H4235 An Act relative to pharmacy practice in the Commonwealth

Summary

THE BOARD OF REGISTRATION IN PHARMACY

SECTIONS 2 & 3. The Board of Registration in Pharmacy is expanded to include 13 individuals, including a minimum of 8 pharmacists from the following practice settings with 7 consecutive years of practice in Massachusetts:

- 2 pharmacists employed in an independent setting (9 or fewer stores in MA and employs not more than 20 full-time pharmacists);
- 2 pharmacists employed in a chain setting (10 or more stores);
- 1 pharmacist employed currently and with 7 years experience in a hospital setting
- 1 pharmacist employed currently and with 7 years experience in a long-term care pharmacy setting;
- 1 Pharmacist currently engaged in and with at least 7 years of experience in the practice of sterile compounding;
- 1 Pharmacist from an academic or scholarly position with an institution of higher learning licensed by the commonwealth.

In addition, the Board will also include 1 pharmacy technician with 7 years of experience, a physician, a nurse, a member of the public with experience in health care service delivery, administration or consumer advocacy, 1 expert in patient safety and quality improvement (this individual may also be a pharmacist).

The Governor appoints board members for a term of 3 years beginning on the first day of the month following the member’s appointment. No member shall serve more than 2 consecutive terms but will be eligible for reappointment after not serving for at least 1 term. A member may serve up to 1 year as secretary and up to 1 year as president during any single term.

Members of the Board will be subject to the provisions in Mass General Laws Chapters 268A (code of conduct for public officials) and 268B (financial disclosure requirements of certain public officials) and a “more restrictive” code of ethics to be established by the Board and filed with State Ethics Commission.

SECTIONS 4 & 5. All agents (inspectors) must be trained in chapters 795 and 797 of the United States Pharmacopeia and the National Formulary and other courses as required by the Board.

SECTION 16. Removes the current law that states that if the board does not act on the registration application of a pharmacy within 150 days, the registration is automatically approved.
SECTION 20. Requires the board to participate in any national data reporting system which provides information on individual pharmacies, pharmacists and pharmacy technicians including, but not limited to, relevant databases maintained by the National Association of Boards of Pharmacy and the federal Food and Drug Administration.

SECTION 21. The board and board president to, without holding a hearing, suspend or refuse to renew a pharmacy license if the board or board president finds reasonable cause to believe that the health, safety or welfare of the public warrants this action. The board must, within 7 days of such action, afford the licensee the opportunity of a hearing. Any suspension imposed by the board or board president shall remain in effect until the conclusion of the proceedings, including any judicial review.

If, based upon evidence, the board or board president determines that a registrant or licensee or the drug preparations prepared by a registrant or licensee are an immediate threat to the public health, safety or welfare, the board or board president may: (i) issue a cease and desist notice or quarantine notice requiring the cessation or restriction of any and all pharmacy operations and prohibiting the use of medications prepared by or in possession of a pharmacy; or (ii) issue a cease and desist notice or quarantine notice placing non-disciplinary restrictions on a board registrant or licensee, to the extent necessary to avert a continued threat, pending final investigation results. The board shall promulgate regulations.

SECTION 14. The board must submit an annual report to the department of public health, the joint committee on public health and the joint committee on health care financing on or before December 31. The report shall detail the investigatory and disciplinary actions conducted by the board and the data gathered from reports by pharmacies and pharmacy managers of any improper dispensing that results in serious injury or death, any serious adverse drug events, and any recalls of compounded medications. The report will be made public and posted on the DPH website.

CONTINUING EDUCATION

SECTION 13. For all pharmacists license renewal will now require 20 hours of CE each calendar year of the 2-year renewal cycle. Any pharmacist overseeing or directly engaged in the practice of sterile compounding or practicing in a licensed specialty sterile compounding pharmacy must devote at least 5 of the 20 contact hours to the area of sterile compounding. Any pharmacist overseeing or directly engaged in the practice of complex non-sterile pharmaceutical compounding or practicing in a licensed specialty complex non-sterile compounding pharmacy shall devote at least 3 of the 20 contact hours to the area of complex non-sterile compounding.

The board will conduct audits of randomly selected renewed licenses. The name of licensees included in an audit shall be posted on the board’s website. Licensees who are not in compliance with the contact hour requirements or fail to provide the requested documentation within 7 days of receiving a request shall be fined not more than $1,000.
Section 42D of Chapter 112 is added and authorizes the Board to assess monetary penalties.

