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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MINUTES

DATE: June 2, 2017

LOCATION: Sheraton Park Hotel
1855 S. Harbor Blvd.
Anaheim, CA 92802

COMMITTEE MEMBERS PRESENT: Amy Gutierrez, PharmD, Licensee Member, Chair
Allen Schaad, Licensee Member, Vice Chair
Stan Weisser, Licensee Member
Valerie Muñoz, Public Member

COMMITTEE MEMBERS NOT PRESENT: Greg Lippe, Public Member
Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Julia Ansel, Chief of Enforcement
Tom Lenox, Chief of Enforcement
Laura Freedman, DCA Staff Counsel
Christine Acosta, PharmD, Supervising Inspector
Laura Hendricks, Staff Analyst

Note: The webcast of this meeting may be found on the board's website.
http://www.pharmacy.ca.gov/about/meetings_enforcement.shtml

I. Call to Order, Establishment of Quorum and General Announcements

President Gutierrez called the meeting to order at 8:33 a.m. Board members present: Amy Gutierrez, Valerie Munoz, Stanley Weisser, and Allen Schaad.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Note: The board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

John Gray, pharmacist from Keck Medical Center of USC, read the following statement.

> *I would like to request the addition of an agenda item to the next appropriate Board meeting. Section 1735.6(e) in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations states: "Hazardous drug compounding shall be*

completed in an externally vented physically separate room…". Based on recent sterile compounding license inspections and personal discussions with Board of Pharmacy inspectors, it is evident that the Board is interpreting this regulation to mean that "Hazardous drug compounding shall be completed in an externally vented physically separate room which is separately vented from the room's primary engineering controls." In practice, depending upon the characteristics of the negative pressure room and the Biological Safety Cabinets, it is possible to meet the room performance requirements described in sections 1735.6(e)(1)&(2) and 1735.1(e)(2) by externally exhausting the room air through the grille in front of the BSC, which is manufactured, tested, and certified for this specific purpose as a PEC.

I would like to request that the Board review the actual language and its current interpretation of Section 1735.6(e). In doing so, I would encourage the Board to recognize that external venting of a negative pressure room for hazardous drug preparation via a Class II Type A2 BSC is not a threat to patient or employee safety and is one appropriate mechanism to meet the external venting requirement described in Section 1735.6(e).

The committee thanked Dr. Gray and requested a picture to help illustrate the flow of room air out of a negative pressure room for hazardous drug preparation via the biological safety cabinet.

Douglas Barcon, pharmacist, asked the committee to consider how AB 443, which would allow optometrists to provide certain vaccinations, might affect the practice of pharmacy.

Dieter Steinwetz, pharmacist from Coast Compounding Pharmacy, asked the committee to consider reevaluating the pharmacy technician ratio in compounding pharmacies.

III. Review and Discussion of Board's Compounding Regulations, CCR Section 1735 et seq., and Section 1751 et seq., and Relevant Chapters of USP Pharmacopeia relating to Compounding

President Gutierrez explained that CCR section 1735 et seq., and CCR section 1751 et seq., establish the requirements for compounding drug preparation.

President Gutierrez stated that Business and Professions Code (BPC) section 4127.1 requires the board to adopt regulations to establish policies, guidelines and procedures to implement Article 7.5, Sterile Drug Products. BCP 7127.1 also requires the board to review any formal revisions to General Chapter 797 of the United States Pharmacopeia and the National Formulary (USP-NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official.

President Gutierrez noted that updates to USP 797 are pending, but there is currently no timeline for their finalization.

President Gutierrez reported that in April 2015, the board formally initiated a rulemaking to promulgate the board's compounding regulations. The final version of the regulation language was adopted by the board on January 19, 2016, and approved by the Office of Administrative Law on September 13, 2016. She added that the effective date of the regulations was January 1, 2017.

President Gutierrez explained that since adoption by the board, both the committee and board have received public comment regarding the impact of the regulations on patient populations, including

animals. Although comments have been provided in several areas, many of the comments are focused on the board's requirements for the assignment of a Beyond Use Date (BUD).

