California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

DRAFT

COMPOUNDING COMMITTEE MEETING MINUTES

DATE:	July 11, 2019
LOCATION:	Department of Consumer Affairs California State Board of Pharmacy – Building Two 1747 N. Market Blvd., Room 186 Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Maria Serpa, Licensee Member, Chairperson Greg Lippe, Public Member Allen Schaad, Licensee Member
COMMITTEE MEMBERS NOT PRESENT:	Victor Law, Licensee Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Interim Executive Officer Julia Ansel, Chief of Enforcement Christine Acosta, Supervising Inspector Debbie Damoth, Staff Services Manger Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel

1. **Call to Order and Establishment of Quorum**

   Chairperson Serpa called the meeting to order at 10:01 am. Board members present: Maria Serpa, Allen Schaad and Greg Lippe. A quorum was established.

2. **Public Comment on Items not on the Agenda/Agenda Items for Future Meetings**
   Chairperson Maria Serpa invited public comment.

   Seth DePaquale of BET Pharm, Lexington, Kentucky suggested the following items be considered:
   - Extension of Beyond Use Dating for sterile preparations
   - Office use for veterinary compounding for sterile preparations

3. **Discussion and Consideration of Proposed Amendments to Regulations Related to Pharmaceutical Compounding of Nonsterile Preparations**

   CCR 1735 Compounding in Licensed Pharmacies

Chairperson Serpa began the discussion by recommending to the committee and the full board to promulgate regulations as necessary to mirror structure of United States Pharmacopeia (USP) chapters. She recommended that as regulations for the respective chapters are finalized that the board initiate the rulemaking process one chapter at a time to allow for more immediate transition to the new regulations. Draft regulations as prepared by staff, were presented to the committee to be considered. Chairperson Serpa stated the draft regulations are to repeal Article 4.5 and replace it with an entirely new Article 4.5, nonsterile compounding.

DCA Counsel, Laura Freedman suggested, with board approval, there may be some non-substantive edits that can be addressed outside of the meeting that can be handled organizationally.

Mr. Lippe asked if the public should be afforded the opportunity to comment on non-substantive changes.

Ms. Freedman stated any changes made whether substantive or non-substantive would go to the full board for review.

Dr. Serpa advised everyone present that as the committee moved forward with its discussion, each section would be discussed one at a time. Further, Dr. Serpa would provide opportunity for board member comments followed by public comment. Dr. Serpa noted that the proposed language would be projected and during the discussion live edits would be made and documented through consensus.

The committee initiate its review with Section 1735, entitled, "Compounding in Licensed Pharmacies"

As part of public comment on this section, Danny Martinez, CPhA, asked if CCR 1735(b) and (c) are necessary. Business and Professions Code (BPC) 4052.7 addresses repackaging. Mr. Martinez suggest striking these two sections as he believes they are duplicative and unnecessary, particularly in a hospital setting. Dr. Serpa asked for clarification on why this would be more problematic in a hospital setting. Mr. Martinez stated he would provide further clarification at a later date.

Mr. Martinez referenced CCR 1735 (d), noting that that obtaining further documentation that a prescription from a prescriber has approved use of a compounded drug preparation will be laborious for compounders. He stated patient care will be delayed by this section and asked that it be stricken. He recommended if the board is unwilling to strike this, he is suggested to add the following after the first sentence, "If it is unclear whether a compounded preparation was intended, approval shall be obtained orally or in writing." Mr. Martinez commented if the prescription is written for a compounded product, there should not be a need to call the prescriber back to verify.

Christine Versichele, Dynalabs, under CCR 1735(c) , suggested that the word "repackaging" be corrected to read "reconstitution."

Marie Cottman, Pacific Compounding Pharmacy, suggested an allowance for a delay in the implementation of these regulations as some of the suggested language is an undue burden.