(Note: the implementation date of this section is 90 days after the date the bill was signed into law - July 10, 2014. However, the Board is likely to clarify this requirement and may push the implementation date to Jan. 2015.)

Section 18.
Creates 6 new sections of law.

(1) Chapter 112 39D: Contains important definitions such as:

“Compounding”, the preparation, mixing, assembling, packaging or labeling of 1 or more active ingredients with 1 or more other substances by or under the supervision of a licensed pharmacist within a licensed pharmacy to create a final drug preparation that is formulated:

(1) for use on or for a patient as a result of a practitioner’s prescription order, based on the relationship between the practitioner, patient and pharmacist in the course of routine professional practice to meet the unique medical need of an individual patient by producing a significant difference between the compounded drug preparation and a comparable commercially available drug that is justified by a documented medical need as determined by the prescribing practitioner including, but not limited to, the removal of a dye for medical reasons, a change in strength, a change in dosage, form or delivery mechanism; provided, that a price difference shall not be a significant difference to justify compounding;

(2) in anticipation of prescription orders based on routine, regularly-observed prescribing patterns which can be verified by accountability documentation; or

(3) for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing.

Except as provided in clause (1), “compounding” shall not include the preparation of commercially available, federal Food and Drug Administration approved drugs or drug preparations.

(Note: Unless addressed by regulation, the law does not allow for compounding of commercially available drugs when there is a shortage.)

“Compounded complex non-sterile drug preparation”, a compounded preparation which requires special training, a special environment or special facilities or equipment or the use of compounding techniques and procedures that may present an elevated risk to the compounder or the patient, as defined by the board through regulation; provided, that the regulations promulgated by the board, which are applicable to this definition, shall be consistent with the category of complex non-sterile compounding described in chapter 795 of the USP.

“Sterile drug preparation”, a compounded biologic, diagnostic, drug, nutrient or radiopharmaceutical, which under chapter 797 of the USP or the cGMP shall be compounded using aseptic techniques; provided, that "sterile drug preparation" may include, but shall not limited to, implants, injectables, parenteral nutrition solutions,
irrigation solutions, inhalation solution, intravenous solutions and ophthalmic preparations.

**High Volume & In Anticipation of a Prescription**
An entity that intends to compound and distribute a sterile drug preparation or a complex non-sterile drug preparation to pharmacies, wholesalers or prescribers within or outside of the commonwealth: (i) in anticipation of a prescription, (ii) in volumes inconsistent with routinely observed volume patterns associated with patient-specific prescriptions or (iii) in the absence of accountability documentation shall adhere to the most current standards established under cGMP when engaging in any form of compounding. **Such pharmacies shall obtain and hold a manufacturer’s license appropriate to this practice, from the federal Food and Drug Administration, before engaging in any sterile compounding or complex non-sterile compounding.**

A pharmacy shall not compound any drug preparations banned by the federal Food and Drug Administration because of safety concerns.

**RETAIL STERILE COMPOUNDING PHARMACY LICENSE**

(3) Chapter 112, section 39G
Establishes a retail sterile compounding pharmacy license. Good for one year; the facility must be inspected prior to renewal. The fee will be determined annually by the Secretary of Administration & Finance. The board shall conduct unannounced random and risk-based inspections of retail sterile compounding pharmacies licensed under this chapter, as well as the sterile drug preparations compounded by these pharmacies.

Retail sterile compounding pharmacies must report to the board, on an annual basis, a list of prescriptions dispensed within and outside of the commonwealth, and the volume of these prescriptions. A retail sterile compounding pharmacy that ships compounded drug preparations out of state must also report the names of the states to which the pharmacy has shipped sterile drug preparations.

The board shall establish a list of procedural criteria on which a retail sterile compounding pharmacy shall be evaluated at the time of inspection. The procedural criteria shall contain a predetermined list of standards and safeguards upon which a retail sterile compounding pharmacy shall be inspected, as well as a predetermined yet alternating list of variable criteria upon which the pharmacy may be inspected without prior notice as to which subset of these variable criteria shall be included in the inspection.

To renew, the licensee must certify that their employees have been trained in lean concepts, which are tools that assist in the identification and steady elimination of waste and promote continuous improvement in quality and efficiency.