President Gutierrez reported that during the committee's April meeting, a presentation was provided by Road Runner Pharmacy regarding concerns about the board's regulation relating to the requirements for the establishment of the BUD of veterinary products. The committee was advised of some of the challenges for compounding medications for their patient population. The committee was also advised about the cost impacts of the board's current regulations and the resulting impact on consumers and their pets. President Gutierrez explained that after hearing the presentation and public comments about the board's regulation, the committee determined it was necessary to schedule a special meeting to focus on several different aspects of the board's compounding regulations.

President Gutierrez stated that during the May 2017 board meeting, members heard comments on the issue, including reference to the DQSA and its lack of applicability to veterinary compounding. She explained that since the May meeting, board staff has confirmed that the provision of the DQSA relates specifically to human drug compounding, meaning the compounding provisions for 503A and 503B provisions apply only to human drugs. President Gutierrez also noted that California pharmacy law does not differentiate between compounding for humans versus animals. Staff has confirmed with USP (Untied State Pharmacopeia) that all compounding chapters apply to human and animal patients and that USP <795> includes a section specific for animal patients.

IV. Discussion on Possible Recommended Changes to the Board's Compounding Regulations, CCR Section 1735 et seq, and Section 1751 et seq

President Gutierrez explained that at this meeting, committee members will have the opportunity to discuss possible changes to the board's compounding regulations being brought forward by both staff and stakeholders.

President Gutierrez reviewed the following recommended changes provided by board staff.

- 1735 Compounding in Licensed Pharmacies: Board staff does not believe that the mixing of ingredients from a compounding kit purchased from an FDA approved manufacturer needs to be included in definition of compounding if done according to the manufacturer instructions.

- Section 1735.2 Compounding Limitations and Requirements; Self-Assessment: Board staff recommends changes to the establishment of the BUD to more closely align with the requirements of USP <795> (for nonsterile products) and USP <797> for sterile products including changes to 1735.2(i)(1), 1735.2(i)(2) and 1735.2(i)(3).

- Section 1751.1 Sterile Compounding Recordkeeping Requirements: Staff recommends clarifying the requirements for smoke studies, including both the applicable area where such studies must be performed (ISO Class 5) as well as the frequency in which they must be conducted (semi-annually).

- Section 1751.4 Facility and Equipment Standards for Sterile Compounding: Staff recommends clarifying that cleaning must be done whenever hazardous drugs are being compounding as well as clarifying where the cleaning must occur.

Eric Kastango, from Critical IQ, thanked the board for working on harmonizing the California regulations and the USP chapters wherever possible as this will protect human and animal patients. He noted that in light of the BP syringe problem that occurred several years ago the board must be very cognizant of what type of containers compounded medications are being stored in in order to ensure they maintain their stability.

President Gutierrez asked Dr. Kastango if he had any recommendations on areas where the board should focus. Dr. Kastango responded that the board should harmonize the terminology used in its regulations with those used in USP. He also stated that there are major differences between potency over time and stability – mainly that potency over time does not look at impurities or the inactive drug once it has been subject to degradation. Dr. Kastango also stated that there are differences between cleaning and disinfecting, he noted that he agreed with the comments submitted by CPhA in this area.

Senator Stone thanked the board for being receptive to the concerns being raised by the regulated public. He stated that the goal for compounding pharmacists to ensure that their patients receive save and effective medications. Senator Stone added that these compounding pharmacies must have the ability to continue to provide their patients with these very important compounded medications in a safe manner. The committee thanked Senator Stone for attending the meeting and for his support.

Note: All written comments submitted to the committee were provided in the meeting materials and have also been provided immediately following these minutes.

Jon Roth, representing the California Pharmacists Association, reviewed the following changes being requested by CPhA.

- 1735.1(l) Amend the definition of "daily."
- 1735.1 (n) Amend the definition of dosage unit to beyond one administration and allow for the dosage unit to be considered a quantity prescribed.
- 1735.1 Add a definition of sterility.
- 1735.2 (i)(1) – (3) Amend the BUD requirements.
- 1735.2 (4) Change requirements relating to the extension of BUD provisions to what appears to be allowing analogous versus identical ingredients.
- 1735.2 (5) Correct the drafting error where the board inadvertently indicated that shorter dating can be done.
- 1735.2 (6) Request recognition of potency over time study as applicable to the compounded formulations can be used to validate stability and assign extended beyond use dates.
- 1751.1(a)(5) Clarify smoke studies in an ISO Class 5 certified space.
- 1751.4(d) Clarify that cleaning does not need to happen daily, but rather every day the facility is used to prepare sterile drug compounds.
- 1751.4(k) Remove minimum room temperature requirement.
- 1751.6(e) Correct typo by removing redundant "sterile" and indicate that training can vary for someone only directly supervising individuals compounding, not performing it themselves.
- 1751.7(e)(1) Allow for an equivalent method of testing as those described in USP 71 and exempt pyrogen testing from irrigation.

