

Housekeeping and Updates:

New Members: Vote

Agenda:

- I. Senator Evan Vickers- Legislative Update
- II. Venkata Yellepedi- Roseman University presentation on resources for pharmacies to become compliant with USP standards and other regulations.
- III. Kyle Anderson- Prescription Requirement Guidance Discussion
- IV. Trip Hoffman- Bulk Drug Substance Inclusion and Exclusion List Update
- V. Sharilee McIntyre- Sterile inspection update and educational pearls
- VI. Travis Drebing- Non-sterile inspection update and educational pearls

USP <800> Discussion will follow regular meeting- Task Force Only Please

Next Meeting: May 16, 2017

Task Force Meeting Minutes

Agenda

- Task Force Meeting Attendance:

- Members: Trip Hoffman (University Pharmacy), Chris Cox (Smith Rexall Drug), Rob Muellreck (Intermountain Healthcare), Russell Findlay (UofU), Dean Jolley (Jolley's), Christine Jacobsen (Wasatch Family Care), Koby Taylor (Fusion), Rob Smith (Rock Canyon), Evan Vickers (Bulloch Drug), Karin Carestia (Alpine Apothecary), Mary Rogers (Bountiful Drug), Kyle Anderson (Medquest Pharmacy), Adam Jones (UPHA).
- Guests: Mckinzi Hammon, Bart Nielson, Phung Matthews, Janet Zardnt, Darren Seegmiller, Camille Farley, Sharilee Mcintyre, Travis Drebing, Glenn Carmody, Donelle Perez, Tony Rhodes, Bill Stilling, Chris Orton, Lynn Hooper.

Housekeeping and Updates:

- USP 800 CE course available at www.usp.org (6 1/2 hour long session). USP 800 Gap Analysis gap tool can be found at (800gaptool.com). Self-assessment tool by critical point is online. Critical point performs sterile compounding pearls of knowledge. Feburary can be found at <https://www.criticalpoint.info/sterile-compounding-pearls-of-knowledge-february-2017-edition/>. Also, great article in Pharmacy Purchasing and Products Journal January 2017 issue titled Developing a USP 800 Compliance Gap Analysis (<https://www.pppmag.com/article/1989>).
- Follow-up from USP 800 timeline. Implementation date set for July 1, 2018. The pharmacy state board was in agreement with extending the enforcement of USP 800. It looks like complete enforcement of USP 800 will be delayed until July 2020 by two years. There is still some details and legal questions that need to be figured out first; but Trip is optimistic this will be approved or passed.
- Adam from UPHA has set up social media sites to help disseminate task force agendas, minutes, and updates. (www.upha.com)
- **Compounding Pharmacy in Utah**
- The Compounding Task Force meets regularly and has asked the UPhA to develop a list for communicating information to compounding pharmacies. The link below will provide an opportunity to sign up to receive compounding specific information from UPhA. This email list is managed by Association Solutions, the UPhA

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management team. No information will be shared with outside organizations, including DOPL. The link below will take you to a constant contact sign up form.

Please watch future emails as we further develop a Compounding Pharmacy In Utah section of our newsletter. If you have great information you would like to have shared with other compounding pharmacies in Utah, please email us at upha@upha.com.

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- [Compounding Email List Sign Up](#)

Did you know that the Compounding Task Force meeting minutes are available to view following their meetings?

- [August 2016 Meeting Minutes](#)
- [May 2016 Meeting Minutes](#)
- [March 2016 Meeting Minutes](#)

For previous meeting minutes you can see the DOPL website.

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- Brian Horn and Kort DeLost are no longer serving as members of the task force. We would like to thank them for their work and leadership while serving on the task force.
 - New Members: Kyle Anderson (MedQuest), Karin Carestia (Alpine Apothecary), and Mary Rogers (Bountiful Drug) received unanimous vote to join task force.

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- **Evan Vickers updated on legislation related to compounding pharmacy:**
 - Utah HB- 189 sponsored by Bountiful Doctor Raymond P Ward. The Dr is worried about pricing and Epi-pen and other inflating prices. The Bill amends certain state prohibitions against the compounding of drugs in the Pharmacy Practice Act. The bill amends the definitions of compounding; and amends the definition of unprofessional conduct related to compounding of certain drugs. It essentially removes the restriction of compounding pharmacies to make exact formulas of commercially available products. The bill has passed the rules committee and will be debated on the house floor but Evan does not see it making it past the Senate. The Board of Pharmacy has sent a letter to the House and Senate in opposition to this Bill as it goes against federal law and there appears to be no need for the admendment.

- The other bill SB 246, a bill sponsored by Evan does three things. Allows pharmacists to do long acting injections (mainly psychotropic and HIV medications); creates a requirement for non-resident compounding pharmacies to submit a VPP (NABP) inspection or a State inspection from their home State before renewal or upon a new application; exempts hospitals from certain compounding labeling requirements
- Non-sterile and sterile permits was an item discussed at our last meeting and Trip explained that in order to create a new licensure category this requires an OPPLAR committee review. This is a huge undertaking and will require preparations and months of work. He thinks this is a good project for next year or late fall.