The board **shall** establish supplementary regulations including, but not be limited to: (i) enhancing environmental monitoring procedures; (ii) enhancing media fill testing
procedures; (iii) enhancing non-sterile active pharmaceutical ingredient controls; (iv) enhancing procedures testing endotoxin and bioburden levels of sterile drug preparations; (v) enhancing procedures surrounding process validation and reproducibility of sterile drug preparations; (vi) enhancing procedures related to end stage testing of sterile drug preparations; (vii) enhancing procedures relating to the storage and beyond-use-dating of sterile drug preparations; (viii) enhancing the physical inspection process for finished sterile drug preparations; (ix) developing effective formulation records for retail sterile compounding pharmacies; (x) developing effective compounding records for sterile drug preparations produced at retail sterile compounding pharmacies; and (xi) developing effective procedures to maintain a drug preparation’s quality and control after the sterile drug preparation leaves the retail sterile compounding pharmacy.

RETAIL COMPLEX NON-STERILE COMPOUNDING PHARMACY LICENSE

(4) Chapter 112, section 39H
Establishes a retail complex non-sterile compounding pharmacy license. The requirements for licensure and renewal are the same as section 39G.

The board shall establish supplementary regulations for all retail complex non-sterile compounding pharmacies intending to compound or dispense complex non-sterile drug preparations in the commonwealth. The regulations shall include, but not be limited to: (i) enhancing non-sterile active pharmaceutical ingredient controls; (ii) enhancing procedures surrounding process validation and reproducibility of complex non-sterile drug preparations; (iii) enhancing procedures related to end stage testing of complex non-sterile drug preparations; (iv) enhancing procedures relating to the storage and beyond-use-dating of complex non-sterile drug preparations; (v) developing effective formulation records for retail complex non-sterile compounding pharmacies; and (vi) developing effective procedures to maintain a drug preparation’s quality and control after the complex non-sterile drug preparation leaves the retail complex non-sterile compounding pharmacy.

INSTITIONAL STERILE COMPOUNDING PHARMACY LICENSE

(5) Chapter 112, section 39I.
Establishes an institutional sterile compounding pharmacy license. The requirements for license and renewal are identical to those of section 39G (retail sterile compounding); and:

The board shall review current regulations applicable to institutional pharmacies and shall promulgate regulations for the administration of paragraphs (1), (2) and (3) of this subsection appropriate to the practice setting of entities subject to an institutional sterile compounding pharmacy license and which minimize regulatory and reporting duplication; provided, that no such regulation shall exempt an institutional sterile compounding pharmacy from compliance with the most current standards established by USP, all chapters.
SECTION 25. **Permits the board to issue a 1-time provisional license** for a period of not more than 1 year to an applicant for an initial pharmacy license in the categories of retail sterile, complex non-sterile, institutional sterile or non-resident, which is not in full compliance with applicable requirements but which the board finds is in substantial compliance with such requirements and demonstrates potential for achieving full compliance within the provisional licensure period. A provisional license issued to a pharmacy shall not be extended or renewed.

**NON-RESIDENT PHARMACY LICENSE**

(6) Chapter 112, section 39J.
Establishes a non-resident pharmacy license.

The board shall take steps to ensure that all shipments of pharmaceuticals from in-state pharmacies to out-of-state destinations are in compliance with the licensing procedures applicable to pharmacies in the commonwealth.

A non-resident pharmacy shall designate a pharmacist in charge who shall register with the board and shall be responsible for the pharmacy’s compliance with this chapter. Such pharmacist in charge shall be licensed and in good standing with the state board of registration in pharmacy in which the pharmacy is located.

The pharmacy shall notify the board of any enforcement or disciplinary action taken against the pharmacy regardless of the state in which the enforcement action is taken.

The designated pharmacist in charge shall certify to the board that the pharmacy maintains records of all drugs dispensed to patients in the commonwealth, and that these records are readily available, upon the request of the board. A list of drugs dispensed in the commonwealth shall be sent to the board annually.

No pharmacy or pharmacist operating outside of the state shall prescribe, ship, mail, sell, transfer or dispense drug preparations in the commonwealth unless the drug preparations are produced in a pharmacy that has been granted a non-resident license.

No pharmacy or pharmacist operating outside of the commonwealth shall be authorized to prescribe, ship, mail, sell, transfer or dispense sterile drug preparations or complex non-sterile drug preparations in the commonwealth unless the sterile drug preparations or complex non-sterile drug preparations are compounded in a pharmacy that has been granted a non-resident sterile compounding license or non-resident complex non-sterile compounding license.

