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### **Fact Sheet on Sterile Compounding in Arkansas**

- The Arkansas Pharmacists Association is saddened by the recent deaths from meningitis traced back to steroid injections from New England Compounding Center of Framingham, MA.
- The Arkansas State Board of Pharmacy actively regulates compounding pharmacies in Arkansas, sets high standards and actively inspects pharmacies on an annual basis. There are very few states that have the same degree of oversight. There are many pharmacists in Arkansas who safely compound life-saving medications for their patients every day.
- The Arkansas Pharmacists Association has 94 pharmacists in its Compounding Academy, a network for pharmacists who work in compounding. Dr. Kristen Riddle of U.S. Compounding in Conway is the current president of the Compounding Academy.

### **What is Pharmaceutical Compounding**

- Compounding can be as simple as reconstituting a dry powder or mixing two creams together, all the way to creating highly sophisticated sterile products.
- Compounding is an important and long-standing practice that meets important patient needs in hospitals, nursing homes and many community settings. Many patients have unique medical needs that pharmacists and physicians cannot meet using commercially available medication dosage forms.
- Some patients need strengths, liquid dosage forms or combinations of ingredients that are not available from manufacturers. In addition, compounders have compounded many life-saving drugs in the wake of the drug shortages that have impacted hospitals and other health care facilities. The American Society of Health- System Pharmacists maintains a [web page that lists new drug shortages](#) regularly.
- Compounders take finished drugs or bulk powders and scientifically manipulate them into unique, unavailable dosage forms. Compounds are made by pharmacists in local pharmacies, not drug manufacturers.
- Compounders depend on U.S- based chemical companies like Professional Compounding Centers of America (PCCA) to source top quality chemicals.

### **Who Regulates Compounding**

- Compounders are regulated by State Boards of Pharmacy like the [Arkansas State Board of Pharmacy](#).
- The Food and Drug Administration (FDA) provides oversight through regulation of the integrity of the drugs and of the Active Pharmaceutical Ingredients (APIs) ordered, stored, and used in

compounds. Pharmacists who compound are expected to follow appropriate procedures for the types of products compounded.

- The Drug Enforcement Agency (DEA) regulates handling of controlled substances used in the preparation of compounded medications.
- An independent organization called United States Pharmacopeia (USP) sets standards for sterile compounding. USP Chapter 797 is issued by U.S. Pharmacopoeia and applies to any pharmacy that prepares “compounded sterile preparations” (CSPs). These standards have been incorporated into Arkansas law and are required practice in Arkansas.
- Pharmacies can voluntarily become accredited by the Pharmacy Compounding Accreditation Board (PCAB). PCAB Accreditation denotes a more stringent, comprehensive standard of quality in compounding. PCAB provides compounding practices an opportunity to compare their practices against national standards and achieve accreditation that provides consumers an indicator of quality practices.

### **How Does Arkansas Regulate Compounding Pharmacies**

- Arkansas State Board of Pharmacy adopted USP Chapter 797 in 2003 and requires both sterility and potency testing. USP Chapter 797 is a far-reaching standard that governs a wide range of pharmacy policies and procedures. It is designed both to increase quality to patients through pharmaceutical products and to better protect staff working in pharmacies in the course of their exposure to pharmaceuticals.
- The Arkansas State Board of Pharmacy inspects every pharmacy facility in the state annually. There are only a handful of other states that do that. For example, some state Boards may only employ a single pharmacist; the Arkansas State Board has three pharmacists doing routine inspections.
- The Arkansas State Board of Pharmacy has shared its guidelines for inspecting sterile compounding pharmacies with other states.
- At the University of Arkansas for Medical Sciences College of Pharmacy, first-year pharmacy students get a more thorough education on compounding than at most other state colleges of pharmacy.

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*The Arkansas Pharmacists Association, founded in 1882, is the statewide professional association representing approximately 2,200 pharmacists in Arkansas. APA strives to further the professional advancement of pharmacists, advocate the value of pharmacy, and safeguard the health and well-being of every Arkansan. Its mission is to advance a professional and business environment for Arkansas pharmacists to be successful and fulfilled in serving patients.*