FLORIDA | Board of Pharmacy
Compounding Committee Meeting

DRAFT
June 25, 2018 – 1:00 p.m.

Telephonic Conference Call
Conference Call Number: (888) 670-3525
Conference Code Number: 5134896685

Mark Mikhael, PharmD,
Chair, Compounding Committee

C. Erica White, MBA, JD
Executive Director

Thursday, June 25, 2018

Those present for all or part of the Compounding Committee Teleconference Meeting included the following:

COMMITTEE MEMBERS PRESENT:

- Mark Mikhael PharmD – Chair
- Richard Montgomery, BPharm, MBA
- Blanca Rivera, BPharm, MBA
- David Wright, BPharm

BOARD MEMBERS PRESENT:

- Jonathan Hickman, PharmD
- Jeenu Philip BPharm
- Jeffrey Mesaros, PharmD, JD

BOARD COUNSEL:

- David Flynn, Assistant Attorney General
- Lawrence Harris, Assistant Attorney General

STAFF PRESENT:

- C. Erica White, MBA, JD, Executive Director
- Robert DiFiore, , RPh, Pharmaceutical Program Manager – Department of Health, Division of Medical Quality Assurance - Bureau of Enforcement

AUDIO from this meeting may be found online at: http://floridaspharmacy.gov/

The Committee Discussion convened at approximately 1:00 p.m.

Call to Order:
(*Facilitator – Dr. Mikhael)*

Dr. Mikhael called the meeting to order, and thanked everyone for attending the call. Dr. Mikhael stated that Chapter 795 is coming into effective in December 2019. The public comment section is ending in July 2018, and that some other Boards of Pharmacy have issued a response regarding the effect of the changes to this chapter.

Ms. White took a roll call. All committee members were present along with Board Staff and Board Counsel.

Opening Comments:
(*Facilitator – Dr. Mikhael)*

Dr. Mikhael stated that the rewrite to Chapter 795 has some serious implications to the profession of pharmacy. Looks like USP is working into three (3) distinct chapters:

- Complete full re-write of USP Chapter 795
- Extensive re-write of USP Chapter 797
- Introduction of USP 800

Dr. Mikhael stated that USP goal is to push all of these amendments together for release in December 2010. Dr. Mikhael further stated that from the Board's perspective, we need decide or start to look at what aspects are going to come into play within the State of Florida. What is going to be enforceable, and what really makes sense for the public safety and welfare.

USP 795 is going to have a dramatic impact to the retail market. Dr. Mikhael has some concerns regarding what this may do to the profession of pharmacy or industry within the state. We saw, unfortunately, through the New England Compounding Center (NECC), as USP 797 came into play, it really created this market of outsourcers that were following USP 797, and able to sell to these pharmacies. With a lot of the restrictions being within USP 795, Dr. Mikhael's fear and his concern, it is going to create another outsourcing non-sterile market which may go unregulated.

The DQSA is specifically detailed for sterile human products. Without that direct reporting on USP 795, Dr. Mikhael has concerns for people may get into the potential outsourced non-sterile market, and really create havoc and unsafe conditions around the State of Florida.

Mr. Wright stated that he does a lot of non-sterile compounding, and just reading through the re-write of USP 795, it would completely "up-end" the industry as we know it. It seems like the rewrite was not well thought through. All of the ramifications of activities of what they are saying need to be done. Mr. Wright has huge concerns, and agrees with Dr. Mikhael, that the outsourcing will probably be where it will go to, because the vast majority of these things a retail pharmacies couldn't comply with. A lot of time you have to compound because something is not available, and the general health of our constituents would be in jeopardy.

Ms. Rivera stated that the financial implication on this would be huge. Having to redo an entire sterile room would be very costly to do. Dr. Mikhael stated that the financial burden associated with the new proposed requirements of USP 795. Mr. Montgomery asked if there was going to be a differentiation between 503a and 503b facilities? He thinks that there needs to be a difference between patient-specific medication and mass production.