The committee thanked Mr. Roth for his testimony and asked him to provide an example of the medications that would be covered under 1735.1 (n).

Erik Tosh and Anthony Grzib, representing The International Academy for Compounding, spoke in support of the testimony provided by CPhA, especially their request to change requirements in 1735.2 (4) relating to the extension of BUD provisions to what appears to be allowing analogous versus identical ingredients.

President Gutierrez asked Allen Schaad to lead the discussion on Kaiser's comments as she is employed by Kaiser.

Corbin Bennett, representing Kaiser, reviewed the following changes being requested by Kaiser.

- 1735.1(r) and 1735.6(e) Requests changing the hazardous provisions to mirror the requirements in USP 800.
- Requests clarification on smoke study environments.
- 1751.4(d) Requests that the regulation specify that ready-to-use germicidal detergent, including sterile water, is acceptable.
- 1751.4(g)(1) Requests addition of a requirement for two pairs of standard gloves for all hazardous compounding.
- 1751.3 and 1751.4 Request clarification on the need for sampling for the segregated compounding areas outside of the ISO-5 environment. Question: Is the sampling plan and procedures for nonviable particle samples as well as violation air and surface limited to ISO certified areas, or does it also apply to segregated compounding area outside the ISO environment.
- Request clarification if a pharmacy can contract with another pharmacy for compounded products or just parenteral.

Erik Tosh, Vice President of Professional Services at Letco Medical, stated that Letco Medical supports the comments made by CPhA and Kaiser. Dr. Tosh asked the board to modify 1735.2(i) as the board's interpretation of "identical" is too limiting.

Mark Johnston, Senior Director of Regulatory Affairs for CVS, Laura Churns, Legislative and Regulatory Affairs for Albertsons and Rob Mullens, Divisional Pharmacy Vice President for Rite Aid, asked the board to amend 1735.8 (c) so that retail pharmacies can continue to provide simple non-sterile compounded medications to their patients at a reasonable cost.

Mr. Johnston explained that much of the compounding done in retail pharmacies are simple and moderate, non-sterile compounding (e.g magic mouthwash prepared from a kit or the mixing of two creams from a manufacturer's packaging). He advised the committee that costs associated with complying with 1735.8 exceed total profitability and therefore it is not fiscally responsible to compound low volumes necessary for their patients.

Laura Churns provided examples of how patients would be negatively impacted if retail pharmacies are no longer able to provide simple, non-sterile compounded medications such as magic mouthwash and Tamiflu. The committee asked if the presenters could provide additional examples of the types of simple, non-sterile compounds they would like to have exempted from the definition of "compounding."

Mr. Mullens explained that patients in rural communities rely on their local retail pharmacies to provide them with simple, non-sterile compounded medications. President Gutierrez asked if the comments made by the presenters only referred to topical and oral non-sterile medications. Mr. Mullens confirmed.

Mr. Schaad asked if the presenters could provide a partial list of the compounding medications provided by these retail pharmacies.

Mr. Weisser expressed his support for these pharmacies providing their patients with these simple non-sterile compounded medications. Mr. Mullens noted that while it is not done very frequently, it is often for children or critically ill patients.

President Gutierrez asked if a compounding log is kept for these medications. Mr. Johnson confirmed that a compounding log is kept.

Rick Rhoads, Director of Compounding at University Compounding Pharmacy, reviewed the following recommended amendments.

- 1735.1(r) Harmonize the definition of hazardous to mirror the USP <800> definition
- 1735.1 Add a definition of "Stability"
- 1735.2(i)(3) Change the requirements to extent a BUD
- 1735.6(e) & 1751.4(g)(1) Create and exception allowing a pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastics
- 1751.3(c) Provide detailed description of the information standard operating procedures (SOP) must include for sterilization and depryogenation processes
- 1751.11 Add provisions to establish requirements for sterilization and depryogenation

There were no questions from the committee or the public.

