

MEDCHI, THE MARYLAND STATE MEDICAL SOCIETY  
HOUSE OF DELEGATES

Resolution 26-19

INTRODUCED BY: Montgomery County Medical Society

SUBJECT: Physician In-Practice Preparation of Medicine

---

Whereas, the Drug Quality and Security Act of 2013 increased Food and Drug Administration oversight of compounding pharmacies and has led to burdensome regulatory restrictions on simple preparation of manufactured FDA-approved medications for the office-based procedures in which aseptic technique is routine and appropriate, such as buffered lidocaine; and

Whereas, Patients risk losing access to safe and effective office-based procedures; and

Whereas, US Pharmacopeia (USP) has revised its standards on compounded sterile preparations, Chapter 797, which provides equipment and process requirements that state policymakers (e.g. state pharmacy boards, state medical boards) may adopt; and

Whereas, Chapter 797 includes a time-based exemption in Section 1.3 if administration begins within 4 hours following the start of preparation, among other provisions of this section.

Whereas, the Maryland Board of Pharmacy requires licensed pharmacies to comply with USP Chapter 797;

Whereas state policymakers have adopted a variety of restrictions on compounding but little is known how individual states are interpreting USP Chapter 797 to affect physicians; and

Whereas, more individualized education is needed to help further physician advocacy on this issue; therefore be it

Resolved, That MedChi oppose any state medical board action or legislative action to delegate authority or oversight of physicians preparing medications in physicians' offices to another regulatory body (e.g., state pharmacy board); and be it further

Resolved, That MedChi proactively work to preserve a physician's ability to prepare medications in physicians' offices and be able to do so without being subject to unreasonable and burdensome equipment and process requirements; and be it further

Resolved, That MedChi oppose efforts requiring physicians to comply with Section 1.3 Immediate Use [Compounded Sterile Preparations] of USP Chapter 797 – Sterile Compounding and seek at least a 7 day exemption; and be it further

Resolved, That it is MedChi policy that the act of preparing medications in physicians' offices for their patients is not considered compounding.

---

As amended and adopted by the House of Delegates at its meeting on November 2, 2019.