December 8, 2017

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd, Suite N 219
Sacramento, CA 95834
Sent via Email to: Virginia.Herold@dca.ca.gov

Re: International Academy of Compounding Pharmacists Supports the California Pharmacists Association's Modifications to Sections 1735 and 1751

Dear Ms. Herold:

The International Academy of Compounding Pharmacists (IACP) represents more than 4,000 pharmacists, technicians, students, and members of the compounding community who focus on the specialty practice of pharmacy compounding. Compounding pharmacists work directly with prescribers including physicians, nurse practitioners and veterinarians to create customized medication solutions for patients and animals whose health care needs cannot be met by manufactured medications. IACP works diligently to preserve patient access to these vital compounded medications.

IACP would like to thank the California Board of Pharmacy, Enforcement & Compounding Committee (the "Committee") for this opportunity to present thoughts on current regulations applicable to compounding pharmacies. IACP supports the Committee's mission to ensure that patients throughout the State of California receive safe, effective and quality compounded medications. IACP understands and supports the need to protect public health. However, when developing and implementing regulations, it is essential to preserve patient access to vital compounded medications, the physician-patient-pharmacist triad, and the right of a patient to choose their pharmacist. Prescribers must have the right to prescribe medications that best fit the needs of their patients.

IACP has reviewed the current California regulations and has heard from pharmacists as well patients that specific provisions of the regulations are causing significant constraints in patients being able to access care resulting in decreasing patient access to vital compounded medications. Additionally,

IACP had the opportunity to review the recommendations being submitted by the California Pharmacists Association (CPhA) and would like to take this opportunity to express full support for the CPhA's proposed modifications to Sections 1735 and 1751 of the California Code of Regulations. The proposed changes are necessary to ensure that Sections 1735 and 1751 conform to other standards currently governing compounding pharmacies. The CPhA's recommendations will safe-guard patient safety and place the regulations in line with best practices while also preserving patient access to compounded medications.

In particular, CPhA's amendments to Section 1735.2(i), related to beyond use dates, are necessary to ensure consistency and clarity among all requirements governing compounding pharmacies. We commend the Board for taking action to amend Section 1735.2(i)(1) related to the Beyond Use Date requirements for non-sterile compounds in order to align California regulation with the nationally recognized standards of USP Chapter <795>. Unfortunately, these amendments did not extend to the sterile compounding Beyond Use Date requirements of Section 1735.2(i). As it stands, the testing requirements to extend Beyond Use Dates of sterile compounds set forth in Section 1735.2(i) appear to exceed USP <795> and <797> standards. In fact, they appear to mimic current Good Manufacturing Practices ("cGMP") requirements, which are applicable to drug manufacturers and not compounding pharmacies.

Unlike drug manufacturers, compounding pharmacies prepare unique medications for particularized medical needs when a prescriber determines a commercially available drug is not suitable for treatment. The Food Drug & Cosmetic Act ("FDCA") requirements for manufactured drugs, including cGMPs, were not designed for these specialized medications. cGMP testing practices are extremely expensive and are therefore not economically practical when small amounts of customized drug product are being produced. This is one of the very reasons why commercial drug manufacturers only produce very large quantities of medication in standardized strengths and dosage forms. Compounding pharmacies cannot, therefore, with any economic feasibility, comply with cGMP testing requirements. If compounding pharmacies were required to comply with cGMP, the increased cost to do so would either be passed on to patients or result in pharmacies discontinuing compounding activities. In either case, patients would suffer due to drastically increased prices and restricted access to necessary medications.

IACP appreciates the opportunity to fully support CPhA's recommendations and request full adoption. IACP wishes to work with the Committee toward the mutual goal of protecting and promoting the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals while preserving patient access to vital compounded medications.

Sincerely,

Cynthia Blankenship
Executive Vice President
International Academy of Compounding Pharmacists