Lee Martin, PIC for Road Runner Pharmacy, reviewed the following requested amendments. He also noted that the board's regulations far exceed USP standards in a number of areas.

- 1735.2(a) Remove the requirement to document a prescriber's authorization to compound a product
- 1735.2 Make stability, container closure, sterility and testing frequency consistent with USP standards

President Gutierrez clarified that Road Runner is asking the board to align with USP 795 for non-sterile compounding. Dr. Martin confirmed that they would like the board's regulations to mirror USP 795 for non-sterile compounding.

Adam Landsmen, Regional Sales Manager for Road Runner Pharmacy, stated that he has seen many of their competitors ignoring the board's compounding regulations. He expressed concern that there is an uneven playing field for pharmacies that are spending money to comply with the regulations. President Gutierrez asked the presenters to keep their comments to specific sections of the regulations that they would like amended.

Note: Road Runner Pharmacy provided documents to the board, however DCA legal counsel asked that the board not review the documents as they contained a complaint against another licensee. Staff collected the documents.

Anthony Grzib, director of pharmacy compliance for Wedgwood Pharmacy, and Rachel Pontikes, national counsel for Wedgwood Pharmacy, spoke in support of CPhA's recommendation to modify 1735.2 (i) to amend the BUD requirements. Dr. Grzib also reviewed the following requested amendments.

- 1735.2(c) Change the prescriber office use provisions to expand the conditions under which prescriber office dispensing can be done and change the definition of reasonable quantity.
- 1735.2(d) Change regulation to indicate that the prohibitions to compound only apply to human drugs.

President Gutierrez asked what type of medications Wedgewood Pharmacy compounds. Dr. Grzib responded that they compound sterile and non-sterile veterinary medications.

Dr. Grzib also noted that due to the extensive cost that the pharmacy would have to pay to conduct stability testing, and they would have to reduce the number of sterile products that they can provide to California patients.

President Gutierrez asked if other states that Wedgewood Pharmacy operates in permit prescriber office use. Ms. Pontikes asserted that there are only 15 states that require patient specific compounding and the rest of the states allow for prescriber office use. She noted that this only applies for veterinary medicine.

A representative from Golden Gate VPC spoke in support of the comments submitted by CPhA.

The committee recessed for a break at 9:51 a.m. and returned at 10:07 a.m.

Steve Pomerance, representing Town Center Pharmacy, stated that his pharmacy wants to comply with the regulations and asked where he could find a copy of the regulations. Ms. Sodergren directed Mr. Pomerance to speak with Christine Acosta, Supervising Inspector. Ms. Herold added that the board has a self-assessment form available in its website that will guide pharmacists through the requirements.

Ken Schell, representing Sharp Health, thanked the committee for their efforts and encouraged them not to simply adopt the USP chapters in totality. He expressed concern with the specific temperature ranges that are outlined in 1735.1. Dr. Schell also asked the board to consider allowing central repackaging pharmacies to provide compounded products to outpatient pharmacies.

Jerry Green, representing San Diego Compounding Pharmacy, stated that most California compounding pharmacists are following the regulation and want to provide the best care to their patients. He expressed his opposition to the board's new BUD requirements. Mr. Green noted that on bad pharmacy should not negatively impact the other compounding pharmacies who are doing the right thing.

Mike Cooks, representing Central Admixture Compounding Services, agreed with the comment that Dr. Kastango made at the beginning of the meeting, that potency tests over time do not demonstrate stability. He also noted that USP has an FAQ on their website as well as a study outlining the difference between potency and stability testing.

David Joseph, representing Absolute Pharmacy in Florida, expressed his support for the comments made by CPhA and Dr. Kastango. Mr. Joseph stated that the tragedy in New England was not caused by under regulation, it was caused by the lack of enforcement of the existing regulations. He added that USP 797 and 795 are good standards for compounding and if followed protect the public.

David Smith, representing A&O Specialty Pharmacies, stated that it would very difficult to coordinate a 14-day BUD for a pediatric patient that needs an oral suspension medication. He suggested allowing for a 30-day BUD for oral non-sterile compounded medications.

