

Prescription Requirements in Maryland

Linda M. Bethman

Assistant Attorney General

Board Counsel, MD Board of Pharmacy

Maryland Prescription Requirements: Definitions (Health Occ. § 12-101(e))

(1) “Compounding” means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(i) *As the result* of a practitioner’s prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; ...

(2) “Compounding” includes the preparation of drugs or devices in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

Maryland Prescription Requirements: Exception

Pharmacies may provide to an ophthalmologist for office use, without a patient-specific prescription:

- Compound antibiotics for the emergency treatment of bacterial endophthalmitis; and
- Compound antivasular endothelial growth factor agents for the emergency treatment of neovascular glaucoma, wet macular degeneration, or macular edema;

Pharmacy must require ophthalmologist to provide patient identities upon administration.

(Health Occ. § 12-403(c)(22))(2014))

Maryland Prescription Requirements: Exception

- AG advice provided to General Assembly that any state exception to allow for office supply compounding for ophthalmologists would not effect federal law requiring a valid prescription order for an identified patient
- Board has no notice of any pharmacies that are relying on state exception for ophthalmologists

Maryland Prescription Requirements - Office Supply

Entities (outsourcing facilities) preparing and providing non-patient specific sterile drug products must have:

- Wholesale distributor permit
- Inspection indicating compliance with cGMP standards

Health Occ. § 12-6C-03.2

Maryland Prescription Requirements - Inspections

- Inspect inventory/equipment for indications of batch compounding (bulk ingredients; powder hood; anticipatory stock)
- Question pharmacist/techs
- Dispensing reports
- Investigative inspections upon complaint

Maryland Prescription Requirements: Typical Compounding Violations

- 797 violations
- Compounding copies of commercially available products
- Domperidone
- Non-patient specific non-sterile compounding