HOUSE . . . . . No. 4235

The Commonwealth of Massachusetts

The committee of conference on the disagreeing votes of the two branches with reference to the Senate amendment (striking out all after the enacting clause and inserting in place thereof the text contained in Senate document numbered 1907) of the House Bill relative to pharmacy practice in the Commonwealth (House, No. 3672, amended), reports recommending passage of the accompanying bill (House, No. 4235). June 29, 2014.

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HOUSE . . . . . No. 4235

The Commonwealth of Massachusetts

In the Year Two Thousand Fourteen

An Act relative to pharmacy practice in the Commonwealth.

Whereas, The deferred operation of this act would tend to defeat its purpose, which is to enhance forthwith the safety of drug compounding in the commonwealth, therefore, it is hereby declared to be an emergency law, necessary for the immediate preservation of the public health.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Section 35X of chapter 10 of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by adding the following subsection:-

(e) There shall be deposited into the fund any monetary penalties collected pursuant to section 42D of chapter 112. Monetary penalties collected shall be held separately and used by the commissioner in accordance with the requirements of said section 42D.

SECTION 2. Chapter 13 of the General Laws is hereby amended by striking out section 22, as so appearing, and inserting in place thereof the following section:-

Section 22. (a) There shall be a board of registration in pharmacy, called the "board" in this section and sections 23 to 25A, inclusive. The governor shall appoint 13 members to the board. Members shall be residents of the commonwealth. No person who has been convicted of a felony or other crime involving embezzlement, theft, fraud or perjury shall serve as a member of the board. 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.

(b) The 8 registered pharmacists of the board shall each have had at least 7 consecutive years of experience in the practice of pharmacy and shall be currently employed in the practice of pharmacy in the commonwealth at the time of appointment or reappointment.

(c) At the time of appointment or reappointment to the board, at least 2 of the 8 registered pharmacist members shall be independent pharmacists employed in the independent pharmacy setting. For the purposes of this section, "independent pharmacist" shall mean a pharmacist actively engaged in the business of retail pharmacy and employed by an organization, which is registered under section 39 of chapter 112, has 9 or fewer registered retail drugstores in the commonwealth and employs not more than 20 full-time pharmacists.

(d) At the time of appointment or reappointment to the board, at least 2 of the 8 registered pharmacist members shall be chain pharmacists employed in the chain pharmacy setting. For the purposes of this section, "chain pharmacist" shall mean a pharmacist employed by a retail drug organization that operates 10 or more retail drug stores within the commonwealth and is registered under section 39 of chapter 112.

(e) At the time of appointment or reappointment to the board, at least 1 of the 8 registered pharmacist members shall have had at least 7 years of experience in a hospital setting within the commonwealth.

(f) At the time of appointment or reappointment to the board, at least 1 of the 8 registered pharmacist members shall have had at least 7 years of experience being employed in a long-term care pharmacy setting.

(g) At the time of appointment or reappointment to the board, at least 1 of the 8 registered pharmacist members shall have had at least 7 years of experience in the practice of sterile compounding, as defined in section 39D of chapter 112, and shall be engaged in sterile compounding as a routine function of the member's employment.

(h) At the time of appointment or reappointment to the board, at least 1 of the 8 registered pharmacist members shall be employed in an academic or scholarly position related to the practice of pharmacy with an institution of higher learning licensed by the commonwealth.

(i) Not more than 1 pharmacist in any 1 practice setting defined in subsections (e) and (f) may serve on the board at any 1 time. Not more than 2 pharmacists in any 1 practice setting defined in subsections (c) and (d) may serve on the board at any 1 time.

(j) At the time of appointment or reappointment to the board, the pharmacy technician member shall have had at least 7 years of practical experience as a pharmacy technician and shall be engaged in the practice of pharmacy as a routine function of the member's employment.

(k) At the time of appointment or reappointment to the board, no registered pharmacist or pharmacy technician shall have had any type of disciplinary or enforcement action taken against

them by the board, the federal Food and Drug Administration or the federal Drug Enforcement Administration during the 10 years preceding their appointment to the board.

