Tuesday, May 17, 2016

# Task Force

## Roll

- Committee chair; Trip Hoffman (University Pharmacy)
- Committee members; Rob Smith (Rock Canyon), Chris Cox (Smith Rexall Drug), Rob Muellreck (Intermountain Healthcare), Jacob Corsi (Isomeric), Dean Jolley (Jolley's Compounding),
- Attendees; Bart Smith (South Valley Compounding), Jeanne Brennan, Travis Drebing (DOPL Inpector), Jennifer Healey (DOPL Investigator), Mary Rogers (Prescriptions Plus Pharmacy), Donelle Perez (Petersons), Mckinzi Hammon (Medicine Center), Glenn Carmody (Cardinal Health), Matt Higley (Intermountain Health)

## Agenda

- Old Business
  - PIC requirement / sterile permit for non-resident
    - In order for Utah to require other states PICs to be registered in Utah it would require change in Utah state law. This is a bigger hurdle than what was initially considered. Other suggestions considered by the task force was a requirement for sterile compounding pharmacies to obtain a sterile permit. Trip noted a PEW study that recommends better record keeping of who is compounding sterile. Jacob Corsi is going to write the first draft and language for state law for next session of congress.
    - Jacob Corsi gave an outsourcing pharmacy update: Many states are trying to determine how to license sterile pharmacies. Outsourcing pharmacies follow GMP guidelines and that seems to be national trend. Jacob recommends states develop laws regarding outsourcing pharmacies. Inspectors are recommended to attend Critical Point for training. It was pointed out that none of the current DOPL inspectors have a certified training for USP 797. Utah is ahead of the curve and require outsourcing pharmacies to be USP 797 compliant. Other states like Texas require PICs to get additional CE.

- There are currently are not any inspectors who have attended Critical Point. DOPL inspectors/ investigators would like to see a push from pharmacies requesting DOPL investigators with Critical Point certifications. Trip is going to bring it up next board meeting. It is a free course for investigators and would help improve inspections.

- Critical Point/NABP combo class is geared more for investigators and not necessarily recommended for pharmacists.

- New Compounding Labeling Requirements

  - The law is now in place as of April 21st and all pharmacies need to be compliant. Trip explained it is not a new law and mimics and mirrors USP 795 and 797. The update is found in rule number R156-17b-614a-3d on DOPL website. Trip advised the task force board to get the word out to colleagues.

- USP 800.

  - July 1, 2018 is the deadline for becoming USP 800 compliant.

  - Some Utah colleagues are suggesting not to adopt USP 800 and to write its own policy and procedure. There was discussion among task force board members but the consensus was to move forward in preparations for USP 800 as is.

  - Compounding Today has provided a GAP analysis for USP 800. Trip explained it as very useful tool to determine a pharmacy's compliance with USP 800. It can be downloaded for free at www.compoundingtoday.com.

  - Pharmacists who want to compound need to become familiar with USP 800. It can be purchased at USP website. Jacob Corsi explained that a risk analysis of compound ingredients can be done to determine whether a chemical may be included or excluded from a pharmacy's hazardous drugs list. There may not be a need to include everything on NIOSH list.

- USP 797 update

  - Public comment has closed as of Jan. 31, 2016 and USP is going to most likely have first version out this fall.

- ASHP has come out challenging many of the items and proposed changes to USP. See document at ASHP website.

- 3 new draft documents released by FDA; Prescription requirement under section 503a Draft Guidance; Hospital and Health System Compounding Under the Federal FDCA Draft; Facility Definition Under Section 503b of the Federal

  - Trip would like to form a sub- committee to work on the 3 above mentioned documents. The meeting will take place in room 474 of DOPL meeting on Tuesday 5/24/15. His vision is to draft a response letter to be submitted to feedback by July 15th deadline.

- Prescription requirement under section 503a Draft Guidance

  - Trip expressed several concerns regarding FOU and the limits 503a will place on compounding pharmacies regarding 503a. Non-sterile compounds are not being provided by outsourcing pharmacies.

  - Dean is going to be in Washington DC next week and is seeking the task force's input to share with legislators.

- Hospital and Health System Compounding Under the Federal FDCA Draft

  - Rob Muellreck expressed concerns on page 9 of Hospital and Health System Compounding Under the Federal FDCA Draft. There will be 1 mile radius around compounding pharmacy that Rob had concerns with and wants to see clarification. He also wants to see clarification about receipt of distribution. The draft doesn't define distribution.

- Facility Definition Under Section 503b of the Federal

  - Facility Definition Under Section 503b of the Federal. Jacob Corsi who helps operate a 503b facility was not surprised by this definition. Because of new definition they ended up dropping the non-sterile compounding. Jacob looks forwards to inspections and have found them to be very helpful.

  - Trip said state inspectors have been working diligently to inspect state pharmacies.

