

MARYLAND STERILE COMPOUNDING PERMIT LAW

Support House Bill 181 and Senate Bill 96

BACKGROUND: In 2013, as a result of the fungal meningitis outbreak traced back to a Massachusetts' compounding center, which occurred in the fall of 2012, Maryland enacted the sterile compounding facility permit law. The intent of the law was to provide enhanced oversight for bulk compounders. These "bulk compounders" fell through the regulatory crack because they did not meet the definition of manufacturer but it was difficult for state pharmacy boards to regulate them as traditional pharmacies. During testimony, it was stated that Maryland's law was needed until the FDA created a permanent solution for regulating these entities under a national standard. After Maryland passed its law during the 2013 Session, federal law was enacted to regulate bulk compounders as well as strengthen states oversight of traditional compounders.

WHAT DOES THE LAW REQUIRE? Maryland law requires sterile compounding facilities (includes pharmacies, health care practitioner's offices and any other place where sterile compounding is performed) to obtain a permit from the Maryland Pharmacy Board, comply with USP797 standards, be inspected by the Board, maintain certain reporting and quality assurance activities, etc. The law is supposed to take effect July 1, 2015.

EFFECT ON PHYSICIANS AND PATIENTS: The main issue surrounding Maryland's law is the use of the term "compounding," which includes the acts of reconstitution and mixing medication in accordance with manufacturer guidelines. As a result, virtually every physician office and specialty area would be affected and be required to obtain a permit from the Maryland pharmacy board and comply with USP797 standards. Federal law specifically exempts mixing and reconstitution from the definition of compounding.

HB181/SB69: Following a workgroup convened by Senator Joan Carter Conway and Delegate Peter Hammen, it was agreed by the DHMH and the Board of Pharmacy and the Board of Physician to repeal Maryland's Sterile Compounding Facility Permit Law in its entirety. HB181 and SB69 accomplish this agreement. Given the passage of the federal law, Maryland's law is no longer necessary and, because of the overexpansion definition of compounding, would create access issues for patients.

WHAT TO DO: Call/write/e-mail your legislators and ask them to support HB181 and SB69 to repeal the Maryland Sterile Compounding Permit Law.