(l) For the purposes of this section, "representative of the public" shall mean a person whose background and experience qualifies that person to act on the board in the public interest, including experience in health care service delivery, administration or consumer advocacy and who meets the requirements of paragraph (4) of subsection (a) of section 9B.

(m) At the time of appointment or reappointment to the board, no member of the board who is licensed to practice by the department of public health, division of professional licensure or by the board of registration in medicine shall have had any type of disciplinary or enforcement action taken against them by their respective licensing board, the federal Food and Drug Administration or the federal Drug Enforcement Administration during the 10 years preceding their appointment to the board.

(n) Board members shall be appointed and shall serve for a term of 3 years. The term shall begin on the first day of the month following the member's appointment. A member whose term has expired shall continue in office until a successor is appointed. No member shall serve more than 2 consecutive terms on the board. Members who have served the maximum number of consecutive terms shall be eligible for reappointment after not serving for at least 1 term.

(o) Board members may only be removed by the governor for reasonable cause of neglect of duty, misconduct, malfeasance or misfeasance in office. Prior to removal, the member shall be given written notice of the basis for removal and be afforded a hearing before the governor or a designee. The member may appear at the hearing with witnesses and be represented by counsel. The hearing shall be held within 21 days of the notice.

(p) Chapters 268A and 268B shall apply to the members of the board; provided, however, that the board shall establish a code of ethics, which shall be more restrictive than said chapters 268A and 268B, for all members, investigative agents appointed pursuant to section 25 and employees. A copy of the code shall be filed with the state ethics commission. The code shall include provisions reasonably necessary to carry out the purposes of this section and any other laws pertaining to the jurisdiction of the board including, but not limited to: (i) requiring the disclosure of any gifts received by board members by any person or entity subject to the jurisdiction of the board; (ii) prohibiting the participation by board members in a particular matter, as defined in section 1 of said chapter 268A, that affects the financial interest of a relative within the third degree of consanguinity or a person with whom the board member has a significant relationship as defined in the code; and (iii) providing for recusal of a board member in a licensing decision due to a potential conflict of interest.

SECTION 3. Section 23 of said chapter 13, as so appearing, is hereby amended by adding the following paragraph:-

A member may serve up to 1 year as secretary and up to 1 year as president during any single term.

SECTION 4. Section 25 of said chapter 13, as so appearing, is hereby amended by striking out, in line 1, the words “no more than six”.

SECTION 5. Said chapter 13 is hereby further amended by inserting after section 25 the following section:-

Section 25A. As directed by the board, all agents appointed pursuant to section 25 shall be trained in chapters 795 and 797 of the United States Pharmacopeia and the National Formulary as well as additional sterile compounding and non-sterile compounding surveyor courses. This training shall include, but not be limited to, programs offered free of charge by the National Association of Boards of Pharmacy.

SECTION 6. Section 21 of chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by adding the following 2 paragraphs:-

The labeling provisions of this section shall apply to the compounding and dispensing of drugs on the oral or written prescription of a licensed and registered prescriber under section 9. All drug preparations compounded, made or formulated by a pharmacy licensed by the board of registration in pharmacy shall have affixed to their container by the compounding pharmacy a label notifying prescribed users and practitioners that the drug is either a sterile or non-sterile compounded drug preparation.

All pharmacies engaged in sterile or complex non-sterile compounding and licensed under sections 39G to 39I, inclusive, of chapter 112 shall provide a telephone number to foster communication between patients in the commonwealth 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, alongside the label notifying prescribed users and practitioners of the fact that the drug is a compounded drug preparation. This paragraph shall not apply to an institutional pharmacy licensed pursuant to section 39I of chapter 112 if the sterile drug preparation compounded by such pharmacy is to be administered to an individual admitted as an inpatient within the same hospital.

SECTION 7. Subsection (a) of section 51H of chapter 111 of the General Laws, as so appearing, is hereby amended by striking out the definition of “Serious adverse drug event” and inserting in place thereof 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.

SECTION 8. Subsection (b) of said section 51H of said chapter 111, as so appearing, is hereby amended by adding the following sentence:- A facility that discovers a serious adverse drug event resulting from a patient's use, consumption or interaction with any pharmaceutical or drug preparation, shall report the event to the federal Food and Drug Administration's MedWatch Program, as well as the pharmacy from which the drug was produced, compounded or dispensed in addition to all other reporting requirements.

