto the same area	CCR 1751.5(a)(3) Sterile Compounding Attire	Emergency Department Satellite Pharmacy- Implemented an additional line of demarcation to delineate the separate areas of where staff will don shoe covers, and then wash hands. Operating Room Satellite Pharmacy- Implemented an additional line of demarcation to delineate the separate areas of where staff will don shoe covers, and then wash hands. Pharmacy staff educated regarding purpose of new lines and delineated areas, importance of traffic flow by donning shoe covers and then washing hands to prevent street shoe
floor as street shoe contamination. 2A. The pharmacy did not have policies and procedures (P&P) specific to how to notify staff in changes to compounding P&P (only	2A. CCR 1735.5 (c)(1) Compounding Policies and Procedures	contamination. 2A. Language specific to the communication of sterile compounding policies was inserted into the Pharmaceutical Services 2018 Scope of Services Statement Section VI Standards or Guidelines.
a hospital-wide/pharmacy-wide one). 2B. The P&P for compounding does not list the specific agents used in cleaning the cleanroom and equipment/supplies (i.e. primary engineering controls).	2B. CCR 1735.5 (a) Compounding Policies and Procedures	2B. Language in Pharmacy Policy and Procedure 6.6: <u>Cleaning and Disinfection of IV</u> <u>Preparation Area</u> was updated to reflect the specific cleaning and sporicidal agents used for daily and monthly cleaning. The monthly cleaning log was also revised to specify the sporicidal cleaning agent and the required wet contact time.
3A. The pharmacy was relying on the digital system to alert staff of out of range values, with no visual check of the digital system for out of range alerts of gauge and pressure, or documentation that the daily pressure is within range.	3A. CCR 1751.1(a)(8) Sterile Compounding Recordkeeping Requirements	3A. Language in Pharmacy Policy and Procedure 6.2: Responsibility of Compounding Personnel, was updated to reflect the that compounding personnel were responsible for visually checking the digital system for out of range alerts on a daily basis, and documenting that values are within acceptable range.



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3B. The pharmacy was relying on the alarm of the 24/7 temp tracking system to alert staff of out of range values, with no visual check of the digital system for out of range alerts of temperature, or documentation that the daily temperature is within range.	3B. CCR 1751.1(a)(6) Sterile Compounding Recordkeeping Requirements	3B. Each shift the lead pharmacist will document that temperatures within the sterile compounding area are within acceptable range, and communicate this information with the next on-coming lead pharmacist.