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

A Pharmacist's Guide to Proposed Regulations: An Update from the MA BORP

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Learning Objectives

1. Recognize Board of Registration in Pharmacy proposed regulations related to 247 CMR 9.00 (Practice Standards).
2. Discuss sterile and non-sterile compounding requirements for human and animal patients.
3. Recognize the Board of Pharmacy's proposed regulations related to 247 CMR 17 (sterile compounding) and 247 CMR 18 (non-sterile compounding).
4. Identify requirements for pharmacists dispensing naloxone by standing order.

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

Pharmacy Board Make-Up

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

* new seat
** 1 added seat

BORP Staff

- Executive Director
- Associate Director
- Director of Pharmacy Quality Assurance
- Quality Assurance Pharmacist
- Board Counsel
- Administration

12/1/15

Office of Public Protection

- Director of Enforcement
- Director of Compliance
- Compliance Officers (2)
- Probation Monitor
- Investigators
  - Full time (10)
  - Contractor (1)

Promulgation of Regulations

The Process

- Develop Draft regulations
- Establish and Schedule Public Comment Period
- Hold Public Hearing
- Review Public Comment and make Revisions based on comments considered (if applicable)
- Final draft approved by Board
- New Regulation published and implemented

Outreach & Implementation

- Early stakeholder involvement has been a key component to our implementation strategy
- Feedback prior to Board voting will allow stakeholders to be part of the process and ensure practicality
- Stakeholder involvement will help ensure better understanding and compliance among our licensees moving forward

Implementation

247 CMR 4 Continuing Education Requirements

Draft approved by Board on September 30, 2014

Public Comment Period Pending

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

Implementation

247 CMR 6

Licensing Requirements

- Sterile
- Non-sterile complex
- Non-resident

Draft approved by Board on January 6, 2015

Public Comment Period Pending

License Categories

- Non-resident (retail and compounding, as applicable)
  - Required for shipping any medication into MA
  - Manager of Record must be licensed in MA
- Sterile Compounding
- Non-Sterile Complex Compounding
- Institutional Sterile Compounding
- Provisional
- **Technician in Training** — New Individual License

Implementation

247 CMR 9

Pharmacy Practice Standards

Draft approved by Board on May 5, 2015

Public Comment Period Pending

247 CMR 9

MOR Requirements

Perpetual Inventory

12 hour work limit (mandatory break period between 12 hour shifts)

CVI 1 year validity

E-Kits

Daily Dosing Planners

Specialty Patient Packaging

- Daily Dosing Planners
- Single-drug-single-dose packaging
- Multi-drug-single-dose packaging
- Oral-liquid-single-dose packaging

Redispensing

247 CMR 9.01 (7)

A pharmacy shall accept a medication that is previously dispensed to a patient if the medication:

a) was dispensed to the patient in error; or
b) is suspected to be defective or contaminated

12-hour work shift limit

- Expanded to include pharmacy interns and technicians
- Mandatory break period between shifts defined
- Extenuating services exception

NABP e-Profile

247 CMR Section 9.01 (24)

A pharmacist shall maintain an NABP e-profile number

Dispensing and Refilling Prescriptions

Schedule VI medication

- Valid for one year from date written
- May not be refilled after one year
- Professional judgement allowance for up to a 7 day supply to provide continuity of care

Daily Dosage Planners

- May not repackage medications previously dispensed by a different pharmacy

Requirements

- Policy & Procedures
- Designates a Space
  - orderly placement of equipment,
  - prevention of cross-contamination
- Proper Labeling
- Appropriate Cleaning
- Pharmacist Final Verification

247 CMR Section 9.05

9.05(5): The pharmacy labels each daily dosage planner with all information required by M.G.L. c. 94C, § 21 for each medication

9.05(6): A pharmacist shall visually inspect and verify the contents of a daily dosage planner prior to dispensing

Oral-Liquid-Single-Dose

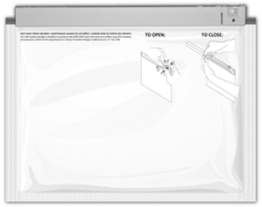
Package has a child proof design
- Placed into amber vial or
- Appropriate child safety container
- Waiver obtained
- Medication exempt from requirements

One commercially available medication or compounded preparation

16 CFR 1700 - POISON PREVENTION PACKAGING
http://www.gpo.gov/fdsys/granule/CFR-2012-title16-vol2/CFR-2012-title16-vol2-part1700/content-detail.html

Stink Sack

https://stinksack.com/project/child-resistant-bags/



According to their website, Stink sack conforms to the requirements of Poison Prevention Package (16 CFR 1700).