SECTION 9. Said section 51H of said chapter 111, as so appearing, is hereby further amended by inserting after the word "reduction", in line 29, the following words:- , the bureau of healthcare safety and quality within the department and the board of registration in pharmacy.

SECTION 10. Section 1 of chapter 111N of the General Laws, as so appearing, is hereby amended by inserting after the word "device", in line 15, the following words:- compounding or.

SECTION 11. The first paragraph of section 2 of said chapter 111N, as so appearing, is hereby amended by inserting after the first sentence the following sentence:- For the purposes of this section, an entity that is involved in pharmaceutical compounding shall also be subject to said marketing code of conduct.

SECTION 12. Section 24 of chapter 112 of the General Laws, as so appearing, is hereby amended by striking out the words "twenty-five to forty-two", in line 5, and inserting in place thereof the following words:- 25 to 42D.

SECTION 13. Section 24A of said chapter 112, as so appearing, is hereby amended by striking out the second paragraph and inserting in place thereof the following 3 paragraphs:-

The board shall require each registered pharmacist seeking personal registration renewal to complete continuing education requirements as a condition precedent to such renewal. No registrant shall be eligible for renewal of a personal registration without completion of the requisite number of contact hours for such renewal. A registrant seeking renewal of a personal registration shall complete a minimum of 20 contact hours each calendar year of the 2 year renewal cycle. Any pharmacist licensed by the commonwealth overseeing or directly engaged in the practice of sterile compounding or practicing in a pharmacy licensed pursuant to 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 section 39H shall devote at least 3 of the 20 contact hours to the area of complex non-sterile compounding.

The board shall, in addition to the requirements listed in this section, adopt further rules and regulations for a system of continuing education. The board shall accept all conferences and programs from providers approved by the Accreditation Council on Pharmacy Education meeting these requirements.

The board shall conduct audits of randomly selected renewed licenses. The board shall initiate the audit by sending selected licensees a request to provide documentation, which evidences the completion of the required contact hours. The name and date 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 14. Said chapter 112 is hereby further amended by inserting after section 25 the following section:-

Section 25A. The board shall 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 shall detail: (1) each complaint received by the board or initiated by the board; (2) the date of the complaint; (3) the violation alleged; (4) the name of any state or federal agency that collaborated with the investigation; (5) the summary of the final decision of the board to: (i) dismiss the complaint, (ii) impose an informal sanction or penalty, (iii) impose a formal sanction or penalty or (iv) amend a previously issued sanction or penalty; and (6) whether the board reported the result of its investigation to another state board, federal agency or external entity.

All relevant data collected and analyzed under subsections (b) to (e), inclusive, of section 39D shall be summarized and included in the report. The report shall be made available, including by electronic means, to the public and all hospitals, pharmacies and health care providers doing business in the commonwealth. Said report shall be posted on the department of public health's website.

SECTION 15. Section 32 of said chapter 112, as appearing in the 2012 Official Edition, is hereby amended by adding the following paragraph:-

The board shall participate in any national data reporting system that 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 16. The second paragraph of section 39 of said chapter 112, as so appearing, is hereby amended by striking out the second sentence.

SECTION 17. Said section 39 of said chapter 112, as so appearing, is hereby further amended by adding the following paragraph:-

The board may establish specialty pharmacy licensure categories beyond those delineated in this section, and in sections 39A to 39C, inclusive, and in sections 39G to 39J, inclusive, through the promulgation of regulations as deemed necessary by the board in consultation with the commissioner of public health. The board shall determine which regulations, applicable to a retail drug business registered pursuant to section 39, shall apply to a pharmacy registered pursuant to this section and may establish regulations that shall only apply to a licensure category established pursuant to this paragraph. The licensure fee shall be determined annually by the secretary of administration and finance under section 3B of chapter 7.

