Sterile Compounding in Maryland

Prepared by the

Maryland Board of Pharmacy

HB 986 State Board of Pharmacy – Sterile Compounding – Permits, 2013

In light of the tragedies resulting from compounded medications distributed into MD, the Board worked with the MD Department of Health and Mental Hygiene to craft legislation to close gaps in safety for patients that receive sterile compounded prescription drugs.

Health Occupations Article, Title 12, Subtitle 4A, New Definitions

- “Sterile Drug Product” - a drug product that must be prepared using aseptic techniques and is not required to be prepared in response to a patient specific prescription.

- “Sterile Compounding Facility” - a pharmacy, a health care practitioner’s office, or any other setting in which sterile compounding is performed pursuant to a patient specific prescription.

Health Occupations Article, Title 12, Subtitle 4A - Regulatory Scheme

The Board will regulate sterile compounding in 3 ways:

1) Sterile Compounding Permit (patient specific);
2) FDA Permit and MD Wholesale Distributor Permit (office use); or
3) Waiver for those that are unable to obtain an FDA permit meeting certain criteria.

Health Occupations Article, Title 12, Subtitle 4A – Waiver Criteria

Clinical Need

A waiver may be issued only for specified sterile compounded preparations or sterile drug products for which there is a clinical need, as determined by the Board, with input from licensed health care providers in MD.

Health Occupations Article, Title 12, Subtitle 4A – Waiver Criteria

Exigent Circumstances

Exigent circumstances must also exist that, as determined by the Board, would otherwise prevent health care professionals from obtaining, in the size and strength needed, the specified sterile compounded preparations or sterile drug products.

Health Occupations Article, Title 12, Subtitle 4A – Waiver Criteria

Board Requirements

If the facility meets the following Board requirements:

a) Provision of reports of inspections;
b) Statement of compliance with USP 797;
c) Review of adverse regulatory action; and
d) Other requirements as determined by the Board

Health Occupations Article, Title 12, Subtitle 4A – Inspections

- Pharmacies are inspected annually in MD.
- Sterile Compounding Facilities are inspected at a frequency as determined by Board in regulations based on risk level.
- Non-resident compounding facilities will be inspected by a Board approved/recognized regulatory unit or a Board designee.

Proposed revisions to COMAR 10.34.19

New Regulations provide requirements for:

- Sterile Compounding Permit Application,
- Inspections of Sterile Compounding Permit Holders,
- Reporting for Sterile Compounding Permit Holders,
- Sterile Drug Products, and
- Sterile Drug Product Waivers.

CHALLENGES

- Office Use products provided by pharmacies;
- Coordination of inspections for non-residents;
- Communication with Stakeholders;
- Implementation:
  - Staffing;
  - New licensure category;
  - Computer system alignment.

2014 Maryland Legislative Session

HB 1088

Allows pharmacies to compound for office use without a prescription only to Ophthalmologists for:

(1) antibiotics for emergency treatment ; and

(2) antivascular endothelial growth factor agents for the emergency treatment of neovascular glaucoma, wet macular degeneration, and macular edema.

HB 1410

Clarifies a permit exemption for "Immediate Use"

SB 1108

Clarifies a permit exemption for "Immediate Use" AND

An exemption for Oncologists

References

Existing Regulations

http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.34.19.*

Proposed Regulations

http://www.dsd.state.md.us/MDRegister/4102.pdf

References

Existing Statute

http://mgaleg.maryland.gov/webmga/frmStatutesText.aspx?article=gho&section=12-4A-01&ext=html&session=2014RS&tab=subject5

Proposed Legislation

http://mgaleg.maryland.gov/webmga/frmMain.aspx?id=hb1088&stab=01&pid=billpage&tab=subject3&ys=2014RS

http://mgaleg.maryland.gov/2014RS/bills/hb/hb1410F.pdf

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