Multi-Drug-Single-Dose Packaging

Schedule II or III controlled substance prohibited

34 day supply of medication limit

Regularly scheduled medications

medications to be taken on an as needed basis (PRN) prohibited

247 CMR Section 9.06 (4)

a) A licensee may not dispense more than a 34 day supply of medication in a multi-drug-single-dose package
b) A licensee may not dispense Schedules II or III controlled substances in multi-drug-single-dose package
c) A licensee may not dispense medications to be taken on an as needed basis in a multi-drug-single-dose package

247 CMR Section 9.06 (5)

Return and Repackaging of Multi-Drug-Single-Dose Packaging

a) A pharmacy or pharmacist may accept a return of a multi-drug-single-dose package that the pharmacy previously dispensed to a patient for the purpose of repackaging and re-dispensing to that same patient

(i)If a patient's medication was discontinued, a pharmacy may remove the discontinued drug(s) from the multi-drug-single-dose package and re-dispense the remaining medications in the multi-drug-single-dose package to the same patient.

(ii)If a patient's drug therapy changed, a pharmacy may remove the discontinued drug(s) from the multi-drug-single-dose package(s) and may add a new medication(s) to the multi-drug-single-dose package and re-dispense the multi-drug-single-dose package to the same patient

Return and Repackaging of Multi-Drug-Single-Dose Packaging con't.

iii. A pharmacy shall label the multi-drug-single-dose package in accordance with 247 CMR 9.07(6) prior to re-dispensing.

iv. A pharmacy shall implement policies and procedures pertaining to security and accountability of controlled substances during return and repackaging.

b) A licensee may not return any medication removed from a multi-drug-single-dose package to inventory or dispense to any patient.

Return to Stock

Returning medication(s) to the manufacturer's stock bottle or PPA is prohibited

Pharmacy technician in training may not return medications to stock

Pharmacy technicians may not return CII medications to stock

Medication(s) to be returned to stock shall be

- in the original patient container or another appropriate container
- properly labeled with following information:
  - Product name
  - Strength or concentration
  - Name of the manufacturer, supplier, or NDC number, and
  - The expiration date assigned at the time of filling
- verified by the pharmacist

247 CMR 9.11

9.11(1): In the event a pharmacy fills and prepares a prescription but the patient does not pick up the medication, the pharmacy may return the medication to stock. A pharmacy shall ensure the following conditions are satisfied if it returns a medication to stock:

(a) A pharmacy may not return a medication to the manufacturer's stock bottle or PPA. A pharmacy shall keep a medication to be returned to stock in the original patient container or place medication an appropriate container and shall affix a label to the container containing the following information:

1. Product name
2. Strength or concentration
3. Name of the manufacturer, supplier, or NDC number, and
4. The expiration date assigned at the time of filling

Pharmacy Operations

- Current Plumb's Veterinarian Reference
- Dedicated equipment for highly cross-sensitive medications and hazardous drugs
- Ensure the accuracy and performance of electronic counting machines
- Ensure a qualified vendor is certifying equipment at least once every two years

Security of Controlled Substances

Schedule II Perpetual Inventory

- Adjustment performed only by the Pharmacist Manager of Record or pharmacist designee
- Prohibits entries or adjustments by pharmacy technician or other unlicensed individual
- Perpetual inventory requirements apply to controlled substances that are expired, quarantined, or pending reverse distribution

Pharmacist Manager of Record

Manager of Record is responsible for the following:

- Planning and maintaining adequate staffing that promotes patient safety
- Ensuring that all licensees working in the pharmacy have completed continuing education requirements
- A Manager of Record shall work at least 30 hours per week at the pharmacy he/she manages

247 CMR Section 9.21

9.21(2): A Manager of Record is responsible for the following:

(a) Operation of the pharmacy in compliance with laws and regulations governing the practice of pharmacy
(c) Planning and maintaining adequate staffing that promotes patient safety
(i) Ensuring that all licensees working in the pharmacy have completed continuing education requirements

9.21(3): A Manager of Record shall work at least 30 hours per week at the pharmacy he/she manages

Pharmacy Practice Advisory

Staffing Ratios

247 CMR 8.06(3)(a) Supervisory Ratios
(a) A pharmacist utilizing pharmacy interns, certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees to assist in filling prescriptions may utilize such support personnel in accordance with the following ratio requirements:

1:4 One pharmacist for a maximum of four support personnel; provided:
a. at least one of the four support personnel is a certified pharmacy technician and one is a pharmacy intern; or
b. at least two of the support personnel are certified pharmacy technicians.

1:3 One pharmacist for a maximum of three support personnel; provided at least one of the three support personnel is a pharmacy intern or a certified pharmacy technician.

Pharmacy Practice Advisory

Licensing and Certification of Staff

All pharmacies must adhere to the staffing ratios set forth by the Board pursuant to 247 CMR 8.05(3)(a) in real time.