Non-resident pharmacies must comply with the requirements of Chapter 94C, section 24A (the prescription monitoring program).
ADDITIONAL LICENSE CATEGORIES

SECTION 17. The board may establish specialty pharmacy licensure categories beyond those that currently exist and those established by this bill. The board may establish regulations that only apply to a particular licensure category.

SECTION 22. Creates 3 new sections in Chapter 112:

A PUBLIC SEARCHABLE WEBSITE

(1) Section 42B, requires that DPH develops and operates a searchable website, which includes:
   (i) copies of all enforcement action records of any pharmacy or pharmacist licensed by the department whether they are located within or outside of the commonwealth;
   (ii) copies of any records of serious adverse drug events, as defined in section 51H of chapter 111, and data relative to such events collected and reported pursuant to section 39D, suffered by a patient or user of medications as a result of their use of medication prepared, made or constituted by a pharmacy or pharmacist licensed by the board whether within or outside of the commonwealth;
   (iii) the names, locations and central points of contact for all licensed compounding pharmacies based in the commonwealth as well as licensed non-resident pharmacies shipping compounded drugs into the commonwealth; and
   (iv) any other relevant information specified by the commissioner.
   (c) The searchable website shall allow users to search electronically by field in a single search and shall allow users to parse, query or aggregate the data and download information yielded by a search. The website shall permit users to search by a particular pharmacy or pharmacist or by a specific medication.
   (d) The searchable website shall include and retain information for not less than 10 years.

LABELING REQUIREMENTS FOR COMPOUNDED DRUGS

SECTION 6. All compounded drug preparations must have a label notifying prescribed users and practitioners that the drug is either a sterile or non-sterile compounded drug preparation.

CUSTOMER SERVICE HOT LINE

Sterile compounding pharmacies must provide a customer service number 7 days a week for at least 56 hours per week (with an exception for hospitals that administer sterile drug preparations only to inpatients at that hospital). The telephone number must be affixed to the compounded drug preparation container.
RESTRICTIONS ON MARKETING

SECTIONS 10 & 11. Requires compounders to comply with the marketing code of conduct that govern the marketing and sale of prescription drugs or medical devices by a pharmaceutical or medical device manufacturer – see MGL Chapter 111N (the code of conduct was established with two goals in mind, (1) to limit sales and marketing activities between pharmaceutical and medical device manufacturers and health care providers that may influence prescribing patterns and/or adversely affect patient care, and (2) increase transparency with regard to industry interactions with health care providers, health care administrators (responsible for purchasing drugs and medical devices ) and health plan benefits administrators.

SERIOUS ADVERSE DRUG EVENTS

SECTION 7. The definition of a “Serious adverse drug event” in MGL section 51H of chapter 111 of the General Laws, as so appearing, is replaced with the following definition:

Serious adverse drug event, any untoward, preventable medical occurrence associated with the use of a drug in humans that results in any of the following outcomes: (i) death; (ii) a life-threatening outcome; (iii) inpatient hospitalization or prolongation of existing hospitalization; (iv) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; (v) a congenital anomaly or birth defect; or (vi) any other kind of harm as determined by the department in regulation; provided, however, that adverse medical occurrences directly associated with the use of a drug in humans that may not immediately result in 1 of the outcomes listed in clauses (i) to (vi), inclusive, may be considered a serious adverse drug event when they develop into or result in any of the outcomes listed in clauses (i) to (vi), inclusive.

SECTIONS 8 & 9. Requires any healthcare provider who discovers a serious adverse drug event resulting from use of any drug preparation, effective 12/31/14, to report the event to the federal Food and Drug Administration's MedWatch Program, as well as the pharmacy from which the drug was produced.

AN ADVISORY COMMITTEE TO THE BOARD

(2) Section 42C. Establishes an advisory committee to the board. The committee shall consist of the commissioner of public health or a designee and 7 members who shall be appointed by the commissioner: 1 of whom shall be an expert in chapter 71 of the USP; 1 of whom shall be an expert in chapter 795 of the USP; 1 of whom shall be an expert in chapter 797 of the USP; 1 of whom shall be an expert in cGMP for aseptic processing; 1 of whom shall be an expert in pharmacoeconomics; 1 of whom shall be an expert in clinical pharmacology; and 1 of whom shall be a microbiologist. At the request of the board, the commissioner may appoint additional members knowledgeable in the fields of
Each member of the advisory committee appointed by the commissioner shall serve for a term of 3 years. The advisory committee shall meet at least semi-annually but may meet as often as the members or the board shall determine or at such other intervals as established by the commissioner to fulfill its duties. Members of the advisory committee shall serve without compensation and shall be free of any liability incurred by their proposed recommendations to the board. The department of public health shall provide the advisory committee with support services. Any recommendation made by the advisory committee shall be posted on the department of public health’s website and a copy shall be transmitted to the clerks of the senate and house of representatives, who shall forward the report to the joint committee on public health and the joint committee on health care financing.