David Kazarian, representing Pharmetric Lab and Infuserve America, recommended that the board harmonize its regulations with USP, specifically by allowing for alternative sterility testing methods. Dr. Kazarian thanked the board and Dr. Christine Acosta for providing guidance on complying with the regulations. He also cautioned the board to not make the regulations so onerous that patients can no longer get safe medication in a timely manner.

Eric Feinstein, representing Axia Pharmacy, spoke in support of previous commenters and encouraged the committee to base their regulations on scientific data. He also explained that according to Business and Professions code 4127.7 all compounding must be done in an ISO 5 setting. He stated that this requirement is not logical as you wouldn't want high-risk, non-sterile powders to aerosolize into the HEPPA filters.

Joe Gartner, representing Good Pharma Compounding Pharmacy, expressed his concern that the regulations would potentially make it difficult for female patients to obtain hormone creams at a reasonable price.

Sam and Anthony Barrack, representing Innovative Compounding Pharmacy, stated that the FDA should not have jurisdiction over compounding pharmacies in California. They asked the board to consider the cost increase that patients may face due to the board's regulations. They also stated that it undermines the pharmacists credibility with a patient when the pharmacists has to inform the patient that a medication that they have been using now has a shorter BUD.

Bob Bretzel, President of Script Works Pharmacy, explained that suspensions are commonly used in the veterinary practice. He asked the committee to differentiate between suspensions used in veterinary practices and solutions used for human medications when they are drafting the requirements for stability testing and BUDs.

Sarah Bonsonte, a pharmacy technician, stated that the increased costs of compounded medications because of the board's regulations will negatively impact small businesses and patients.

Robert Easton, representing Scripts Health, asked the board to amend the regulations to only require smoke studies every 6 months in ISO Class 5 settings. He explained that smoke studies will require the hospital's fire alarm system to be disabled during the study.

A pharmacist from Children's Hospital of Orange County explained that not only small businesses are affected by the cost of complying with the sterile compounding regulations. She asked the board to carefully consider the definitions of identical vs. analogous. She stated that there are shortages of certain medications and supplies and she encouraged the committee to not make it more difficult to obtain or compound these medications that are in short supply by requiring shorter BUDs. The pharmacist also spoke in support of the board's current language defining hazardous drugs.

Dana Gordon, Central Avenue Pharmacy, spoke in support of CPhA's recommended amendments.

Joe Gartner, representing Good Pharma Compounding Pharmacy, expressed his concern with having to inform patients that hormonal creams they are being prescribed are considered hazardous.

Christine Versical, from DynaLabs, stated that since January 1, 2017, DynaLabs has received approximately 5,000 samples from California pharmacies. She explained that the potency failure rate for those samples was only 1.8 percent. Ms. Versical added that the sterility, endotoxin, and particulate matter testing had zero failures. Ms. Versical also offered to share information with the board from the USP regarding the definitions of potency over time, stability and sterility.

Trish Cook, pharmacist from Taylor's Compounding Pharmacy in Florida, stated that the definition of the quality assurance plan in 1735.8(c) is ambiguous. She asked the board to modify the definition to clarify if the definition applies to non-sterile or sterile compounding.

1735.8(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

President Gutierrez explained that the committee would review each of the staff recommendations provided in the meeting materials and either approve the recommendation and/or provide direction on how to modify the language based on the comments received during the meeting. Below is a summary of each staff recommendation and the committee's action.

Staff Recommendation - 1735 Compounding in Licensed Pharmacies: The mixing of ingredients from a compounding kit purchased from an FDA approved manufacturer will not be included in definition of compounding if done according to the manufacturer instructions.

Jenny Partridge, compounding pharmacist, noted that some of the kits contain hazardous materials and should not be included in this exemption. The committee agreed that this exemption should only apply to non-hazardous kits.

The committee agreed with the staff's recommendation, but asked that language be added to ensure that it only apply to non-hazardous kits.

Motion: The mixing of ingredients from a non-hazardous compounding kit purchased from an FDA approved manufacturer will not be included in definition of compounding if done according to the manufacturer instructions.

M/S: Weisser/Schaad

Support: 4 Oppose: 0 Abstain: 0

Staff Recommendation - Section 1735.2 Compounding Limitations and Requirements; Self-Assessment: Board staff recommends changes to the establishment of the BUD to more closely align with the requirements of USP <795> (for nonsterile products) and USP <797> for sterile products including changes to 1735.2(i)(1), 1735.2(i)(2) and 1735.2(i)(3).