SECTION 18. Said chapter 112 is hereby further amended by striking out section 39D, as so appearing, and inserting in place thereof the following 6 sections:-

Section 39D. (a) As used in this section and in sections 39F to 42D, inclusive, the following words shall, unless the context clearly requires otherwise, have the following meanings:-

“Accountability documentation”, physical documentation validating the lot numbers and expiration dates or beyond-use dates of drugs or drug preparations with a patient drug prescription order from a practitioner listed in section 9 of chapter 94C; provided, that "accountability documentation" shall include evidence of receipt of patient-specific prescriptions prior to dispensing in accordance with section 17 of said chapter 94C. The purpose of accountability documentation shall be: to facilitate tracing of a complex non-sterile drug preparation or sterile drug preparation back to the pharmacy where it was compounded; identify the individual, pharmacy technician or automated compounding device that compounded the complex non-sterile drug preparation or sterile drug preparation; and identify the prescription order that generated the compounding of the complex non-sterile drug preparation or sterile drug preparation.

“Beyond-use date”, the date or time beyond which a drug preparation is not recommended to be dispensed, administered, stored or transported; provided, that the "beyond-use date" shall be determined from the date or time the drug preparation is compounded.

“cGMP”, Current Good Manufacturing Practice regulations enforced by the federal Food and Drug Administration.

“Complex non-sterile compounding”, engaging in the compounding of a complex non-sterile drug preparation.

"Complex non-sterile drug preparation", a compounded drug 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.

"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.

"Institutional pharmacy", the physical portion or satellite unit of an organization including, but not limited to, hospitals, health maintenance organizations and clinic pharmacies, whose primary purpose is to provide a physical environment for patients to obtain health care services under the supervision of a licensed pharmacist and is authorized to dispense controlled substances.

"Institutional sterile compounding pharmacy", an institutional pharmacy that prepares a sterile drug preparation.

"Manager of record" or "pharmacist in charge", a licensed pharmacist who signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of

pharmacy and the sale and dispensing of controlled substances. The manager of record shall personally supervise the pharmacy and pharmacy personnel as required by section 39.

"Non-resident pharmacy", any pharmacy located outside of the commonwealth that prescribes, ships, mails, sells or dispenses medications in the commonwealth.

"Pharmacy", any entity engaged in the drug business, as defined in section 37, or that engages in the practice of compounding to fulfill a practitioner prescription.

"Practitioner", a person who, under section 9 of chapter 94C, may prescribe or dispense controlled substances.

"Quality assurance", a set of activities used to ensure that compounding processes lead, with a high degree of assurance and certainty, to finished drug preparations meeting pre-determined specifications and standards of quality.

"Retail complex non-sterile compounding pharmacy", a retail pharmacy or facility that prepares a complex non-sterile drug preparation.

"Retail sterile compounding pharmacy", a retail pharmacy or facility that prepares a sterile drug preparation.

"Sterile compounding", engaging in the compounding of a sterile drug preparation.

"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.

"USP ", the current edition of the United States Pharmacopeia and the National Formulary.

(b) A pharmacy shall inform the department of public health of any improper dispensing of a prescription drug that results in serious injury or death, as defined by the department in regulations, as soon as is reasonably and practically possible, but not later than 7 business days after discovery of the improper dispensing.

(c) The manager of record of a pharmacy shall report any serious adverse drug event, as defined in section 51H of chapter 111, occurring as a result of the patient's interaction with any drug or pharmaceutical manufactured, produced or compounded at the manager of record's pharmacy, to the board, the federal Food and Drug Administration MedWatch Program and the Betsy Lehman center for patient safety and medical error reduction. This data shall be reported to the board within 7 business days of the knowledge of any serious adverse drug event by any pharmacy employee.

(d) All data concerning serious adverse drug events reported to the board shall be collected, synthesized and analyzed by the board in a traceable and easily navigable database format using information technology. The board shall use the data to track trends in serious adverse drug events and to warn patients, consumers and pharmacies of any trends which could pose a danger to public health and safety. Data collected pursuant to this subsection shall be made available on the searchable website established pursuant to section 42B.

(e) If a pharmacy knows or should have reason to know that a drug preparation compounded, dispensed or distributed by the pharmacy is or may be defective in any way, the pharmacy shall immediately recall the drug preparation. Any of the same drug preparation remaining in the possession of the pharmacy shall be located and segregated and shall not be distributed or dispensed. A defective drug preparation log documenting the recalled drug preparation shall be kept by the pharmacy including information on:

(1) the drug preparation name, potency and dosage form;

(2) the reason for the recall;

(3) the amount of the drug preparation made;

(4) the date that the drug preparation was made;

(5) the amount of the drug preparation dispensed or distributed;

(6) the actual drug preparation potency and dosage form; and

(7) any and all serious adverse drug events related to the drug preparation in question.

