Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Division of Health Professions Licensure

Board of Registration in Pharmacy

Massachusetts Board of Registration in Pharmacy:

Oversight of Sterile Compounding: Then and Now

Learning Objectives

Provide background on the Board of Pharmacy's response to the events of 2012.

Review Chapter 159 of the Acts of 2014, "An Act Relative to Pharmacy Practice in the Commonwealth".

Explain new Massachusetts specialty licensing for sterile compounding, non-sterile complex compounding and non-resident licensing requirements.

Recognize the Board of Pharmacy's authority regarding sterile compounding within hospitals and other institutions.

Review the Board of Pharmacy's proposed regulations related to 247 CMR 17 (sterile compounding).

What we do …
Current Jurisdiction

Licensing

- Pharmacists
  - Foreign
  - Reciprocity
- Interns
- Pharmacy Technicians
- CE Program Review
- Facilities
  - Community Pharmacies
  - Nuclear Pharmacies
  - Wholesale Distributors

Consumer Protection

- Complaints
- QREs
  - Consumer Complaints
  - Self-reported
- Abnormal Results
- Probation Monitoring
- Diversion
- Inspections
  - Sterile 797
  - Non-Sterile 795
  - Routine (with 795 section)
  - Nuclear
  - Wholesale Distributor

Background

- Following the 2012 national fungal meningitis outbreak tied to New England Compounding Center ("NECC"), Governor Patrick directed the Board to undertake a comprehensive approach to improving state oversight of the compounding pharmacy industry in Massachusetts.

- Governor Patrick also convened a Special Commission on the Oversight of Compounding Pharmacies, charging them to analyze the needs and gaps of the industry in order to formulate recommendations on necessary policy, regulatory and legislative changes.

Response

Multiple regulatory, monitoring, enforcement, training and other administrative efforts have been undertaken by the Board since Fall 2012 to aggressively address the compounding pharmacy challenges.

Chapter 159 of the Acts of 2014: Pharmacy Reform

- Changes to Pharmacist Continuing Education
- New License Categories
- Board of Pharmacy Make Up
- Regulations for Sterile and Non-Sterile Compounding (USP <795> & USP <797>)
- Requirements for Pharmacy Inspections and Investigator Training
- Pharmacy Advisory Committee

Oversight of Sterile Compounding

- Chapter 159 contains several provisions for enhancing oversight of sterile compounding including:
  - Compounding pharmacies must comply with the current standards established by USP
  - The board shall establish inspectional criteria for sterile compounding pharmacies
  - The board shall promulgate supplementary regulations to enhance safety of sterile compounding activities

Chapter 159 of the Acts of 2014: Sterile Compounding

Advisory Committee

- Experts appointed by the Commissioner of DPH
- Guide the Board of Pharmacy on various practice models, etc.

Sterile Compounding

- USP <797>
- 247 CMR 17 (under development)

Board of Pharmacy Inspections

- Investigator Training
- Inspectional Criteria- Audit Tools

Additional Statutory Requirements

- Labeling
- Defective Product recall and documentation
- No compounding drug preparations banned by the FDA

Advisory Committee

- cGMP Expert
- USP <797> Compounding Expert
- USP <795> Compounding Expert
- USP <71> Expert
- Microbiologist
- Expert in Pharmacoeconomics
- Expert in Pharmacology
- Others appointed by the Commissioner of DPH

Advisory Committee

- Propose regulations on quality assurance, inspection and testing of compounded drugs
- Evaluate current trends in pharmacy in MA, and recommend improvements
- Evaluate volume and revenue generated by each sterile compounder
- Investigate and formulate approach to address drug shortages
- Advise the Board on “special” issues

Inspectional Criteria

- USP <797>
- Procedural criteria for evaluation
  - Predetermined list of standards and safeguards inspected against
  - Predetermined alternating variable criteria, subset included in inspection

Inspector Training:

- Trained in USP <797>
- Sterile surveyor courses
- NABP training

Inspections Trends

- **2012**: 43 sterile compounding inspections
  199 retail compliance inspections

- **2013**: 55 sterile compounding inspections / visits
  3 non-sterile compounding inspections
  63 retail compliance inspections

- **2014**: BORP added 4 additional pharmacy inspectors
  65 sterile compounding inspections / visits
  35 non-sterile compounding inspections
  942 retail compliance inspections

- **2015** (approximate data through November 1, 2015):
  46 sterile compounding inspections / visits
  32 non-sterile compounding inspections
  856 retail compliance inspections

Challenges for Oversight of Sterile Compounding Pharmacies

- USP <797> is written like an academic treatise, not as a compliance or enforcement tool
  - Broad language
  - “should” vs “shall”
- Subject to interpretation; Board may have different interpretation than pharmacy
- Inspectors and Board staff need specialized training in USP <797> and appropriate inspection tool
- Inspections are a snapshot in time

Challenges for Sterile Compounding Compliance

- Renovations to physical plant: aging facilities, HVAC design
- Air sampling and environmental monitoring principles
- Education requires knowledge of aseptic processing, microbiology and HVAC principles
- Quality / Risk Management (CAPA)

Implementation

247 CMR 17

Sterile Compounding

Currently in Progress

Next Board Meeting - Tuesday, November 24, 2015

Key Components to 247 CMR 17:

Facility Monitoring

Personnel Monitoring

Product Monitoring

Facility Monitoring

- General Facility Design and Layout
- Primary/Secondary Engineering Controls
- Environmental monitoring
  - Non-viable air sampling
  - Viable air sampling
  - Surface sampling
  - Temperature and Humidity Monitoring
  - Airflows and Pressure Differential Monitoring

Personnel Monitoring

- Glove and fingertip sampling
- Hand Washing and Garbing
- Personnel Media- Fill Challenge Testing
- Aseptic Technique

Product Monitoring

- Beyond Use Dating (BUD)

USP 797 BUDs	Room Temp	Cold Temp	Frozen
Low Risk	48 hours	14 days	45 days
Medium Risk	30 hours	9 days	45 days
High Risk	24 hours	3 days	45 days

- BUD exceeding USP Chapter <797> must be supported by scientific evidence or validation studies by direct testing
- BUD Never Exceeds
  - **45 days for high risk**
  - **90 days for low and medium risk**

Product Monitoring (con't.)

Sterility and Endotoxin Testing

- Sterility Testing is based on USP <71>
- Endotoxin Testing is based on USP <85>

•Conducted on **ALL** CSPs when **exceeding** USP <797> Beyond Use Date

•CSPs are quarantined until confirmation of sterility and endotoxin testing

Where Massachusetts is Today

- Frequent, unannounced inspections
- Mandatory reporting of above action limit environmental monitoring results
  - Environmental monitoring is excellent indicator cleanroom control
- Developing sterile compounding inspection tool that clearly states the Board's interpretation of USP 797
  - Distributed tool to all sterile compounding pharmacies; encouraging use as self inspection tool
  - Includes "best practices"
- Promulgating new regulations with concrete sterile compounding standards in order to resolve ambiguity in USP 797; raise standards above USP 797 where appropriate

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Questions?