

5-20-2014

COMPOUND TASK FORCE MEETING

Attendees:

Trip Hoffman	University Pharmacy
Rob Smith	Rock Canyon Pharmacy
Rebecca Holt	Jolley's Compound Pharmacy / Holt's Pharmacy
Karin Carestia	Alpine Apothecary
Danelle Perez	Peterson's Pharmacy
Jennifer Jeppsen	Walgreens
Robert Muelleck	IHC Supply Chain Center
James Ruble	University of Utah
Dean Jolley	Jolley's Compound Pharmacy
Bryan Horne	Lone Peak Pharmacy
Chris Cox	Smith Rexall Pharmacy
Koby Taylor	Fusion Specialty Pharmacy
Kort Delost	The Medicine Shoppe
Christine Jacobson	Wasatch Pharmacy Care
Jacob Corsi	Isomeric

Conducting: Trip Hoffman

Opening Comments:

- Next meeting scheduled for August 19, 2014 at 7:00 at the IHC Supply Chain Facility.
- USP 795/797 1 day meeting for each at USP headquarters July 16th and 17th.
- Discussed writing a list of approved or suggested labs for testing
 - (noted that we must be careful not to endorse any specific lab, but to just have the information as a reference) ARL, Dynalabs, Eagle Analytical among the top labs.
- Discussed providing guidance on cleaning supplies and disposable equipment
- Possible potency test at time of inspection (MO and TX) or to be included as part of a quality assurance program that would ensure quality and hold your compounders more accountable. Measure quality and quality goes up.
- Please be thinking about our vision as a task force and provide ideas to Trip

Notes from IACP Conference (Koby Taylor):

- Still waiting for more information on 503A and 503B
- Talk on Insurance and Audits
 - Pushing for PBM transparency
 - Insurance are starting to push for accreditation

- MOU – Memorandum on Understanding
- Insurance denying claims shipped to other states where pharmacy not licensed
- Lots of waiting and still few answers

Information about 503A and 503B (Jim Ruble and Trip Hoffman)

- Next step is the formation of advisory committee
- Chemicals must be from USP or NF source and from an FDA approved facility
- Spoke on “Joint” investigation not really being joint and there being a disconnect between agencies and information
- Talk of inspections at every license application and renewal
- Talk of samples coming to doctors offices from out of state...debate over the issue
- For office use-wait and see how FDA and advisory board define in upcoming months. APHA reporting some guidance will be issued soon (795 likely and 797 highly unlikely).

Information and Guidelines about “Magic Mouthwash” (Jennifer Jeppsen)

- Considered moderate compound
- Provided general guidelines for discussion (a few changes made)
 - Talk of creating a template for use as a Formula Master Worksheet
 - Only allowed to mix commercial products (not including opening capsules)
 - Suggested to remove the “Magic” from the name
 - Suggested to add that it wordage suggesting this applies to all pharmacy classes
 - Suggested to change to “This is a Compounded Preparation” (this is Utah law – not 795)
 - Question posed as to whether the above statement is required for inpatients (not specifically answered)
 - Changes to guidelines to include:
 - Remove title of Magic Mouthwash and rename Compounded Mouthwash
 - Remove statement on powder usage (only allowed to use manufactured liquids)
 - List ingredients allowed for use (Lidocaine, Antacid, Benedryl)
 - Some debate about including Prednisolone and Nystatin
 - Add that it applies to all classes of pharmacy
 - Add “This is a Compounded Preparation”
- Talked about First Compound Kit and how pharmacies will still have to meet the same standard as it is a “compound kit”-simple category standard. Tamiflu or any other FDA medication with a compounding formula included in the package insert would be considered a simple compound according to USP 795.

Information and Concerns about Pain Creams (Dean Jolley)

- Concerns over current approach
 - Non-pharmacy marketing machines only interested in the money
 - Marketers that are paid as subcontract work (1099) not allowed (503B?)
 - Fraud, Waste and Abuse issue
 - Sample are being given to doctors offices
 - Out of State issues
- Jim Rubble (I think) suggested that this should involve the UMA

- Large concern over ethics, fraud and abuse
- Motion was made to attack this problem in an effort to save the pharmacy as a profession from an embarrassing expose or media blast
- Motion not immediately seconded and after more conversation motion changed to explore the issue further.
 - Sub-committee formed to look into the issue
 - Committee to include Dean Jollley, Kort Delost, Christine Jacobson, Jim Ruble, Rob Smith and Koby Taylor

USP 800 (Jim Ruble and Trip Hoffman)

- Webinar on USP – please watch
- Proposed chapter-1st draft-Exec. Committee of USP changes next year
- Focuses on containment of hazardous chemicals and protection of compounders
- Pushes toward negative pressure room
- Note that it will be enforceable under 1000
- Might become cost prohibitive – suggestions about breaking down the NIOSH list into categories-should handling and compounding guidelines of a hormone vs. an antineoplastic be the same
- Asked to read rules, watch webinar and send suggestions or comments to Trip by July 1st
- Also look through list and send a list of the medications on the list that each of us use in compounding

TrekView (Trip Hofman)

- Used for validation in shipping
- 1079 speaks of validating shipping methods
- Validation should be incorporated into policies and procedures
- Cost of \$45 each – minimum order of 10 pieces (can be split among multiple pharmacies)
- Very impressed with the capabilities

Assignments:

All Task Force Members – read USP 800, watch webinar, and submit comments to trip by July 1st

All Task Force Members – make list of hazardous chemical that you use from the NIOSH list by July 1st.

All Task Force Members- Make a list of cleaning supplies and equipment to submit to Trip to create a master list to compare by June 15th.

Jennifer Jeppsen – make changes outlined for “Magic Mouthwash and submit to Trip before state board meeting (Trip will email out proof before submitting to state board of pharmacy).

Dean Jolley – head the new pain cream committee and plan meetings

NOTE – first meeting scheduled for Wednesday, June 11th at 7:00am at
Jolley's Store (1702 S 11th E, Salt Lake City)

Pain Cream Committee – come to next Task Force meeting with information and suggestions on the concerns over the pain creams

Next Meeting – August 19th at 7:00am at the IHC Supply Chain Center