Certified technicians may only be counted as "certified" if they are BOTH licensed AND certified. If a certified technician is unlicensed, the technician will be counted as a technician in training for the purposes of calculating ratio. Technicians in training waiting for licensure, and licensed technicians awaiting certification examination results must be counted under their current credentials for ratio purposes.

Implementation

247 CMR 18
Non-Sterile Compounding
Draft approved by Board on October 9, 2014
Public Comment Period Pending

247 CMR 17
Sterile Compounding
Currently in Progress

Non-Sterile Compounding

Non-Sterile Compounding Levels
- Simple
- Moderate
- Complex

USP <795>

247 CMR 18 (draft approved by the Board)

USP <795> Compounding Levels

Simple / Moderate- making a preparation that appears in a peer reviewed article that contains:

- Specific quantities for all components
- Compounding procedures and equipment
- Stability data for that formulation with beyond use date (BUD)

USP <795> Compounding Levels

Complex- making a preparation that requires special training, environment, facilities, equipment, and procedures that may present an elevated risk to the compounder or the patient

The pharmacist pictured here is compounding an omeprazole suspension. Based on discussions today regarding sterile and non-sterile compounding, please answer the following question.

The pharmacist is compounding omeprazole. Based on what you know about draft regulations 247 CMR 18, please answer the following question.

This pharmacist is preparing a prescription for "complex." Based on what you know about draft regulations 247 CMR 18, please answer the following question.

247 CMR 18

18.03 Facility

Complex

- **Specialty License required**
- Designated compounding room that is at least 100 square feet
- Containment hoods that vent the exhaust away from the hood and filter the exhaust

Simple / Moderate

- **Drug Store License**
- Designated compounding area that is at least 10 square feet minimizing contact with water from sink

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

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

Where Massachusetts is Today

- Frequent, unannounced inspections
- Mandatory reporting of above action limit environmental monitoring results
  - Environmental monitoring is excellent indicator cleanroom control
- Developed 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

Advisory Committee

- Chaired by Associate Commissioner Tucker
- Members appointed by the Commissioner
  - 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

- Meetings Open to the Public
- Meeting Announcement, Agenda and Minutes posted on Board's website
  - 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

Sterile Compounding

Sterile Compounding Levels
- Low
- Medium
- High

USP <797>

247 CMR 17 (under development)

USP <797>

- USP <797> describes the standard of care for sterile compounding pharmacies
- Low and medium risk level: combining two or more sterile products using aseptic technique in a sterile environment
  - TPNs, IV antibiotics, IV pain medications
- High risk level: combining non-sterile ingredients and processing to produce a sterile product
  - customized medications for health care providers; medications in short supply; designer / specialty medications; preservative free medications

Components of USP <797>

- 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

Components of USP <797> (con't.)

- Cleaning and Disinfecting
- Compounding Processes
- Aseptic Technique
- Equipment Calibration
- Product Sterility Testing
- Final Release Checks

USP <797> Compounding Levels

Low and Medium: combining two or more **sterile** products using aseptic technique in a sterile environment.

- IV antibiotics, IV pain medications, TPN

High risk: using **non-sterile** ingredients (API) and using sterility processes to create a sterile product.

- Customized medications to remove preservatives or dyes, medications in short supply, designer / specialty medications

Chapter 159 Requirements: Institutional Sterile Compounding

Chapter 159 of the Acts 2014 grants the Board authority over institutional sterile compounding

Proposed Effective Date: June 30, 2015 — **In Progress**

Institutional Pharmacies will be required to obtain a sterile compounding license from the Board

Standards for Institutional Sterile Compounding- USP <797> and 247 CMR 17

Advisory: Pre-filled Insulin Syringes

Sterile compounding may not be conducted at a pharmacy without a Board approved clean room pursuant to 247 CMR 6.01(5)(c). This includes any practice related to the non-aseptic manipulation of sterile products intended for injection.

For example, ONLY pharmacies with an appropriate and approved clean room that upholds the standards set forth by the Board and USP <797> may pre-fill insulin syringes for patients.

http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/pharmacy-advisory-insulin.pdf

Implementation

247 CMR 19	Hazardous Drugs
247 CMR 20	Reporting
247 CMR 2	Definitions

Other Updates

Opioid Patient Fact Sheet

Vaccine Administration

- Zostavax Advisory
- Pharmacy interns administering vaccines

Expedited Partner Therapy (EPT)

Commissioner Updates

- MassHealth Provider Copay Notice
- OTC Sale of Hypodermic Needles

Naloxone by Standing Order

Opioid Patient Fact Sheet

Chapter 244 of the Acts of 2012

A pharmacist shall distribute the pamphlet when dispensing a narcotic in Schedule II or III.

