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1735(b)	Stanford Health Care	**Comment:** Can the pharmacist-in-charge assign themselves to be the designated person? For smaller pharmacies with a limited number of employees, it may be difficult to identify someone interested and willing to take on the responsibilities of the designated person. **Recommendation:** Revise language to allow the pharmacist-in-charge the option to assign themselves to be the designated person.	Board staff have reviewed the comment. While Board staff believe the language would allow for the PIC to also serve as the designated person, the comment submitted indicates that is not clearly the case. As such, Board staff recommend a change to the proposed text to provide clarity to the proposed regulation text. 1735 (b) 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 nonsterile preparations ("CNSP") for the purposes of this article). Nothing in this definition allows for a designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require the professional judgment of a pharmacist. **Nothing in this definition shall prohibit the PIC from also serving as the designated person.**
1735(c)	Alliance for PHY Compounding	If this is specifically related to manufactured products, it will work. If this is used when speaking to compounded preparations, it must specify that it is referring to USP grade purified water or USP grade sterile water. USP grade water is required as a component of nonsterile compounds. Recommendation: Accept section 1735.4(b) identification of water types.	Board staff have reviewed the comment and do not recommend a substantive change to the proposed text. Staff note that USP 795 6.1.2 speaks to the quality of water that must be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water. The Board's proposed text is consistent with the Chapter and provides clarity to the Chapter by providing examples of the acceptable types of water that may be used for reconstitution. Board staff recommend the following technical changes to reflect the language of the Chapter. 1735 (c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as *Pp*urified ~~w~~*W*ater or *Ss*terile ~~w~~*W*ater.
1735(d)	Outsourcing Facilities Association	This definition creates incoherence and confusion in conjunction with proposed § 1735.1(f), as explained in § A, *infra*.	Board staff have reviewed the comment. Board staff appreciate the comments submitted by the commenter and highlighting the potential conflict. Staff note that the Board does not have regulatory authority over the prescribing practitioner. Staff note

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			that the practice of pharmacy includes pharmacists verifying that a prescribed medication is clinically appropriate for a patient irrespective of whether it is a compounded medication. Staff recommend the following change to the language to remove the potential confusion and concern that the Board is attempting to regulate the prescriber. 1735 (d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active ingredient(s)(API) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that products for that patient a clinically significant difference, as **~~determined~~ verified and documented** by the **pharmacist ~~prescribing practitioner~~**, between that compounded preparation and the comparable commercially available drug product.
1735(d)	Alliance for PHY Compounding Wedgewood Pharmacy	The FDA defines an "essential copy" as the same API; same route of administration; same, similar, or easily substitutable strength; and same characteristics as the combination of two or more commercially available drug products in the 503A copies guidance. The proposed definition makes many compounded medications copies of manufactured drugs for simply sharing the same API. Recommend aligning with the FDA approach. We continue to recommend that California aligns its definition of "essentially a copy" with the FDA's for clarity and ease of compliance.	Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a pharmacist to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended text, the Board would be limiting this flexibility and a clinician's professional judgment. Staff note that it appears the commenter is referring to a draft definition provided in an FDA guidance document (as opposed to the language contained within FDCA 503a). The federal statutory definition, similar to the Board's proposed regulation, requires that the compound must produce a significant difference in the patient. The Board's proposed text is clarifying federal law to ensure the significant difference is clinical in nature. Such an approach provides flexibility for a pharmacist to use clinical judgment.
1735(e)	Torrance Memorial	The proposed language does not distinguish commercially available drug products with the same	Board staff have reviewed the comment and believe the commenter is referring to 1735(d).

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		active pharmaceutical ingredient(s) (API(s)) with drug dosage form(s). To make it clear that drug dosage forms not available commercially can be compounded for patient specific clinical needs. **Recommendation:** Recommend the board to add language to the definition of "essentially a copy" to include "the same dosage form" in addition to the same active ingredient(s) (API(s)).	Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a pharmacist to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended language, the Board would be limiting this flexibility and a clinician's professional judgment.
1735.1	Assoc of NorCal Oncologists and Medical Oncology Assoc. California Rheumatology Alliance CalDerm CA Medical Association	We are concerned that the proposed regulations will require a pharmacist to be present during these types of activities, which would be an onerous burden on community sites of care, particularly those in rural settings. ANCO and MOASC are concerned that these proposed regulations, if adopted, would result in cancer patients being forced to obtain their chemotherapy at a hospital or infusion center, which would place new burdens on patients who are already fighting for their lives. 1735.1. In addition to the standards in USP Chapter 795 and, Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the compounding of a CNSP shall meet the following requirements of this article. This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes

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			them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese A copy of this communication is provided in attachment 6.
1735.1(d)	Wedgewood Pharmacy	"Reasonable quantity" needs to be defined clearly to avoid ambiguity, provide clear compliance standards, and make clear what enforcement will entail. It is unfair to place the burden of determining a "reasonable quantity" on the pharmacist when it is a) an unclear standard and b) the pharmacist doesn't know the prescriber's patient base nor their needs. Recommendations: Change terminology "veterinary office" to "veterinary practice". Mobile veterinarians practice in the field, not an office. Eliminate the words "Reasonable quantity". Clauses 1 and 2 of this provision and the phrase "estimated by the prescriber" establish clear criteria for the amount of office stock drugs that can be ordered and sold. The prescriber is in the best position to determine based on their practice the amount of drugs that are appropriate. A pharmacy	Board staff have conferred with its expert in veterinary practice who has confirmed the term "veterinary office" is appropriate. The expert further commented about the need for some limitations on the volume of compounding to be reasonable, noting that the FDA has publicly expressed concerns regarding 'large-scale drug manufacturing under the guise of pharmacy compounding.'' The practicing veterinarian, in selecting a California licensed pharmacy to supply drugs to their patients, has no way to determine if the compounded drugs are being made in accordance with state and federal regulations. The egregious violations of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) along with multiple violations of pharmacy law, is not only potentially

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		has no reasonable basis to determine what a particular practice may need particularly when the practice is permitted to both administer drugs in office and dispense.	injurious to the animal patients, but also places the veterinarian at risk of liability for use of these drugs. As the commenter notes, reasonable quantity is further clarified in paragraphs (1) and (2). Board staff don't recommend a change in response to the comment; however, staff believe that given that the proposed change is in nonsterile compounding, staff believe an extended day supply may be possible. (d) (2) for furnishing of not more than ~~**7-day supply, or up to no more than**~~ 14 days ~~**for antibiotics**~~, for an individual patient, as fairly estimated by the prescriber, and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing for an individual patient.
1735.1(e)	Alliance for PHY Compounding	Prior version cited 21CFR353a. Replacing the citation with "federal law" is vague and could apply to any federal law. We still assert that referencing specific regulations instead of the general "federal law" provides clarity and specificity to which laws this applies.	Board staff have reviewed the comment and do not recommend a change. Staff note that it is incumbent on the pharmacist to maintain an understanding of all relevant laws. The Board notes that the practice of compounding is a complex area of practice for which pharmacists must possess a strong understanding of all relevant laws. The Board's inclusion of a single code reference as suggested by the commenter may inadvertently suggest to a pharmacist that is the only relevant section of the law to be considered. In such an instance, the Board's regulation would be potentially misleading, as the pharmacist must consider all relevant sections of the law applicable to the compounding being performed.
1735.1(e)(1)	Wedgewood Pharmacy	Recommendation: Edit 1735.1 (e) to align with the language that is more appropriate in 1736.1 (e)	Board staff have reviewed the comment and believe the commenter is suggesting that the Board consider its comments from 1735.1(e) to similarly apply to 1736.1(e)(2). With this understanding, staff note that the suggestion to incorporate GFI #256 was reviewed by staff and a Board's expert on veterinary compounding. Staff recommend the following to respond to the comment.

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			1735(e)(2) Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.
1735.1(e)(1)	Alliance for PHY Compounding	There is no accommodation for veterinary compounds, which are regulated under different provisions of federal law. A reference should be made to the appropriate guidance, and a section should be added to allow for compounded preparations being sold for veterinary office use where the API appears on the lists of approved or under consideration APIs for veterinary use. Subpoint A indicates that the drug must be on shortage 'at the time of compounding and at the time of dispensing'. There should be a transition period from the time of the end of shortage. We recommend a 30-day transition period. The final compounding regulations should reference GFI #256 where it applies to animal drug compounders. APC recommends aligning with what is required in the FDA's Essential Copy Guidance document, which does require documentation when a pharmacist dispenses a medication for which a change is made so it is not a copy of an FDA-approved product. The prescriber makes the determination that the compound is required, and the Board should not intend to question the prescriber's judgement. We also recommend that California provide	Board staff have reviewed the comment and believe the commenter may be referring to separate issues within a single comment. In this response staff will respond to the portion of the comment that appears to be related to the provisions in (e)(1), essentially a copy. Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a pharmacist to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended language, the Board would be limiting this flexibility and a pharmacist's professional judgment. Further, Board staff note that the commenter appears to suggest that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simple defer their judgment to another individual. This is obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5.

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		examples of appropriate documentation to allow for all inspectors to apply the rule consistently. The Board's own definition of "essentially a copy" is as determined by the prescribing practitioner, not the pharmacist. Likewise, the pharmacist is not the one that makes the determination that the medication is required, but does document the determination on the prescription.	
1735.1(e)(1)(A)	CSHP Cedars-Sinai Torrance Memorial Wedgewood Pharmacy Kaweah Health	The ASHP and FDA drug shortage lists do not always reflect real-time drug shortages. As an example, the 2023 Akorn recall was posted after the State Board notification of the company shut down which resulted in multiple drug shortages. Additionally, wholesalers themselves often run out of supplies of critical medications (pre-shortage situations). Inability to procure medications or restrictions to compound in these events will contribute to heightened risk and safety concerns for patients. This proposed regulation has the potential to dramatically impact public heath by disabling health system pharmacies in their efforts to provide life-saving medications to acutely ill patients during the scenarios above. (e)(1) Is essentially a copy of one or more commercially available drug products, unless: (A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or (B) The pharmacist determines and documents that the preparation produces a clinically significant difference based on the medical need of an identified individual patient	Board staff have reviewed the comment and appreciate that the commenter has raised this issue. Staff note that the Board agreed with the policy raised in this comment related to sterile compounding. Board staff agree that a similar accommodation is appropriate for nonsterile compounding, specifically for inpatients of a hospital and suggests the following modification. 1735.1(e)(1)(A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, **or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or**
1735.1(e)(2)	Dan Baxter CA Veterinary Medical Assoc Alliance for PHY Compounding	Is made with any component not suitable for use in a CNSP for the intended ~~veterinary~~ animal population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA) and, if applicable, the Federal Food and Drug Administration Guidance for Industry #256 (GFI 256)."	Board staff have reviewed the comment and believe the commenter may be referring to separate issues within a single comment. In this response staff will respond to the portion of the comment that appears to be related to the provisions in (e)(2) specifically related the GFI #256.

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	Wedgewood Pharmacy	Commenter requests the inclusion of the reference to the Federal Drug Administration's Guidance for Industry #256 (GFI 256), in addition to the current reference to the Animal Medicinal Drug Use Clarification Act (AMDUCA). While AMDUCA is relevant to the provisions at issue, it alone does not provide the level of detail and specific guidance needed for licensees to understand what is allowable in compounding compounded nonsterile preparations and compounded sterile preparations. AMDUCA amended the Federal Food, Drug, and Cosmetic Act to legalize extralabel drug use (ELDU) under a valid veterinarian-client-patient relationship (VCPR), and to specify conditions and requirements for use, record keeping, and labeling according to FDA regulations. In August of 2022, the FDA developed and published GFI 256, which serves as an inclusive list of active pharmaceutical ingredients permissible for use in compounding medications for animal patients. FDA has generally exercised enforcement discretion with regard to animal drug compounding from bulk drug substances under certain circumstances. Namely, the FDA recognizes that many vital animal drugs are unavailable in FDA-approved form and that veterinarians must be able to treat animals with needed medications, despite the pharmaceutical industry's inability or unwillingness to bring them to market. GFI 256 is intended to provide clarity to veterinarians and pharmacists about the FDA's current thinking on compounding from APIs. The guidance identifies the FDA's enforcement priorities regarding animal drugs compounded from bulk drugs substances and describes the circumstances under which the FDA does not intend at this time to take enforcement action for violations of the Food, Drug and Cosmetic Act with respect to the compounding of animal drugs from bulk drug substances.	Staff note that the suggestion to incorporate GFI #256 was reviewed by staff and an external expert on veterinary compounding. The expert reported that inclusion of the GFI #256 is ill-advised. Staff recommend the following change in response to the comment. (e)(2) Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). **When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.** The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice including veterinary compounding. This is obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5.
1735.1(e)(1)	Alliance for PHY Compounding	There is no accommodation for veterinary compounds, which are regulated under different provisions of federal law. A reference should be made to the appropriate guidance, and a section should be added to allow for compounded preparations being	Board staff have reviewed the comment and believe the commenter may be referring to separate issues within a single comment. In this response staff will respond to the portion of the comment that appears to

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		sold for veterinary office use where the API appears on the lists of approved or under consideration APIs for veterinary use. Subpoint A indicates that the drug must be on shortage 'at the time of compounding and at the time of dispensing'. There should be a transition period from the time of the end of shortage. We recommend a 30-day transition period. The final compounding regulations should reference GFI #256 where it applies to animal drug compounders. APC recommends aligning with what is required in the FDA's Essential Copy Guidance document, which does require documentation when a pharmacist dispenses a medication for which a change is made so it is not a copy of an FDA-approved product. The prescriber makes the determination that the compound is required, and the Board should not intend to question the prescriber's judgement. We also recommend that California provide examples of appropriate documentation to allow for all inspectors to apply the rule consistently. The Board's own definition of "essentially a copy" is as determined by the prescribing practitioner, not the pharmacist. Likewise, the pharmacist is not the one that makes the determination that the medication is required, but does document the determination on the prescription.	be related to the provisions in (e)(2), specifically related to GFI #256. As stated previously, board staff recommend the following change. 1735.1(e)(2) Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). **When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.** The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice including veterinary compounding. This obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5.
1735.1(e)(1)(B)	Kaweah Health	Recommend: strike (B)(iii) to be consistent with proposed language in 17**36**.1(e)(1)(B) unless there is a compelling reason the language for CNSPs in this section needs to vary. If staff do not agree with the above recommendation, the staff recommended modified changes should be clarified to improve readability and at minimum a renumbering is required. There is a B(iii) without a B(i) or B(ii).	Board staff have reviewed the comment and note that the language referenced in the comment was already identified for removal in the prior comment period.
1735.1(f)	Outsourcing Facilities Association	The proposed amendment should not be adopted, for the reasons stated in §§ A–D, *infra*.	Board staff have reviewed the comment. [**Note** while the comment referenced 1735.1(f), Board staff believe the comment is related to 1735.1(e).] Board staff note that the suggested conflict is proposed to be resolved

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			through an update to the definition section, referenced, above to proposed section 1735 (d). Conforming change is also necessary in 1735.1(e)(1)(B) as follows: 1735.1(e)(1)(B) The pharmacist ~~**determines**~~ **verifies** and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient, ~~as determined by~~:
1735.1(f)	Keck / USC	This requirement exceeds current FDA guidance for the industry and will impose an unjustified burden on health-system pharmacies, creating gaps in patient care and negatively affecting clinical outcomes. The FDA guidance uses the term "should" when discussing compounding in 503A facilities. By prohibiting this practice, the BOP would impose a burden on inpatient hospital pharmacy licensees and negatively impact patient outcomes when a drug is unavailable within the institution, yet there is an urgent clinical need. Additionally, determining that the compounded product produces a clinically significant difference for the medical need of a patient will be challenging and subjective. Maintaining retrievable justification documentation each time a medication is compounded will burden operations and may impact timely patient care. Furthermore, USP 795 allows for any CNSP compounding when the master formulation record (MFR) is available. To allow for continuity of care, change the language to "In addition to prohibitions and requirements for compounding established in federal law, **no CNSP should** be prepared that".	Board staff note that the commenter referenced the wrong section. [**Note** while the comment referenced 1735.1(f), Board staff believe the comment is related to 1735.1(e).] In response to this and other comments received Board staff recommend a change to the proposed regulation text. The language recommended is the following: 1735.1(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispensing, or **in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained**, or
1735.1(f)(1)(A)	Walgreens	Understandably, the Board would like to impose strict and clear guardrails for compounding to inspect and enforce when commercially available products are on the market. However, the language will cause issues for patients and limit their ability to access compounded medications, especially in times of need. This language appears to come from an FDA guidance document; however, commercial products become unavailable for patients long before they appear on the referenced databases and the board should weigh the pros and cons of trusting	Board staff have reviewed the comment and believe the commenter is referring to the new proposed 1736(e)(1)(A). Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff note that the use of a compounded drug (which can create higher risks to patients) when an FDA manufactured product is available. Further staff notes that the FDA has stated that "A drug 'appears on the drug shortage list in effect under section 506A' if the drug is 'currently

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		manufacturers to appropriately report shortages of their medications. Walgreens suggests the board allow the compounding of a copy or essentially a copy of a commercial product so long as there is a clinically significant, therapeutic reason, such as a documented allergy or product shortage. (A) the drug product appears in an American Society of Health- System Pharmacists (ASHP) or FDA Drug Shortages Database ~~that~~ or are in short supply at the time of compounding ~~and at the time of dispensing,~~ or	in shortage' status (and not in "resolved status) in the FDA's drug shortage database. The FDA notes: "Commercially available drugs are available on the market, and they are generally subject to FD&C Act requirements relating to approval, labeling, and CGMP requirements, and the copies restriction applies to all such drugs because section 503A is not intended to provide a means for compounders to produce compounded drugs exempt from the Act's requirements that are essentially copies of commercially available drug products."
1735.1(i)	CVS Health	If the Board is to consider flavoring as compounding, CVS Health requests an exemption to labeling. We also believe that the compounding cleaning and record keeping requirements are excessive for flavoring. While we prefer that flavoring is exempted from compounding, we understand the Board to not be amenable. Thus, in order for CVS Health to consider flavoring prescriptions in California, we request the following, which is mainly derived from the Missouri Board of Pharmacy's 2020 Pharmacy Practice Guide: *(i) Using sound professional judgment, a pharmacist may authorize the flavoring of a prescription unless the prescriber expressly prohibits flavoring upon issuing the prescription.*	Board staff have reviewed the comment and appreciate the commenter providing recommendations to help facilitate the compounding with a flavoring agent. Board staff recommend the addition a subdivision specifically related to flavoring agents and an addition to 1735.1(i) related to compounding by combining a flavoring agent with an FDA approved drug in an oral liquid solution. The recommended text is provided below. **(i) 1735.1(i) A facility that limits compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13** **1735.15. Flavoring Agents.** **(a) In addition to the standards in USP Chapter 795 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:** **1. Provisions of accommodations as described in Personnel Preparation, Section 3.1 of USP Chapter 795** **2. Provisions for cleaning and sanitizing designated compounding area when in use.**

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			3. Provisions to ensure documentation is available and maintained confirming the quality of the medication is not impacted by the adding of the flavoring agent. 4. Provisions for maintaining the elements of the compounding record to ensure information is readily retrievable upon request. 5. Provisions to ensure the prescription label includes information that a flavoring agent was added. 6. Provisions to ensure documentation is available to support the establishment of a BUD. (b) A pharmacist may compound by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of the patient or patient's agent without consultation with the prescriber or the prescriber's authorized agent. A pharmacist performing such compounding must document the compounding on the prescription record.
1735.3(a)	Stanford Health Care	**Comment:** This language does not align with the BOP's requirement for sterile compounding. The BOP's proposed section 1736.3 does not require a supervising pharmacist to evaluate all sterile compounding personnel for specific contaminating conditions before entering the compounding area. This requirement may not be feasible for a high-volume pharmacy (e.g., a large hospital pharmacy) with numerous employees who may be asked to compound at any given time. Additionally, supervisors have raised concerns that this may require them to ask staff personal questions about their health conditions, which may be seen as inappropriate. Remove language to be consistent with USP 795, where it is the responsibility of the compounding person to report contaminating conditions to the designated person(s); or Revise the language to read:	Board staff have reviewed the comment and do not recommend a change to the proposed text based on this comment. Commenter is suggesting that the Board remove the current flexibility provided in the proposed text and instead prohibit any such personnel. Board staff believe the current approach providing flexibility to the worksite for nonsterile compounding is appropriate and consistent with the USP 795 Chapter.

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		"If the supervising pharmacist observes personnel experiencing any of the conditions mentioned above and determines that such personnel pose a risk to CNSPs or the environment, the supervising pharmacist shall prohibit the individual from entering the compounding area."	
1735.4(b)	John Gray Kaiser Walgreens	~~*Purified water, distilled water, or reverse osmosis water, or*~~ ~~*higher quality water shall be used for rinsing equipment and utensils.*~~ The Board has still not provided any empirical evidence of untoward effects associated with the water used to rinse equipment and utensils used for non-sterile compounding. Instead of providing actual evidence to substantiate the purported risk, the Board has added additional unreferenced, unsubstantiated risks to its Modified Initial Statement of Reasons. Because the Board has no concrete evidence to support the need for this regulation and because USP Chapter 795 adequately addresses the recommended use of purified, distilled, or reverse osmosis water for rinsing equipment and utensils, we continue to recommend that this requirement be deleted. If the Board chooses not to delete this requirement, then we encourage the Board to provide a definition of the term "higher quality water."	Board staff have reviewed the comment and do not recommend any change to the proposed regulation text. Staff note that USP identifies various grades of water including in Section 4.3 of the Chapter for rinsing; however, the permissive language of the Chapter is not appropriate given the patient safety concerns described below. Staff notes that the quality of water is of significance for patient safety as contaminated water will contaminate the equipment used for CNSP. It is relevant to note that the Chapter requires the use of specific water in the preparation of the CNSP. Allowing for the use of tap water then for example, undermines the patient protection of the higher quality water used in the CNSP. As an example, tap water may be contaminated with fungus, bacteria, and other elements that could contaminate the equipment used in the preparation of CNSPs. It is important to note that this section of the proposed regulation text speaks to rinsing (as opposed to cleaning).
1735.4(c)	Alliance for PHY Compounding	APC Recommendation: California regulations could reference FDA's Insanitary Conditions guidance for clarity.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that a pharmacist may determine that additional standards established in the FDA's Insanitary Conditions Guidance can be incorporated into the facility's SOPs.
1735.5 (a)	Walgreens	Commenter believes this is unnecessary and overly burdensome language that does not improve patient safety. This language could be interpreted to require pharmacies to list the specific brand or manufacturer of commonly used cleaning and sanitizing products Requiring pharmacy teams to follow USP guidelines and instructions for cleaning is sufficient to ensure patient safety.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that it is regrettably a common occurrence for a pharmacy to be unable to provide inspector staff with the name of cleaning and sanitizing agents used. Failure to maintain documentation of the products used prevents the facility and the Board from verifying compliance with SOPs established.

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		Recommended: (a) The facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include the identity of the person completing the cleaning and sanitizing, as well as ~~the product name(s) of~~ the cleaning and sanitizing agent(s) used.	
1735.5(c)	CVS Health	If the Board is to consider flavoring as compounding, CVS Health requests an exemption to labeling. We also believe that the compounding cleaning and record keeping requirements are excessive for flavoring. While we prefer that flavoring is exempted flavoring prescriptions in California, we request the following, which is mainly derived from the Missouri Board of Pharmacy's 2020 Pharmacy Practice Guide: *(c) When flavoring a prescription, this section is*	commenter for offering recommendations to facilitate compliance with compounding with flavoring agents. to 1735.1(i) related to compounding by combining a flavoring agent with an FDA approved drug in an oral liquid solution. Further staff recommend adding next section 1735.15 Flavoring Agents. The draft text is provided in response to the comment from CVS related
1735.6(a)	Stanford Health Care	Comment: Manufacturer specifications are not always available for all compounding equipment (e.g., mortar and pestle). Recommendation: Revise language to read: "Any equipment used to compound a CNSP shall be used in accordance with the manufacturer's specification or, in the absence of such specifications, in accordance with professional standards for use."	Board staff have reviewed the comment. While staff believe the language is sufficiently clear, submission of the comment indicates otherwise. Board staff believe additional clarification of the language may be appropriate to provide that a manufacturer's specifications for use must be followed when provided by the manufacturer. Staff note that where a manufacturer has provided specifications for use, such specifications **MUST** be followed. 1735.6.(a) In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding. (a) Any equipment used to compound a CNSP shall be used in accordance with the manufacturer's specifications, **where established by the manufacturer**.
1735.7(a)(1)	Walgreens	We ask the board to clarify and specify the requirement for readily retrievable at the time of compounding. Does the board intend for this information to be immediately available to the retrievable if requested by the pharmacist or board?	recommend a change to the proposed text. Staff notes that the term "readily retrievable" is used throughout Pharmacy Law and its regulations. Board it should be separate from this discussion as it would impact several other areas of Pharmacy Law.

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		If the board's intent is for the pharmacist to have the source referenced for the master formulation record in hand at the time of compounding, this would further limit locations that could provide compounding services. USP monographs are widely referenced for beyond- use date assignments; however, access to these monographs is limited and cost prohibitive for many pharmacies. Often, if requested by the compounding pharmacist, a copy of the materials supporting the extended BUD will and can be provided but are not sent to the pharmacist for review, unless requested. **Recommended language:** (1) If a source is referenced to support the assigned beyond-use date (BUD), each source referenced shall be available upon request prior to compounding ~~readily retrievable at the time of compounding~~ and shall be retrievable ~~maintained~~ for three years from the date each CNSP is dispensed.	
1735.7(c)(1)	John Gray Kaiser Stanford Health Care Alliance for PHY Compounding CVS Health	Commenters request the elimination of "and time" or clarification with respect to what "time" is referring to. Possible additional language is: "(1) The date and time of compounding, which is the time when compounding the CNSP began, and is the time from which the assigned BUD is determined."	Board staff have reviewed the comments and believe a change to the proposed language as suggested is appropriate. Board staff believe deletion of (c)(1) is appropriate. 1735.7(c)**~~(1) The date and time of compounding, which is the time when compounding the CNSP started, and which determines when the assigned BUD starts.~~**
1735.7(c)(2)	UC San Diego CSHP Cedars-Sinai Torrance Memorial UC Health	Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. To prevent delays in care to acutely ill patients, recommend striking (c)(2) or add an exemption for health care facilities licensed under section 1250 of the Health and Safety Code.	Board staff have reviewed the comment and do not recommend a change to proposed text. Staff note that upon inspections, inspectors note that health systems maintain this information within its electronic system. The noticed proposed text in the 30-day comment period specifically provides that a facility is not required to maintain the information in a single document. If information is required by the Board, the information must be retrieved from the electronic system and provided to the Board as a single document.

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1735.7(c)(2)	Alliance for PHY Compounding	The manufacturer of each component is a trade secret that is not required to be disclosed by federal law or federal regulation. Suggest changing the word manufacturer to supplier. Per the Civil Code, "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique or process that (1) derives independent economic value, actual or potential, from being generally known to the public or to other persons who can obtain economic value from its disclosure or use, and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Some pharmacy vendors maintain that the manufacturers they source API from is a trade secret and disclosure would cause economic injury.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further note that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturer or vendor; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of a compounders knowing your suppliers -- https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers. Lastly, simply identifying the manufacturer of a component without more does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d).
1735.7(c)(4)	Alliance for PHY Compounding	Compounding software programs typically require the metric quantity of a batch prepared, but do not document the quantity of each individual unit. Recommend aligning with USP Chapter <905>, *Uniformity of Dosage Units*, for ease of compliance.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board have reviewed the USP Chapter referenced and note that the intent of the referenced chapter is to ensure the consistency of dosage units, each unit in a batch should have a drug substance content within a narrow range around the label claim. Dosage units are defined as dosage forms containing a single dose or a part of a dose of drug substance in each unit. The Board's proposed regulation text in this subdivision is related to documentation for a compounding record.
1735.7(c)(5)	Stanford Health Care	***Comment:*** *The pharmacist who has direct supervision and* *control of compounding is often the pharmacist verifying the final drug preparation.* ***Recommendation:*** *Revise language to read:*	Board staff have reviewed the comment. While staff believe the language is sufficiently clear, submission of the comment suggests otherwise. Board staff believe the additional language submitted by the commenter may provided additional clarity to the regulated public.

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		"(5) The identity of personnel performing the compounding, the pharmacist verifying the final drug preparation, as well as the pharmacist who has direct supervision and control of compounding if different from the pharmacist verifying the final drug preparation."	1735.7(c)(5) The identity of personnel ~~each person~~ performing the compounding, pharmacist ~~the person~~ who has direct ~~oversight~~ supervision and control of compounding, and the pharmacist verifying the final drug preparation, **if different**. (Note: with the recommended deletion of 1735.7(c)(1) above, this paragraph will be renumbered to 1735.7(c)(4).)
1735.7(d)	CVS Health	If the Board is to consider flavoring as compounding, CVS Health requests an exemption to labeling. We also believe that the compounding cleaning and record keeping requirements are excessive for flavoring. While we prefer that flavoring is exempted from compounding, we understand the Board to not be amenable. Thus, in order for CVS Health to consider flavoring prescriptions in California, we request the following, which is mainly derived from the Missouri Board of Pharmacy's 2020 Pharmacy Practice Guide: *(d) When flavoring a prescription, this section is satisfied by only notating the act of flavoring in the pharmacy's prescription record, including in a logbook or in the prescription record.*	Board staff have reviewed the comment and thank the commenter for offering recommendations to facilitate compliance with compounding with flavoring agents. Board staff recommend the addition a subdivision specifically related to flavoring agents and an addition to 1735.1(i) related to compounding by combining a flavoring agent with an FDA approved drug in an oral liquid solution. Further staff recommend adding next section 1735.15 Flavoring Agents. The draft text is provided in response to the comment from CVS related to 1735.1(i).
1735.9(d)	CVS Health	If the Board is to consider flavoring as compounding, CVS Health requests an exemption to labeling. We also believe that the compounding cleaning and record keeping requirements are excessive for flavoring. While we prefer that flavoring is exempted from compounding, we understand the Board to not be amenable. Thus, in order for CVS Health to consider flavoring prescriptions in California, we request the following, which is mainly derived from the Missouri Board of Pharmacy's 2020 Pharmacy Practice Guide: *(d) When flavoring a prescription, this section is satisfied by indicating that the product was flavored on the patient's container.*	Board staff have reviewed the comment and thank the commenter for offering recommendations to facilitate compliance with compounding with a flavoring agents. Board staff recommend the addition a subdivision specifically related to flavoring agents and an addition to 1735.1(i) related to compounding by combining a flavoring agent with an FDA approved drug in an oral liquid solution. Further staff recommend adding next section 1735.15 Flavoring Agents. The draft text is provided in response to the comment from CVS related to 1735.1(i).
1735.10(a)	Stanford Health Care	**Comment:** Electronic health record (EHR) systems use the 24- hour format for time entries. **Recommendation:** Revise language to include 24-hour time format (e.g., 23:59).	Board staff have reviewed the comment. While staff believe the language is sufficient clear, submission of the comment indicates clarification may be necessary. Board staff believe modification to the language can provided additional clarity to the regulated public.

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			1735.10. Establishing Beyond-Use Dates. In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding. (a) Beyond-use dates (BUDs) assigned with only a date shall expire at 11:59 p.m. **or 23:59** on that date.
1735.10(c)(1)	CVS Health	CVS Health is supportive of prescription flavoring within our pharmacies and supportive of the overwhelming majority of states who do not consider flavoring as compounding. We believe that the increased potential for adherence to medication regimens and thus increased public safety for California residents (particularly children) is evident and any perceived risk to public safety has not been substantiated with data or evidence.	Board staff have reviewed the comment and believe that the intent of the comment was to express the commenter's support of flavoring. Staff note that the commenter did not appear to offer any recommended changes specifically to this section of the proposed text.
1735.10(b)(1)	Alliance for PHY Compounding	Components such as pH adjusters should be excluded from impacting the BUD of the formula on. These are typically made fresh, used, and disposed of. If the pharmacy were to document a 1-day BUD for the pH adjuster, then this language as written would cause the final preparation to have a 1-day BUD. Recommend aligning with USP's approach to exclude pH adjusters from the determination of the BUD.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that USP Chapter 795 does not establish provisions such as those referenced by the commenter. Board staff agree with the USP Expert Committee that this is not necessary. Staff note that this comment would be relevant in the compounding of a sterile preparation.
1735.10(b)(2)	Alliance for PHY Compounding	Leachables per USP are extensive studies that cost several hundred thousand dollars for each drug product. It is not reasonable for compounding pharmacy to study leachables. There are several USP chapters that apply to leachables and extractables. They apply to manufacturers making packaging materials and do not apply to pharmacies. USP 795 10.2 does indicate that a pharmacy should consider leachables, but does not indicate that the pharmacy itself must conduct leachable studies.	Board staff have reviewed the comment and do not recommend changes to the proposed text. USP Chapter 795, Section 10.2 specifies that when establishing a BUD for a CNSP, compounders MUST consider parameters that may affect quality, including compatibility of the container closure system with the finished preparation (e.g. leachables). The Chapter requires this be done. The comment appears to suggest that the pharmacy itself must conduct the leachable studies. The Board's proposed regulation text does not require the pharmacy to conduct the test, rather it requires the pharmacist to ensure that the BUD does not go beyond what the parameters reveal to support the BUD, which could be done by review of a test conducted outside of the pharmacy. Any cost incurred for this determination (e.g. leachables) are a function of compliance with the Chapter, not the Board's regulations. The Board's regulations merely ensure that a pharmacist uses the

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			information it obtains through the USP requirements in establishing a BUD to not exceed the parameters.
1735.11(a)(1)	Alliance for PHY Compounding Wedgewood Pharmacy	USP chapters over 1000 are not written for compliance purposes. See this quote from the USP General Notices: "General chapters numbered 1000 to 1999 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any official article, regardless of citation in a general chapter numbered below 1000, a monograph, or these General Notices." Recommendation: USP Chapters above 1000 are for informational purposes only. They **contain no mandatory tests, assays, or other requirements applicable to any article, regardless of citation in a general chapter below 1000**, a monograph or these General Notices. The Board's assertion that it is just listing out all the tests required on API (and other requirements in Chapters above 1000) is untrue. Per USP, these tests are not required, even if they are cited in chapters below 1000. We recommend removing all requirements for pharmacies outlined in the proposed regulations that reference USP chapters above 1000.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8, establishes compliance with pharmacy compounding chapters. Staff further notes, USP has stated, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."
1735.11(a)(2)(E)	Alliance for PHY Compounding	The statement "validated processes" is unclear and undefined. APC recommends changing the wording to "process validation" as it has a specified definition and is not up for interpretation.	Board staff have reviewed the comment do not recommend a change to the proposed text. Staff note that it does **not** believe that full "process validation," is necessary. "Process validation" is a costly and extensive process defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product. The FDA guidance describes process validation activities in three stages; 1) Stage 1 – Process Design, 2) Stage 2 – Process Qualification, 3) Continued Process Verification.
1735.12(a)	Alliance for PHY Compounding	USP chapters over 1000 are not written for compliance purposes. See this quote from the USP General Notices: "General chapters numbered 1000 to 1999 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any official article, regardless of citation in a general chapter numbered below 1000, a	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff note that the Initial Statement of Reasons documents the basis for inclusion of USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. Business and Professions Code section 4126.8,

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		monograph, or these General Notices." Recommendation: USP Chapters above 1000 are for informational purposes only. They **contain no mandatory tests, assays, or other requirements applicable to any article, regardless of citation in a general chapter below 1000**, a monograph or these General Notices. The Board's assertion that it is just listing out all the tests required on API (and other requirements in Chapters above 1000) is untrue. Per USP, these tests are not required, even if they are cited in chapters below 1000. We recommend removing all requirements for pharmacies outlined in the proposed regulations that reference USP chapters above 1000.	establishes compliance with pharmacy compounding chapters. Staff further notes, USP has stated, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements."
1735.12(a)(2)	John Gray Kaiser	~~*(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.*~~ The USP 795 chapter addresses temperature monitoring, documentation, and follow-up for areas where CNSPs are stored in sufficient detail that requiring a written standard operating procedure would be duplicative. In the Modified Initial Statement of Reasons, the Board claims that this regulation is necessary to "ensure appropriate action will be taken timely should it be needed to ensure patient safety." The Board fails to recognize that existing regulations (e.g. 16 CCR 1714(b)) require all pharmacies to ensure that medications are "safely and properly maintained and secured" and that existing law (e.g. BPC 4084 and 4086) prohibits pharmacies from trading in adulterated drugs. Because the USP 795 Chapter and existing law and regulation require pharmacies to store drugs at the appropriate temperature, the proposed regulation in 1735.12(a)(2) is unnecessary.	Board staff have reviewed the comment. Board staff thank the commenter for underscoring the applicability of CCR 1714(b) that extends to all drug storage areas within a hospital. With that common understanding, Board staff believe that the recommended change by the commenter to delete proposed text 1735.12(a)(2) is appropriate. 1735.12. ~~**(a) (2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.**~~
1735.12(b)	John Gray Kaiser CSHP Alliance for PHY Compounding	~~*The Board shall be notified in writing within 72 96 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug experience as defined in 21 CFR 310.305(b) drug*~~ *event involving a CNSP.* The modified regulation text references the definition of the term "adverse drug experience" provided in federal regulations pertaining to drug manufacturers	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that BPC 4126.9 requires reporting to the Board only in the event of a recall. The proposed regulation text requires notification specifically regarding a complaint of a potential quality problem or an unexpected ADE. Nothing in the proposed regulation text is intended to require reporting of an expected outcome stemming

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		and distributors. The referenced definition of the term adverse drug experience is too broad and would explicitly include untoward effects resulting from "intentional overdoses, drug abuse, and failures of expected pharmacological action." Business and Professions Code section 4126.9 already requires a pharmacy that issues a recall notice for a CNSP to notify the patient, prescriber, and Board within 12 hours of the recall notice if certain conditions are met. The requirement in existing law ensures that the Board is notified of serious quality and safety issues while reducing the administrative burden associated with reporting events that are in no way related to the quality of products compounded by the pharmacy (e.g., intentional overdose). One could argue that, as written, the proposed regulation would require a pharmacy to report cases in which it becomes aware that an individual died after ingesting an aid- in-dying drug under the California End of Life Option Act.14 Given these factors, we recommend deleting this requirement from the proposed regulation. If the Board believes that this additional requirement to report adverse drug events to the Board be maintained in the regulation, then we encourage the Board to modify the regulation to align the requirement with Business and Professions Code section 4127.1(f). If the language is not stricken, amend to read: (b) The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint of a potential quality problem or **and** the occurrence of a **serious and unexpected** adverse drug experience as defined in 21 CFR 310.305(b) involving a CNSP.	from the intended use of a compounded preparation for a specific outcome, such as, a patient dying after taking an aid-in-dying drug.
1735.12(c)	Cedars-Sinai Torrance Memorial	A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. Recommendation (c)All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or	Board staff have reviewed the comment and do not recommend a change in the proposed staff. Staff are concerned that a "business day" varies greatly depending on the practice site and differing operating hours.

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		occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.	
1735.13	Alliance for PHY Compounding	The statement "validated processes" is unclear and undefined. APC recommends changing the wording to "process validation" as it has a specified definition and is not up for interpretation.	Board staff have reviewed the comment do not recommend a change to the proposed text. Staff note that it does **not** believe that full "process validation," is necessary. "Process validation" is a costly and extensive process defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product. The FDA guidance describes process validation activities in three stages; 1) Stage 1 – Process Design, 2) Stage 2 – Process Qualification, 3) Continued Process Verification.