



**State Compounding Task Force
Minutes/Assignments**

November 12, 2013

7am

Wasatch Conference Room, Intermountain Supply Chain Center

Committee Members – Present indicated by (x):

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|---|---|
| (x) Trip Hoffman hoffjentrip@msn.com | (x) Koby Taylor kobytaylor@utah.edu |
| (x) Dallas Moore dallas.moore@imail.org | (x) Kort Delost kdelost@xmission.com |
| (x) Angela Whitney angela.whitney@imail.org | (x) Christopher Cox tophercox@gmail.com |
| (x) Rob Muelleck rob.muelleck@imail.org | (x) Dean Jolley dean@jolleydrug.com |
| (x) Christine Jacobsen christineph@wasatchpharmacy.com | (x) Jacob Corsi jcorsi@slhsrx.com |
| Bryan Horne b.horne@comcast.net | (x) Jennifer Jeppsen jennifer.jeppsen@walgreens.com |
| Kavish Choudhary kavish.choudhary@hsc.utah.edu | (x) Rob Smith robbie@rockcanyonpharmacy.com |
| Sara Ridges sara.ridges@hsc.utah.edu | (x) Evan Vickers evickers@le.utah.gov |
| Alisyn Hansen – U of U PGY1 Resident – alisyn.hansen@hsc.utah.edu | (x) Susan Andersen susan.andersen@imail.org |
| Caroline Heyrend – Pharmacy Student Intern – cheyrend@student.roseman.edu | |
| (x) Angeli – Intern | |

Agenda Item (Topic & brief description, and presenter)	Outcome and Next Steps (includes brief overview of discussion/decision and proposed timing for implementation)	Follow up and Responsible Individual (lead)	Due Date/ Timeline
I. Review of October Minutes <ul style="list-style-type: none"> • USP 797 Committee • USP 795 Committee 	Minutes from both the USP 797 and 795 committee meetings were reviewed and approved.		
II. Posting of Information from Compounding Taskforce	It was suggested that minutes and agenda items from this taskforce should be posted on websites to give information and guidance to DOPL and other interested parties. Dean motioned that the minutes from this taskforce be posted on the DOPL website, seconded by Trip. UPHA and USHP would also be willing to post this task force meeting information on their sites.	Minutes, agenda items, other information will be posted on the DOPL, UHPA, and USHP websites. Trip will provide information to be posted.	Now

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	<p>which supports the guideline. Trip suggested that the comment column also include actions taken if necessary. This document is not intended to add additional requirements, but to be used as a document for individual pharmacies to evaluate themselves.</p> <p>The document is intended to be used for pharmacies to go through each guideline and make sure that all of their requirements are included. It should be used to identify how they assess each item and provide documentation to support how the site tried to identify and define what is supposed to be done.</p> <p>Intermountain is calling the 797 document a Gap Analysis.</p>	<p>attend this task force meeting next month to give feedback.</p> <p>Angie will resend all of the documents from both committees to the group.</p> <p>Trip will share both documents with DOPL.</p> <p>Comments and/or changes to be returned to Angela and Jennifer for final editing. Trip will send to Rich before the next DOPL meeting.</p>	
IV. Legislation Update / HB 3204	<p>HB 3204 addresses “for office use”. NCPA – supports it. PCCA – either for it or neutral. IECP – against it. None the groups really liked the bill and all three would have liked to re-write it. They felt that the problems in the bill could be addressed and that it was better to approve what was written than to change it.</p> <p>More discussion will need to take place regarding interstate transport and a definition of what excess of 5% of total compounded drugs in any 6 month period means. Also how intra-company transfers relate.</p> <p>Jacob indicated that Tramadol is on the federally controlled substance registry for proposed controlled substances and that by May it could be approved.</p>	<p>5% rule will need to be clarified. Suggestion that 5% mean number of prescriptions and not a dollar amount.</p>	