Effective Friday, October 23, 2015

Pharmacist Administration of Vaccines

105 CMR 700.004(B)(6) and M.G.L. c 112 section 24G

The regulations allow pharmacists to administer vaccines approved by the Department to adults 18 years and older by prescription and / or standing order.

The Department of Public Health Drug Control Program and Board of Registration in Pharmacy issued guidance on vaccine administration via a joint policy, which was recently amended (helpful resource link). Vaccines covered by the policy **include only those listed in the Adult immunizations Schedule.**

http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/pharmacy-advisory-zostavax.pdf

ADVISORY: ZOSTAVAX IMMUNIZATIONS

According to the CDC:

2006: Herpes Zoster Vaccine (Zostavax): was licensed and recommended in 2006 for prevention of herpes zoster among adults aged 60 years and older.

March 2011: FDA approved the use of Zostavax in adults aged 50 through 59 years.

June 2011: ACIP declined to recommend the vaccine for adults aged 50 through 59 and reaffirmed its current recommendation that herpes zoster vaccine be routinely recommended for adults aged 60 years and older.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6044a5.htm

Vaccine Administration by Pharmacy Interns

Statutory Authority

Created by S 2127 Chapter 488
Amends M.G.L. c 112 by adds section 24G

Authorizes Pharmacy Interns to administer vaccines under the direct supervision of pharmacist

- Training program
- BLS certification
- Registered and *in good standing* as an Intern with the Board of Pharmacy

Vaccine Administration

247 CMR 8 Pharmacy Intern definition and criteria draft approved by the Board on August 4th amends language to be consistent with PharmD programs

2015-01 Jt. Policy Pharmacist Administration of Vaccines
Recently amended to include pharmacy interns
Amend list of approved vaccines to reference the CDC Adult Immunization Schedule

Additional Guidance
- Pharmacy Preceptors oversight
- Supervisory Ratios

Expedited Partner Therapy (EPT)

Statutory Authority, July 2010
MGL Ch111 § 121B

2015-03 Guidance for Filling Expedited Partner Therapy Prescriptions

The pharmacy can fill the prescription without knowing the name and address of the sex partner

DUR is limited to the information known to the pharmacist

Pharmacy shall refer patient to another pharmacy if unable to fill

Reminders from the Commissioner

MassHealth Provider Regulations: Co-Pay Notice
130 CMR 450.130(G) and 450.130(F)

- Pharmacies and hospitals must post a notice about MassHealth copayments in areas where copayments are collected
- Provider Manual contains guidance on copays, including exemptions

http://www.mass.gov/eohhs/docs/masshealth/regs-provider/regs-allprovider.pdf

Reminders from the Commissioner

Over-The-Counter Sales of Needles and Syringes
M.G.L. c. 94C Sections 27 and 32I

- Any person providing identification validating the individual is age 18
- No record requirements
- No limits on amount to be sold

http://www.mass.gov/eohhs/docs/dph/aids/needles-syringes-purchase-sale.pdf

Opiate Abuse and Overdose Crisis

March 2014:

- Public Health Emergency declared by Governor
- Emergency Powers to DPH Commissioner to address the Commissioner, with approval of Public Health Council, issued an order authorizing pharmacies to dispense naloxone via standing order

Naloxone

Standing Orders for dispensing to individuals
- at risk of experiencing opiate overdose
- able to assist (the by-stander)

Pharmacy Dispensing of Naloxone by Standing order:
- File orders with Board
- MOR attests that staff have been trained
- Assemble and label kits accordingly
- Log or track sale of kits
- Provide counseling

Committed to Rx Drug Abuse Education and Prevention

I pledge that I will make a difference, as a pharmacist and member of my community to help with the drug abuse epidemic. I will provide information about prescription drug abuse in my pharmacy, office, or other practice setting to make my patients and colleagues aware of the epidemic facing our nation. I will address prescription drug abuse as a pharmacist should by applying my knowledge, skills, and experience. I will be involved. I will take action. I will be a pharmacist who saves peoples' lives!

http://www.awarerx.org/pharmacists-pledge

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

POLICY No. 2015-01 ADMINISTRATION of VACCINES

http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/policy-2015-01.pdf

Helpful Resources

Expedited Partner Therapy (EPT)

http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/expedited-partner-therapy.pdf

Dispensing of Naloxone by Standing Order

http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html

Chapter 244 of the Acts of 2012: "Opioid Prescription Drug Fact Sheet"

http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/opiod-fact-sheet.pdf

Helpful Resources

Board of Pharmacy Advisories

Pre-filled Insulin Syringes

http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/pharmacy-advisory-insulin.pdf

Staffing Ratios

http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/pharmacy-advisory-ratio.pdf

Zostavax Administration

http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/pharmacy-advisory-zostavax.pdf

Contact Info

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Questions?