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Board of Registration in Pharmacy

Policy 2024-02: Implantable Infusion Pumps

In order to safeguard patients, licensees must assure that compounded sterile preparations ("CSPs") intended for use in an implantable infusion pump maintain their stability and compatibility (with each other as well as the pump) at the applicable temperature for the full duration of the infusion. Compounded sterile drugs or drug combinations may not be used with an implantable infusion pump and infused over an extended period of time unless:

1. The drug(s) are FDA-approved for such use; or
2. documentation is obtained from relevant and reliable sources; or
3. direct testing supports such use.

In exercising due diligence prior to compounding these CSPs for extended infusion periods (i.e., time exceeding the CSP's beyond use date), a pharmacist must consider at least the following elements:

- duration of infusion
- temperature range at which the CSP will be held (e.g., account for normal body temperature, fever, etc.)
- stability/potency through entire infusion time
- physical and chemical compatibilities between all drugs in the CSP
- CSP compatibility with a specific pump

Board-licensed sterile compounding pharmacies are required to adhere to all current chapters of United States Pharmacopeia ("USP"). While administration is not in the scope of USP <797>, M.G.L. c. 112, § 39G and M.G.L. c. 112, § 39I require the Board to develop additional procedures to maintain the quality of CSPs after they leave the pharmacy.

In accordance with the FDA alert and using the pharmacist's corresponding responsibility, evaluate each CSP prescription for adherence with evidence-based practice and ensure that the compounding and dispensing are done in accordance with acceptable standards of practice.

Please direct any questions to: **Pharmacy.Admin@mass.gov**