100 Daingerfield Road, Suite 401
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Alliance for Pharmacy Compounding

January 19, 2021

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

Dear Chair Serpa,

Thank you for the opportunity to comment on your committee's deliberations regarding the compounding of methylcobalamin.

The Alliance for Pharmacy Compounding (formerly the International Academy of Compounding Pharmacists) is the voice for pharmacy compounding, representing thousands of pharmacists, technicians, students, researchers and suppliers. Compounding exists for patients and animals who are not served by traditional pharmaceutical manufacturers. We create custom medications that patients simply cannot get anywhere else. Every day, our members play a critical, often life-or-death role in patients' lives. They are a valued part of the healthcare team, creating essential treatments unavailable elsewhere for a range of issues, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, and many others.

As the California Pharmacists Association has noted in its helpful letter to the committee, the FDA's interpretation of "an applicable USP or NF monograph" refers to a drug monograph as it relates to conditions under which a 503A compounding pharmacy may compound from bulk drug substances. Though methylcobalamin may not have a specific USP drug monograph, a monograph is but one option that the Food, Drug and Cosmetic Act requires for compounding from bulk. Indeed, methylcobalamin not only "appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A (Category 1 list)," but also is "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."

As the Board explores the possibility of lifting the current ban on 503B outsourcing facilities for providing patient-specific compounded prescriptions, we urge that it not presume that because a compounded product is prepared under cGMP standards, as opposed to USP standards, it is somehow a "safer" medication. Both cGMP and USP are internationally accepted standards for compounded medications and both standards provide for safely compounded sterile products, as evidenced by the thousands of compounded sterile products that are made every day without incident.

We believe that any effort to permit 503B outsourcing facilities to compound methylcobalamin while prohibiting 503A pharmacies from doing so will result in patient access barriers to this medication. Currently, the overwhelming majority of 503B outsourcing facilities in the United States make only certain strengths of methylcobalamin. To prohibit 503A pharmacies from providing tailormade dosage strengths according to each patient's needs creates gaps in patient care and limits access to medications that enhance their lives.

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In short, current California regulations regarding the proper testing and sterilization of sterile compounds – which adhere to FDA's own requirements – are entirely appropriate and sufficient. We urge that any change to those restrictions should be made via statute, not regulation that exceeds what FDA itself recommends.

Thank you again for the opportunity to comment. Please contact me at scott@a4pc.org if APC can be helpful.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer