March 20, 2023

Debbie Damoth
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California Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
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Re: Comments Relative to the Discussion, Consideration and Possible Action on Proposed Changes to Regulations Related to Pharmaceutical Compounding of Sterile Preparations (Repeal Article 7 and sections 1751-1751.10 and add new titles and sections 1736-1736.21 to Article 4.5 of Division 17 of Title 16 of the California Code of Regulations)

Dear Ms. Damoth and Members of the Board of Pharmacy,

I thank you for the opportunity to submit my comments regarding proposed regulation changes relative to sterile compounding. I have owned and operated Pacific Compounding Pharmacy in Stockton for 17 years. I have a passion for caring for my patients and a profound desire to comply with the regulations promulgated by this Board. I appreciate the reorganization of the compounding regulations to synchronize with the new USP <795> and <797> chapters and I hope that you find my input useful, clear, and balanced.

Though you may not agree with all of my comments below, I hope that you will recognize the critical need for clarity in the word choices for this evolution of compounding regulations in California. If we (the Board, licensees, and community) do this process right, we will avoid repeating the drawn out process we endured with the last revision of the sterile compounding regulations.

Specifically, I request that each of you assure that the regulations you approve are clear, concise, and necessary for patient safety. It is hugely problematic for both compounding licensees and inspectors when regulations are written with poorly defined words, may have multiple interpretations, or conflict with other regulations. I believe that the compounding community and your inspectors would agree that an easy to understand set of regulations will make all our lives better (and potentially improve the relations between licensees and inspectors, as well).

Further, poorly defined words used in regulations actually have a negative impact on patient care and safety. First, the compounder struggles to understand what the regulation requires and has difficulty, frustration, or unnecessary expenses with the attempt to comply. Then enforcement may be inconsistent amongst inspectors who have (reasonably) different interpretations of the poorly defined words used in the regulations. These are both followed by compounders and business owners deciding that the guessing game of compliance is not worth the stress nor expense and they stop offering compounding altogether!

But the patients of California still need safe, high-quality compounding.

The result of poorly defined regulatory wording will ultimately be patient suffering because compounding will not be readily available in the state of California. Limited access to compounds will make safe, high-quality compounds harder for patients to locate and more expensive to acquire.

Patient safety should not be compromised, but due attention to the importance of establishing a body of regulations that create an environment owners are willing operate within, is simultaneously critical to the longevity of pharmacy compounding in California.

Thank you for your time and consideration of my comments above and below,

Marie Cottman, Pharm.D.

BOP Proposed Item 1736 (c):

"Designated person(s)" means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded sterile preparations ("CSP" for the purposes of this article). Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not the pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement."

Comment: This language is directly out of USP and is a good first example of how USP is written as a guideline, not regulation. What does it mean for the PIC to be "responsible and accountable"? If the PIC supervises the DP who follows 100% all the guidelines for training, validation, quality assurance, etc. and an employee makes a mistake that is undetectable on final review, is the PIC now accountable for that human error?
If a pharmacist who has been through and passed all the appropriate training neglects to follow an SOP, is that the responsibility of the PIC?
Further, in what situations will PIC be held "accountable" for the performance of the facility? If the power goes out, is it now my fault? This may seem ridiculous, but the language is so broad and encompassing that it discourages pharmacists from being willing to be PIC or DP.

When language in a regulation causes licensees to ask so many questions, it probably should be clarified as to the intent of the regulation and how it will improve patient safety.

Recommendation 1736 (c):
"Designated person(s)" means one or more individuals assigned by the pharmacist-in-charge as described in USP <797>. Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not the pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement."

BOP Proposed Item 1736 (d):

"Essentially a copy" of a commercially available drug product means all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

Comment: The FDA has already defined "essentially a copy" in its January 2018 Guidance for Compounding and adding ANOTHER different definition of the same term is confusing. Further, the term "comparable" is open to interpretation as it does not have a succinct definition. Adopting the language from FDA's guidance document would be more appropriate.

Recommendation 1736 (d): ***Change to read like FDA guidance:***
"Essentially a copy"
A compounded drug preparation will be considered essentially a copy of a commercially available drug product if it has all of the following characteristics:
a) has the same API(s) as a commercially available drug product and
b) has the same, similar, or easily substitutable dosage strength as a commercially available drug product and
c) can be used by the same route of administration as the commercially available drug product
unless a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product.

Reference:
The FDA has already defined "essentially a copy" on page 5 of **Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry.**

BOP Proposed Item 1736 (h):

"Preparation "means a compounded drug or nutrient."