Mr. Flynn mentioned that the Florida Board of Pharmacy recently amended Rule 64B16-27.700, F.A.C., in the case of compounded products intended for human use, if you are going to do outsourcing (non-patient specific) you have to be compliance with 353b, which, in turn, means that they would have to be today compliant with Current Good Manufacturing Practices (CGMP). We have addressed it a little bit, just as a reminder. There doesn't seem to be a state statute or law nor a federal statute on point on outsourcing or compounding, non-patient specific, for non-sterile human drug products. In Florida, if a pharmacy goes to the concept of making it in bulk, without a prescription, there will be some safety parameters in place. Rule 64B16-27.700(3)(g), F.A.C., pushes the pharmacy to comply with 353b.

Draft Revisions to USP Chapter 795:
(*Facilitator – Dr. Mikhael)*

CVS Health submitted comments to the Committee Chair, Dr. Mikhael regarding discussion on the USP 797 Draft, and Dr. Mikhael used this document as a "springboard" for the Committee discussion on the draft revisions:

- **USP Ch. 795 Should Be Further Revised to Tailor the Nonsterile Compounding Requirements to the Category of Compounding Being Performed (i.e. Simple, Moderate, Complex) in a Facility**
  Dr. Mikhael stated that in the USP 795 rewrite, the terms "Simple, Moderate, Complex" were deleted, and Dr. Mikhael asked the Committee members if they were in agreement with eliminating these terms? Mr. Wright stated that he does not agree doing away with these terms. Mr. Montgomery and Ms. Rivera also agree that these terms should not be eliminated. Mr. Philip stated that there needs to be an understanding of risk and the risk management associated with simple compounds versus the other types of compounds.

  Dr. Mikhael requested the following be included in the comments to the USP on the afore-referenced point: Not all compounded is created equally, and compounding should be looked at in different categories based on the risk to the public.

- **Introduction and Scope - Definition of Nonsterile Compounding (lines 1-11)**
  Dr. Mikhael stated that alteration is not a defined point, and he is concerned that this term is not clearly defined. He stated that if you split a tablet, then you have "altered" a tablet – referenced performing this action for elderly patients. Altering may include performing actions to allow ease of use by the patient. Mr. Montgomery stated that he doesn't see the harm in altering a sterile drug to a nonsterile drug within certain parameters. Dr. Mikhael also stated that adding flavoring of suspensions could be inhibited by the word "alteration". Ms. Rivera stated that she agreed, and stated the proposed language which references reconstitution would change standardized practices used by pharmacies for years.

- **Compounding of Hazardous Drugs (lines 24-26)**
  Dr. Mikhael does not necessarily agree with the CVS Health comments on this point. For the purposes of the reply letter to the USP, Dr. Mikhael doesn't really have any issue with the language in the proposed revision. Mr. Montgomery stated that he thinks that we need to have some standards in the proposed revision to protect pharmacists and pharmacy technicians. Mr. Flynn stated that in the event that the Board went through rulemaking would adopt USP 795, it would need to make the decision to also USP 800, since it is an internal reference within the proposed rule. At this time, Dr. Mikhael does not want to include this comment in the Board's letter to the USP, because he wants the comments to center around public health and safety.

- **Affected Personnel and Settings (lines 41 – 58)**
  Ms. Rivera had concerns about whoever is transporting medications needing to have a certain level of competencies, and the language does not seem to provide for any delineation or responsibility. Mr. Montgomery agrees with Ms. Rivera, and he thinks that it is a reach to try and manage your people and delivery folks. Mr. Wright concurs. Dr. Mikhael thinks that this provision overshoots, way too far, the intent of what is intended by the revision.

Dr. Mikhael's point is that we want to ensure that: (1) the person doesn't have to be on site, and (2) this should only be required for the complex compounding, not simple compounding. Ms. Rivera also added, it should also be applicable only for the person who is doing the compounding. Dr. Mikhael stated that and additional point would be that: (3) this proposed language should not be applicable to all compounding, and that the training needs to be specific to the job functions being performed (which is in line with USP 797). The final point would be : (4) there is already someone in the pharmacy, the Prescription Department Manager, who is responsible for the functions of the pharmacy.