Dr. Cottman commented that under CCR 1735(a) USP describes compounding to include "all places but not limited to pharmacies". Dr. Serpa explained the purview of the board is limited to what occurs in a pharmacy, thus the limitation. Dr. Cottman suggested 1735(d) to replacing "perpetrations" with "preparations" and replace "noncommercial" with "noncommercially". Dr. Cottman referred to the

word disposal under CCR 1735(g) and stated under CCR 1707.2 disposal is not referenced. She suggested the board consider adding the word disposal under Duty to Consult language.

Dr. Serpa responded that any discussion on the delay of implementation needs to be related to language the board drafts in the regulation that goes above USP guidance.

Ranel Larsen, compounding pharmacist, commented that under BPC 4037(a), compounding is defined and is unclear why we are restating the definition under 1735(a). Dr. Larsen noted that she did not see reference to this definition in USP 795 and suggested it should be removed from this regulation entirely. Dr. Larsen mentioned under 1735(e)(3), "documented medical need" is not defined and as such should be defined or removed. She requested that discussion should be had on delay on implementation of of 1735(i) and (j) and suggested they be combined as they are very similar. Dr. Larsen asked for clarification on CCR 1735(b), specifically why it references repackaging for nonsterile compounding when USP 795 is silent on repackaging when it comes to nonsterile drug preparations. She stated repackaging needs to be addressed for sterile preparations but not nonsterile.

Lorri Walmsley, Walgreens, explained that the proposed regulations could prevent community pharmacies from potentially flavoring antibiotics if they are not USP 795 compliant. Inspector Christine Acosta stated the USP 795 committee intended for the inclusion of a flavoring agent to be considered compounding.

Joe Grasela, University Compounding Pharmacy, referred to 1735(d) and stated contacting a doctor every time to confirm a compound is overwhelming and unnecessary. He agreed with Mr. Martinez's statement regarding the conditions under which such documentation would be appropraite if it is unclear whether a compounded product is necessary. Mr. Grasela asked that this section be stricken from the draft regulation. Dr. Acosta responded that the expectation is not to be documented on every prescription. MDr. Serpa added part of the intent is to make the patient aware a product they are receiving is compounded and not manufactured, but it is certainly not intended for each and every compounded product.

Board staff noted their belief that the proposed regulation provision is consistent with federal law governing 503A facilities, but staff would confirm.

Nichole DiLoretta, Dynalabs, commented that with respect to repackaging, many pharmacists are making compounded kits and they would appreciate guidance on these products. She asked if it would be possible for a pharmacist to perform an assessment of risk when making compounding kits. Dr. Acosta stated 1735(c) is attempting to clarify compounding kits. Dr. Acosta clarified that if the kit does not have FDA approved labeling then reconstitution is compounding. Dr. Serpa stated the board and staff is considering drafting FAQs to provide additional education on the regulation.

Dr. Serpa reviewed the proposed edits offered through public comment for section 1735 and asked the committee members if they agree with said changes. The committee reached consensus on proposed changes to the drafted language.

1735.1 Introduction and Scope and Compounding Definitions

The committee continued its review and proceeded to Section 1735.1 including public comment.

Ask part of public comment, Marie Cottman commented there is no definition of potency in the new language and requested it be added. She stated section (f) is missing from the document and quality

and strength are both listed as section (k). Dr. Cottman stated that in 1735.1(g), repackaging sounds like dispensing and asked for clarification on the differences between the two. Dr. Acosta stated that definition is taken from USP 797 and the regulation is attempting to explain what is meant by repackaging. Dr. Serpa asked if adding words at the end of that section to read, "that is not pursuant to a patient prescription", would make the section clearer. Mr. Lippe agreed the section clearer with that edit.

Dr. Acosta suggested under (j) to have it read "potency means an active ingredient strength typically within +/-10% (or range specified in USP) of the labeled amount". Ms. Freedman suggested cross referencing USP to be clear. Ms. Sodergren wanted to make clear that potency will be defined with the language of "+/-10% of the labeled amount".

Dr. Larsen suggested under 1735.1(a) to add "approved mixing directions" for continuity. She recommended under (b) that the word clinically be removed for clarity. Ms. Sodergren stated it was a deliberate deviation. Dr. Acosta said there is a distinct difference between a "clinically significant" and "significant" noting that wanting to decrease the cost of producing a product could fall under the latter. Dr. Acosta stated clinically significant could mean the patient cannot take this drug because he will have an allergic reaction versus cost savings. Dr. Larsen requested to add back the words "sterile product" under section (g) for the definition of repackaging. Dr. Serpa stated that was not the intent of this section and that this regulation is for nonsterile and specifically sterile was removed.

The discussion continued regarding 1735(a) regarding adding "mixing directions". Dr. Acosta requested that Dr. Larsen provide more information on this section.

Public comment suggested that referring to potency with a +/- 10% range is not appropriate. It was suggested that a USP monograph be used instead.

Mr. Grasela suggested using FDA guidelines under section (b) to make the section clearer.

Dr. Cottman, suggested to simplify section (g) add a comma after manipulation so the section reads: "manipulation, not pursuant to a prescription." She suggested to add potency to the definitions or remove it from 1735.8.

Jacqueline Sitack, Dignity Health, suggested that for strength and potency, to revise the term to reference "labeled strength". Dr. Serpa stated concern with limiting this to labeled strength because a compounder could have strength in the master formula and the definition would not apply.

Dr. Serpa reviewed the proposed edits for CCR 1735.1(a) – (j) and asked the committee members if they agree with said changes. The committee reached consensus on proposed changes to the drafted language. A definition of potency will be added and under (g) repackaging – the words "that is not pursuant to a prescription" will be added.

1735.2 Personnel Training and Evaluation

Having reached consensus on section 1735.1, the committee moved to review and consideration of proposed section 1735.1. Mr. Lippe asked that CSNP be changed to CNSP in section (b). The committee then received public comment.

As part of public comment, Mr. Martinez stated that CCR 1735.2 (a),(b), and (e) in that the proposed regulation restates information in USP on training and is duplicative. Dr. Serpa stated it may be appropriate to provide an FAQ for clarity on this section.

Dr. Cottman suggested changing section (b) to read "in all skills as listed in USP 795". Dr. Acosta stated the intent of the requirement is for the pharmacist to have documented skills for anything they oversee. Dr. Serpa noted that everyone involved in the compounding process should have the necessary skills and demonstrate proficiency. The committee decided to keep the language as written.

Dr. Serpa asked if the committee or board staff had any concerns about the changes suggested in CCR 1735.2 and stated these changes will be presented in the motion at the end of the meeting. The committee reached consensus on the section.

CCR 1735.3 Personal Hygiene and Garbing

With no comments being made from members, the committee heard public comments related to Section 1735.3

Dr. Cottman suggested changing the phrasing "shall not be allowed" to "should not allow" in section (a). She stated that she would like to exercise professional judgment to determine if compounding personnel with specified conditions should be prohibited from entering the compounding area because of potential risk of contamination. Dr. Cottman suggested if you be appropriate to allow the supervising pharmacist to make the decision whether to allow personnel into the compounding area. Dr. Serpa suggested the section be more specific and suggested a brief break to allow for drafting of possible revision to the language for consideration.

After the break the following language was drafted by staff 1735.3(a):
"The supervising pharmacist shall evaluate compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection and or any other conditions to determine if such condition could contaminate a CNSP or the environment. The supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area."

Dr. Serpa asked the public if this section satisfied the publics concerns. Dr. Cottman stated the language is good and acceptable, but these conditions are already stated in USP 795. She suggested the following alternative language "The designated person or pharmacist supervisor shall document evaluation of individuals posing a possible contamination risk prior to allowing the individuals to enter the compounding area." Dr. Cottman agreed to the statement as drafted by board staff.

Dr. Cottman stated section (b) indicates any exposed piercing must be removed noting she believes including ear piercings in this instance or nose piercings that are covered by a hair or face mask is excessive and unnecessary. She mentioned under section (f), having to wash glasses multiple times a day is excessive. Dr. Acosta clarified that section (f) states the facility can determine through their SOPs how and when they want to wash glasses.