The defective drug preparation log shall be made available to the board within 7 days of the recall and shall be kept on record for at least 10 years. Upon submission of the defective drug preparation log to the board, the pharmacy shall work with the board to develop a corrective action plan that rectifies the error that resulted in the defective drug preparation.

(f) The department of public health shall promulgate regulations for the administration and enforcement of this section.

Section 39F. (a) A pharmacy shall not engage in sterile compounding nor shall a pharmacy prescribe, ship, mail, sell, transfer or dispense sterile drug preparations in the commonwealth unless the pharmacy has obtained a license from the board pursuant to section 39G, 39I or 39J.

(b) No pharmacy shall engage in complex non-sterile compounding nor shall a pharmacy prescribe, ship, mail, sell, transfer or dispense complex non-sterile drug preparations in the commonwealth unless the pharmacy has obtained a license from the board pursuant to section 39H or 39J.

(c) 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.

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

Section 39G. (a)(1) The board shall establish a category of pharmacy licensure for retail pharmacies engaged in sterile compounding. A retail sterile compounding pharmacy license issued by the board shall be obtained in addition to and not in place of any other permit or license a pharmacy holds.

(2) A retail sterile compounding pharmacy license shall be non-transferable and shall be renewed annually. The fee for the renewal shall be determined annually by the secretary of administration and finance pursuant to section 3B of chapter 7.

(3) A retail sterile compounding pharmacy license shall not be renewed until each location where a licensee compounds sterile drug preparations has been inspected by the board and found to be in compliance with this chapter and regulations adopted by the board. 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.

(4) A retail sterile compounding pharmacy licensed by the commonwealth shall adhere to the most current standards established by USP, all chapters, when engaging in any form of sterile compounding. Such pharmacy shall also adhere to the additional regulations promulgated by the board pursuant to subsection (c).

(5) All retail sterile compounding pharmacies shall report to the board, on an annual basis, a list of prescriptions dispensed within and outside of the commonwealth, as well as the volume of these prescriptions. A retail sterile compounding pharmacy that ships compounded drug preparations outside of the commonwealth shall, in addition to the requirements in this section, report to the board the names of the states to which the pharmacy has shipped sterile drug preparations.

(6) A retail sterile compounding pharmacy license shall not be renewed until the licensee certifies 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.

(b) A retail sterile compounding pharmacy shall designate a manager of record who shall:

(i) disclose to the board the location, name and title of all principal managers and the name and Massachusetts license number of the designated manager of record;

(ii) certify the retail sterile compounding pharmacy's compliance with reasonable informational requests made by the board;

(iii) certify to the board that the manager of record has fulfilled continuing education requirements for sterile compounding and ensured that all pharmacy staff has received the appropriate training and education required by law and regulation before engaging in compounding;

(iv) submit to the board the names and titles of all individuals employed by the pharmacy; and

(v) annually, and within 30 days after any change of office, corporate office or manager of record, file a report containing the information disclosed under clause (i).

(c)(1) 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.

(2) The board shall develop a quality assurance procedure for retail sterile compounding pharmacies to adhere to including, but not limited to, procedures to enhance physical inspection, compounding accuracy checks and sterility testing.

(3) The board shall establish supplementary regulations for all retail sterile compounding pharmacies intending to compound or dispense sterile drug preparations in the commonwealth. The regulations shall include, 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.

(4) The board shall promulgate regulations for the administration of paragraphs (1), (2) and (3) of this subsection, provided that no such regulation shall exempt a retail sterile compounding pharmacy from compliance with the most current standards established by USP, all chapters.

Section 39H. (a)(1) The board shall establish a category of pharmacy licensure for retail pharmacies engaged in complex non-sterile compounding. A retail complex non-sterile compounding pharmacy license issued by the board shall be obtained in addition to and not in place of any other permit or license a pharmacy holds.

(2) A retail complex non-sterile compounding pharmacy license shall be non-transferable and shall be renewed annually. The fee for the renewal shall be determined annually by the secretary of administration and finance pursuant to section 3B of chapter 7.

(3) A retail complex non-sterile compounding pharmacy license shall not be renewed until each location where a licensee compounds complex non-sterile drug preparations has been inspected by the board and found to be in compliance with this chapter and regulations adopted by the board. The board shall conduct unannounced random and risk-based inspections of all retail complex non-sterile compounding pharmacies licensed under this chapter, as well as the complex non-sterile drug preparations compounded by these pharmacies.

(4) A retail complex non-sterile compounding pharmacy licensed by the commonwealth shall adhere to the most current standards established by USP, all chapters, when engaging in any form of complex non-sterile compounding. Such pharmacy shall also adhere to the additional regulations promulgated by the board pursuant to subsection (c).

(5) All retail complex non-sterile compounding pharmacies shall report to the board, on an annual basis, a list of prescriptions dispensed within and outside of the commonwealth, as well as the volume of these prescriptions. A retail complex non-sterile compounding pharmacy that ships compounded drug preparations outside of the commonwealth shall, in addition to the requirements in this section, report to the board the names of the states to which the pharmacy has shipped complex non-sterile drug preparations.

(6) A retail complex non-sterile compounding pharmacy license shall not be renewed until the licensee certifies 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.

(b) A retail complex non-sterile compounding pharmacy shall designate a manager of record who shall:

(i) disclose to the board the location, name and title of all principal managers and the name and Massachusetts license number of the designated manager of record; (ii) certify the retail complex non-sterile compounding pharmacy's compliance with reasonable informational requests made by the board;

(iii) certify to the board that the manager of record has fulfilled continuing education requirements for complex non-sterile compounding and ensured that all pharmacy staff has received the appropriate training and education required by law and regulations before engaging in compounding; and

(iv) submit to the board the names and titles of all individuals employed by the pharmacy; and

(v) annually, and within 30 days after any change of office, corporate office or manager of record, file a report containing the information disclosed under clause (i)..

(c)(1) The board shall establish a list of procedural criteria on which a retail complex non-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 complex non-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.

(2) The board shall develop a quality assurance procedure for retail complex non-sterile compounding pharmacies to adhere to including, but not limited to, procedures to enhance physical inspection and compounding accuracy checks.

(3) 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.

(4) The board shall promulgate regulations for the administration of paragraphs (1), (2) and (3) of this subsection, provided that no such regulation shall exempt a retail complex non-sterile compounding pharmacy from compliance with the most current standards established by USP, all chapters.

Section 39I. (a) (1) The board shall establish a category of pharmacy licensure for institutional pharmacies engaged in sterile compounding. An institutional sterile compounding pharmacy license issued by the board shall be obtained in addition to and not in place of any other permit or license an entity operating an institutional pharmacy holds.

(2) An institutional sterile compounding pharmacy license shall be non-transferable and shall be renewed annually. The fee for the renewal shall be determined annually by the secretary of administration and finance pursuant to section 3B of chapter 7.

(3) An institutional sterile compounding pharmacy license shall be valid only for the premises and shall list the specific locations on the premises where a licensee compounds sterile drug preparations.

(4) The license shall not be renewed until each location where a licensee compounds sterile drug preparations has been inspected by the board and found to be in compliance with this chapter and regulations adopted by the board. The board shall conduct unannounced random and risk-based inspections of all institutional sterile compounding pharmacies licensed under this chapter, as well as the sterile drug preparations compounded by such pharmacies.

(5) An institutional sterile compounding pharmacy licensed by the commonwealth shall adhere to the most current standards established by USP, all chapters, when engaging in any form of sterile compounding. Such pharmacy shall also adhere to the additional regulations promulgated by the board pursuant to subsection (c).

(6) All institutional sterile compounding pharmacies shall report to the board, on an annual basis, a list of prescriptions dispensed within and outside of the commonwealth, as well as the volume of these prescriptions. An institutional sterile compounding pharmacy that ships compounded drug preparations outside of the commonwealth shall, in addition to the requirements in this section, report to the board the names of the states to which the pharmacy has shipped sterile drug preparations.