President Gutierrez explained that this modification would allow pharmacies to use published studies to extent the BUD for aqueous solutions.

The committee agreed with the staff recommendation.

There were no comments from the public.

Motion: Change the establishment of the BUD to more closely align with the requirements of USP <795> (for nonsterile products) and USP <797> for sterile products including changes to 1735.2(i)(1), 1735.2(i)(2) and 1735.2(i)(3).

M/S: Weisser/Schaad

Support: 4 Oppose: 0 Abstain: 0

Staff Recommendation - Section 1751.1 Sterile Compounding Recordkeeping Requirements:
Staff recommends clarifying the requirements for smoke studies, including both the applicable area where such studies must be performed (ISO Class 5) as well as the frequency in which they must be conducted (semi-annually).

The committee agreed with the staff recommendation.

A pharmacist from Central Compounding Pharmacy stated requiring smoke studies every six months is beyond the requirements of GMPs and asked that smoke studies only be required when there is a change in the hood. It was noted that the six-month requirement for smoke studies in ISO Class 5 areas is consistent with USP 797.

Motion: clarifying the requirements for smoke studies, including both the applicable area where such studies must be performed (ISO Class 5) as well as the frequency in which they must be conducted (semi-annually).

M/S: Weisser/Munoz

Support: 4 Oppose: 0 Abstain: 0

Staff Recommendation - Section 1751.4 Facility and Equipment Standards for Sterile Compounding:
Staff recommends clarifying that cleaning must be done whenever hazardous drugs are being compounding as well as clarifying where the cleaning must occur.

The committee agreed with the staff recommendation.

There were no comments from the public.

Motion: Clarify that cleaning must be done whenever hazardous drugs are being compounding as well as clarifying where the cleaning must occur.

M/S: Munoz/Schaad

Support: 4 Oppose: 0 Abstain: 0

President Gutierrez next reviewed the comments submitted in writing by stakeholders. Below is a summary of each comment.

1735.1: Amend the definition of "daily" in 1735.1 to specify that electronic monitoring of temperatures is allowable.

Ms. Sodergren asked that staff be allowed time to research the comment and provide a recommendation at the next committee meeting. She also noted that it might be best for this issue to be clarified in an FAQ.

Dosage Unit: Amend the definition of "dosage unit" to beyond one administration and allow for one "dosage unit" to be one prescription.

Ms. Sodergren asked that staff be allowed time to research the comment and provide a recommendation at the next committee meeting.

Sterility: Recommend addition of a definition of sterility for clarity.

Ms. Sodergren asked that staff be allowed time to research the comment and provide a recommendation at the next committee meeting.

1735.2 (4): Change requirements relating to the extension of BUD provisions to what appears to be allowing analogous versus identical ingredients.

Ms. Sodergren asked that staff be allowed time to research the comment and provide a recommendation at the next committee meeting.

1735.2 (5): Correct the drafting error where the board inadvertently indicated that a shorter dating can be done.

Ms. Sodergren noted that staff would like to review the language to ensure that this is in fact a drafting error.

1735.2 (6): Recognition of potency over time study as applicable to the compounded formulations can be used to validate stability and assign extended beyond use dates.

Ms. Sodergren asked that staff be allowed time to research the comment and provide a recommendation at the next committee meeting.

1751.4 (d): Clarify that cleaning does not need to happen daily, but rather every day the facility is used to prepare sterile drug compounds.

President Gutierrez asked staff to research this item and provide a recommendation at the next committee meeting. A member of the public noted that a clean room is actually cleaner when you do not enter it.

1751.4(k): Remove the minimum room temperature requirement.

Anne noted that staff has researched this item and they believe that removing the minimum room temperature requirement is consistent with USP. She added that staff will bring draft language to the next meeting.

1751.6(e): Correct typo by removing redundant “sterile” and indicate that training can vary for someone only directly supervising individuals compounding, not performing it themselves.

Ms. Sodergren stated that she would like the opportunity to discuss with DCA Legal what the ramifications of this change would be before staff provides a recommendation.

1751.7(e)(1): Allow for an equivalent method of testing as those described in USP 71 and exempting pyrogen testing from irrigation.

President Gutierrez asked staff to perform a technical review of this recommendation and provide a recommendation at the next meeting.

