3/8/2016

Task Force

Roll

Committee chair; Trip Hoffman (University Pharmacy)

Committee members; Rob Smith (Rock Canyon), Chris Cox (Smith Rexall Drug), Koby Taylor (Fusion Specialty), Bryan Horne (Isomeric), Christine Jacobson (Wasatch Pharmacy Care), Rob Muelleck (Intermountain Healthcare), Kyle Kitchen (Intermountain Healthcare), Jacob Corsi (Isomeric), Dean Jolley (Jolley's Compounding)

Attendees; Anthony Stephens (Roseman intern studen); Janet Zarndet (HCA); Mckinzi Hamman (Medicine Center); Karin Carestia (Alpine Apothacary); Donelle Perez (Petersons)

Agenda

- USP 797 (Jacob Corsi gave update)
  - The earliest USP 797 published date will be 5/1/2017 before it will take effect. There has been many comments and most likely will be several versions. There are several areas of ambiguity that need clarification.
  - IACP comments on USP 797 were emailed to the taskforce. Jake recommends reading and understanding the comments.
  - Next revision may be out in the next several months.
  - Eric Kastango at Clinical Point- Has a webinar regarding updates and Trip will email out details.
  - IACP will also have a webinar this Thursday on USP 797.
- FOU (Trip Hoffman gave update)
  - Several US Senate and congress bills are in process that will address FOU.
  - DQSA will be updated and fixed in several of the proposed bills. There has been a move by Congress to have the FDA allow FOU again and to do so within 90 days.
  - Trip has asked DOPL and the Board if compounders can start FOU again last week (Feb 10th). No decision has been made but Trip feels that DOPL/ board is ready to

move and may approve FOU in the interim. He is hoping there will be discussion next week at the Board meeting.

- Town hall meeting at IACP today for members.
- Dean is going to IACP and is going to pass along the boards desires to allow FOU compounding again.

- USP 800 (Rob Muellreck gave update)
  - There are many interpretations of USP 800, which won't be implemented until 7/1/2018. All pharmacies at that time must be compliant.
  - Rob emailed out a document available for review with USP 800 highlights. The latest version of USP 800 came out in February.
  - USP 800 pertains to all healthcare locations that handle hazardous drugs and material.
  - Each facility will need to become familiar with and have a list of hazardous drugs that mostly follow NIOSH list.
  - Hazardous material does not need to be stored separately if not used for compounding.
  - Each facility will need a designated person over USP 800 to act compliance officer.
  - Each facility must perform hazardous compounding in a negative pressure room with 12 or more air changes per hour.
  - Each facility must have a place to unpackaged and store hazardous areas.
  - Storage of hazardous drugs must be stored in room with negative pressure with at air changes of >12 times/ hour
  - C-PEC must have vented or double HEPA filtered and in a specific hazouroud designated area.
  - C-PEC walls must be easily cleaned without crevices in order to prevent accumulation of hazardous material.
  - C-SEC devices must be externally vented and negatively pressured.

- Compounding pharmacies will need to incorporate ante-room and hazardous room, and non-hazardous rooms.
- In order to compound hazardous and non-hazardous equipment extensively cleaning and documentation must be taken.
- Sterile USP 800 requiremetns.
  - Must be externally vented.
  - Type A2 cabinets.
  - The CPEC must be located in the CSEC. Will need ISO-7 air in ante and buffer area.
  - 30 air changes per hour in compounding areas including ante and buffer.
  - Need to used devices that prevent aerosolization.
  - Environmental wipe sampling should be performed regularly. No current standard but watch for future clarification.
  - PPD for sterile and non-sterile. Gowns, 2 pair of shoe covers, and 2 pairs of gloves along with other protective attire.
  - Need to change gloves every 30 min.
  - Respirator mask.
  - Established policy and procedures.
  - Deactivating, removing, disinfecting, and cleaning police. All reusable devices must go through process before reuse.
  - SOP must be evaluated every 12 months by designated USP person.
  - Need to do evaluations of staff to determine potentates effects and screen for exposure.
  - USP 800 is found on USP.org and membership is $120 per year for those who wish to join.
  - USP has CE and webinar on March 24 from 9-4 at USP.ORG on USP 800.

  - Critical point is another great resource and have useful documents regarding USP 797.

- The state board is going to re-start a newsletter to help update pharmacies. The next issue is 8/1/16. Task force members may send any ideas to Trip about topics.

- Compound labeling law and requirements have been updated were sent out for review.

Trip proposed a requirement change for pharmacies shipping compounds into Utah to have PIC or staff pharmacist to pass Utah pharmacy law exam. The task force was in favor of stricter requirements and favored pushing forward for stricter guidelines. Texas just implemented this in their Rules.

Inspection update (DOPL inspectors)

New compounding self-inspection forms will be available soon and are waiting on website developers to finish polishing. Expect to see them post in the next few months.

Inspections and non-compliance have been the same problems.

Annual training

SOP missing

Documentation on training.

Initials.

Updating and housecleaning their records.

Class A expirations.

Inspectors look at number of expired, how far expired, and past problems to determine severity of punishment.

Currently inspecting 2013 pharmacies and should be caught up and on track inspecting pharmacies every 2 years. Will be starting on class b pharmacies thereafter.

Next task force meeting will be May 16, 2016. 7AM.