- Prescription Requirement Guidance Discussion - Kyle Anderson and Phung Matthews (see attached document)

FDA website for draft and final guidances:

<http://www.fda.gov/RegulatoryInformation/Guidances/default.htm>

***This FDA guidance deals with and addresses 3 areas of compounding (compounding after receipt of prescription, compounding before the receipt of prescription, and compounding for office use).**

- Anticipatory compounding -30 day rule: 503a final guidance document states that if anticipatory compound preparations are not prescribed within 30 days they are in violation of the DQSA. There needs to documentation that your anticipatory compounds are based on history of receipts of valid prescriptions.
- Office Use: The FDA considers this a non-patient specific compounding product. Only 503b pharmacies are allowed to offer FOU compounds. Some state boards of pharmacies have passed state laws to allow FOU, but the FDA deems these incongruous with federal law. Utah does not allow FOU compounding; all compounds must be for an identified, individual patient.
- Page 1 of FDA guidance is not law and states such on page 1 of FDA's prescription requirement under section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry.

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- There is US legislation to overturn FDA's FOU to allow non-sterile and possibly sterile FOU. It is not moving at a fast pace to overturn, so stay tuned, but do not hold your breath.
- **Bulk Substance Inclusion and Exclusion list update:**
 - Can find out information on FDA's website (www.fda.gov/Drugs/DrugSafety/ucm532474.htm). Trip gave update on inclusion and exclusion list.
 - Drugs on inclusion list; Cantharidin, Brilliant Blue G, diphenylcyclopropanone, N-acetyl-D-glucosamine, squaric acid dibutyl ester, thymol iodide.
 - Drugs on exclusion list; oxitriptan, piracetam, silver protein, tranilast.
- **Sharilee McIntyre (DOPL Inspector) gave update on sterile inspection and educational pearls.**
 - She wants pharmacies to know "What we do, what we do about inspections" She doesn't want people to be nervous about inspections. Sterile inspection form was disseminated to task force.
 - She asks for a tour and will get a read on the pharmacy and how to best proceed with inspection and where areas will be needed.
 - She asks for SOPs and will read SOPs and observation operations to ensure pharmacy is following their own SOPs.
 - 5 parts
 - SOPs - make sure SOPs are specific and pharmacy is following SOP
 - Training- Personnel and documentation; Hazardous training documentaion
 - facility- environmental monitoring, hoods, cleaning, etc. Please be sure to read cleaners and instructions. Pay close to attention to recommended dwell time and contact time. Surface sampling must be conducted and documented. Cleaning training should occur every 6 months along with media fill testing for high risk and once per year with low and medium sterile compounding.

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- Compounding. technique, gowning, hand washing, compounding, cleaning hoods and tool use.
- Final checks- How are they conducted. Needs to be double check on compounding and ways to develop double checks. Spraying down compounding products from one room to another room. Cardboard is not sterile items removed
- Quality assurance. Quality control vs quality assurance. Written quality assurance program is a focus of DOPL investigators. Any questions about USP 797 when digging into rule may be highlighted and used in a SOP.
- Inspections are taken 2-3 days to conduct. Often the pharmacy will fix the problem found on day 1 but will still be listed on inspection report.

It is imperative to have enough coverage of employees to allow your compliance officer/PIC/ and/or compounding pharmacist/technician to be with the inspectors
- **Travis Drebing (DOPL Inspector) gave update on non-sterile inspection and educational pearls:**
 - SOPs continue to be trouble spot. He has seen them from all over the place but most are lacking.
 - 6 areas that need to be addressed with SOPs that can be found in chapter USP 1163. Please make sure to purchase the USP compendium at <http://www.usp.org/store/products/usp-compounding-compendium>. Many chapters are referenced in USP 795 and 797, like 1163, so they need to be followed as well.
 - Section 1163 is referenced in USP 795 and is a great resource to developing SOPs. Some of the suggested areas to focus on for SOPs are the following:
 - • Beyond-Use dating
 - • Chemical and physical stability
 - • Cleaning and disinfecting
 - • Component quality evaluation
 - • Compounding methods
 - • Dispensing
 - • Documentation
 - • Environmental quality and maintenance
 - • Equipment maintenance, calibration, and operation
 - • Formulation development
 - • Labeling

