

# Task Force Meeting

## Minutes

### Discussion items:

Welcome: Nov 10, 2015 is next task force meeting 7 AM at DOPL.

1. Membership: Trip Hoffman outlined the commitment level of task force membership which used to meet monthly and now meets quarterly. Trip has been in touch with all board members to assess their interest and ability to work as members of the task force. Angela Whitney has been involved for a several years with the task force and she was formally recognized and will be stepping away from the task force. All other task members expressed interest and will remain. There are currently 12 members on the task force. Two members were added to the board after motion and unanimous vote; Kyle Kitchen and Rob Smith.
2. Goals for future. The task force will continue to meet at the same time moving forward on a quarterly basis on the 3rd Tuesdays at 7AM at DOPL building. Trip organized the task force into groups of sub committees that will report back to the task force on specific needs and challenges. He asked for volunteers or recommendations to head the subcommittees USP 795, USP 797, USP 800, political liaison and minutes. Koby Taylor will head USP 795, Robert Muelleck will head USP 797, Jacob Corsi will head USP 800, Kavish Choudhary will head political liaison affairs, and Chris Cox will head minutes.
3. Sterile inspection form. DOPL had good intentions in creating a self-inspection report that was extensive and exhaustive. The sterile self-inspection report grew to 24 pages from 2 pages. Many of the biggest questions for DOPL investigators were regarding fines, citations, and disciplinary actions. Many members wanted clarification about non-compliant status and how many infractions determines a pharmacy non-compliant. Other concerns discussed by task force was pharmacies ability to respond to issues and citations. Many members would like to see more educations and less citations and disciplinary actions. The investigators responded by informing the task force they are approaching pharmacies in the spirit of education. They are not "going in with guns blazing". They mostly focus on issues that pose serious harm to the public.

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Task force members would like to see more follow-up inspections. Inspectors are trying to put more education in their inspections. There are not any means or mechanisms to provide warnings. DOPL inspectors follow the law and do not have any means of providing warnings. Pharmacies are welcome to call DOPL and ask for help in preparing for an inspection. DOPL has inspected 4-5 sterile pharmacies to date and the processes takes anywhere from 3-4 hours. They have started inspecting dispensing medical providers (DMP) and have had a great response. There have been no issues with them whatsoever. DOPL investigators will start inspecting class b pharmacies in the next few months. Investigators are focusing on non-compliant hoods.

The board of pharmacy would like to see pharmacies before they end up on probation. Jacob Corsi would like to see someone with knowledge or an expert that could provide consultation with inspectors.

Jim Ruble would like to see inspectors provide more education and minor course adjustments that can build confidence. He has seen many pharmacies who are on probation who can easily turn it around when given course correction.

Trip would like to see more networking among the task force and their pharmacy constituents. He would like to expand the pharmacies we are in touch with. He would like to see more smaller group discussions.

4. Compounding labeling requirements. The compounding labeling policy and procedure is being updated, edited, and changed by the board of pharmacy. Batch labels do not need to be labeled. The task force has a concern with duplicate labeling of master formulas. Concerns have been expressed about the burden that places on the compounding pharmacy regarding duplicate labeling. In order to make accommodations with the task force DOPL investigators are going to call USP to see what changes are allowed concerning labeling and clarification. Trip will email out investigator findings and seek further discussion via email.

Jim Ruble would like to see active ingredients defined. Trip will email more information to the task force.

5. FOU (for office use) update. There is some traction with FOU and it is on the national radar. There is no update on timing but hopefully in the near future something will happen. DOPL provided pharmacies a way to allow FOU compounds. A pharmacy must be PAF classified and a consulting

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pharmacy for a clinic. The pharmacy may put an e-kit in a provider's office. The e-kit must be a locked container accessed only by nurse, Dr, PA, or health care provider. There must be a dispensing log that contains patient's name. It must be unit dosed. The consulting pharmacy must reconcile the records.

6. USP 800 update. Public comments ended May 31, 2015 on USP 800. There has been a new committee chosen and there isn't likely any movement on USP 800 until Feb 2016.

Meeting adjourned.

Task member attendees: Kavish Choudhary, Trip Hoffman, Christine Jacobsen, Robert Muelleck, Kyle Kitchen, Jake Corsi, Bryan Horne, Chris Cox, Kobey Taylor, Dean Jolley, Jim Ruble

Non task member attendees: Chris Cantrell, Jonathan Gurney, Anton Nguyen, karin Carestia, Jeanne Brennan, russell Findley, William Black, Kyle Anderson, Mary Rogers, Bill Stilling, Donnelle Perez, Bren Nielson, DOPL Investigators.