(7) The license shall not be renewed until the licensee certifies that their employees engaged in sterile compounding 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.

(b) An institutional sterile compounding pharmacy shall designate a manager of record who shall:

(i) disclose to the board the name, title and Massachusetts license number of all licensed pharmacists managing or supervising a specific location on the premises where a licensee compounds sterile drug preparations; (ii) certify the institutional sterile compounding pharmacy's compliance with reasonable informational requests made by the board;

(iii) certify to the board that the manager of record has fulfilled continuing education requirements for sterile compounding and ensured that all pharmacy staff has received the appropriate training and education required by law and regulations before engaging in compounding; and

(iv) submit to the board the names and titles of all individuals employed by the licensee engaged in sterile compounding;

(v) annually, and within 30 days after any change of office, corporate office or manager of record, file a report containing the information disclosed under clause (i)..

(c)(1) The board shall establish a list of procedural criteria on which an institutional 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 institutional 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.

(2) The board shall develop a quality assurance procedure for institutional sterile compounding pharmacies to adhere to including, but not limited to, procedures to enhance physical inspection, compounding accuracy checks and sterility testing.

(3) The board shall establish supplementary regulations for all institutional sterile compounding pharmacies intending to compound or dispense sterile drug preparations in the commonwealth. The regulations shall include, 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 compounded drug preparations; (v) enhancing procedures surrounding process validation and reproducibility of compounded 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 institutional sterile compounding pharmacies; (x) developing effective compounding records for drug preparations compounded by institutional sterile compounding pharmacies; and (xi) developing effective procedures to maintain a drug preparation's quality and control after the sterile drug preparation leaves the institutional sterile compounding pharmacy.

(4) 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 39J. (a) The board shall establish a procedure to license non-resident pharmacies, which prescribe, ship, mail, sell or dispense medications in the commonwealth, that pertains to the practice of pharmacy. The board shall also 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.

(b) 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.

(1) The designated pharmacist in charge shall disclose to the board the location, name and title of all principal managers and the name and Massachusetts license number of the designated pharmacist in charge, if applicable, and a letter from the in-state board of registration of pharmacy certifying that the pharmacist in charge is in good standing with the in-state board of registration. The designated pharmacist in charge shall submit a report containing this information and a copy of the certifying letter of good standing on an annual basis and within 30 days after any change of office, corporate office or manager of record.

(2) The designated pharmacist in charge shall certify to the board that the pharmacy maintains, at all times, a current unrestricted license, permit or registration to conduct the pharmacy in compliance with the laws and regulations of the jurisdiction in which it is licensed to practice. The pharmacy shall certify its compliance with reasonable informational requests made by the board. The pharmacy shall also notify the board of any enforcement or disciplinary action taken against the pharmacy regardless of the state in which the enforcement action is taken.

(3) 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.

(c) 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 pursuant to this section.

(d) 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 pursuant to this section.

(d) Non-resident pharmacies holding a non-resident pharmacy license under this section shall be subject to the requirements of section 24A of chapter 94C; provided, however, that non-resident pharmacies shall not be eligible for a waiver under said section 24A. An application for licensure under this section shall not be approved unless the applicant has demonstrated the ability to comply with said section 24A. The board may revoke a non-resident pharmacy license for failure to comply with said section 24A.

SECTION 19. Said chapter 112 is hereby further amended by striking out sections 41 and 42, as so appearing.

SECTION 20. Section 42A of said chapter 112, as so appearing, is hereby amended by inserting after the first paragraph the following paragraph:-

The board shall 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. Said section 42A of said chapter 112, as so appearing, is hereby further amended by adding the following 2 paragraphs:-

The board or board president may, 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 the summary action; provided, however, that the board shall, within 7 days of such action, afford the licensee the opportunity of a hearing pursuant to chapter 30A. Any suspension imposed by the board or board president shall remain in effect until the conclusion of the proceedings, including any judicial review thereof, unless sooner dissolved by a court of competent jurisdiction or withdrawn by the board.

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 pertaining to the issuance of cease and desist and quarantine notices.