Comment:
Why define preparation differently from USP <797>? USP applies to "…preparing compounded sterile preparations (CSPs) for human and animal drugs".
What is the definition of "nutrient"? What is the difference between a nutrient and a dietary supplement?
Since all compounding must be done pursuant to a prescription, if a nutrient is prescribed, does it not become a drug by CCR 4022(c)? Even though the nutrient itself is not a "dangerous drug," since it cannot be made by a 503A compounder without the order of a prescription, by default it becomes one.
Further, proposed regulation 1736.9 (e) prevents compounding without a USP monograph or an API listed on the 21 CFR 216, making this definition irrelevant.

Recommendation 1736 (h):
Remove this definition

BOP Proposed Item 1736 (j):

"Quality" means the degree to which the components and preparation meets the intended use or purpose, complies with relevant law and regulation, and means the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formula record as specified in USP 797.

Comment: Currently "quality" is defined in section 1735.1 (ae) which is virtually the same as in the proposed revisions of section 1735(f) for NSCPs: "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, or the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record."
The addition of "the degree to which to components and preparation meets the intended use or purpose" puts an unreasonable expectation that when a compounder makes a preparation on the order of a prescriber, it will ALWAYS meet the intended purpose. (i.e. if the preparation is intended to treat cancer, but the cancer doesn't disappear, has the compounder not made a "quality" preparation?) Compounders cannot be responsible for the ***therapeutic outcome*** of the preparation.

Recommendation 1736 (d): ***Continue to have the SAME definition of quality for all compounded preparations.***
"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, or the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 797.

References: CCR 1735.1 (ae) and Minutes from 2/27/2023 Compounding and Enforcement Committee Meeting.

BOP Proposed Item 1736.1 (c):

"A limited quantity of CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where, and solely in such quantity, as is necessary to ensure continuity of care for individual patients of the pharmacy based on a documented history of prescriptions for those individual patients."

Comment:
1- Minor typo of "CNSP" should be "CSP"
2- Section 503A of the FDC Act **allows** limited quantity compounding in anticipation of prescriptions for individual patients. The subtle change of the wording in this proposed 1736.1(c) only allows for anticipatory compounding for existing/known patients. Some prescribers are ordering a limited number of doses for NEW patients each week which would eliminate preparing CSPs prior to receipt of that individual patient's prescription. This will delay care as the pharmacist will have to wait for the prescription before preparing the CSP which may also require USP <71> and or <85> testing prior to release. This will have a particularly detrimental effect on patient's access to custom eye drops for severe and complex eye infections at 4:30pm on a Friday afternoon.

Recommendation 1736.1 (c): ***Keep and renumber the existing language from CCR 1735.2 (b).***
"A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population."

References: CCR 1735.2 (b)

BOP Proposed Item 1736.1 (d)(2):

"(d) In addition to prohibitions established in federal law, no licensed pharmacy personnel shall compound a CSP that:
(2) Is made with any component not intended for use in a CSP for the intended patient population."

Comment: Compounding is often a solution for patients with unique and unusual needs. The language of "intended patient population" is too broad. I believe this language was meant to prevent compounding with a component that is **known to be contraindicated in a specific patient**. But that is not what it says. If this becomes letter of the law, it will be too restrictive. Estrogen will not be able to be used in a man (who might be undergoing transition therapy), nor methotrexate for a pregnant patient (with an ectopic pregnancy).

Recommendation 1736.1 (d)(2): Remove this clause from 1736.1 (d) and allow our Scope of Practice to suffice: *"4050(b) Pharmacy practice is a dynamic,* ***patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy****, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities." (bold emphasis added)*

References: BPC 4050(b)

BOP Proposed Item 1736.1 (d)(3):

"(d) In addition to prohibitions established in federal law, no licensed pharmacy personnel shall compound a CSP that:
(3) Is made with a component for which a conventionally manufactured sterile product is available and appropriate for the intended CSP."

Comment:
What is the intent of this section? I can't figure out what I am prohibited from preparing. Does it mean, "Don't use conventionally manufactured sterile products"?
Paragraph d is clear: Do not compound a CSP that…
Paragraph 3 is **unclear**: … is made with a component that is manufactured sterile. And
… is appropriate for the intended CSP.

Further, USP <797> Section 9.3.1 State "Conventionally manufactured sterile products should be used when available and appropriate for the intended CSP."

Recommendation 1736.1 (d)(3):
Remove section (3) and allow Section 9.3.1 of USP <797> to say enough.

References: <797> Section 9.3.1

BOP Proposed Item 1736.2 (b):

"Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in compounding drug preparations. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met:
1. The SOPs are identical
2. The facility designs are identical
3. The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning."