Dr. Larsen noted her concurrence with Dr. Cottman on the jewelry removal issue, indicating that a compounding professional should be able to determine whether jewelry will interfere. Dr. Larsen agreed that hand and wrist jewelry should be removed, as that would be the most problematic in compounding, but that not all jewelry should be included in the removal requirement under section (f).

Mr. Martinez stated CPhA will be submitting a full letter with all the suggested changes they have from its members. He mentioned that if you are a CPhA member and have suggested changes that are not voiced today they will incorporate those suggestions in their letter to the board. Mr. Martinez noted that he will submit the letter in a timely matter, so it is available for review at the full board meeting.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.3 and stated these changes will be presented in the motion at the end of the meeting.

1735.4 Building and Facilities

Having no committee discussion on section 1735.4, the committee entertained public comment on section 1735.4.

As part of public comment, Mr. Martinez commented that under section (d), the proposed regulation is very vague and open to interpretation regarding the compounding area. He stated many activities other than compounding occur during the compounding operations. Mr. Martinez suggested adding the phrase "when compounding is performed no other activity shall take place in the adjacent area without adequate controls to prevent contamination of the compounding area and preparations". Dr. Serpa requested clarification on what "adjacent area" means, as it is very broad. She stated the board was attempting to provide some flexibility in this instance. Mr. Martinez stated they will work on this issue in the document they will be presenting to the board.

Dr. Cottman, suggested alternative language to section (d): "If compounding is performed daily, activities not related to the preparation of CNSPs shall not take place in the compounding area." Dr. Serpa noted the challenge with the language as there are different compounding environments and the board's goal is to not limit compounding but to assure that compounding occurs in a safe environment. Ms. Sodergren and Dr. Acosta suggested removing this section. Dr. Serpa noted that removing the section doesn't impact patient safety, but it does impact practice environment.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.4 including removing (d) relating to the compounding area. She stated these changes will be presented in the motion at the end of the meeting.

CCR 1735.5 Cleaning and Sanitizing

The committee did not have comments on section 1735.5 and requested public comments.

As part of public comment, Dr. Cottman commented under 1735.5(a) that cleaning is done all the time as part of the practice. Dr. Cottman noted her belief that compounding staff will just write it down, that cleaning occurred, even when it has not. She questioned the value of such documentation and how it was related to consumer protection. Dr. Serpa explained there has to be minimum amount of documentation. Dr. Cottman encourage documentation at least once a day, but not every time and suggested it may be a training issue, that an SOP needs to be written, it needs to be monitored and a daily documentation of what agents were used is appropriate.

Dr. Acosta stated the intention is to capture documentation of the cleaning and sanitizing of the compounding area to include the personnel who are performing this task and the agents used.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.5. She stated these changes will be presented in the motion at the end of the meeting.

CCR 1735.6 Equipment and Components

Dr. Serpa stated section 1735.6 discusses new technology, which will require new equipment to be purchased and that the committee and board may want to consider a delay in implementation. She encouraged the public to provide comments specific to delayed implementation and timelines.

As part of public comment, Dr. Walmsley, Walgreens, and Michael Cuellar, Manager of Walgreens compounding center, suggested striking 1735(b) relating to the required use of a closed system processing device for any weighing, measuring, or other manipulations of components in powder form. She stated in the current version of USP 795 it references that an assessment of whether powder should be handled in a BSC or CVE and would like this USP guidance to stand. Dr. Cuellar mentioned the requirement of an assessment being captured in an SOP as to whether or not a hood is required for a nonsterile preparation is appropriate. Dr. Walmsley commented the would have a significant cost component for pharmacies and believes an enforcement delay would be appropriate as powder hood would need to be purchased and there have been significant delays for 800 compliant hoods of up to 8 to 16 weeks.