SECTION 22. Said chapter 112 is hereby further amended by inserting after section 42A the following 3 sections:-

Section 42B. (a) For the purpose of this section, the following words shall, unless the context clearly requires otherwise, have the following meanings:-

"Enforcement action records", any documents issued by the department of public health to a pharmacy or pharmacist relating to an infraction or violation of a state or federal statute or regulation by the pharmacy or pharmacist; provided, that enforcement action records shall include, but not be limited to, consent decrees or judgments entered into between the department and a licensed pharmacy or pharmacist as a result of a charge or complaint filed by the department against a pharmacy or pharmacist for a statutory or regulatory violation or infraction or any other type of voluntary resolution of a charge or complaint filed by the department.

"Searchable website", a website that allows the public to search for and obtain, at no charge, enforcement action records and records of serious adverse drug events, as defined in section 51H of chapter 111, pertaining to pharmacies licensed by the commonwealth and other relevant information related to pharmacy licensure.

(b) The commissioner of public health shall develop and operate 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.

(e) The commissioner of public health shall update the searchable website as new data becomes available. All agencies or boards of the department of public health shall provide to the commissioner all data that is required to be included in the searchable website, not later than 30 days after the data becomes available to them. The commissioner shall provide guidance to agency or board heads to ensure compliance with this section.

(f) This section shall not be construed to require the disclosure of information of patients or users of medication that is confidential under state or federal law.

(g) The commissioner of public health shall be considered not in compliance with this section if the data required for the searchable website is not available in a searchable and aggregate manner or if the public is redirected to other government websites, unless each of those websites complies with the requirements of this section.

Section 42C. (a) There shall be 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 pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine or related specialties.

(b) Each member of the advisory committee appointed by the commissioner shall serve for a term of 3 years; provided, however, that additional members shall serve for a term determined by the commissioner not to exceed 3 years. Any person appointed to fill a vacancy on the committee shall serve for only the unexpired term of the member who vacated. Members shall be eligible for reappointment. A member of the committee appointed by the commissioner may be removed by the commissioner for cause. Members of the committee shall serve without compensation and shall be free of any liability incurred by their proposed recommendations to the board. 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. The department shall provide the advisory committee with support services necessary to complete needed research and analysis and enable the committee to make effective recommendations. 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.

(c) 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.

(d) The advisory committee shall 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. Nothing in this section shall authorize the committee to obtain individually identifiable patient information.

(e) 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 42D. (a) The board may 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.

(b) The board may assess a pharmacy, licensed pursuant to this chapter and ordered to correct a violation of regulations or administrative rules established under any general law that governs the practice of pharmacy, 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.

(c) Upon making an assessment, the board shall give the licensee notice of the matters alleged and the law relied upon and shall afford the licensee an opportunity for a hearing upon a written request within 15 business days of the assessment. If after a hearing, or if the licensee waives the licensee’s right to a hearing, the board determines that cause exists, the board shall make an appropriate assessment. The affected licensee shall pay such assessment except to the extent that, upon judicial review, the reviewing court may reverse the final decision of the board.

(d) 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 payable brought in the name of the commonwealth in the

superior court. Funds collected pursuant to subsection (b) shall be paid as described in subsection (c). Assessments collected pursuant to this section shall be deposited in the Quality in Health Professions Trust Fund established by section 35X of chapter 10 and shall be 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, in consultation with the division, including the establishment of eligibility criteria, program requirements and assessment and reporting processes.

SECTION 23. Section 187 of chapter 149 of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after the word "community health agency", in line 6, the following word:- , pharmacy.

SECTION 24. Notwithstanding any general or special law to the contrary, the department of public health, in consultation with the board of registration in pharmacy and the advisory committee established by section 42C of chapter 112 of the General Laws, shall 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 also 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.

SECTION 25. Notwithstanding any general or special law to the contrary, the board of registration in pharmacy may issue a 1-time provisional license for a period of not more than 1 year to an applicant for an initial pharmacy license issued pursuant to sections 39G to 39J, inclusive, of chapter 112 of the General Laws, 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.

SECTION 26. 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.

SECTION 27. 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 29. Section 42C of chapter 112 of the General Laws and sections 24, 26 and 27 shall take effect upon the passage of this act.

SECTION 30. Unless otherwise provided, this act shall take effect 90 days after the effective date.