- Requirement pharmacies that are on probation to attend two task force meeting.
  - Another provision would have pharmacies that are placed on probation will be given a task force member as mentor.
  - Outdates seem to be a continued problem. Another common problem is not marking 3 years from the date a chemical was received if it has no expiration date. Formula worksheets continue to be a problem
  - The task force was in favor of Trip's proposal and will help the pharmacy board with pharmacist who are on probation with educations and follow-up. Details will be forth coming.
- Compounding commercially available FDA-approved products.
  - DOPL investigators would like to see documentation like "medically necessary" or documented case of patient failure. There has to be a reason to compound something a certain way.
  - There was discussion and many compounders that expressed concerns over this point. Task force members do not feel obligated to call the doctor to verify every Rx.
  - The task force members would like to speak with DOPL compounding experts to get on the same page before it is unrolled to Utah at large.
  - DOPL investigators will keep us in the loop concerning compounding commercially available FDA-approved products.
  - Dean expressed a formal response to DOPL investigation. His points are;
    - It is sufficient documentation for the doctor to document on the hard copy his specifics direction regarding dyes, flavors, excipient, and base when compounding a commercially available product. i.e. patient allergy.
    - It can not be a copy of commercially available product.
    - Be judicious in compounding commercially available products.

- New PEW compounding study

  - The purpose of the study is to inform the public of best practices for state oversight regarding compounding. Some recommendations the PEW study concluded includes;

    - Have minimum quality standards for compounding.

    - Have systems in place that track compounding pharmacies and require pharmacists to get meaningful relevant education.

    - Ensure policies in state are in line with federal law.

    - Establish meaningful oversight for compounding that occur in dr offices.

    - Move to annual inspections for sterile pharmacies.

**Meeting Adjourned**

**R156-17b-614a. Operating Standards - General Operating Standards, Class A and B Pharmacy.**

(1) In accordance with Subsection 58-17b-601(1), the following operating standards apply to all Class A and Class B
pharmacies, which may be supplemented by additional standards defined in this rule applicable to specific types of Class A and B
pharmacies. The general operating standards include:
(a) shall be well lighted, well ventilated, clean and sanitary;
(b) if transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, if
any, shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean
rooms where sterile products are prepared. Clean rooms should not have sinks or floor drains that expose the area to an open sewer.
All required equipment shall be clean and in good operating condition;
(c) be equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit
clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product
inventory;
(d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary
scope of practice to be conducted within that facility;
(e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner
consistent with the public health, safety and welfare; and
(f) if dispensing controlled substances, be equipped with a security system to:
(i) permit detection of entry at all times when the facility is closed; and
(ii) provide notice of unauthorized entry to an individual; and
(g) be equipped with a lock on any entrances to the facility where drugs are stored.
(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. If a
refrigerator or freezer is necessary to properly store drugs at the pharmacy, the pharmacy shall keep a daily written or electronic log of
the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain each log entry for at least three years.
(3) Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be
required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency
where applicable and sterility. The following requirements shall be met:
(a) Facilities shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if
compounding sterile preparations.
(b) Facilities may compound in anticipation of receiving prescriptions in limited amounts.
(c) Bulk active ingredients shall:
(i) be procured from a facility registered with the federal Food and Drug Administration; and
(ii) not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market
for reasons of safety or effectiveness.
(d) All facilities that dispense prescriptions must comply with the record keeping requirements of their State Boards of
Pharmacy. When a facility compounds a preparation according to the manufacturer's labeling instructions, then further documentation
is not required. All other compounded preparations require further documentation as described in this section.
(e) A master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile

pharmaceuticals to be prepared. Once approved, a duplicate of the master formulation record shall be used as the compounding record
from which each batch is prepared and on which all documentation for that batch occurs. The master formulation record may be
stored electronically and shall contain at a minimum:
(i) official or assigned name;
(ii) strength;
(iii) dosage form of the preparation;
(iv) calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;
(v) description of all ingredients and their quantities;
(vi) compatibility and stability information, including references when available;
(vii) equipment needed to prepare the preparation;
(viii) mixing instructions, which shall include:
(A) order of mixing;
(B) mixing temperatures or other environmental controls;
(C) duration of mixing; and
(D) other factors pertinent to the replication of the preparation as compounded;
(ix) sample labeling information, which shall contain, in addition to legally required information:
(A) generic name and quantity or concentration of each active ingredient;
(B) assigned beyond use date;
(C) storage conditions; and
(D) prescription or control number, whichever is applicable;
(x) container used in dispensing;
(xi) packaging and storage requirements;
(xii) description of final preparation; and

