

Dear Board of Pharmacy,

Thank you for all efforts relative to implementation of the new USP. I believe that the eventual reorganizing of our pharmacy laws will be much clearer than what we have today.

I am confused by this Draft Policy Statement. Based on this statement, I don't know if you expect me to implement the new USP by Nov 1 or if I can transition over time and if so, what is the time frame? I would greatly appreciate more direct and complete guidance from the Board.

I have two possible solutions that could help prevent confusion going forward.

First- I propose this Board consider applying the OAL emergency rule-making process in order to protect patient safety. Repeal CCR Articles 4.5 and 7 which you have already voted to repeal at your April Meeting. By repealing these Articles, you will protect patients from harm by providing clarity that compounders must upgrade to the new USP guidelines effective Nov 1, 2023. in compliance with BPC 4126.8 Compounding Consistent with United States Pharmacopeia.

If that isn't a good option, then please consider rewording your statement to read more like one of these:

*In recognition of the significant changes to the practice of pharmacy compounding, a transitional period from November 1, 2023 until the completion of the rulemaking process to repeal and revise CCR Articles 4.5 and 7 is recognized by the Board and their Inspectors. Pharmacists must be in compliance with their P&Ps which shall remain congruent with either existing law or the new USP effective November 1, 2023. The Board expects pharmacies to continually update their compounding practices to become consistent with the new USP.*

Or this-

*Beginning November 1, 2023 and until such time as the rule making process is completed for the proposed changes to CR Articles 4.5 and 7 relative to compounding, licensees are expected to implement USP General Chapters as is consistent with BPC 4126.6.*

By adopting clear and concise language, you will remove ambiguity for your compounding licensees and thus improve the safety and consistency of pharmacy compounding for California patients.

Thank you for your time, attention, and consideration I look forward to a clear policy that I can implement in my practice.

**Marie Cottman, Pharm.D.**

Clinical Pharmacist/ Co-Owner

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