

Task Force Meeting Minutes
05/09/2017

John Pritchett (Associate Director of Pharmacy for ACHC) gave presentation to compounding task force on USP 800.

- Compounding Compliance
 - 1-3% of prescriptions are compounds
 - USP is not a governing body and it is up to each state to determine how to incorporate USP 800. As such this ACHC will wait for states to implement USP 800 and for now will accredit pharmacies based on USP 795 and 797 guidelines. If a pharmacy wishes to be USP 800 then it can apply for a USP 800 distinction/certificate. As the landscape changes USP will make adaptations and incorporations as states come on line with USP 800.
- ACHC/PCAB work together to accredit pharmacies.
 - Accreditation is a survey rather than an inspection. John explained the process of accreditation and each pharmacy will receive the following;
 - Sheet of findings
 - Certificate
 - Anniversary Checkups
 - Surveyors
 - Educational workshops

USP 800

- Hazardous Drugs is the focus of USP 800 and was written to protect the employee and indirectly the customer.
- Has ramifications on USP 795- 797 and most likely be expensive to pharmacies to implement.
- US Safety Data sheets that are often thrown away or disregarded should become part of the pharmacy SOPs and staff should be educated on USDS sheets and implications.
- All containers need to be labeled with appropriate hazardous codes.

John's tidbits to start USP 800 compliance today

- Hazardous Drug List (NISOH) - separate hazardous from other non-hazardous drugs
 - Review Annually- documented and label hazardous ingredients.
- Install powder containment hoods.
- Document what exposure looks like to pharmacy.

NON-STERILE USP 800 COMPOUNDING

- C-PEC - powder containment hood
- Separate room for hazardous compounding
- Compounding rooms should contain the following;
 - Negative pressure
 - Hazardous drugs storage
 - Externally vented and HEPA filtered
 - Coated walls, crown moldings
 - Garbing in separate area
 - Sink available for hand washing

- Passthrough options
- Disposing of PPE
- Double Gloves- changed every 30min
- Gowns disposable- changes 2-3 hours
- Eye/Face protection
- Sterile Compounding
 - Externally vented
 - Negative Pressure
 - Sink 1 meter from negative pressure door
 - Buffer area - 2 layers of clothing
 - Pass- through
 - Refrigerator - put it near exhaust
 - Eye Wash Station
 - Sterile Gown and Sleeves
 - Eye/ Face Protection
- Shipping / Delivery SOPs will need to USP 800 compliant
- Personal - Person in charge of your hazardous drug compliance
- SOP - document and detailed
 - Waste Disposal

Compounding Task Force Meeting-

Task force attendees:

Trip Hoffman

Chris Cox

Sharilee McIntyre

Rob Muelleck

Matt Higley

Christine Jacobson

Mary Rogers

Jennifer Zaelit

Adam Jones

Jacob Corsi

Kyle Anderson

Koby Taylor

Dean Jolley

Jim Ruble

The Utah State Board of Pharmacy commissioned the task force to discuss and make recommendation to the board how Utah should implement USP 800.

Agenda items discussed.

- Utah state legislation update: House Bill 189: Allowed compounding pharmacies to compound any products without restriction to commercial patents. Bill surprisingly made it through house and was debated on senate floor but failed there.
- Utah Board of Pharmacy opposed bill.
- The task force is sending a survey to all State Boards of Pharmacy via a NABP link to analyze the plans for adoption and implementation of USP 800. Results will be back in by late June.
- Task force would like to send out survey to Utah pharmacies on USP 800 implementation to determine Utah pharmacy's status and understanding of USP 800. Survey will be sent out in the next few weeks.
- Ramifications if Utah or if Utah pharmacies did not adopt USP <800. Discussion led and presented by Jim Ruble.
 - Criminal ramifications for not ing USP 800 are not likely, Administrative ramifications for not adopting USP 800 are not likely, Civil Risk ramifications for not adoption USP 800 are plausible.
 - Jim asked task force to consider implications of implementing USP 800 in Utah by considering the balance between regulation, patient access, and cost.

Presentations:

- Koby Taylor read a document compiled by Karin Carestia concerning the effectiveness of powder containment hoods
- Kyle Anderson gave an update on 800 in CA and TX
- Kyle Anderson gave an overview on Lloyd Allen's document "800 Alternatives for State Boards of Pharmacy"
- Christine Jacobsen gave a synopsis of the WA State Hazardous Drug Handling Program for Community Pharmacies.
- Trip led a discussion on what is the primary objectives of USP 800 implementations. After much discussion, it was decided and voted on by the task force with unanimous approval to sequentially review each section of USP 800 to decide what policies to adopt and how and when to implement them.
- The task force decided to meet monthly for the next few months until all 18 sections have been reviewed.
- The task force will try to review 8 sections at a time.
- The sections were divided among members to the task force and assigned as follows:
 - Mary Rogers: sections 1 to 2
 - Koby Taylor: sections 3 to 4
 - Rob Muelleck: sections 4 and 5
 - Kyle Anderson: section 6 and 7
 - Karin Carestia: section 8 and 9
 - Christine Jacobsen: section 10
 - Matt Higley: section 11

- Jacob Corsi: sections 12 to 14
- Jim Ruble: section 15 and 16
- Russell Findlay: section 17 and 18
- Jim Ruble has 3 students that will help organize, prepare, and write task force recommendations about USP 800.
- Meeting Adjourned

Next meeting: 6/20/2017 7:00 AM UofU College of Pharmacy- Sections 1 to 8 to be discussed

Future scheduled 800 meetings: July 11th (Sections 9 to 14) and August 15th (Sections 15 to 18)