Compounding Task Force meeting August 19, 2014

Attendance:

Jennifer Jeppsen (Walgreens)

Bryan Horne (Lone Peak Pharmacy)

Christine Jacobsen (Wasatch Pharmacy)

Sharelee Mcintyre (DOPL)

Jennifer Healey (DOPL)

Travis Drebing (DOPL)

Camille Farley (DOPL)

Kort Delost (Medicine Shoppe)

Rob Smith (Rock Canyon Pharmacy)

Karin Caestia (Alpine Apothecary)

Jeanne Brennan (Attorney)

Dean Jolley (Jolley's Compounding Pharmacy)

Jacob Corsi (Isomeric)

Robert Muelleck (IHC)

Jim Ruble (University of Utah)

Trip Hoffman (University Pharmacy-Chair of Task Force)

For Office Use Discussion and Update:

See attached Memorandum from the Board

NABP does not see an exemption in the federal law authorizing individual states to allow office use compounding (sterile or non-sterile). NABP would not approve language that we drafted at this time because of the lack of guidance from the FDA. So, Rich Oborn and Trip Hoffman had a conference call with the FDA last Thursday to get clarification. They spoke with FDA representatives, Jane Axelrod and Danielle Grote, concerning our newly adopted rules and to see if we were on target with these rules. Rich Oborn was extremely supportive and proactive to get approval of our rules and to get answers regarding guidance on FOU and the FDA's position on allowing FOU compounding products. The FDA made it very clear from the start of the conversation that at this time 503s (traditional

compounding of the DQSA) requires an RX and 503b (outsourcing facilities) does not require an RX. Then they went on and said a pharmacy could be in compliance with our state rules and regulations but in essence be in violation of the federal law. Then they went through and pointed out the vagueness and leaving things wide open as in section 6 of our rules (mainly needs to be more strict limitations).

It still seems like the FDA will provide more guidance in this arena of FOU compounding but with no set deadline of when that might occur.

Per Pharmacy Board Meeting on August 26th, the board wanted to check with other states (Idaho and Colorado), the Attorney General's Office, and try to correspond with the FDA about a possible time frame of more FOU guidance and answers. Wait and see once again.

Discussed creating a list of much needed FOU items to provide the FDA. Please send in a list of compounded FOU products to Trip.

USP 800 Update:

Lloyd Allen, from IJPC, has reported we could potentially see this at the earliest next spring 2015 and then we would have 6 months to implement and to become compliant. We could see further dealy as the committee is expected to change early next year. Most likely there will be another comment session in about 3 or 4 months. The first comment session ended July 31st and it will be interesting to see the responses and issues.

Some of the main issues:

Biggest is the cost associated with a negative pressure room and the lack of evidence it is an absolute to protect the public and compounders. Economics of implementation could ultimately impact overall healthcare cost to provide certain vital compounded medications.

Powder containment hoods-Not adequate to keep everyone safe? Where is the evidence that this is a problem.

USP 800 is very detailed with handling, receiving, and garbing practices. It is extremely important to protect workers and patients with contact but it is difficult to wrap your head around putting progesterone and all HRT's in the same category of risk with a nitrogen mustard or other chemo drugs.

Positive note: the training programs and the medical surveillance programs are truly great.

****Jim Ruble** is putting together a **research proposal** to look at the implementation of compounding guidelines and issues related to quality, access, and cost.

Pain Cream Committee Update:

Billing inappropriate amounts, providing samples without an RX, and utilizing 1099 marketers are big concerns for our industry at this time and it needs to be addressed. DOPL will begin to look at closer

and said pharmacies should file a complaint with DOPL with any concerns on this topic if compounding pharmacies are not following the rules.

Cleaning Supply list:

Please provide cleaning supply list to Trip to create a master list of cleaning supplies.

DOPL Inspections:

Violations routinely seen upon inspections:

Expired compounded products on the shelf as well as bulk chemical materials used for compounding

Master Formulation Records are incomplete- sample labeling information inadequate and/or incomplete.

Extended beyond use dating (BUD) information not verified and supported with peer-reviewed literature

BUD are extended beyond 795 and 797

3a

MEMORANDUM

To: Utah Board of Pharmacy
From: Richard J. Oborn, Bureau Manager, DOPL
Date: August 26, 2014
Subject: Consideration of Proposed Standards for Office-Use Compounding

There is a question of whether the Division should allow a pharmacy to sell compounded medications to a practitioner for office-use without a patient-specific prescription. Senate Bill 77 required that the Division establish standards in rule for office-use compounding *(See Exhibit A).*

At the July Board meeting, Board members recommended that the Division adopt rules allowing this practice; however, since that meeting, the Division was informed by representatives of the Food and Drug Administration (FDA) that a pharmacy could comply with the office-use compounding standards outlined in the Utah Administrative Code but be fined or cited by the FDA for failure to comply with the Drug Quality and Security Act (DQSA).

Does the Board of Pharmacy recommend that the Division adopt rules that put a Utah pharmacy in this position?

Reasons to adopt the office-use compounding standards as proposed in *Exhibit B* include the following:

- **Practice is legal in other states.** Florida recently adopted a rule that allows a pharmacy to sell compounded medications to practitioners for office-use without a patient-specific prescription under certain conditions. Idaho is in drafting phase of a similar rule.