- **Training Requirements (lines 62-116)**

  Mr. Philip stated that at the chain level, there should be language included which includes an option for training to be provided by a clinical central group. Dr. Mikhael stated that notwithstanding any training provided, it is the responsibility of the PDM or pharmacist on staff, that there is some sort of checklist training to do that. Mr. Philip states that there are two (2) different parts to training: development and execution of the training. Dr. Mikhael suggested that the point be made in the USP letter that appropriate training needs to be done based on the job functions performed, and it is responsibility of the facility to ensure that before those job functions are performed that staff is trained appropriately.

  Mr. Wright wants the point added regarding having an approved training program (corporate vs. independent). The question is what are the standards (i.e. – outline) for an approved training program. Dr. Mikhael suggested that we include language in the letter which states that the Board would like to see a little bit more guidance around an approved training program. More direction (or an outline) is requested regarding what would be an approved training program.

  Dr. Mikhael stated that there is a huge costs associated with access to USP compounding monographs, other applicable general chapters, and other relevant literature. Does a local independent pharmacy need to have access to this information? Dr. Mikhael does not know if a normal local drug store, needs to have access to this information. Mr. Montgomery stated that there are other sources out there that can be used for simply compounding. He doesn't think that the USP monographs the only source of truth to make a good, safe product. Mr. Wright also stated that none of us use USP. We all use PCCA or Medisca or one of these guys that provide chemicals, but also have professional staff that's doing testing.

  Dr. Mikhael stated that there are other providers of monographs which should be deemed as acceptable. He asked language be included in the introductory paragraph of to the Board's letter to USP, that the alot things outlined within the rewrite of the chapter 795 are not day-to-day pharmacy practice and thus inhibiting what we consider the practice of pharmacy.

- **Personal Hygiene and Garbing**

  Mr. Montgomery thinks that there needs to be some kind of safe handling. It should be a clean area. Dr. Mikhael stated that it inhibits the standard of practice for the profession of pharmacy. This is simple compounds and simple procedures, and there should be some procedures implemented for simple non-sterile preparations that do not go into this level.

- **Buildings and Facilities**
  Mr. Wright stated that there are costs associated with some of these provisions. Dr. Mikhael stated that if you are doing patient specific compounds, and if you are not doing them in bulk, that these provisions are overreaching. Mr. Philip stated that it is not really clear in the language what level of separation is necessary. These provisions are not necessary for simple compounding processes.

- **Cleaning and Sanitizing**
  Ms. Rivera stated that at a hospital, you don't asked for hands to be washed, and there are certain hand sanitizers that are used. In the proposed language, it is asking for people to wash their hands every single time they come into the pharmacy area. The proposed language appears to be overreaching.

- **Equipment and Components / Component Handling and Storage**

  Dr. Mikhael asked how many retail pharmacies or hospitals will be able to add containment hoods, as required in the proposed language? He thinks that all of these things tie into what is the level of compounding and the current provisions are too overreaching. Mr. Montgomery thinks that the hood is overkill, but there are other types of containment devices that are smaller.

  The Committee discussed the proposed language to include in the USP letter, is the containment hood "overkill" for simple compounding. They would like this to be broadly worded that there should be adequate measures in place that applies protection to both the compounder and the finished product. Mr. Wright said that the cost here is huge, and he is concerned that a lot of people will drop out of compounding. He thinks that USP 800 going to be the preventive we need for hazardous materials, and not have to do this for simple compounding.