Public comments under section (b) included adding the word "containment" before "ventilated enclosures" to reflect the CVE as the enclosure.

Tim Frost, CVS Health, suggested removing section (b) as he is concerned on how this would affect access and patient safety (particularly patients who cannot swallow pills). Dr. Frost stated if this is not stricken then he would like the board to consider and amendment to include single use containment glove bags as a third option.

Dr. Cottman agrees with section (d), but in existing law 1735.3(c) or (e) compounders use commercially made FDA approved products and crush them to make smaller strengths. She explained this requires a Certificate of Analysis (CofA) for any API or added substance, but there is no CofA for tablets. In our current language we do have that a CofA is not required for FDA approved products. She would like to see this added to section (d). Dr. Acosta stated API is a bulk substance not a manufactured product and suggested to reference USP 800. Dr. Serpa suggested to address this issue in a FAQ.

Dr. Cottman added she would like to see FAQ information on section (e) regarding when components not used in compounded can be returned to the original container versus when such components must be discarded. She asked for clarification on where to you draw the line on what has been removed from the original container and are you able to add product back into a container if removed by a single use disposable spoon? Dr. Cottman suggested "should be discarded" instead of "shall be discarded". Ms. Freedman suggested changing the language to "shall be discarded if the returning to the original container could result in contamination". Dr. Cottman suggested the following "Once removed form the original container, components that have been contaminated and not used in compounding shall be discarded." Dr. Acosta responded that such an approach could create challenges with enforcement of the requirement. Dr. Cottman noted that the requirement as written would increase cost, decrease access and increase waste. Dr. Acosta stated USP is written as "should" versus "shall" and suggested to eliminate section (e).

Mr. Martinez asked for clarification on (b)(1) in that for CVEs there are no guidelines. Dr. Acosta said currently there are no guidelines for CVEs, but that they are under way in a new revision of CETA. Dr. Acosta noted that vendors know to certify to CETA guidelines and are specific to each unit.

Dr. Larsen stated under (c)(1), relating to requirements for components used, that a National Formula (NF) doesn't exist for everything and suggested adding the phrase "if one exists" as without this phrase there is confusion. Dr. Acosta stated this is much broader than a monograph and doesn't change the context. Dr. Serpa noted that the regulation is referring to the concepts in USP not drug specific information in USP. She noted that Dr. Larsen and Dr. Acosta are both correct. Dr. Acosta stated this is not referencing a specific product, it is a specific component, noting this section is not referring to the end product.

Dr. Serpa noted that section 1735.6 is probably the most significant of regulations as it will change how pharmacy is practiced in facilities where powders are being used. She asked how to implement this section in a manner that does not limit access to patients. Mr. Schaad questioned the value of requiring a CVE for nonsterile compounding, but noted the need for hazardous compounded preparations.

Dr. Acosta noted that one of the challenges with the assessment approach is determining the standard for such an assessment. Dr. Serpa stated safety of patient, personnel and environment should drive the decision.

The committee considered the requirement of the CVE and significant public comment, both in support of and opposed to the mandated requirement. Ultimately the committee reached consensus and removed the requirement but agreed to readdress the issue at a later time.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.6. She stated these changes will be presented in the motion at the end of the meeting.

1735.7 Master Formula and Compounding Records
The committee did not have comments on section 1735.7 but heard public comment.

As part of public comment, Dr. Cottman stated that in USP 795, already reference to "API or added substance identities and amounts must include at least a salt form and purity grade". Dr. Acosta stated yes, but after that phrase USP states, if applicable and makes this optional. Dr. Cottman agreed with (a)(2) regarding container closure but she believes the "at least volume" is not practical and excessive, particularly in the veterinary world based on the size of an animal. Dr. Acosta noted the difference between making a 10ml vial and a 1ml vial and the master formula should tell you how much and how many you are making.

Dr. Cottman requested that under 1735.7(c) the board can change the word "log" to "record", so it is congruent with USP 795.

