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Board of Registration in Pharmacy

Policy 2020-02: Compounding Copies of Commercially Available Drugs

State and federal law prohibit the compounding of sterile and non-sterile medications that are essentially copies of commercially available products. 21 USC § 353a(b)(1)(D); M.G.L. c. 112 § 39D.

Compounding, including veterinary compounding, in Massachusetts must:

- Be pursuant to a patient specific prescription or in anticipation of a patient specific prescription based on routine, regularly observed prescribing patterns.
- Meet the unique medical need of an individual patient by producing a significant difference between the compounded drug preparation and a comparable commercially available drug.
- Be accompanied by a documented medical need **as determined by the prescribing practitioner** for the compounded preparation. Reasons may include the removal of a dye, change in strength, change in dosage form, or delivery mechanism (i.e., product formulation change).

Please note that a price difference between a compounded preparation and commercially available product is not a significant difference to justify compounding.

The Board intends to follow FDA's guidance on what constitutes:

- commercially available drug products;
- essentially a copy of a commercially available drug products; and
- a statement of significant difference.

Please refer to the FDA guidance document *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act* for more information:
https://www.fda.gov/media/98973/download

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