



State of Utah Utah Board of Pharmacy Compounding Task Force

July 18, 2013

SUBJECT: Creation of Board of Pharmacy Compounding Task Force

Dear Utah Pharmacist:

The Utah Department of Commerce, Division of Occupational and Professional Licensing (DOPL) and Board of Pharmacy have formed a Compounding Task Force. The purpose of the Task Force is to facilitate communication between DOPL, the Utah Board of Pharmacy, and pharmacy professionals regarding public policies and new compounding regulations in the aftermath of sterile compounding contaminations originating in New England.

The Task Force hopes to support DOPL, the Board of Pharmacy, and all compounding pharmacists in being in concurrence with respect to compounding laws and regulations on the state and national level. The Task Force formation supports a proactive commitment of DOPL and the Board of Pharmacy toward optimal patient safety in sterile and non-sterile compounded medications and maintaining patient access to these customized medications in Utah.

More information from the Task Force is forthcoming; in the meantime, it is essential for all licensed pharmacy professionals practicing compounding to:

- understand United State Pharmacopeia (USP) General Chapters 795 and 797; (<http://www.usp.org/store/products-services/usp-compounding>);
- conduct a USP gap analysis (e.g., <http://www.ijpc.com/USP/>) and ensure compliance with USP if a gap analysis has not yet been completed; and
- complete the DOPL/Board of Pharmacy compounding self-inspection report available on the DOPL website and submit it to DOPL if this report has not already been submitted.

Licensed pharmacies that conduct sterile and non-sterile compounding activities should review their standard operating procedures (SOP). There are many examples of SOP templates available and many of these templates are offered through commercial programs. While DOPL and the Board do not specifically endorse these vendors, it may be useful for you to study some templates and compare them against your SOP. For example, see the International Academy of Compounding Pharmacy (IACP) at the following link: (<http://compoundingtoday.com/SOP/>). Other templates can be obtained from the Professional Compounding Centers of America (PCCA), the American Society of Health-System Pharmacists (ASHP), and Critical Point. In the future, the Task Force may provide additional assistance and guidelines for creating SOPs.

The Task Force is also considering creation of a voluntary, peer-reviewed inspection program to facilitate standardization among pharmacies who conduct compounding activities. This program

is intended to facilitate networking to increase compliance throughout all compounding pharmacies licensed in Utah.

In May 2013, DOPL investigators participated in an intense training program (Critical Point USP) to enhance their understanding of USP 795 and 797. In addition, DOPL is looking into providing financial assistance to a limited number of licensed pharmacists in Utah who are interested in attending a compounding training program. The Task Force, in coordination with the Utah Pharmacists Association (UPhA), has worked with IACP leadership to schedule a regional presentation on compounding in Salt Lake City in September 26, 2013. You may be interested to know that the Utah Society of Health System Pharmacists (USHP) will provide training on compounding at its annual meeting on September 14, 2013.

The Task Force typically meets at 7am on the Tuesday one week prior to Board of Pharmacy meetings. Items on the agenda for future Task Force meetings include beyond use dating and expiration dates, standard operating procedures (SOPs) and creating templates for standardization, considering a national accreditation process such as Pharmacy Compounding Accrediting Board (PCAB), voluntary peer-reviewed inspection program, and defining traditional compounding and manufacturing. If you have items that you would like to add to the agenda, please contact DOPL directly at doplbureau3@utah.gov or (801) 530-6288.

Sincerely,

Compounding Task Force Members

Trip Hoffman, Utah Board of Pharmacy Board Member and University Pharmacy
Senator Evan Vickers, Bulloch's Drug Store
Kavish Choudhary, University of Utah Health Care, Pharmacy Services
Missy Duke, Utah Society of Health-System Pharmacists, USHP
Angela Whitney, Intermountain Health Care
Dallas Moore, Intermountain Health Care
Dean Jolley, Jolley's Compounding Pharmacy
Kort Delost, Medicine Shoppe
Christopher Cox, Smith Rexall Drug
Christine Jacobson, Wasatch Pharmacy Care
Victoria Zippi, Infusion Innovations
Jim Ruble, University of Utah College of Pharmacy