Comment: This is a great concept! The idea of allowing compounding personnel to learn aseptic manipulations and transfer that skill to another facility is fantastic (especially with the shortage of technicians and absenteeism)!

Based on the text of USP <797> (Section 2.3), "aseptic manipulation competency evaluation consists of a visual observation, media-fill testing, followed by a gloved fingertip and thumb sampling of both hands, and surface sampling of the direct compounding area…"

However, the specifics in this proposed CCR are too specific.
Sentence two is the key *Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in compounding drug preparations.* How an employee moves in the cleanroom, how they puncture a vial with a needle, where they place their items in a Laminar Air Flow Work Bench are skills that can be used in multiple similar settings. (An independent pharmacy's LAFW to a hospital's LAFW, for instance.) Further, the fingertip touch test and the media fill tests validate that a compounder can "manipulate" in a specific type of PEC (LAFW vs BSC vs CACI, etc) and these tests take 7 days and 14 days respectively. In contrast, gowning and cleaning P&P can be taught quickly! I believe it will negate the usefulness of this CCR to require that the SOPs and facility designs are IDENTICAL. I do agree that the PEC's need to be of the same type.

Recommendation 1736.2 (b): Change the conditions 1, 2, and 3. To be:
Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in compounding drug preparations. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met:

1. *The PECs are of the same type (LAF, BSC, CACI, etc)at both premises*
2. *The compounder has read all the sterile policies and procedures and*
3. *The compounder has at minimum, completed training on policies and procedures for gowning, cleaning, and compounding records at the additional premises.*

BOP Proposed Item 1736.2 (c):

"Aseptic manipulation ongoing training and competency shall occur each time the quality assurance program yields an unacceptable result as defined in the SOPs referenced in section 1736.17 that may indicate microbial contamination of CSPs. Aseptic manipulation ongoing training and competency procedures shall be defined in the facilities SOPs."

Comment:
Based on the text of USP <797> (Section 2.3), "aseptic manipulation competency evaluation consists of a visual observation, media-fill testing, followed by a gloved fingertip and thumb sampling of both hands, and surface sampling of the direct compounding area…" and (<797> Section 18) "quality assurance is a **system** of procedures, activities, and oversight…"
Thus the phrases "quality assurance program yields an unacceptable result" and "may indicate microbial contamination" are problematic.

a. Both a QA and QC program will have detailed SOPs (as required by <797> Section 18) these SOPs should define "unacceptable results" and provide actions when they occur. Forcing manipulation competency on an unspecified number of compounders may shut down an operation for

up to 2 weeks with the way that 1736.2(c) is currently written.

b. What does "may indicate microbial contamination" mean? Is it when a compounder fails a fingertip touch plate (which would be part of a QC program)? Is it when quarterly testing yields colonies above the action limit? Is it when a sterility test fails?

Further, who will receive the training? Everyone involved and/or overseeing the process, or just the compounder?

Recommendation 1736.2 (c): Change language to be clear and followable by DPs and PICs.
Aseptic manipulation ongoing training and competency shall be defined in the facilities SOPs. Aseptic manipulation ongoing training and competency shall additionally occur for personnel directly involved with the compounding of a CSP found to have microbial contamination.

References: USP <797>

BOP Proposed Item 1736.2 (d):

"Compounding personnel or persons with direct oversight over personnel performing compounding, verifying and/or handling CSPs who fail any aspect of aseptic manipulation evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs."

Comment:
I believe that this is too punitive. Note that USP <797> (Section 2.3) **defines** "aseptic manipulation competency evaluation" and it includes all of the following: a) a visual observation, b) media-fill testing, c) gloved fingertip and thumb sampling of both hands, and d)surface sampling of the direct compounding area…"

1) Those who can't do, teach. A pharmacist who has oversight of other compounders and only performs gloved fingertip touch testing every 3 to 6 months, may have a failure (1 cfu = failure), but this does not mean that they are suddenly incapable of overseeing technicians compounding CSPs for the next 7 days that it takes to pass competency (what about the oversight they had during the 7 days that you assumed they would pass?) As A PIC, should I let the pharmacist have a week off because they cannot oversee compounding?
2) Further, a technician who fails a surface testing after successfully completing media fill testing may continue to be very capable of cleaning and disinfecting the cleanroom. Please consider deferring to the facilities SOPs for actions on failures during the aseptic manipulation evaluation.
3) Additionally, USP <797> FAQ #52 specifically says that compounders who fail part of the aseptic competency do NOT have to stop compounding, but facility must evaluate cause of failure and determine appropriate corrective actions. If Ca BOP wants to be more restrictive, there should be a patient safety rational for the increased restriction.

