

## Massachusetts Society of Health-System Pharmacists

### FAQ for Chapter 159 of the Acts of 2014 Compounding Law

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#### Background

In response to the tragic events after contaminated sterile products were dispensed by a Massachusetts pharmacy, Massachusetts passed H-4235 (<https://malegislature.gov/Bills/188/House/H4235>). This law sets out new requirements for all practice settings, changes the composition of the Board of Pharmacy (BoP) and creates new pharmacy licensure categories. MSHP, in collaboration with the Massachusetts Hospital Association (MHA) and other state-wide pharmacy groups, is working with MA BoP to help implement the law. This FAQ attempts to answer some of questions many are asking in the hospital pharmacy community.

#### 1. What is the composition of the BoP?

The board shall be comprised of: 8 registered pharmacists; 1 pharmacy technician; 1 representative of the public with experience in health care service delivery, administration or consumer advocacy, subject to section 9B; 1 physician registered pursuant to chapter 112; 1 nurse registered pursuant to said chapter 112; and 1 expert in patient safety and quality improvement. The one hospital pharmacist seat is maintained. The law adds pharmacy technician and QI specialist. The law also requires the public member have some healthcare or consumer advocacy experience.

#### 2. What are the new labeling requirements?

All sterile and complex non-sterile medications must be labeled in a way that notifies prescribed users and practitioners that the drug is either a sterile or non-sterile compounded drug preparation. Examples of possible complex non-sterile medications include transdermal dosage forms, modified release preparations and some inserts and suppositories for systemic effects.

#### 3. What is the telephone number requirement and what is exempt from the requirement?

All pharmacies engaged in sterile or complex non-sterile compounding shall provide a telephone number to foster communication between patients and a pharmacist employed by the pharmacy who has access to the patient's records. The phone shall be staffed during regular hours of operation every day and not less than 56 hours per week. The phone number shall be affixed to the drug's container. This paragraph shall not apply to a hospital pharmacy if the medication is to be administered to an individual admitted as an inpatient within the same hospital. The state has not determined the definition of an inpatient. It is unclear whether ambulatory clinics in your hospital will require the telephone number.

Each hospital must identify who the patient should call and have a process to get the patient the requested information.

**4. How does the law change my current reporting requirement to the MA DPH for Serious Reportable Events (SRE)?**

The law requires reporting of preventable SADE's that cause serious harm or death. This requirement is in line with current reporting requirements for SRE medication errors that occur at your facility. The law expands a hospital's reporting requirement to include SADE's that become known to the hospital arising from a medication error that occurred from an outside pharmacy. The event must also be reported to FDA's MedWatch Program and the outside pharmacy from which the drug was produced, compounded or dispensed in addition to all other reporting requirements.

**5. What are my Continuing Education (CE) Requirements?**

The law increases the number of CE required each year from 15 to 20, effective in 2015. The law also requires those pharmacists involved in sterile compounding, including managers, to receive 5 credits in sterile compounding and those pharmacists involved in complex non-sterile compounding, including managers, to receive 3 credits in complex non-sterile compounding. The law grants the BoP authority to fine any pharmacist up to \$1,000 for non-compliance with CE requirements.

**6. Will the BoP make investigatory findings available?**

The BoP will summarize each complaint submitted to the Board. The summary will include nature of complaint, findings and disposition. The report will be publically available on the BoP website.

**7. Will my hospital pharmacy have to register with the BoP?**

All pharmacies performing sterile compounding must register with the BoP. The institutional sterile compounding license will be in addition to the any other license the entity operating the pharmacy must hold. The hospital pharmacy is not required under the law to register to perform complex non-sterile compounding. Despite hospitals not having to register to perform 795 activities, pharmacists performing those duties will still be required to have the extra CEU's for that practice.

**8. What is the deadline for hospital pharmacy registration?**

The law provides that the provision(s) requiring hospital pharmacy registration take effect on June 30, 2015.

**9. Will my hospital pharmacy be inspected?**

As part of the registration, the BoP will perform on-site inspections. The BoP will follow a list of procedural requirements that will be available to all hospital pharmacies. The BoP may issue a full registration or a one-time provisional license for those pharmacies demonstrating substantial compliance with a plan for full compliance.

**10. Will my pharmacy be required to report any compounding volume data to the BoP?**

Each licensed hospital pharmacy must submit a list of dispensed orders/prescriptions on an annual basis. This includes the volume of said orders/prescriptions.

**11. What are my responsibilities if my pharmacy discovers a medication has been sterilely compounded in a defective way?**

The medication must be recalled and quarantined. The incident must be documented on the pharmacy's defective drug preparation log. The event must be reported to the BoP, the Betsy Lehman Center and FDA MedWatch Program.

**12. What are the manager of record (MoR) responsibilities?**

The MoR must disclose the names of all employees engaged in sterile compounding, certify that those individuals have received the appropriate training, and disclose all pharmacists who manage or supervise sterile compounding operations.

**13. Will I be able to research potential outsourcing pharmacies?**

The BoP will develop a searchable website that lists all licensed compounding pharmacies. The public will be able to obtain information about any of those pharmacies, including disciplinary actions and reports of SADE's.

**14. Will the BoP be empowered to fine a hospital pharmacy for non-compliant practice?**

The law authorizes the BoP to issue fines of the pharmacy (not pharmacist) of up to \$25,000 for each violation of a regulation or administrative rule. Further, after a violation has been identified by the BoP and ordered/agreed to be corrected, the BoP may issue a fine of \$1,000 per day each day the violation exists past the prescribed day for correction.