## Compounding Task force Meeting November 10, 2015

## DOPL Building- North Conference Room

*Old Business/Housekeeping*

1. Minutes posted on DOPL website (within 2 weeks)
2. USP accredited CE –
    - USP 795: 4 hour course June 16th ($200) on USP's website
    - Revision coming for 797
    - Eric Kastango : course on 797 revision (end of October) comparison of old/new guidelines and regulation for safety; includes meningitis outbreak info (Trip will send webinar slides)
    - Course by Pharmacist Letter: 8 hours; introduction
    - Roger Fitzpatrick: board member; law review webinar that includes a compounding section with the U of U.
    - If good program found or being utilized by task force members (major violations commonly seen in compounding pharmacies), then please email Trip what is working for your pharmacies

*Hospital Inspection Update*

1. Long inspection taking place: Taking 6 hours, for 2 people; more automation/sterile hoods takes longer time to inspect; currently inspectors need to use 4 forms (795, 797, automation and closed door-Class B forms)
    - Helps if DOPL can walk through inspection and knows aspects of inspection
    - Difficult with rural sites
2. Annual s, out-dates are usual things seen and other common items seen are the following:
    - Environmental monitoring issues
    - Hood inspections
    - Dynamic smoke studies should be performed during certification of hoods
    - Incorrect aseptic technique
    - Documentation of training and cleaning procedures
    - Not coming in to shut down; would like to increase compliance
    - Class B/automation/non-sterile more likely to cite against
    - Sterile less likely to cite against (unless very negligent)
    - More likely letter to pharmacist in charge with 21 days to address problems
    - Other issues: Ceiling tiles not sealed properly, media fills, fingertip cultures, flush ceilings
    - Proper documentation in regards to batch compounds- Compounding records
3. Rob Muelleck
    - What is/constitutes a batch? (Hospital Setting)
        i. Patient specific labels for next 8 hours (Wave vs batch; Single patient vs. multiple patients)
        ii. Will batch commonly used items
        iii. Definition: More than 1 unit made with same characteristics and quality
        iv. Does it require individual compound record?
            1. Normal batch would mean 15-20 compounding records
            2. Not clear if necessary
            3. DOPL:
                a. If can track it there is recall; i.e., track from patient to specific batch then should be sufficient
                b. Dose-edge, BDK should help with tracking

c. IV list could be printed and stapled to compounding sheet: can show needed tracking

v. MFR/CR
    1. Can multiple patients be linked to one CR?
    2. Lists of doses printed and attached to compounding sheet
    3. Can be stored electronically

*DOPL will contact USP and Eric Kanstango (Clinical IQ) as well as work with one stakeholder entity to gather what will meet USP standards.

*USP 797 Revision*

- Set out to (last revision over 8 years ago-2008)
    i. Improve layout and flow
    ii. Remove redundancies
    iii. Reflect new science
- Major Changes
    i. Now 2 risk levels (instead of 3 risk levels)
        1. Level 1 – isolator/hood in a non-classified space
            a. 12 hours to use
        2. Level 2 – hood in classified space
            a. Can assign BUD (new chart provided in revision)
    ii. If CAI then need upgrade equipment locations: HEPA in ceiling; (Hazardous) Iso 7 or 8 with Ante room being ISO Class 7
        1. Will impact Class B significantly
    iii. Emergency provision
    iv. Requiring documentation of training for those compounding more frequently
        1. Certifications quarterly
        2. Air/surface sampling every month
    v. In-use time – once IV bag started/spiked, how long you have to use
    vi. Recertification: Every 6 months
    vii. Quality assurance/control
        1. Now has more definitions and more focus
    viii. Side note: NABP reports up to 20% of board exams to deal with both non-sterile/sterile compounding
    ix. Garbing more stringent and defined
    x. BUD and storage times changed with a maximum of 45 days regardless of sterility testing
    xi. Master formulation and compounding records will be required for all batch and non-sterile compounding
    xii. Removal of HD handling and cross-referenced to USP 800
- Can comment until January 31, 2016
    i. Email Trip if interested in participating
- What will this do to community pharmacies
    i. Will increase price; not workable? Environmental monitoring?
    ii. Will it be worth it? Impact of quality on cost? Cost of supply goes up and medical access goes down.
- Quality vs Access vs Cost

*USP 800 Update*

- Nothing new to date; possibly new revision first of next year
- DOPL: Allow 6 months to come into compliance? Longer than usual amount of time
- Board to adopt; stay tuned, coming soon.

*SB 1406 – David Vitter*

- Bring For Office Use Back
- MOU Clarification
    i. DOPL hasn't discussed at this point
    ii. Not clearly defined yet

*DQSA – MOU discussion*

- Looking like 30% (States will decide to sign or not to sign- 5 to 30%?)
- FDA currently defines distribute as any product that leaves the pharmacy
- Waiting for FDA MOU to be released (February)
- Controversy: non-binding in nature, does not offer rights, FDA "guidance" only and not enforceable
- 5%=distribute/dispense+distribute
    i. Uses terminology that are not reconcilable under definitions
- Can State change %?
    i. Yes, but not known what is considered legal
    ii. Liability for states; statutory guidelines of MOU
    iii. FDA authority?
- How can this prevent NECC from happening again?
    i. % doesn't seem to affect adverse outcomes
- Suggestion to have meeting after MOU comes out

*AJHP Nov Issue: Syringes not considered final storage container (sterile and non-sterile)*

- Rubber plunger and end caps need to be plastic

*NCPA Survey*

- Vet Compounding: Be aware; be sure to participate

*Compounding Labeling*

- Electronic version ok as long as a paper trail or audit trail exists
- Crossing out may work with USP but still need duplicate label attached to CR; alteration trail needs to be clear
- Can sticker on CR with lot#/BUD
- DOPL needs to see how it is being altered
    i. Reasoning: Duplicate label for QA or control focus; if there are problems, label can be reproduced in original form and shown on compounding record; process protects pharmacy and is necessary
- Discussion on practicality of duplicate label system
    i. Back label discussion – is it sufficient?
        1. Duplicate label – meaning duplicate info
        2. Back tag OK as long as same info (e.g., sometimes regenerated labels have different dates)
    ii. Electronic scanned copy is ok as long as it cannot be altered
    iii. Main requirements: Trackable, unalterable and ability to reproduce
    iv. Audit trails in system is okay – need to be able to see changes
    v. Decided to define duplicate label and take to Board meeting

*Duplicate label is defined by the Board of Pharmacy in conjunction with DOPL to mean the following:

A label or information that is dispensed on the final product or container ultimately given to the patient which contains sample labeling information (active ingredients, beyond-use-date, storage conditions and lot number).

Along with labeling information as specified in 58-17b-602, a duplicate label shall contain information that is dispensed on the final product or container as defined in 58-17b-614a (3)(e)(ix)(a-d).

Proof of the labeling information shall be kept by the pharmacy. It shall be reproduced in the original format that was dispensed, or an electronic format, or a scanned electronic version. The record shall be trackable and traceable or reproducible and unalterable or contain an audit trail at the time of inspections and shall be readily retrievable. If the record is maintained electronically, it shall be unalterable or contain an audit trail.

This will be reviewed by DOPL and presented at December Board meeting for final approval.

*Next meeting- January 19th (3rd week) to discuss in more detail 797 revision and plan to comment as a group.*