



**TESTIMONY OF  
CONNECTICUT HOSPITAL ASSOCIATION  
SUBMITTED TO THE  
GENERAL LAW COMMITTEE  
March 12, 2019**

**SB 1006, An Act Concerning Revisions To The Pharmacy  
And Drug Control Statutes**

The Connecticut Hospital Association (CHA) appreciates this opportunity to submit testimony concerning **SB 1006, An Act Concerning Revisions To The Pharmacy And Drug Control Statutes**. CHA opposes Section 1 of the bill based on two major concerns. CHA takes no position on Section 2 as it does not apply to Connecticut's hospitals. CHA supports Section 3 and Section 4.

Before commenting on the bill, it's important to point out that Connecticut hospitals and health systems provide high quality care for everyone, regardless of their ability to pay. By investing in the future of Connecticut's hospitals, we will strengthen our healthcare system and our economy, put communities to work, and deliver affordable care that Connecticut families deserve.

Section 1 of SB 1006 seeks to make changes to how pharmacies that do sterile compounding are regulated in Connecticut. CHA appreciates the importance of ensuring that pharmacies that compound sterile drugs and medications for patients operate within appropriate care and safety standards. However, this bill will not achieve better safety, and will create unnecessary regulation and cost for hospitals' compounding pharmacies.

The bill seeks to expand significantly the requirements to comply with the United States Pharmacopeia ("USP") as set by the USP Convention, a private organization that publishes, for substantial fees, standards that it develops. Current Connecticut law requires adherence to "the most recent version of the United States Pharmacopeia, Pharmaceutical Compounding - Sterile Preparations" when compounding sterile drugs. The bill seeks to add "and related chapters" to the requirement to comply with the USP. Unfortunately, the language "and related chapters" is too vague to allow those who would need to comply to do so.

The USP is a massive guidance document, currently comprising five printed volumes organized into multiple chapters, tables, charts, lists and other resources, including the National Formulary (NF) Monographs. A different (smaller) product sold by USP includes the USP Compounding Compendium, which the USP website describes this way:

The USP Compounding Compendium contains the 5 essential compounding chapters, over 40 supporting general chapters, and more than 170 compounded preparation monographs. You can purchase the USP Compounding Compendium online at the USP store or by contacting USP Customer Service. You may also purchase copies of individual chapters by contacting USP Customer Service.<sup>1</sup>

If the bill intends to require pharmacies that compound sterile preparations to abide by an unnamed and unknown number of the “over 40” supporting chapters and “more than 170 monographs,” that’s unacceptable, and it fails to meet basic standards for informing pharmacists subject to the law about what is reasonably expected.

It is important to understand that the USP Convention is not a governmental body, and its standards are not created or devised by the Centers for Disease Control and Prevention, the Food and Drug Administration, the U.S. Department of Health and Human Services, or any other federal agency. USP is a private, international, scientific organization that seeks to reach consensus on various drug nomenclature, safety, and preparation standards. The USP is not updated in the way a law or regulation is updated, whereby adequate notice and clear standards are made freely available for public access and review. In addition, the USP is subject to revision at least three times a year, and sometimes more frequently.<sup>2</sup>

As with any statute or regulation, due process dictates that fair notice must be given to individuals who are expected to comply with the law’s requirements. To the extent that Connecticut wants to adopt specific chapters and supporting materials of the USP, the law should clearly and carefully delineate exactly what is being adopted. We urge you to reject this change set forth in Section 1 of HB 1006.

CHA’s second major concern with the bill is the new requirement at lines 170-193 to appoint a “designated pharmacist” with individual responsibility for USP compliance at each location that compounds sterile pharmaceuticals. In addition, no pharmacist could be the “designated pharmacist” for more than one location at the same time. That requirement does not increase safety or quality, and will create significant cost for hospitals. We urge you to reject this unnecessary and costly control.

Hospitals in Connecticut *must* engage in certain amounts of sterile compounding to deliver proper patient care, and hospitals strive to do that in an affordable manner. Although the 2012 tragedy with a for-profit Massachusetts compounding pharmacy was horrific, there have not been widespread health or safety concerns emanating from Connecticut hospitals’ compounding pharmacies that would justify increasing regulatory burdens and costs on hospitals. We urge you to reject Section 1 of HB 1006.

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<sup>1</sup> See FAQ #2, <http://www.usp.org/frequently-asked-questions/compounding> (accessed 03/07/2019).

<sup>2</sup> A new edition of USP is published every year, usually with an official date of May 1st. Each year, two supplements to the new edition are published, usually with an effective date of August 1 (1st supplement) and December 1 (2nd supplement). In addition, the USP chapters are subject to accelerated revisions that could occur at any time. See FAQ #2, <http://www.usp.org/frequently-asked-questions/identifying-official-text> (accessed 03/06/2019).

CHA would be happy to work with the Legislature and Drug Control on meaningful solutions to ensure safety and quality are maintained for hospitals' compounding pharmacies.

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