

October 11, 2012

Indiana Board of Pharmacy  
Statement regarding compounding pharmacies

The Indiana Board of Pharmacy takes patient safety very seriously, and the Indiana Code and our administrative rules are aimed at protecting the public. Compounding is an integral part of the practice of pharmacy. Compounding is safe when conducted within the confines of the law and when it does not extend into the realm of manufacturing.

Sterile compounding is addressed at 856 IAC 1-30, and pharmacies engaging in sterile compounding must comply with the USP 797 national standards. In-state pharmacies, including those engaging in sterile compounding, are subject to inspection by the Board of Pharmacy's Compliance Officers. The Board's administrative rules and our inspections of sterile compounding facilities address, among other things: policies and procedures; engineering controls/physical requirements; personnel training; labeling and documentation/records and reports; and quality assurance measures. The Board of Pharmacy works hard to ensure that our licensed facilities are thoroughly inspected.

Non-resident pharmacies registered in Indiana are required by Indiana Code to comply with the laws and rules of the state in which they are domiciled. In order to be registered as an Indiana non-resident pharmacy, an applicant must submit numerous documents and fulfill various duties, including verification of the pharmacy's licensure in its home state. The Indiana Board of Pharmacy relies on other state Boards of Pharmacy to regulate licensees in their jurisdiction.

The Board is following the developments of the meningitis outbreak closely. The New England Compounding Center is licensed in Indiana as a non-resident pharmacy. The Board has referred the matter to the Office of the Indiana Attorney General for investigation.

Patient safety is of utmost importance to the Indiana Board of Pharmacy. The Board of Pharmacy Compliance Officers thoroughly inspect our licensees with the aim of ensuring patient safety.