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V. "For Office Use" Allowed? / Prescriptions	<p>For office use means that the product must be administered by the health care practitioner. The practitioner needs to provide notice within 7 days that the product was dispensed. This should be tracked in office and send back to pharmacy.</p> <p>Some problems with the rule is that it is difficult to enforce when the Dr. doesn't provide the list back to the pharmacy. Also, it is difficult for the pharmacy know if the office used the product.</p> <p>Intent is to encourage practitioners to track and trace substances that are given in their office. Similar to the Controlled Substance law.</p> <p>Sterile for office use may be different than non-sterile.</p> <p>Questions about how the office can be compliant because the pharmacist doesn't have the option to counsel the patient. Sometimes the Dr. Office doesn't realize it is a compounded medication.</p> <p>Dean presented a motion to have Trip to take these committees suggestions to the board, seconded by Rob.</p> <p>For office use regarding compounded products – need to have a counseling sheet that given to the patient to read and sign. Contact information about the pharmacy that compounded should be given. Inherent in that document would be a contract that the office agrees to provide counseling to the patient. Pharmacy could provide education regarding the compounded product to the office.</p> <p>Practitioner should report what was given and to who every 7 days. They could report on a specific day and if</p>	<p>Table for now until we see if the house resolution passes.</p> <p>Suggestion to have some writing in place that could be added to pharmacy rules if the resolution doesn't pass.</p> <p>Request to make sure 5% means of total number of prescriptions, not a dollar amount.</p> <p>Trip take this committees recommendations regarding "for office use" to the Board.</p> <p>Evan could present it to the Legislature in January if the Board has approved it.</p>	

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	<p>no report, the pharmacy could contact to find out.</p> <p>30 states permitted "for office use" 14 states – undefined 2 states – only nuclear pharmacy could provide 2 states – no office use allowed</p> <p>Most states that permit it define a reasonable quantity, some a time for reporting. Also would want to make sure the compounded product is given in line with what it is intended for.</p>		
VI. Class B Self-Inspection Report <ul style="list-style-type: none"> • Labels and ingredients 	Kavish is working on self-inspection report and training for hospitals.		
VII. Class B Pharmacy Inspector Training Update <ul style="list-style-type: none"> • Automation • Compounding Practices • General Procedures 	Deferred		
VIII. Master Formulation Sheets	797 committee was asked to bring master formulation sheets, both forms and formulations would be nice to have as well.		
IX. Meeting Dates	<p>The sub committees for USP 797 and 795 meet every other month. 797 Committee meets the week before the board meeting. 795 Committee meets the week of the board meeting.</p> <p>Task Force meets every other month which is generally the 3rd Tuesday but may be held on other weeks so that</p>	797 will meet on December 10 in the Wasatch Conference Room at the Intermountain Supply Chain Center. 795 will meet on December 19 th (morning of the board meeting)	

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	the meeting can be held one week before the board meeting.	In January the full task force meeting will be held January 21 st .	
Compliance Policy Guide	Essentially copies – need a definition of what that means. Interpretation.	Request Jim to attend the task force meeting in January.	January 21,2014
Compounding Information	Rule 156. 17 b 614 a (rule that was adopted last October) was approved by the board. Operating Standards Class B pharmacies Previously said pharmacist must identify all ingredients (fillers, dyes, etc.) It was changed to say that they must identify all components that require a prescription in the product.		
Chain Pharmacies Red Alert	Jacob said that a lot of pharmacies are banding together to create a “Red Alert” system. This would be a state wide alert to let other pharmacies know what the DOPL inspectors are looking for since everyone is having differing experiences. This seems to be happening due to a difference of opinion in what the law says.	Jacob will check with chain pharmacies and will send out their information about how to access the Red Alert System.	
UPHA Meeting	Mark Sims presented information on the Controlled Substance database at the UPHA meeting. They discussed how Positive ID is taken (the ID of the person who is receiving the prescription – not the person who is picking it up). They said a Customer ID – insurance number is OK. Suggest that maybe there are several ways to document the positive ID - Patient profile and also scan the driver’s license? They also discussed how pharmacies should submit to the database. Most have the information they just need to send it. Self-Inspection Program – lots of questions.		

Next meeting will be held, January 21, 2014 in the Wasatch Conference Room.