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- • Materials and final compounded preparation handling and storage
 - • Measuring and weighing
 - • Packaging and repackaging
 - • Patient monitoring, complaints, and adverse event reporting
 - • Patient or caregiver education and training
 - • Personnel cleanliness and garb
 - • Purchasing
 - • Quality Assurance and Continuous Quality Monitoring
 - • Safety
 - • Shipping
 - • Testing
 - • Training and retraining
- 1163 is broken down into several areas and will be helpful in writing, editing, and installing SOPs into compounding pharmacy.
- Trip would like to see USP inspection form put on DOPL's website. UPHA would be willing to place DOPL inspection forms on their website. There was much discussion on complexities of getting latest inspection form made and available.
 - Pharmacy email alert could be another avenue of disseminating inspection forms.
 - UPHA will look into placing forms on their website.
- Email Trip with any questions or items for next task force meeting.
 - Next meeting is the 3rd Tuesday of May.
 - Thanks to all those that attended and continue to be a part of the Task Force group.
 - **Adjourned**

USP 800 update (task members only) brainstorming session

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- Trip explained the possibilities and wants to discuss the pros and cons of USP 800 adapted version or writing our own version.
- Koby asked if the state would get behind USP 800 adapted version for reproductive only category. We would need conclusive evidence to make a move as such.
- Compounding pharmacies need to be compliant with USP 800 by July1, 2018; What about reproductive only hazardous medications -should there be exemptions or a possible carve out. The committee agreed that the adapted version for reproductive only may not be the best option to proceed, but rather looking at ways to help pharmacies to prepare for 800 and helping with documents to maintain compliance within USP 800. Creating a document to understand the process for the risk assessment analysis.

Members of the task force were assigned items for our next meeting:

- Christine going to talk with ZRT labs
- Kyle is going to take with PCCA and IACP.
- Trip is going to meet with DOPL and member of Ohio State Board of Pharmacy.
- VPP (verified pharmacy program) is a great resource and may have tools or inspection form for 800.

****Meeting adjourned with the following plans****

- Survey to boards of pharmacy to gauge plans for adoption of USP 800. How many BOPs will adopt USP 800 into their rules and regulations by July 1, 2018? Do any have plans to re-write some parts? Enforcement delay? Etc.
- Risk assessment document. Help pharmacies determine best practices to perform risk assessment needed with USP 800.
- Encourage DOPL to have a USP 800 inspection form ready by Jan. 1, 2018 in order for pharmacies to perform gap analysis with State requirements in regards to 800.

Next meeting on USP 800 will follow our next task force meeting- May 16th

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FDA website for draft and final guidances:

<http://www.fda.gov/RegulatoryInformation/Guidances/default.htm>

FDA guidances- approximately nine guidances affecting 503A

- Final guidances
 - *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance* (6/2016)
 - *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry* (revised, 1/2017)
 - *Prescription Requirement Under Section 503A of the Federal Food, Drug and Cosmetic Act Guidance for Industry* (12/2016)
 - *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities* (1/2017)
- Draft guidances
 - Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (7/2016)
 - Insanitary Conditions at Compounding Facilities Guidance for Industry (8/2016)
 - Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act Guidance for Industry (4/2016)
 - Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biological License Application (revised 1/2017)
 - Compounding Animal Drugs from Bulk Drug Substances (5/2015)

December “Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry”

- Addresses 3 areas of compounding:
 - Compounding after receipt of prescription
 - Compounding before receipt of prescription (anticipatory compounding)
 - Compounding for office use
- Background
 - Section 503A, added to the FD&C in 1997 states what conditions must be satisfied for human drug “products” to be compounded in a state-licensed facility
 - FDA outlines associated risks with Compounded Drug Products (2012 NECC - 60 deaths / 750 cases of fungal meningitis infection)
 - 503B outsourcing facilities were established
 - Must be compounding sterile and “non-sterile” preparations (which in this guidance document is addressed to allow for sterile and non-sterile compounding to be conducted independently of one another) - pg.11
 - Subject to cGMP requirements
 - Compounding services recognized by FDA to be important

- Established patient-prescriber relationship- ie patient specific prescription
 - To qualify for exemption in 503A
 - Compounding for identified individual patient
 - Compounded in limited quantity
 - Distributed pursuant to a valid patient-specific prescription
 - *“The prescription requirement under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved, are not subject to the requirement that labeling bear adequate directions for use, and are not subject to cGMP requirements, are provided to a patient only based on individual patient need.” - Section B (The Prescription Requirement in Section 503A (a) of the FD&C Act)*
- Part B
 - FDA describes compounding process in 2 situations: **before** and **after** receipt of a prescription
 - After receipt of Valid Prescription
 - Must be patient specific- i.e. *valid prescription order for identified/individual patient*
 - Before receipt defined as “anticipatory compounding” and new limitations have been applied to 503A facilities
 - 30-day rule
 - Based on history of receipts of valid prescriptions
 - Established relationship between pharmacist, prescriber and/or patient
 - Reasoning of 30 days-
 - minimizing contaminations and preparations mix up to patients
 - Works to differentiate traditional compounding and manufacturing on large scale
- Office Use
 - Defined as “non-patient-specific” compounded preparations
 - Reserved for outsourcing facilities per FDA
 - Cannot be performed under section 503A
 - Even if State Boards of Pharmacy allow such practice