Mr. Martinez asked in 1735.7(a)(3) how does a pharmacy make the reference fully available for an inspector and was advised that the pharmacy must have the article fully available and it does not say printed.

Dr. Larsen requested under section (a)(1) to add "if applicable" in congruence with USP, because not every single substance has a salt form and requested that the language be stricken.

Dr. Larsen stated her agreement with Dr. Cottman's comments regarding the container-closure system indicating the proposed language is restrictive and should not include the volume. Public comment noted the difference between CNSPs and CSP and the significance the volume for each.

Dr. Sitack suggested changing, under 1735.7 (a)(b), the wording "master formula document" and "master formula record" to "master formulation record" in congruence with USP.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.7. She stated these changes will be presented in the motion at the end of the meeting.

CCR 1735.8 Release Inspections
No committee discussion.

No public comment.

CCR 1735.9 Labeling
There were not comments by the committee however the committee heard public comments.

As part of public comment, Dr. Cottman inquired about the provisions under (a)(1)(A) and requiring inclusion of the "route of intended administration" on the prescription label. Dr. Serpa stated that the intent is to have the label requirement in the future to be the same across all prescriptions. Dr. Cottman also asked why (a)(2)(B) (regarding labeling) is necessary to provide "any warning statements that are applicable" and was advised that DMSO, and other things that are specific to your product.

CCR 1735.10 Establishing Beyond-Use Dates
There were not comments by the committee however the committee received public comments.

As part of public comment, Mr. Martinez commented that stability studies are left out of the regulation. Ms. Sodergren commented that it was left out because it is referenced in USP 795. Dr. Serpa stated the regulation is addressing items that go above and beyond USP guidelines and USP has written an informative FAQ on this topic.

CCR 1735.11 SOPs
Having no committee comments, the committee entertained public comments.

As part of public comment, Dr. Cottman asked for clarification of what is meant by "procedures for handling, compounding and disposal of infectious materials" and was advised the language is consistent with current law.

CCR 1735.12 Quality Assurance and Quality Controls
No committee discussion.

No public comment.

CCR 1735.13 Packaging and Transporting
There were not comments by the committee however the committee received public comments.

As part of public comment, Dr. Cottman asked under CCR 1735.13 (c) to consider changing the term "delivery" to dispensing.

The committee reached consensus on the section.

CCR 1735.14 Complaint Handling and Adverse Event Reporting
No committee discussion.

No public comment.

CCR 1735.15 Documentation
There were not comments by the committee however the committee received public comments.

As part of public comment, a member of the public asked about documentation in general regarding master formulas if there is an audit trail in the batch record is that satisfactory. Dr. Acosta responded that several vendors have software that allows for edits in the electronic system and the board cannot tell if edits were made. She stated if the compounder is making an edit in the log or the master formula the board wants to be able to see the original record and the edit itself. Dr. Acosta commented that systems need to provide some type of audit trail and not all software has an audit trail. Dr. Acosta noted that a dispensing record can be deleted but a hard copy prescription cannot be deleted.

Dr. Cottman stated when edits are made to master formulas, they are dated and signed and questioned the value of documenting the time an edit occurs. Dr. Acosta stated time is important to documented.

Having reached consensus, the committee concluded its review of the regulation proposal.

Motion: Recommend to the board the approval of the proposal to repeal and replace Article 4.5 related to compounding and propose a new Article 4.5 related to Nonsterile Preparations, including sections CCR 1735 through 1735.15, as reviewed and edited today.

No public comment on the motion.

M/S: Allen/Greg

Support: 3 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law				x
Schaad	x			
Serpa	x			
Lippe	x			

4. Approval of the April 16, 2019 Meeting Minutes

Motion: Approve the April 16, 2019, committee meeting minutes.

M/S: Allen/Maria

Support: 2 Oppose: 0 Abstain: 1

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law				x
Schaad	x			
Serpa	x			
Lippe			x	

5. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for August 28, 2019, in Irvine, California.

6. Adjournment

Chairperson Serpa adjourned the meeting at 3:23p.m.