- **Practice is currently happening in Utah.** Utah pharmacies have long sold compounded medications to practitioners for office-use without a patient-specific prescription. SB 77 was passed partly because pharmacists felt the former law was not sufficiently clear about whether it was legal. They felt it was necessary to specify in the law the conditions under which it could happen and SB 77 allowed that to happen.

- **Practice provides patients immediate access to life-saving medications.** The practice allows a pharmacy to sell to a practitioner a small quantity of a compounded drug that is not commercially available or that is in short supply. When stored in the practitioner's office, a practitioner is prepared immediately administer it to a patient. The practice prepares a pharmacy and a practitioner to better meet the immediate needs of a patient.

Reasons to not adopt the compounding for office use standards as proposed include the following:

- **Informal guidance from FDA indicates that it is prohibited unless exemption requirements are met.** FDA confirms that, unless a pharmacy qualifies for an exemption as defined in federal law, it will issue citations and/or citations to a pharmacy that engages in any selling of compounded medications to practitioners for office-use without a patient specific prescription . This possibility applies to sterile and non-sterile

compounding. FDA claims that because the federal regulations regarding a pharmacy selling compounded drugs without a patient prescription are more strict than Utah law, pharmacies must comply with the federal regulation.

- **NABP has not issued guidance on this issue and has not taken a position.** For this reason, the Division has no model language from NABP to use as a guide in writing legislation.

The Division requests that the Board of Pharmacy recommend whether to adopt the attached standards.

Exhibit A
Senate Bill 77

SB 77: Pharmacy Selling of Drugs to Practitioners for Office Use

58-17b-624. Prescription drugs -- Sale to a practitioner for office use.

(1) A pharmacy licensed under this chapter may, subject to rules established by the division, repackage or compound a prescription drug for sale to a practitioner if:

(a) the prescription drug:
(i) does not include a compounded drug; or
(ii) (A) includes a compounded drug; and
(B) is not a controlled substance;

(b) the pharmacy labels the prescription drug "for office use only";

(c) the practitioner administers the drug to a patient in the practitioner's office or facility; and

(d) the practitioner does not dispense the drug to the patient.

(2) The division shall establish, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, prescription drug labeling and control standards for a prescription drug that a pharmacy provides to a practitioner under this section.

Exhibit B
Proposed Rule

R156-17b-102. Definitions.

"Office-use administration" means the provision and administration of a drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital or ambulatory clinic.

R156-17b-624. Operating Standards. Repackaged or Compounded Prescription Drugs - Sale to a Practitioner for Office-Use Administration.

In accordance with Section 58-17b-624, a pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use administration in compliance with the following standards:

(1) If repackaged or compounded, each drug sold by a pharmacy to a practitioner for office-use administration shall have a label securely affixed to the container indicating the following minimum information:

(a) the name, address, and telephone number of the pharmacy;
(b) the serial, batch, or lot number of the order as assigned by the pharmacy;
(c) the filling date of the order;
(e) the name of the clinic or practitioner ordering the drug;
(f) the directions for use or storage and cautionary statements, if any, which are contained in the order or are needed;
(g) the trade, generic, or chemical name, amount and the strength of dosage form, but if multiple ingredient products with established proprietary or nonproprietary names are prescribed, those products' names may be used;
(h) the beyond use date;
(i) if repackaged and not compounded, the statement: "For office use only. Not for dispensing or resale."
(j) if compounded, the statement: "Compounded medication for office use only. Not for dispensing or resale." and;
(k) if compounded, the name and strength of the preparation list of active ingredients and strengths.

(2) An inventory record of a repackaged or compounded drug shall be kept in the pharmacy in compliance with R156-17b-605 and, if applicable, R156-17b-614a (3). The inventory record shall include the order indicating, if applicable, the formula and quantity ordered.

(3) A pharmacy that compounds drugs for office use administration shall maintain a log of all compounded drugs for office use and shall monitor for recalled components. The log shall include the name of compounded products and ingredients, supplier's

identification (lot numbers), expiration dates, product preparation date, and name of the practitioner or clinic ordering the drugs. If a component is recalled, the compounding pharmacy shall notify the practitioner or clinic that ordered it. The practitioner or clinic is responsible to notify the patient of the reporting procedure for any adverse reaction or complaint in order to facilitate a recall of batches of compounded medications.

(4) Controlled substances shall not be compounded for office use administration.

(5) The repackaged or compounded drug shall be administered in the practitioner's office, health care facility, or treatment setting and not dispensed to the patient.

(6) The quantity of a drug compounded for office use administration shall meet the following requirements.

(a) The quantity shall not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date of the drug;

(b) The quantity shall not exceed a 90-day supply or the amount necessary to accurately compound the preparation. A 90-day supply shall be determined by the average number of dosage units administered during the previous six month period. If no dosage units were administered by the practitioner or clinic ordering the compounded drug during the previous six month period, a 90-day supply shall be determined by the amount reasonably projected to be administered in the next 90 days.

(c) The quantity shall not be greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines.

(7) A pharmacy engaged in the sale of sterile compounded drugs to practitioners must comply with 21 U.S.C. Section 353b, including being registered as an outsourcing facility.

(8) The content of federal law, regulation, or written guidance from the Federal Drug Administration shall supercede any provision of this rule if the federal law, regulation, or written guidance is found to be a stricter standard.

(9) Compounding of drugs used for office-use administration shall be performed in compliance with applicable sections of USP-NF 795 and USP-NF 797.