- **SOPs and Master Formulation and Compounding Records**
  Mr. Wright would completely agree with the comment in the CVS letter. The Committee members discussed this issue and felt that it should only apply to simple compounding procedures. Dr. Mikhael suggested that the comment to be included in the USP letter should be: "Although the Board does support the requirement of a Master Formulation record, we do have concerns with its complexity for the different levels of compounding which may be performed in the pharmacy." Mr. Philip agreed that our comments should include the position stated in the CVS letter that the Master Formulation Record should be optional – not required. Mr. Wright stated that this provision would not be necessary to promote public health or safety of pharmacy constituents. The final suggested comment to be included in the USP letter is that: "The Board would be in support of a Master Formulation Record, but what is currently identified in the USP 795 rewrite is overbroad. The language relating to the Record should only be identified for complex compounds, and only be pertinent to the information needed for the compound itself."

  Ms. Rivera commented that under the proposed re-write to this section, there are some requirements which have the potential to be costly. For example, under box 7-2 related to "Compounding Records", they have things saying that you have the name, vendor, and each ingredient or expiration of the container closure system. Mr. Wright stated that the need for this requirement would rarely happen. Dr. Mikhael stated that this requirement is "completed overkill" – it seems a little bit outside the norm. Mr. Philip suggested that the proposed revised

language in this area is not applicable in most situations. Mr. Montgomery stated that the language would be getting into CGMP and would not be applicable in regular drug stores.

- **Labeling**
  The Committee agrees with the position in the CVS letter that use of the "Beyond the Use Date (BUD)" would be problematic. Mr. Wright stated that for patient understanding it should remain at expiration date. The suggested language in the USP 797 comment letter would be: "Use of the Beyond the Use Date (BUD) instead of the expiration date is too confusing to the public; therefore, the labeling requirement should reference an "expiration date" for the prepared prescription." Ms. Rivera also stated that it would be wise to include language about "release testing" and how this requirement would be overbroad. She would like to have a line added in the USP stating that it would be overkill (see line 418 of proposed revision for reference).

- **Establishing a BUD for a CSNP**
  Dr. Mikhael does not like the requirement of establishing a mandatory BUD requirement, and would not be in favor of predetermined BUDs. Mr. Philip also suggested that the compounding date should be referred to as "Day 0" instead of "Day 1". Should USP continue to use BUDs, the day the product is compounded should be "0". Mr. Wright position does not think that the current standard of days should be changed from what he is currently doing according to standard practice. Dr. Mikhael said that this provision may be applicable in CGMP practices, but would not be applicable in a corner drug store environment.

- **CSNP Handling, Packaging Storage and Transport**
  Dr. Mikhael stated that he thinks that the proposed language in this provision is overbroad. The Committee also discussed that there is no basis for reducing the expiration from 180 to 90 days.

- **Complaints**
  Dr. Mikhael stated that complaints should not be going to USP, but rather should go to the Board of Pharmacy Office. If there are complaints against a pharmacy, it should go to the Board Office responsible for governing (or licensing) the individual pharmacy for action or follow-up. The language should be removed completely from this section because it has no bearing on the compounding of sterile or non-sterile products. The Committee agreed with this point.

- **Documentation**
  Dr. Mikhael stated that this provision is overkill for your standard, traditional drugstore pharmacy. There needs to be a distinction between your CGMP and your standard professional pharmacy.

Mr. Montgomery stated that there is a distinction between the "practice of pharmacy" and manufacturing. We need to make sure where that line is, with the understanding that we need to protect the employee, the pharmacy and the products. Ms. Rivera wanted to address the financial aspects of putting some of these suggestions into place. Mr. Philip stated that we should frame any concerns raised about financial impact around patient access. Due to the increased financial burden, this would have a negative impact to patient access.

Dr. Mesaros stated that he would like to thank the Compounding Committee for taking the time to discuss this matter thoroughly. Mr. Philip thanked Dr.. Mikhael and the Committee for taking the time to address this issue thoroughly.

Public Comment: Dr. Lauren Paul from CVS Health thanked the Board and Committee for the robust discussion on this issue.

Dr. Mikhael thanked Board Staff, Board Counsel, Board Members and Committee members for participating in the call. Motion to adjourn made by Mr. Montgomery and seconded by Mr. Wright.

The Subcommittee Discussion convened at approximately 2:48 p.m.