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ASSEMBLYMEMBER, FIFTH DISTRICT

COMMITTEES

VICE CHAIR, HOUSING AND COMMUNITY DEVELOPMENT VICE CHAIR, UTILITIES AND ENERGY BUDGET PRIVACY AND CONSUMER PROTECTION BUDGET SUBCOMMITTEE NO. 1 ON HEALTH JOINT LEGISLATIVE BUDGET

March 5, 2025

President Seung Oh Board of Pharmacy California State Board of Pharmacy 2720 Gateway Oaks Drive Sacramento, CA 95833

Dear President Oh and Board Members,

I would like to commend the California State Board of Pharmacy for its continued dedication to a safe pharmaceutical supply and its commitment to engaging stakeholders. It is clear that these proposed regulations have been thoroughly debated over several years. However, despite the excellent work, I am writing to express concerns regarding the proposed compounding regulations. I believe the Board should pause and reconsider many of the components of these regulations, especially in light of public safety concerns and the changing federal landscape.

While I understand that the intent of these regulations is to clarify federal rules, regulations, policies, and guidance documents, I believe that they raise several public policy issues and go beyond merely "clarifying" federal law.

Federal Laws Are Likely Changing

Although Board staff has been working on these regulations for many years, the new federal Administration has signaled that healthcare regulations will be evolving. Whether it's the proliferation of peptides, B12 injections, glutathione, or medication flavoring, I am confident that Secretary Kennedy and the U.S. Department of Health and Human Services will be evaluating access to prescribed treatments that are often filled by compounding pharmacies. The regulations proposed by the Board may permanently add new layers of regulations on these treatments, despite the possibility that federal policies will change. At best, the Board cannot be certain of what will happen on the federal level, and thus, the new regulations are premature.

Californians May Lose Access to Treatments Available Elsewhere

Regardless of potential changes in federal law, if the Board adopts these regulations (or any regulations beyond FDA requirements), Californians may lose access to affordable compounded medicines that are available in many other states. With little evidence of harm to consumers, Board staff has proposed regulations that could negatively impact public health by driving up the cost of routine and critical medications and treatments prescribed by healthcare providers.

Worse, these regulations may make such treatments virtually unavailable in California. Imagine similar California-only regulations that would limit access to critical treatments for family planning, chronic diseases, or long-term pain, affecting patients' well-being.

The Proposed Regulations Jeopardize Public Safety

A simple internet search for B12 injections, peptides, or glutathione reveals a wide variety of ways people can obtain these medications. On one hand, individuals can get prescriptions from online providers outside California, and have medications shipped from licensed pharmacies in other states. However, this is usually much more expensive than purchasing locally from pharmacies that pay California taxes.

My primary concern is the potential for dangerous practices if the Board continues down this regulatory path. People will inevitably turn to unregulated platforms that provide substances outside any oversight. This exposes individuals to significant risks. For example, one can legally purchase B12 injections intended for horses from many online retailers. It is clear from user reviews that some individuals are injecting these substances, which undoubtedly fail to meet the standards outlined in the proposed regulations and are not prepared by licensed California pharmacists. By approving these regulations, the Board may inadvertently contribute to the growth of such unsafe practices and further enrich manufacturers of products intended for livestock.

Conclusion

Whether one agrees or not, the federal government has changed, and there are strong indications that further changes are likely. If this occurs, local California pharmacies may be at a significant disadvantage in meeting the needs of their patients.

Without clear evidence of harm to Californians, I urge the Board to reconsider its approach and revisit these regulations once the landscape becomes clearer.

Thank you for your time and consideration. Please do not hesitate to reach out to my office at 916-319-2005 if you would like to discuss this matter further.

Sincerely,

Jee Patterson
Assemblyman
5th District