NUBRATORI RX

October 30, 2023

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, Ca 95833

RE: **Title16. Board of Pharmacy**

Proposal To Add Article 6.5 and Sections 1750 and 1750.1 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 6.5 Outsourcing Facilities

Dear Board Members,

I appreciate and understand the enormity of processing multiple State Assembly bills, new Federal Programs, and new state regulations to help promote consumer safety within the practice of pharmacy. I applaud your efforts.

After review of the Title 16 proposal, specifically as it relates to FDA Registered Outsource Facilities (503b), I have two distinct comments. The first being I am in favor of your wisdom to recognize that 503b Facilities must follow Current Good Manufacturing Practice, cGMP, as pointed out in section 1750(a) as they are referred to manufacturing, however, I am opposed to the state incorporating, interpreting and enforcing Federal Law. The second being that in the interest of consumer safety and protection for residents of the State of California, there should be a very clear line if not a separation, between a 503b which solely manufacturers, and a 503b that manufactures and dispenses patient specific medications.

There is a reason that the terminology for manufacturing is called CURRENT GMP (cGMP), as the word current allows the FDA to utilize FDA Guidelines which help guide the licensees in the current thinking of the FDA. The Guidelines allow all stakeholders to understand not only the current thinking, but as well, how the FDA interprets the CFR, and US Codes, and if the FDA is planning on enforcement action at this time with regard to such rules.

With consideration to the current proposal, I believe it is not in the best interest of consumer safety for the California Board of Pharmacy to incorporate into State Law the following Federal Regulations.

1. Code of Federal Regulations, Title 16, Chapter II, Subchapter E, Part 1700 (commencing with section 1700.1) – Poison Prevention Packaging,
2. Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 210 (commencing with section 210.1) – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General,
3. Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 211 (commencing with section 211.1) – Current Good Manufacturing Practice for Finished Pharmaceuticals,
4. Code of Federal Regulations, Title 21, Chapter II, Parts 1301 (commencing with section 1301.01) – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances,

If you look up each of the Code of Federal Regulations listed above, you will find over 75 additional references within those four suggested Regulations that are connected to other US Codes and Regulations that also must be followed, interpreted, and enforced in order for the four Codes of Federal Regulations listed above to be interpreted, in effect and enforced. An infinite domino effect or daisy chain. Not counting the 75 references, the current four Codes and Regulations comprise over 100 pages, and over 45,000 words. Further, there is no mention whatsoever of FDA Guidelines in the Board proposal. As you are undoubtedly aware, the FDA relies heavily on their Guidance in enforcing and interpreting Federal Codes and Regulations. It is the only way to get to "their current thinking". So, my question and concern is; if the new California regulations were adopted, who will ultimately be responsible for interpreting all of the US Codes and Regulations that apply to 503bs? What will be the increased cost to the Board for the education and learning of these hundreds of pages of new language that the inspectors will be responsible for interpreting and enforcing? Finally, what will happen when there is a conflict in the interpretation of Federal Codes and Regulations between the FDA and CBOP? In my humble opinion, when there is the potential for conflict in the interpretation and enforcement of a regulation between two distinct government agencies, it is not in the best interest of the licensee, patient, or the citizens of California.

My suggestion would be to recognize that 503B facilities are manufactures as stated in the proposal, and allow the FDA to exclusively inspect, interpret and enforce federal laws that apply to 503b facilities. If these new regulations were to be adopted, all other FDA manufactures, including, OTC, supplement, prescription drugs and medical devices would be exclusively inspected and protected by the FDA, except for 503Bs which would be subject to double inspections and audits by both the FDA and California State Board of Pharmacy, potentially creating conflicts - some of which could be contradictory. Allowing the FDA to have exclusive jurisdiction to interpret and enforce Federal Codes and Regulations in regard to 503bs would save money for the budget, allow CBOP inspectors to focus on enforcing California Codes and Regulations, and also increase consumer safety and protection by allowing our inspectors to focus on the other 6000+ 503a and other retail pharmacies in our state.

The second part of the proposal by the board of pharmacy is the distinction that a 503b could dispense patient specific prescriptions. I believe that every state including California has the right to regulate medications that are being dispensed to residents in their state. However, I do not believe the regulations need to be rewritten, as stated in the proposal by incorporating another 6 US Federal Codes. I would suggest that the California State Board of Pharmacy simply state that any pharmacies, including 503b facilities that dispense patient specific prescriptions must follow all California regulations for dispensing. No reason to write anything new. No reason to have two alternating and perhaps diverse interpretations of Federal Code, and the inspectors already know how to inspect and audit licensed facilities that dispense patient specific prescriptions.

In closing my recommendation to the California State Board of Pharmacy would be to allow a hybrid license, if the 503B chooses to only manufacture, then the CBOP will default to the FDA for annual inspections, audits, US Codes/CFR interpretations, Guidelines, and enforcement. However, if the 503b chooses to dispense patient specific prescriptions, then the licensee would be subject to inspections, audits, and interpretations of California regulations as they relate to dispensed medications. I believe this solution will help to decrease the annual spend on the State Budget and is in the best interest of consumer safety and protection.

Respectfully submitted,

Robert P. Nickell, Pharmacist
CEO Nubratori RX

Statistics: If the board was to adopt all of the US Federal Codes listed then there would be over 250 pages, over 100,000 words and over 200 additional US Codes and Chapter references to enforce.