


Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
Board of Registration in Pharmacy




MSHP Annual Meeting
April 12, 2016
Board of Pharmacy: Regulatory Update

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Learning Objectives

1. Recognize how recent regulatory updates will affect the practice of pharmacy.
2. Describe changes to pharmacist continuing education requirements effective January 1, 2015 (247 CMR 4).
3. Recognize Board of Pharmacy's new license (Institutional and Retail) categories (247 CMR 6).

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Learning Objectives

4. Relate NEW pharmacy regulations pertaining to oversight of outsourcers to your pharmacy practice (247 CMR 21).
5. Relate proposed pharmacy regulations 247 CMR 17 providing oversight of sterile compounding to your practice.
6. Recognize abnormal sterile compounding environmental monitoring results and Board of Pharmacy reporting requirements (247 CMR 20).

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Chapter 159 of the Acts of 2014: Pharmacy Reform

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

Massachusetts Board of Registration in Pharmacy 


How many members are appointed to the Board by the Governor?

- A. 11 members
- B. 13 members
- C. 8 members
- D. None of the Above

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How many members on the Board of Pharmacy are Pharmacists ?

- A. 11 members
- B. 8 members
- C. 13 members
- D. None of the Above

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Pharmacy Board Make-Up

2 Chain Pharmacists	1 Long Term Care Pharmacist
2 Independents **	1 Pharmacist from Academia
1 Hospital Pharmacist	1 Physician
1 Sterile Compounder *	1 Nurse
1 Pharmacy Technician *	2 Public Members -Quality Assurance * -Healthcare Administration *

* = new seat
** = 1 added seat

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BORP Staff

- Executive Director
- Associate Director
- Director of Pharmacy Quality Assurance
- Quality Assurance Pharmacist
- Board Counsel
- Administrative staff (3)

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Office of Public Protection

- Director of Enforcement
- Director of Compliance
- Compliance Officers (2)
- Probation Monitor
- Investigators
 - Full time (12)

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Regulatory Review & Reform

- 247 CMR 4.00 Continuing Education
- 247 CMR 6.00 Licensure
- 247 CMR 21.00 Outsourcing Facilities
- 247 CMR 17.00 Sterile Compounding
- 247 CMR 19.00 Hazardous Drugs
- 247 CMR 20.00 Mandatory Reporting

Continuing Education

247 CMR 4.0 Continuing Education Requirements

Draft approved by Board on September 30, 2014

Public Comment Period
Held on January 29, 2016

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Continuing Education

- Effective January 1, 2015, i.e. for the next renewal cycle (2015 / 2016)

	New Requirements (beginning 1/1/15)	Previous Requirements
Total CE hours per year	20	15
Live	5	5
Law	2	2
Sterile Compounding (if engaged or oversee)	5	N/A
Non-Sterile Complex Compounding (if engaged or oversee)	3	N/A


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License Categories

- Sterile Compounding
- Institutional Sterile Compounding
- Provisional
- **Technician in Training**

Draft approved by Board on January 6, 2015

Public Comment Period Pending

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License Categories

- 247 CMR 6.00: Registration, Management and Operation of a Pharmacy or Pharmacy Department:
 - Dedicated to licensing of facilities
 - Practice standards move to section 9.00
 - Reporting requirements moved to section 20.00

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Outsourcing Facilities

- 247 CMR 21.00 Outsourcing Facilities
 - Final Approval January 5th
 - Public hearing / comment period held
 - Effective as of January 29, 2016
 - Registered with the FDA as a 503(b)
 - Must have been inspected by FDA within the last 2 years and in good standing
 - Suitability of owners and PIC

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Oversight of Compounding

- Compounding pharmacies must comply with the current standards established by USP
- The board shall promulgate supplementary regulations to enhance safety of sterile compounding activities

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Sterile Compounding

- 247 CMR 17.00 Sterile Compounding
 - Draft regulations approved by Board
 - February 2, 2016
 - Posted on Board's website
 - Public comment period pending

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Hazardous Drugs


- 247 CMR 19.00 Hazardous Drugs
 - Overview provided January 5th.
 - Draft standards presented to Board:
 - March 8, 2016
 - April 5, 2016
 - Final draft in progress
 - USP <800> will be the baseline

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Sterile Compounding State of Control


Definition
How is this determined? Monitoring of:

- Place
- People
- Product

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Sterile Compounding State of Control


ICH Q10 Definition
State of Control:
A condition in which the set of controls consistently provides assurance of continued process performance and product quality.

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Sterile Compounding State of Control


- Elements:
 - Hand hygiene, garbing, aseptic technique
 - Training
 - Facility design and environmental control
 - Environmental sampling
 - Cleaning
 - Components
 - Sterilization, quality release checks
 - Standard operating procedures

Maintaining a State of Control in Sterile Compounding
Infusion — November/December 2013
Eric Kastango, R.Ph., M.B.A., FASHP

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Facility Monitoring

- Environmental monitoring
 - Non-viable air sampling
 - Viable air and surface sampling
 - Temperature and Humidity Monitoring
 - Airflows and Pressure Differential Monitoring


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BOP Case (Example)

Board staff recently received a report of abnormal environmental monitoring.
Notification from the Microbiology Laboratory included the following:

- 75 cfu/m3 bacillus
- 10 cfu/m3 staphylococcus
- **1 cfu/m3 fungus**


247 CMR requires all sterile compounding pharmacies licensed by the BOP to report abnormal environmental monitoring results

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Audience Participation Questions

What do you do with this report?
Do you need more information?
What is required under USP <797>?
Immediately remediate

What does remediation include?
Root Cause Analysis
Corrective Action Preventative Action
Trend Analysis

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Audience Participation Questions: Other considerations

Can the pharmacy continue to compound during remediation?

What else should the pharmacy consider when making this decision?

- Recent gloved fingertip thumb sampling of staff?
- Recent media fill of staff

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Audience Participation Questions: Other considerations

Should CSPs previously dispensed or released to inventory be retrieved / recalled?

If so, how far back should the pharmacy go?

- CSPs made day of notification
- CSPs made this week? this month?

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Viable Surface Monitoring

Current USP standard- periodically

247 CMR 17 DRAFT

Dependent on risk level of compounding

Monthly is minimum

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Viable Surface Monitoring

Month	Q 6 Months
January	75
February	0
March	0
April	0
May	0
June	90
July	0
August	0
September	0
October	0
November	0
December	110

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Viable Surface Monitoring

Month	Monthly	Q 6 Months
January	75	75
February	100	0
March	50	0
April	20	0
May	15	0
June	25	90
July	50	0
August	85	0
September	85	0
October	100	0
November	100	0
December	100	110

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Other Factors of State of Control

What is another measure of state of control that is monitored in a cleanroom?

What is generally the greatest source of contamination in a cleanroom?

A. Personnel
B. Personnel
C. Personnel
D. Personnel

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Personnel Monitoring


Compounding Personnel Monitoring

- Training and Competency
- Gloved Fingertip Sampling
- Personnel Media-Fill Challenge Testing

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Audience Participation

- Under 247 CMR, what results have to be reported to the Board? Do these results have to be reported to the Board?


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Regulatory Review & Reform

- 247 CMR 20.00 Mandatory Reporting
 - Approved January 5th
 - Consolidates all reporting requirements into a single section
 - Public hearing / comment period pending

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Questions?



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Contact Info

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Helpful Resources

Draft Regulations
<http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/draft-regulations.html>

POLICY No. 2015-02: Sterile and Complex Non-Sterile Compounding CE
<http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/pharmacist-continuing-education.pdf>

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