

#	Section	Commenter	Comment	Staff Response
1	1738.1	B. Go	<p>The response by the Board that both proposed as well as existing regulations on compounding, as currently worded, do not infringe on the practice of compounding by non-pharmacist licensees under the jurisdiction of other California professional boards, is not satisfactory for the following reasons:</p> <p>1. You responded with comments from only one board, the Medical Board of California, which only regulates MD's. This does not apply to other licensees such as DO's, nurses, ND's, dentists, and veterinarians, who may also have the right to compound medications in-office without a pharmacist and without interference by the Board of Pharmacy. Furthermore, even the MD's right to compound is still in jeopardy based on current wording of the Board's regulations, for the following reasons:</p> <p>a. The Medical Board's letter noted that only the Medical Board has the right to discipline its licensees. This would only apply if the licensee was being disciplined as an MD, not if they were being disciplined as a person practicing pharmacy without a license. Again as previously stated, the Board of Pharmacy's jurisdiction is to regulate the practice of pharmacy, and therefore practicing pharmacy without a license would fall within their purview. Both currently existing regulations as well as the proposed changes exclude non-pharmacists from being able to compound, specifically defining the practice of compounding as that which occurs by a pharmacist ONLY. (See proposed regulation 1736.1a (a): "For the purposes of this article, sterile compounding occurs, by or under the direct supervision and control of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article."</p>	<p>Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text.</p> <p>The Board has previously considered this comment and provided responses throughout the rulemaking, including the Board's response in row 2 of the response to comments posted <a href="#">here</a>. The Board respectfully refers the commenter to Business and Professions Code section 4170 as well as the Board's jurisdiction.</p> <p>The Board also recommends that the commenter review the Board's Initial Statement of Reason that describes the Board's jurisdiction to gain a better understanding of the applicability of the Board's regulations.</p> <p>The commenter also appears to be providing comments about a statutory proposal related to the regulation of IV hydration clinics which is outside the scope of this regulation.</p> <p>Staff refer the commenter to the Board's proposed statutory language for an understanding of the Board's legislative proposal. Further, the Board is not aware of any IV hydration clinics that would prepare radiopharmaceuticals.</p>

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			<p>And see currently existing regulation: CCR 1735(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist")</p> <p>b): The Medical Board's letter notes: "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." - they admit that your regulations may affect MD's practice of compounding.</p> <p>I'm not sure why you have so much resistance to adding wording which would only help to clarify the limitations of your role, and would limit the confusion and ambiguity which the current wording is creating. Instead, you have specifically chosen to include wording which is overly broad, and which implies that compounding only may be performed by a pharmacist.</p> <p>2. You claim that regulations specifically state you cannot regulate other practitioners</p> <p>3. Furthermore, you have not directly responded to previous comments that noted the contradiction between your stance on the above and the fact that you are currently making preparations to attempt to regulate what you refer to as 'IV hydration clinics'. These clinics do not have pharmacists, however they do have other non-pharmacist licensees who have the right to compound. The term 'IV hydration clinic' itself is not well-defined by the board, and it is foreseeable that the board could choose to include any medical office that provides IV</p>	

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			<p>hydration or IV nutrients in this category, offices in which compounding might be conducted by any of a variety of types of licensed non-pharmacist practitioners who should not be under the purview of the Board if it were not for the current language in your regulations. Therefore, the claim that your compounding regulations do not or will not interfere with compounding by non-pharmacist licensees is disingenuous. Please do note and respond to this paragraph in full in your reply as well.' Given all of the above, I recommend you add the following or similar wording somewhere within Title 16 CCR: "The regulations in Title 16 CCR Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq do not in any way apply to the practice of compounding by non-pharmacist licensees who have the right to compound based on their own practice act."</p>	