The advisory committee shall evaluate the practice of pharmacy across all settings and recommend to the board any new or revised regulations and policies necessary to improve the delivery of pharmacy services in the commonwealth. The committee shall advise the board: on the establishment of specialty pharmacy licensure categories; on the development of quality assurance, inspection and testing procedures applicable to compounding; on the application of accountability documentation requirements in licensed sterile pharmacies and complex non-sterile pharmacies; the development of regulations to supplement the USP, all chapters; and any other area as requested by the board.

The advisory committee will evaluate the volume and revenue of drug preparations generated by each licensed sterile compounding complex non-sterile compounding pharmacy and pharmacy in the commonwealth, provided, that any item of information which is confidential or privileged in nature or under any other law shall not be regarded as a public record.

The advisory committee shall monitor existing or potential shortages of medically necessary drug products and recommend to the board options available to the commonwealth to mitigate the impact of drug shortages on patients and providers when a sufficient clinical need or a threat to public health and safety exists.

SECTION 24. Requires DPH, in consultation with the board and the advisory committee to conduct an investigation of emerging models of coordinated, remote and shared pharmacy services, including but not limited to: central fill pharmacies; central processing pharmacies; outsourcing facilities; and telepharmacy.

The department shall issue a report indicating its support for or opposition to the adoption of certain pharmacy models in the commonwealth and identifying those elements of said models that should be promoted in support of the commonwealth’s efforts to promote efficient, cost-effective and patient-centered health care in community settings and within integrated care systems. The report shall also include recommendations for appropriate regulations and standards of practice necessitated by said models to ensure compliance
with state and federal pharmacy practice restrictions to safeguard patient safety in dispensing. The department shall file the report on its investigation, including its recommendations and drafts of any legislation, if necessary, by filing the same with the clerks of the senate and house of representatives who shall forward a copy of the report to the joint committee on public health and the joint committee on health care financing not later than December 31, 2015.

FINES

(3) Section 42D. Empowers the board to assess a licensed pharmacy a penalty of not more than $25,000 for each violation of regulations or administrative rules established pursuant to any general law that governs the practice of pharmacy. The board, through regulation, shall ensure that any fine levied is commensurate with the severity of the violation.

The board may assess a a penalty of not more than $1,000 for each violation for each day the violation continues to exist beyond the date prescribed for correction.

The board shall give the licensee an opportunity for a hearing upon a written request within 15 business days of the assessment.

An assessment made under this section shall be due 30 days after notification to the affected licensee, or 15 days after resolution of an administrative appeal. The attorney general shall recover any assessment due and deposited in the Quality in Health Professions Trust Fund used to support initiatives such as: patient safety and quality improvement programs for organizations under the jurisdiction of the division of health professions licensure; training for board and division staff; and to offset the costs of board business, including investigation, enforcement activities and investments in health information technology.

The board shall promulgate regulations for the administration of the fund.

WHISTLEBLOWER PROTECTIONS

SECTION 23. Provides employees of a pharmacy the whistleblower protections contained in section 187 of chapter 149.

REGULATION & EFFECTIVE DATE TIMELINE

The board of registration in pharmacy shall, in consultation with the department of public health and not later than December 31, 2014, promulgate regulations establishing the requirements for specialty licensure pursuant to sections 39G, 39H and 39J of chapter 112 of the General Laws.

The board of registration in pharmacy shall, in consultation with the department of public health and not later than June 30, 2015, promulgate regulations establishing the
requirements for specialty licensure pursuant to sections 39I of chapter 112 of the General Laws.

SECTION 28. Section 18 shall take effect on December 31, 2014; provided, however, that section 39I of chapter 112 of the General Laws shall take effect on June 30, 2015.

Section 42C of chapter 112 of the General Laws and sections 24, 26 and 27 shall take effect upon the passage of this act.

Everything else, not requiring regulation, or given its own effective date, will take effect 90 days after the date it is signed by the Governor.