1735.1(r) and 1735.6(e): Request hazardous provisions in 1735.1(r) and 1735.6(e) mirror requirements in USP 800.

Ms. Sodergren commented that staff would like the opportunity to discuss with item with subject matter experts.

1751.4(d): Requests that the regulation specify that ready to use germicidal detergent including sterile water is acceptable.

Ms. Sodergren stated that this could be clarified in an FAQ. The committee agreed with her statement.

1751.4(g)(1): Adding a requirement for two pairs of standard gloves for all hazardous compounding.

Ms. Sodergren stated that staff will confirm that USP does require two gloves and that the outer gloves must be sterile.

1751.3 and 1751.4: Request clarification on the need for sampling for the segregated compounding areas outside of the ISO-5 environment. Question is the sampling plan and procedures for nonviable particle samples as well as violation air and surface is limited to ISO certified areas or also for segregated compounding area outside the ISO environment.

Ms. Sodergren stated that staff would like to discuss with DCA counsel if this could be clarified in an FAQ or is modification to the regulation would be required.

Contracting with Another Pharmacy: Request clarification if a pharmacy can contract with another pharmacy for compounded products or just parenteral. As part of the comment it is indicated that the clarification is being sought when waiver requests are denied.

Ms. Sodergren responded that this is a statutory provision and staff would discuss this item with DCA counsel.

Stability: Recommend an addition of a definition of stability.

Ms. Sodergren stated that staff will review USP and determine if this addition is necessary.

1735.1 (i)(3): Change the requirements to extend a BUD.

Ms. Sodergren noted that 1735.2(i)(3) applies to all sterile and non-sterile compounded products. She added that the staff recommendation is to add in the word “sterile” to clarify that this section only applies to sterile compounded products. President Gutierrez asked staff to research this and provide a recommendation at the next meeting.

1735.6 (e): Create an exception allowing a pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastics.

Ms. Sodergren stated that staff would like to research this item prior to providing a recommendation.

SOPs for sterilization and depyrogenation process: Provide detailed description of what the SOPs need to include for sterilization and depyrogenation process.

Ms. Sodergen stated that staff will research this item and noted that she is not sure that this would require a change to the regulation.

1751.11: Add provisions to establish requirements for sterilization and depyrogenation

Ms. Sodergren stated that these are provisions proposed in the proposed new USP 797, she recommended waiting until USP finalizes their provisions before the board makes any modifications. President Gutierrez stated that when staff is researching these items it the issue is pending with the new USP 797 the language should not be modified until USP finalizes their language.

1735.2 (a): Concern with the requirement that the pharmacy note on the prescription that the prescriber authorized compounding when the approval is given verbally (for veterinary products).

Ms. Sodergren stated that the board's regulation nor USP differentiate between veterinary and human products. She offered to further research the topic.

1735.2(c): Change the prescriber office provisions to expand the conditions under which prescriber office dispensing can be done and changing the definition of reasonable quantity.

President Gutierrez stated that veterinary industry does not have the option to purchase from a 503B pharmacy, they must use a 503A facility or a manufacturer. Ms. Sodergren responded that staff is researching is veterinary compounding pharmacies can elect to be licensed as a 503B pharmacy. Ms. Pontikes, representing Wedgwood Pharmacy, asserted that 503B facilities cannot make veterinary products and veterinary compounding pharmacies cannot become registered as a 503B facility. Ms. Sodergren stated that staff will continue to research this.

Jenny Partridge, compounding pharmacist, noted that at the January 2017 Enforcement Committee meeting the committee voted to allow the use of double filtration system in lieu of external venting. Dr. Partridge stated that at the following board meeting the board did not vote to ratify the committee's recommendation. Staff stated that they would review the minutes to confirm what action the board took on the committee's recommendation to allow for the use of a double filtration system in lieu of external venting.

Jon Roth, representing CPhA, asked if the board's motion to change the establishment of the BUD to more closely align with the requirements of USP <795> (for nonsterile products) and USP <797> for sterile products applies to both sterile and non-sterile products. Ms. Sodergren responded that staff will be looking at BUDs for both sterile and non-sterile products in sections 1735.2(i)(1), 1735.2(i)(2) and 1735.2(i)(3).

President Gutierrez thanked the public for their participation and adjourned the meeting at 11:55 a.m.