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From: STAQ Pharma

To: California State Board of Pharmacy

Subject: Comments on Agenda Items for June 24, 2026, and June 25, 2026, Board Meeting

To Whom It May Concern,

STAQ Pharma is a hospital owned 503B company with two locations in Columbus, Ohio and Denver, Colorado respectively. Both facilities are registered with the FDA, licensed with California, and undergo regular inspections.

We are providing public comments on items listed on the agenda for the June 24, 2026, and June 25, 2026, Board Meeting.

We are in favor of Rescinding Prior Board Motion to Initiate a Rulemaking to add Sections 1750 and 1750.1 to Title 16 of the California Code of Regulations Related to Outsourcing Facilities.

- Outsourcing facilities do not need a self-assessment form; we are aware that we must follow cGMPs, and we are held to strict standards by both the FDA and the CA BOP with at least annual inspections conducted prior to licensure and renewal.
 - 503B Outsourcing Facilities have robust quality management systems which often consist of, at minimum, semi-annual evaluation of the status of the operations and quality system.
 - cGMP is the highest standard for drug production in the world. We believe independent regulatory inspections, and hiring independent quality consultants to augment internal audits when necessary, is the proven path to improvement in cGMP operations. There are many ways to meet cGMP requirements, and the self-assessment form is not able to capture those actions nor what is discussed during inspections between regulators and firms. In other words, if a company does not have a good grasp and understanding of cGMP, what information and use would a self-assessment form provide?
- Outsourcing Facilities are already aware that if we wanted to dispense patient specific medications, we would be required to follow all the rules and regulations as a State Licensed Pharmacy. There is no need to create a CCR for this is as it is already explicitly

clear, and well understood, what the requirements of dispensing patient specific prescriptions are in the State of California.

In relation to the proposed text of **Title 16 Board of Pharmacy Proposed Regulation Text** Amend Section 1708.2 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows: § 1708.2. Discontinuance of Business/Notice of Closure. (d) (1)-(4).

- We suggest that this regulation be changed to include the concept that the notice occur within 30 days in advance of discontinuation, when possible...

Sincerely,

Joe Bagan – CEO and Emily Reyes, PharmD. – Vice President of Quality and Regulatory Affairs