Recommendation 1736.2 (d): Remove and defer to SOPs for corrective actions. (but if you don't like that, consider the following)
Compounding personnel who fail an aspect of initial aseptic manipulation evaluation shall not be involved in compounding a CSP until they have passed. When compounding personnel fail an aspect of an ongoing aseptic manipulation, the DP shall initiate and document an evaluation of the cause of failure and follow the facilities SOPs for appropriate corrective actions.

References: USP <797>, BOP Meeting Materials for 3/23/23 Compounding and Enforcement Committee.

BOP Proposed Item 1736.2 (e):

"Any person assigned to provide the training specified in this section shall obtain training and demonstrated competency in any subject in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1736.17. Documentation must be maintained demonstrating compliance."

Comment:
Is it the board's intent that a compounder cannot train themselves? How do I know when I have satisfied this? Do you have a specific meaning for "obtain."

“Subject” can be a very broad, encompassing word.
Both of our trainers have been sterile compounding for 20+ years and consistently pass aseptic manipulation competency, sterility, and endotoxin testing. I last attended aseptic training in 2012, how will the board inforce this requirement when initial documentation is lacking?
How long is the documentation maintained for? All other pharmacy related documentation is 3 years--- is this forever? (three years seems reasonable and should be re-demonstrated anyway!)

Recommendation 1736.2 (e):
Clarify language to prevent unnecessary barriers to continuing sterile compounding and to make this clear and followable.
Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1736.17. Documentation of the trainer’s competency must be maintained for three years.

BOP Proposed Item 1736.3 (b):

“The pharmacist overseeing compounding shall not allow personnel to enter the compounding area with non-removable piercings that increase the risk of contamination of CSP.”

Comment:
USP <797> FAQ #65 addresses dermal (non-removable) piercings to be covered with an adhesive bandage or head cover.
How does a non-removable piercing differ from a permanent hearing aid? What is the increased risk to a CSP from the skin of a healthy, healed, non-removable piercing?
Further, this is covered in proposed section 1736.3 (a) which states “The pharmacist overseeing compounding shall not allow personnel with potentially contaminating conditions to enter the compounding area.” So if the piercing were at risk to contaminate a CSP, the personnel would already be restricted from entering the compounding area.

Recommendation 1736.3 (b):
Remove this and allow USP <797> FAQ #65 to guide.

References:
USP <797> FAQ #65 and Proposed CCR 1736.3 (a)

BOP Proposed Item 1736.4 (e):

“Except as provided in (e) dynamic interactions between areas and rooms with classified air shall be controlled through a heating, ventilation, and air condition (HVAC) system. No passive ceiling or wall penetrations are allowed.”

Comment:
Minor typo… Section e should not reference its own section. Should be referencing item (d)?

Recommendation 1736.4 (e):
Except as provided in (d) dynamic interactions between areas and rooms with classified air shall be controlled through a heating, ventilation, and air condition (HVAC) system. No passive ceiling or wall penetrations are allowed.

BOP Proposed Item 1736.6 (b):

"At a minimum, to trend for growth of microorganisms, during biannual (every 6 months) recertification, any microorganism recovered (growth) shall be identified at least to the genus species, regardless of the CFU count. Professional judgement shall be used to determine the appropriate action necessary to remedy identified trends regardless on the action level. Investigation must be consistent with the deviation and must include evaluation of trends."

Comment:
This paragraph is very hard to follow and to determine what is expected of the DP. 1) "At a minimum" is presumed with all of USP <797> and BOP CCRs. It does not need to be stated. 2) Everything else in USP <797> is P&P based. Who will apply their Professional judgement? Why not an SOP like everything else? 3) the last sentence has no reference and is just tacked on.
Minor typo: "*identified trends regardless on the action…" "on" would make more sense as "of"*

Recommendation 1736.6 (b): Clarify what needs to happen and who determines the course of action.
During biannual (every 6 months) re-certifications, to trend for growth of microorganisms, any microorganism recovered shall be identified at least to the genus and species levels, regardless of the CFU count. The DP should use professional judgement to evaluate the microbial growth trends. If a deviation is identified, the DP should conduct and investigation and carry out actions to remedy the identified trends.

BOP Proposed Item 1736.9 (d):

"All components used to compound a CSP shall be manufactured by an FDA-registered facility and suitable for use in sterile pharmaceuticals. A Certificate of Analysis (COA) which includes the compendial name, the grade of the material, and the applicable compendial designations on the COA must be received and evaluated prior to use."

