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To: Massachusetts Pharmacists and Pharmacies

From: David Sencabaugh, R.Ph., Executive Director

Massachusetts Board of Registration in Pharmacy

Date: May 19, 2015

Re: Guidance for Changes to Pharmacist Continuing Education Requirements

Chapter 159 of the Acts of 2014 signed into law on July 10, 2014 increased pharmacist continuing education requirements for **ALL** pharmacists licensed in the Commonwealth.

The Massachusetts Board of Registration in Pharmacy (BORP) has begun the process of writing regulations that define the requirements set forth in chapter 159 of the Acts of 2014; however, the new requirements for continuing education took effect **January 1, 2015**, i.e. for the next renewal cycle (2015 / 2016).

The Board has received various inquiries regarding the continuing education requirements. The attached policy approved by Board Members on May 5, 2015 is meant to address the inquiries received by the Board and help clarify the requirements.

For additional information, please refer to the attached policy "*2015-02 Guidelines for Pharmacist Continuing Education Requirements: Sterile and Complex Non-Sterile Compounding*" and Chapter 159 of the Acts of 2014 link below.

https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter159

If you have additional inquiries after reviewing the policy please feel free to submit your inquiry via email:
Pharmacy.Admin@MassMail.State.Ma.US

Massachusetts Board of Registration in Pharmacy

POLICY No. 2015-02: Guidelines for Pharmacist Continuing Education Requirements: Sterile and Complex Non-Sterile Compounding

I. Purpose

Policy No. 2015-02 sets forth the new requirements of M.G.L. c. 112, § 24A (as amended by Chapter 159 of the Acts of 2014) that all pharmacists licensed by the Massachusetts Board of Registration in Pharmacy ("Board") engaged in or overseeing sterile or complex non-sterile complex compounding or practicing in a pharmacy licensed by the Board be trained in Chapter <797> and/or Chapter <795> of the United States Pharmacopeia ("USP").

II. Sterile Compounding (USP <797>) and Complex Non-Sterile Compounding (USP <795>) Continuing Education Requirements:

Massachusetts General Law c. 112, § 24A (as amended by Chapter 159 of the Acts of 2014) states: "Any pharmacist licensed by the commonwealth overseeing or directly engaged in the practice of sterile compounding or practicing in a pharmacy licensed pursuant to [M.G.L. c. 112] section 39G or 39I shall devote at least 5 of the 20 contact hours to the area of sterile compounding. Any pharmacist licensed by the commonwealth overseeing or directly engaged in the practice of complex non-sterile compounding or practicing in a pharmacy licensed pursuant to [M.G.L. c. 112] section 39H shall devote at least 3 of the 20 contact hours to the area of complex non-sterile compounding."

III. Sterile Compounding Continuing Education Requirement

A pharmacist licensed by the Commonwealth **MUST** complete 5 contact hours of continuing education in the area of sterile compounding if he/she:

- Oversees sterile compounding or is directly engaged in the practice of sterile compounding in a retail pharmacy;
- Oversees sterile compounding or is directly engaged in the practice of sterile compounding in an institution;
- Oversees or supervises sterile compounding activities performed by other qualified compounding personnel;
- Verifies the preparation of sterile compounded products;
- Practices sterile compounding;
- Verifies patient medication orders that may require sterile compounding; or
- Engages in or oversees sterile compounding at any point during the renewal period (i.e. at any point, for any length of time even if temporary).

Non-Residents: A pharmacist who practices in another state, but also holds a Massachusetts license **MUST** complete 5 contact hours of continuing education in the area of sterile

compounding if he/she oversees sterile compounding or is directly engaged in the practice of sterile compounding, as described above.

IV. Complex Non-Sterile Compounding

A pharmacist licensed by the Commonwealth **MUST** complete 3 contact hours of continuing education in the area of complex non-sterile compounding if he/she:

- Oversees complex non-sterile compounding or is directly engaged in the practice of complex non-sterile compounding;
- Oversees or supervises complex non-sterile compounding activities performed by other qualified compounding personnel;
- Verifies the preparation of complex non-sterile compounded products;
- Practices complex non-sterile compounding;
- Verifies patient medication orders that may require complex non-sterile compounding; or
- Engages in or oversees complex non-sterile compounding at any point during the renewal period (i.e. at any point, for any length of time even if temporary).

Non-Residents: A pharmacist who practices in another state, but also holds a Massachusetts license **MUST** complete 3 contact hours of continuing education in the area of complex non-sterile compounding if he/she oversees complex non-sterile compounding or is directly engaged in the practice of complex non-sterile compounding, as described above.

V. Further Guidance on Continuing Education Compliance

- The five (5) sterile or three (3) complex non-sterile compounding CE hours count towards the twenty (20) CE hours required each calendar year and may be completed as home study or in live format.
- Pharmacists licensed in Massachusetts who work in a pharmacy that holds a specialty sterile and/or complex non-sterile compounding license who do **not** oversee or directly engage in sterile or complex non-sterile compounding are **not** required to obtain continuing education credits in compounding.
- Acceptable programs shall refer to the type of compounding covered in the title of the program / course, and must also note learning objectives related to sterile and / or complex non-sterile compounding.
- Continuing education programs that cover the regulatory component of compounding are acceptable to fulfill the requirement of both compounding and law CE credits so long as the regulatory component is approved by ACPE or the Board as a “law” CE program and the compounding component meets the acceptable program criteria set forth above.
- The compounding CE credits must be completed by December 31st of each calendar year. Pharmacists shall retain documentation of the successful completion in accordance with 247 CMR 4.

VI. Recommended Course Components:

1. Overview of recent legislative changes
    a. Purpose of training
    b. Recognize compounding requirements for human and animal patients
    c. Recognize the Board's authority regarding compounding within institutions

2. What is sterile and/or non-sterile complex compounding?
    a. Differentiate compounding from manufacturing
    b. Differentiate sterile and non-sterile compounding
    c. Differentiate simple, moderate, and complex non-sterile compounding, and/or
    d. Differentiate low-, medium-, and high-risk sterile compounding, and
    e. Differentiate hazardous and non-hazardous compounding

3. Facility requirements
    a. General facility design
    b. Primary and secondary engineering controls
    c. Environmental monitoring processes

4. Process requirements
    a. Cleaning and disinfecting
    b. Compounding processes
    c. Aseptic technique
    d. Personnel training and monitoring
    e. Product monitoring and beyond use dating (BUD)
    f. Equipment calibration
    g. Product sterility testing
    h. Final release checks
    i. Corrective Action/Preventative Action (CAPA) plans in response to abnormal environmental and employee monitoring results
    j. Corrective Action/Preventative Action (CAPA) plans in response to defective compounded product and / or abnormal product testing results

5. Other Requirements
    a. Packaging
    b. Labeling
    c. Storing and shipping
    d. Documentation
    e. Counseling
    f. Continuous quality improvement