(xiii) quality control procedures and expected results.
(f) A compounding record for each batch of sterile or non-sterile pharmaceuticals shall document the following:
(i) official or assigned name;
(ii) strength and dosage of the preparation;
(iii) Master Formulation Record reference for the preparation;
(iv) names and quantities of all components;
(v) sources, lot numbers, and expiration dates of components;
(vi) total quantity compounded;
(vii) name of the person who prepared the preparation;
(viii) ;
(ix) name of the person who performed the quality control procedures;
(x) date of preparation;
(xi) assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable;
(xii) duplicate label as described in the Master Formulation Record means the sample labeling information that is dispensed
on the final product given to the patient and shall at minimum contain:
(A) active ingredients;
(B) beyond-use-date;
(C) storage conditions; and
(D) lot number;
(xiv) proof of the duplicate labeling information, which proof shall:
(A) be kept at the pharmacy;
(B) be immediately retrievable;
(C) include an audit trail for any altered form; and
(D) be reproduced in:
(I) the original format that was dispensed;
(II) an electronic format; or
(III) a scanned electronic version;
(xvii description of final preparation;

(xviii) results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids); and
(xix) documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient
or caregiver.
(g) The label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:
(i) the unique lot number assigned to the batch;
(ii) all active solution and ingredient names, amounts, strengths and concentrations, when applicable;
(iii) quantity;
(iv) beyond use date and time, when applicable;
(v) appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning
labels where appropriate; and
(vi) device-specific instructions, where appropriate.
(h) All prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent
shall bear at a minimum in addition to what is required in Section 58-17b-602 the following:
(i) generic name and quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation;
(ii) assigned compounding record or lot number; and
(iii) "this is a compounded preparation" or similar language.
(i) The beyond use date assigned shall be based on currently available drug stability information and sterility considerations
or appropriate in-house or contract service stability testing;
(i) sources of drug stability information shall include the following:
(A) references can be found in Trissel's "Handbook on Injectable Drugs", 17th Edition, October 31, 2012;
(B) manufacturer recommendations; and
(C) reliable, published research;
(ii) when interpreting published drug stability information, the pharmacist or DMP shall consider all aspects of the final
sterile product being prepared such as drug reservoir, drug concentration and storage conditions; and
(iii) methods for establishing beyond use dates shall be documented; and
(j) There shall be a documented, ongoing quality control program that monitors and evaluates personnel performance,
equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.
(4) The facility shall have current and retrievable editions of the following reference publications in print or electronic
format and readily available and retrievable to facility personnel:
(a) Title 58, Chapter 1, Division of Occupational and Professional Licensing Act

(b) R156-1, General Rule of the Division of Occupational and Professional Licensing;
(c) Title 58, Chapter 17b, Pharmacy Practice Act;
(d) R156-17b, Utah Pharmacy Practice Act Rule;
(e) Title 58, Chapter 37, Utah Controlled Substances Act;
(f) R156-37, Utah Controlled Substances Act Rule;
(g) Title 58, Chapter 37f, Controlled Substance Database Act;
(h) R156-37f, Controlled Substance Database Act Rule;
(i) Code of Federal Regulations (CFR) 21, Food and Drugs, Part 1300 to end or equivalent such as the USP DI Drug Reference Guides;
(j) current FDA Approved Drug Products (orange book); and
(k) any other general drug references necessary to permit practice dictated by the usual and ordinary scope of practice to be
conducted within that facility.
(5) The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The
list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be

readily retrievable for inspection by the Division and may be maintained in paper or electronic form.
(6) Facilities shall have a counseling area to allow for confidential patient counseling, where applicable.
(7) A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist or DMP is physically present
and immediately available in the facility.
(8) Only a licensed Utah pharmacist, DMP or authorized pharmacy personnel shall have access to the pharmacy when the
pharmacy is closed.
(9) The facility or parent company shall maintain a record for not less than 5 years of the initials or identification codes that
identify each dispensing pharmacist or DMP by name. The initials or identification code shall be unique to ensure that each
pharmacist or DMP can be identified; therefore identical initials or identification codes shall not be used.
(10) The pharmacy facility shall maintain copy 3 of DEA order form (Form 222) that has been properly dated, initialed and
filed and all copies of each unaccepted or defective order form and any attached statements or other documents.
(11) If applicable, a hard copy of the power of attorney authorizing a pharmacist, DMP, or DMP designee to sign DEA order
forms (Form 222) shall be available to the Division whenever necessary.
(12) A pharmacist, DMP or other responsible individual shall verify that controlled substances are listed on the suppliers'
invoices and were actually received by clearly recording their initials and the actual date of receipt of the controlled substances.
(13) The pharmacy facility shall maintain a record of suppliers' credit memos for controlled substances.
(14) A copy of inventories required under Section R156-17b-605 shall be made available to the Division when requested.
(15) The pharmacy facility shall maintain hard copy reports of surrender or destruction of controlled substances and legend
drugs submitted to appropriate state or federal agencies.
(16) If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls
shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy.