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1738.1	Assoc of NorCal Oncologists and Medical Oncology Assoc. California Rheumatology Alliance CA Medical Association CalDerm	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. 1738.1: In addition to the standards in the USP Chapter 825, the processing of Radiopharmaceuticals shall meet the requirements of this section. 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 that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Professions Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to determine in the practice described if the scenario described their comment is allowable. 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 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

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			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 Business and Professions Code section 4001.1 provides that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. The Board believes the proposed regulations are consistent with its statutory mandate.
1738.4	CSHP	The current USP 825 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients. Recommend the Board of Pharmacy remove the requirement of "PEC unique identifier". Recommendation: (c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type <u>and PEC unique identifier</u> used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same	Staff have reviewed the comment. Staff note that the requirement to document would occur once every three to six months. Staff note that the unique identifier is necessary to identify where the competency was performed. Staff note that maintaining the PEC unique identifier provides the facility with the location of the equipment and is consistent with the standard of practice. The language provides flexibility for each facility to determine the PEC unique identifier, e.g. hood 2.

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		procedures, type of equipment, and materials used in aseptic compounding.	
1738.5(e)	Cedars-Sinai	Per USP 825, for compounding sterile radiopharmaceuticals, the ISO 5 PEC must be placed in a classified area. However, non-radiopharmaceutical sterile compounds were not applicable for this restriction in USP 825. Prohibiting all compounding at SRPA would have a significant impact in the workload on health-systems that does not have a dedicated classified room for radiopharmaceuticals as they would not be able to prepare any supportive meds that has an SRPA. Recommendation: *(d) Radiopharmaceutical compounding shall not take place in the SRPA.*	Board staff have reviewed the comment and believe that 1738.5(e) can be deleted from the proposed regulations. Staff note that the Chapter already specifically details what activities can be done in an SRPA. ~~**(3e) Compounding shall not take place in the SRPA.**~~
1738.10(c)	CSHP	The proposed language is inconsistent with USP 825 recommendations, and will require health-systems to incorporate patient need which may not be pertinent information. We reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients. This proposed regulation fails to demonstrate the necessity for patient safety beyond that required by USP. We recommend that this subsection be deleted.	Board staff have reviewed the comment and thank the commenter for highlighting this section. Upon review of the comment, staff believe the language of the proposed text may require additional amendment to clarify the requirement. Staff note that the intent of the proposed regulation is to ensure the facility has an SOP defining the conditions for minor deviations. Board staff recommend the following change to the proposed text. (c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. ~~**Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.**~~ While the language specifically referring to a pharmacist's clinical judgement is being removed, it is important to note that the recommendation to change the language should not be interpreted as the Board suggesting that a pharmacist does not need to exercise clinical judgment. To the contrary, pharmacists as

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			licensed health care providers must always exercise professional judgment in their practice. This requirement is memorialized in Business and Professions Code section 4306.5.
1738.10(c)	Cedars-Sinai	The proposed language is inconsistent with USP 825 recommendations, will require health-systems to incorporate patient need which may not be pertinent information. Recommendation: (c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, ~~include patient need or~~ facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.	Board staff have reviewed the comment and thank the commenter for highlighting this section. Upon review of the comment, staff believe the language of the proposed text may require additional amendment to clarify the requirement. Staff note that the intent of the proposed regulation is to ensure the facility has an SOP defining the conditions for minor deviations. Board staff recommend the following change to the proposed text. (c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. **Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and ~~radionuclidic purity) as specified in individual monographs, and other applicable parameters as~~ clinically appropriate in the professional judgment of the ~~pharmacist.~~** While the language specifically referring to a ote to that the recommendation to change the language should not be interpreted as the Board suggesting that a pharmacist does not need to exercise clinical judgment. To the contrary, pharmacists as licensed health care providers must always exercise professional judgment in their practice. This requirement is memorialized in Business and Professions Code section 4306.5.
1738.14(b)	CSHP	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 an extended weekend. Recommendation: (b) The board shall be notified in writing within ~~72 hours~~ three (3) business days of a complaint involving a	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff are concerned that the term "business day" could vary greatly based on the practice site and differing operating hours.

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		radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law.	
1738.14(b)	Cedars-Sinai	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. Recommend the board to revise language to be consistent with the updated CA BOP revised changes in section 1735.12 Quality Assurance and Quality Control subsection (b). Recommendation: (b) ~~The board shall be notified in writing within 72 hours of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law~~. The Board shall be notified in writing within 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) involving a CNSP.	Board staff have reviewed the comment and recommend the following change. (b) The Board shall be notified in writing within ~~72~~ 96 hours of the facility's receipt of a complaint of a, excluding delivery delays, involving a radiopharmaceutical. Recalls and adverse drug experiences as defined in 21 CFP 310.305(b) ~~events~~ ~~must~~ shall be reported to the Board and other agencies in compliance with relevant provisions of law.
1738.14(c)	CSHP Cedars-Sinai	The way the regulation is written, suggests that the review must be completed within 72 hours since it states that "such review shall be documented and dated as defined in the SOPs." The proposed language requirement for a documentation and dating of the review together with the preceding sentence's requirement for review within 72 hours from the receipt of the compliant could be seen as requiring the review to be completed within the 72 hours timeframe. A requirement of 72 hours may not provide sufficient time for pharmacies to thoroughly investigate and determine root causes. It is reasonable to expect that a review after a complaint be started within three business days. Investigation could take longer than this due to many factors involved in such an investigation that needs to be looked at. Many of these may not be available or apparent within this timeframe. Recommendation (BOLD): (c) In addition to subsection (b), all complaints made to the facility related to a potential	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff are concerned that the term "business day" could vary greatly based on the practice site and differing operating hours.

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		quality problem with a CSP and all adverse drug experiences, as defined in 21 CFR 310.305(b) shall be reviewed by the pharmacist-in-charge **and shall start within three (3) business days** ~~**within 72 hours**~~ of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.	