california **pharmacists** association

January 20, 2021

Maria Serpa, PharmD
Chair, Enforcement and Compounding Committee
Board of Pharmacy
2720 Gateway Oaks Blvd, Ste. 100
Sacramento, CA 95833

Dear Chair Serpa,

The California Pharmacists Association (CPhA) appreciates the committee's willingness to address the compounding of methylcobalamin on the agenda of the Enforcement and Compounding Committee as well as the opportunity to comment on the topic.

First, CPhA would like to make it clear that we agree with the FDA's interpretation of "an applicable USP or NF monograph" to mean a drug monograph, not a dietary supplement monograph as it relates to the conditions under which a 503A compounding pharmacy may compound using bulk drug substances. As CPhA has stated in prior meetings, while there may not be a specific USP drug monograph for methylcobalamin, this is only one of the options that the Food, Drug and Cosmetic Act require for the ability to compound from bulk substance. The applicable requirement that 503A compounding pharmacies use to compound methylcobalmin is the fact that it "*appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A* (Category 1 list). Further, the other two requirements for bulk substances to be compounded are that it must "*be accompanied by a valid certificate of analysis and must have been manufactured by an establishment registered with FDA under section 510 of the FD&C Act*." Methylcobalamin meets all of these requirements set forth by the FDA as CPhA is aware of FDA-registered facilities that contain valid COAs for the substance.

CPhA understands the direction that the Board is trending towards in terms of exploring the possibility of lifting the current ban on 503B outsourcing facilities for providing patient-specific compounded prescriptions. Certainly the appeal of these facilities, who have to conform to current good manufacturing practices (cGMP), feeds the perception of "safer products" being provided to patients. However, we would caution the Board to not assume that because a compounded product has undergone cGMP standards, as opposed to USP standards, it is a "safer" medication. Both standards are internationally accepted standards for compounded medications and both standards provide for safe compounded sterile products, as evidenced by the thousands of compounded sterile products that are made every day without incident.

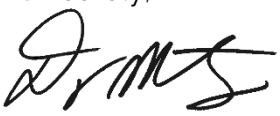
Additionally, if 503B outsourcing facilities are permitted to compound methylcobalamin while 503A compounding pharmacies are not, the Board will be creating access barriers to this medication. By the nature of their business practices, the overwhelming majority of 503B outsourcing facilities across the United States make only certain strengths of methylcobalamin. For example, one 503B located in Texas would make two dosage strengths in bulk which would cover about 70% of patients who need it. The other 30% is not able to obtain the strengths that their physician is prescribing because each patient is different. CPhA is aware of physicians who are frustrated with the lack of varied dosage

strengths made by 503B facilities, which is why they often prefer to work with 503A compounding pharmacies. The nature of 503A is to tailor-make dosage strengths according to each patient's needs. This is especially true in children who have Autism Spectrum Disorder. In addition, if a patient were to obtain their medication from a 503B, it would have to be mailed to the patient's residence. Currently, when a patient gets their methylcobalamin from a compounding pharmacy, the patient has the ability to be with the pharmacist in order to monitor for any adverse reactions. That's not possible for a 503B facility and patients would instead be diverted to a physician's office. We believe this impact will be felt most significantly by patients in underserved urban and rural areas in Califonia who do not have easy access to physicians for an in-office administration. Lastly, CPhA believes that cost of the medication would be a significant concern for the patient. Because cGMP standards require methods that are FAR more expensive than USP standards (which isn't inexpensive either), the cost for obtaining this medication will naturally have to go higher. All of these conditions would result in patient access issues.

CPhA believes that current regulations regarding the proper testing and sterilization of sterile compunds provide the Board the tools it needs to properly regulate this important medication. This is achieved through the Board's explicit allowance of 503A compounding pharmacies to compound methylcobalamin that meets the requirements set forth by the FDA regulations in 503A. We would ask that if the Board feels this is currently not the case in existing law, that it should work with CPhA to propose a statute to this effect.

Should you have any questions about these comments, please feel free to contact me at (916) 779-4519 or at dmartinez@cpha.com. Thank you for your consideration of our comments.

Sincerely,



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