Comment:
"Component" is a term that causes this proposed regulation to conflict with other USP uses of "component." For instance, blood components, commercially available sterile products used as components, sub preparations used as components, etc. Further, container closures may not have COAs if terminal sterilization is conducted.
Based on the requirement to receive and evaluate a COA and the specificity of "compendial name" one might assume that this regulation is meant to refer to all chemical ingredients as "components".
If this is referencing all chemical ingredients, then it excludes using commercially available ingredients because they do not have a COP. We already have in current law (1735.3 (c)) an allowance for use of an FDA approved product ***without*** a COA.

Recommendation 1736.9 (d):
Change the term "components" to "ingredients" and add the phrase from current 1735.3(c) to the end of this paragraph.
All ingredients used to compound a CSP shall be manufactured by an FDA-registered facility and suitable for use in sterile pharmaceuticals. A Certificate of Analysis (COA) which includes the compendial name, the grade of the material, and the applicable compendial designations on the COA must be received and evaluated prior to use. Certificates of purity or analysis are not required for drug products that are approved by the FDA.

References:USP <797> Section 1, 9.2 (description of supplies), 9.3 (components include ingredients and container closures)

BOP Proposed Item 1736.9 (e):

"If a bulk drug substance, or API, is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approve drug, or be listed in CFR List of Bulk Drug Substances That Can Be Used To Compound Drug Products, 21 CFR 216, unless authorized by a public health official in an emergency use situation for a patient specific compounded sterile preparation."

Comment:

"If" should be replaced by "When"
Minor typo: "FDA approve**d** drug"
If California does not allow the sterile compounding of Category 1 Bulk Drug Substances, patients who want those preparations will find other states to compound for them. If you allow your licensees to compound with Cat 1 with the strict guidelines that are being set forth in USP<797>, you will at least have control over the quality of preparation that the people of California can access. Otherwise, patients will find substandard preparations from out of state.

Further, compounders are in need of clarification as to the use of 503B preparations in our 503A preparations. This may come into play with drug shortages or sterile items that can only be procured from an Outsourcing Facility.

A "public health official" is far too undefined. Internet definition: *Any person from the department of Health and Human Services.* A "public health official" may not even be a doctor, nor have the basic knowledge of compounding. Further, without any guidance, this allows public health official to authorize use of ANY drug substance, including those on the "do not compound list or Category 3 of the Bulk Drug Substances List? How will a DP know that the "public health official" actually has authorization to violate item 1736.9 (e)?

Recommendation 1736.9 (e):
When a bulk drug substance, or API, is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, be made by a 503B facility registered in California, be listed in CFR List of Bulk Drug Substances That Can Be Used To Compound Drug Products, 21 CFR 216, or be on the Category 1 of the 503A Bulk Drug Substances List.

In an emergency use situation for a patient specific CSP that is not compliant with the above references, a DP may request an immediate waiver of 1736.9 (e) with the Board of Pharmacy.

BOP Proposed Item 1736.14 (a)(1):

"A CSP's beyond-use date (BUD) shall not exceed:
(1) The chemical and physical stability data of the active pharmaceutical ingredient and any added substances in the preparation,"

Comment:
Data is an undefined term subject to a wide variety of interpretations, which creates difficulty with compliance. "Data" could mean information from referenced journals, extrapolated information from text references, summary data from private sources, or raw data from specific commissioned analysis. Without understanding how this term will be applied to CSPs, a business cannot determine the cost, appropriateness, or applicability of their pharmacist judgement in establishing a BUD. USP's intent is clear that they require that a pharmacist "consider" relevant parameters that could affect quality of the CSP (Section 14.2) which easily could include literature review and compounding knowledge to result in a professional judgement regarding a BUD.
1736.14(a)(1) has the potential as written to compel every pharmacy in every setting to have to independently collect "data" to justify their BUDs rather than using pharmacist judgement.
This comment is in no way alluding to extension of a BUD. What data will the inspectors look for to adequately demonstrate that a formula is stable, both chemically and physically, for 1 day, for 7 days, or frozen for 45 days?

Recommendation 1736.14 (a)(1):
A CSP's beyond-use date (BUD) shall not exceed:
(1) The anticipated chemical and physical stability of the active pharmaceutical ingredient and any added substances in the preparation. The process of evaluating of the chemical and physical stability of the ingredients in each formulation must be documented on the MFR and include at a minimum considerations from USP chapter <1191> Stability Considerations.

References:<USP 797> and <1191>

BOP Proposed Item 1736.15:

USE OF CONVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENT

Comment:
Does this include manufactured 503B products?

Recommendation 1736.15:
In section 1736 STERILE COMPOUNDING DEFINITIONS, Add a definition of “Conventionally Manufactured Products” Ingredient components from any FDA registered entity.