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TO: The Honorable Joan Carter Conway, Chair  
Members, Senate Education, Health and Environmental Affairs Committee

FROM: Danna L. Kauffman  
Joseph A. Schwartz, III  
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J. Steven Wise

DATE: February 11, 2015

RE: **SUPPORT** – Senate Bill 69 – *State Board of Pharmacy – Sterile Compounding – Compliance by Nonresident Pharmacies and Repeal of Permit Requirements*

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On behalf of the Maryland State Medical Society (MedChi), which represents more than 8,000 Maryland physicians and their patients, along with the American Congress of Obstetricians and Gynecologists, Maryland Section (MDACOG), the Maryland Chapter of the American College of Emergency Physicians (MDACEP), the Maryland Society of Eye Physicians and Surgeons (MSEPS) and the Maryland Chapter of the American Academy of Pediatrics (MDAAP), we strongly support Senate Bill 69.

As discussed below, in light of the recent passage of federal law related to sterile compounding, Senate Bill 69 repeals Maryland's sterile compounding facility permit law. The bill also requires nonresident pharmacies that dispense sterile drug products to patients in Maryland, to submit to the Maryland Board of Pharmacy an inspection report demonstrating compliance with USP797, which is a set of sterile compounding standards issued by the United States Pharmacopeia.

Following the 2012 fungal meningitis outbreak traced back to a Massachusetts-based drug compounder, the State enacted Chapter 397 (House Bill 986) during the 2013 Session. The law was intended to address the regulation of bulk compounders, those entities that produce large batches of compounded drugs that are sold to hospitals and physician offices. These entities typically did not meet the definition of manufacturer under federal law nor could they easily be regulated as a pharmacy under state laws. Therefore, Chapter 397 was enacted to address this regulatory gap and require sterile compounding facilities to obtain a sterile compounding facility permit from the Maryland Board of Pharmacy, comply with USP797 and meet certain training and report requirements. While the law was set to take effect in April 2014, the Board of Pharmacy

delayed the effective date until January 1, 2015 and then until July 1, 2015.

Subsequent to the passage of Maryland's law, Congress passed H.R. 3204 *Drug Quality and Security Act* to address the regulation of bulk compounders. This federal legislation creates a new category known as "outsourcing facilities" and requires these facilities to adhere to CGMP manufacturing standards, which is akin to the protections found in Maryland's law. The federal law also addresses traditional compounders and sets strict standards for all entities that engage in sterile compounding.

However, there is one important distinction between the federal law and Maryland's law. Federal law excludes from the definition of compounding "mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling." Maryland's law includes these acts in the definition of compounding, which would therefore require almost all physician offices to obtain a sterile compounding facility permit and comply with USP797 standards, an almost impossible task. Mixing and reconstituting medication is performed in virtually all physician offices in the normal course of treating patients, including the administration of vaccines, pain medication, cancer treatments, etc. Requiring physician offices to obtain a sterile compounding permit and comply with USP797 presents an unnecessary and unreasonable burden and will limit the availability of necessary medication and treatment to patients.

Therefore, the physician community supports the federal law and believes it is the appropriate vehicle for ensuring patient safety by appropriately regulating bulk compounders under a national standard without unduly burdening physician offices. We request a favorable vote.

**For more information call:**

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