

**TESTIMONY OF
CONNECTICUT HOSPITAL ASSOCIATION
SUBMITTED TO THE
GENERAL LAW COMMITTEE
Tuesday, February 21, 2017**

**SB 829, An Act Following The Commission Of Pharmacy To Place Conditions On
Pharmacy Licenses, Permits And Registrations**

The Connecticut Hospital Association (CHA) appreciates this opportunity to submit testimony concerning **SB 829, An Act Following The Commission Of Pharmacy To Place Conditions On Pharmacy Licenses, Permits And Registrations**.

Before commenting on the bill, it's important to point out that Connecticut hospitals provide high quality care for everyone, regardless of ability to pay. Connecticut hospitals are finding innovative solutions to integrate and coordinate care to better serve patients and communities, as well as achieve health equity. These dynamic, complex organizations are working to build a healthier Connecticut. That means building a healthy economy, community, and healthcare system. By investing in the future of Connecticut's healthcare and hospitals, rather than continuing to cut away at them, we will strengthen our economy, put communities to work, and deliver affordable care that Connecticut families deserve.

SB 829 would revise Subsection (a) of Section 20-579 of the Connecticut General Statutes to include two additional provisions to the list of reasons the Commission of Pharmacy may place conditions on pharmacy and pharmacist licenses, permits, or registrations. CHA opposes this bill as written.

It is important to understand that the United States Pharmacopeial Convention (USP) is a non-governmental, privately run business. While it often works to assist the FDA, the USP is not a branch of government. It does not follow governmental regulatory rule-making processes, and it does not dictate the rules, laws, or practices required of pharmacies and pharmacists, such as compounding.

SB 829 seeks to mandate compliance with USP Chapters 795 and 797 by adopting USP guidance as if it were a government agency's rulemaking body. We do not believe we should.

These USP chapters are best practices and technical guidance. They frequently require significant interpretation, and have varied applicability. Access to USP Standards is not open access, as a law or regulation must be. To read and use the USP Standards, first you must purchase manuals or subscriptions from USP.

USP Chapters 795 and 797 contain provisions for best practices for the compounding of non-sterile and sterile drug preparations. The chapters should be viewed as best practices and technical guidance, but not as the only source of information or guidance. For example, the FDA frequently permits an alternate resource or guide to be followed instead of USP Standards. A pharmacy should be permitted to utilize other, recognized resources.

CHA agrees that the Commission on Pharmacy should have oversight of compounding practices. As such, pharmacies and practitioners engaged in compounding activities should be required to have an understanding of identified best practices, and demonstrate competencies. But it is incorrect to wholesale elevate the guidance in USP Chapters 795 and 797 to be used as regulations and adopt them as if they were written in the precise and clear format required of regulatory law and the principles of due process.

The information conveyed in both USP Chapters 795 and 797 is constructed to allow room for interpretation, and is not created or expressed in a manner that an entity can easily know what compliance means. Because of this, CHA strongly objects to the language in SB 829 that indicates the Commission should penalize a pharmacy or pharmacist for having “failed to comply with” either USP Chapter.

CHA urges the bill to be revised, instead, as follows:

(19) has failed to demonstrate appropriate adherence to applicable portions of United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding–Sterile Preparations, as amended from time to time; or (20) has failed to demonstrate appropriate adherence to applicable portions of United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding–Nonsterile Preparations, as amended from time to time.

Thank you for your consideration of our position. For additional information, contact CHA Government Relations at (203) 294-7310.