SENATE . . . . . No. 1907

Senate, October 30, 2013 – Text of the Senate amendment to the House Bill relative to pharmacy practice in the Commonwealth (House, No. 3672, amended),-- being the text of (Senate, No. 1899, printed as amended).

Commonwealth of Massachusetts

In the Year Two Thousand Thirteen

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; provided, however, any 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 who 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 an independent pharmacist 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 who is 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 a chain pharmacist 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 compounding sterile drug preparations, as defined in section 39D of chapter 112, and shall be engaged in compounding sterile drug preparations 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) to (g), inclusive, may serve on the board at any one 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 actually 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) At the time of appointment or reappointment to the board, no member of the board licensed to practice by the department of public health division of health professions 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.

(m) 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. No member may 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.

(n) 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.

(o) Chapters 268A and 268B shall apply to the members of the board; provided, however, that the board shall establish a code of ethics for all members, investigative agents appointed pursuant to section 25 and employees, which shall be more restrictive than said chapters 268A and 268B. A copy of the code shall be filed with the state ethics commission. The code shall include provisions reasonably necessary to carry out 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 National Formulary as well as additional sterile compounding and complex 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 3 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. The label shall also notify prescribed users if the compounded preparation has not been tested or approved by the federal Food and Drug Administration or if the compounded preparation does not meet federal Food and Drug Administration good manufacturing guidelines. In such instances, the label shall notify prescribed users to contact their prescribing health care professional if the prescribed user has any questions.

A compounding pharmacy shall affix a label, which notifies prescribed users and practitioners that the drug is either a sterile or non-sterile compounded drug preparation, to the container of all compounded drug preparations compounded, made or formulated by a retail or hospital pharmacy that is licensed by the board of registration in pharmacy.

All sterile compounding pharmacies and complex non-sterile compounding pharmacies, as defined in section 39D of chapter 112, shall provide a telephone number to patients 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 a hospital pharmacy engaged in sterile compounding or complex non-sterile compounding.

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 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.

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. Of the 20 contact hours effective for the renewal period beginning January 1, 2014 any pharmacist licensed by the commonwealth overseeing or directly engaged in the practice of sterile pharmaceutical compounding or practicing in a licensed specialty sterile

compounding pharmacy shall devote at least 5 of the 20 contact hours to the area of sterile compounding. Of the 20 contact hours effective for the renewal period beginning January 1, 2014 any pharmacist licensed by the commonwealth 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, in consultation with the advisory committee, established by section 42C, 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 for 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) through (e), inclusive, of section 39D shall be summarized and included in the report. The report shall be made publicly available, including by electronic means, to 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 39F to 39I, inclusive, through the promulgation of regulations as the board, in consultation with the commissioner of public health, deems necessary. 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 5 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 of drugs or preparations with a patient drug prescription order from a practitioner listed in section 9 of chapter 94C. The purpose of accountability documentation shall be to: facilitate the tracing of a compounded complex non-sterile drug preparation or compounded sterile drug preparation back to the compounding pharmacy where it was produced; identify the individual, pharmacy technician or automated compounding device that produced the drug; and identify the prescription order that generated the production or compounding of the drug preparation.

"Complex non-sterile compounding", engaging in the compounding of complex non-sterile drug preparation.

"Complex non-sterile compounding pharmacy", any retail or hospital pharmacy or facility where a compounded complex non-sterile drug preparation is compounded or manufactured.

"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.

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

"Compounding", the preparation, mixing, assembling, packaging or labeling of 1 or more active ingredients with 1 or more other substances towards a final drug preparation by a pharmacist within a permitted pharmacy only:

(1) formulated for use on or for a patient as a result of a practitioner's prescription drug 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 of the practitioner;

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

(3) in anticipation of prescription orders based on routine, regularly observed prescribing patterns, which can be verified through accountability documentation.

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

“Facility”, any entity engaged in the drug business, as defined in section 37, or that engages in the practice of compounding and dispensing drug preparations for the purpose of fulfilling a practitioner prescription.

“Manager of record”, 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.

“Practitioner”, a person who is authorized under section 9 of chapter 94C to prescribe or dispense controlled substances.

“Quality assurance”, a set of activities used to ensure that processes used in the preparation of non-sterile or sterile compounded drug preparations lead, with a high degree of assurance and certainty, to finished drug preparations meeting predetermined specifications and standards of quality.

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

“Sterile compounding pharmacy”, any retail or hospital pharmacy or facility, where a compounded sterile drug preparation is compounded or manufactured.

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

(b) A store or pharmacy engaged in the drug business shall inform the department of public health of any improper dispensing of prescription drugs 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 3 business days after discovery of the improper dispensing.

(c) The manager of record of a store or pharmacy shall report any serious adverse drug event, as defined in section 51H of chapter 111, occurring as a result of patient interaction with any drug or pharmaceutical preparation manufactured, produced or compounded at the manager of record's pharmacy, to the federal Food and Drug Administration MedWatch Program and the Betsy Lehman center for patient safety and medical error reduction. The manager of record of a store or pharmacy shall report to the board any serious adverse drug event, as defined in section 51H of chapter 111, occurring as a result of patient interaction with any drug or pharmaceutical preparation manufactured, produced or compounded at the manager of record's store or pharmacy that is suspected to be caused by the drug preparation, drug compounding or other pharmacist error. This data shall be reported to the board within 3 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 sterile compounding pharmacy or complex non-sterile compounding pharmacy knows or should have reason to know that a compounded sterile drug preparation or compounded complex non-sterile drug preparation dispensed or distributed by the pharmacy is or may be defective in any way, the pharmacy shall immediately recall the preparation. Any of the same preparation remaining in the possession of the pharmacy shall be located and segregated,

and shall not be distributed or dispensed. A defective preparation log documenting the recalled preparation shall be kept by the pharmacy including information on:

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

(2) the reason for the recall;

(3) the amount of the preparation made;

(4) the date that the preparation was made;

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

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

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

The defective preparation log shall be made available to the board within 7 days of the recall. Defective preparation logs shall be kept on record by the board indefinitely and shall be kept on record by the pharmacy for at least 10 years. Upon submission of the defective 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 preparation.

(f) The advisory committee, established by section 42C, shall make recommendations to the department for hospital based accountability documentation, taking into account various factors including, but not limited to, the current state of technology of electronic medication administration records and automated medication dispensing machines as they apply to the inclusion of lot numbers of sterile and complex non-sterile compounded drug preparations in patient records and documentation. The recommendations should further the goal of incorporating accountability documentation into the current technology of electronic medication administration record systems and automated medication dispensing machines.

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

Section 39F. (a) The board shall establish a category of pharmacy licensure for pharmacies engaged in the practice of compounding sterile drug preparations. A pharmacy shall

not engage in sterile compounding nor shall a pharmacy prescribe, ship, mail, sell, transfer or dispense sterile compounded drug preparations in the commonwealth unless the pharmacy has obtained a sterile compounded drug preparations specialty license from the board pursuant to this section.

(b) A sterile compounded drug preparations specialty license issued by the board shall be obtained in addition to and not in place of any other permit or license a sterile compounding pharmacy holds. The 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.

(c) A pharmacy licensed by the commonwealth that intends to compound sterile drug preparations and dispense compounded sterile drug preparations in or out of the commonwealth shall adhere to regulations promulgated by the board pursuant to subsection (g) of section 39H, in consultation with the advisory committee, established by section 42C.

(d) A pharmacy licensed by the commonwealth that intends to compound and distribute compounded sterile drug preparations to pharmacies, wholesalers or prescribers in or out of the commonwealth: (i) in anticipation of a prescription, in volumes inconsistent with routinely observed volume patterns associated with patient-specific prescriptions, or (ii) in the absence of accountability documentation, shall adhere to the most current standards established under cGMP when engaging in any form of sterile 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 and shall notify the board of the acquisition, renewal or revocation of the license, as applicable, within 30 days of the action.

(e) This section shall not apply to a hospital pharmacy engaging in compounded sterile drug preparations.

(f) A pharmacy shall not compound sterile drug products that are essentially copies of commercially available, federal Food and Drug Administration-approved drug preparations or drug preparations banned by the federal Food and Drug Administration because of safety concerns. A drug product shall not be considered a copy of a commercially available preparation if the compounded preparation produces, for the patient, a significant difference between the

compounded drug and the comparable commercially available drug preparation, as determined by the prescriber as necessary for the medical best interest of the patient. A significant difference may include, but shall not be limited to, the removal of a dye for medical reasons, a change in strength, dosage form or delivery mechanism. A price difference shall not be a significant difference to justify compounding.

Section 39G. (a) The board shall establish a category of pharmacy licensure for pharmacies engaged in the practice of compounding complex non-sterile drug preparations. A pharmacy shall not engage in complex non-sterile compounding nor shall a pharmacy prescribe, ship, mail, sell, transfer or dispense complex non-sterile compounded drug preparations in the commonwealth unless the pharmacy has obtained a complex non-sterile compounded drug preparations specialty license from the board pursuant to this section.

(b) A complex non-sterile compounded drug preparations specialty license issued by the board shall be obtained in addition to and not in place of any other permit or license a sterile compounding pharmacy holds. The 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.

(c) A pharmacy licensed by the commonwealth that intends to compound complex non-sterile drug preparations and dispense compounded complex non-sterile drug preparations in or out of the commonwealth shall adhere to regulations promulgated by the board pursuant to subsection (g) of section 39H, in consultation with the advisory committee, established by section 42C.

(d) A pharmacy licensed by the commonwealth that intends to compound and distribute compounded complex non-sterile drug preparations to pharmacies, wholesalers or prescribers in or out of the commonwealth: (i) in anticipation of a prescription in volumes inconsistent with routinely observed volume patterns associated with patient-specific prescriptions, or (ii) in the absence of accountability documentation shall adhere to the most current standards established under cGMP when engaging in complex non-sterile 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 complex non-sterile compounding and shall notify the

board of the acquisition, renewal or revocation of the license, as applicable, within 30 days of the action.

(e) This section shall not apply to a hospital pharmacy engaging in compounded complex non-sterile drug preparations.

(f) A pharmacy shall not compound complex non-sterile drug products that are essentially copies of commercially available, federal Food and Drug Administration-approved drug preparations or drug preparations banned by the federal Food and Drug Administration because of safety concerns. A drug product shall not be considered a copy of a commercially available preparation if the compounded preparation produces, for the patient, a significant difference between the compounded drug and the comparable commercially available drug preparation, as determined by the prescriber as necessary for the medical best interest of the patient. A significant difference may include, but shall not be limited to, the removal of a dye for medical reasons, a change in strength, dosage form or delivery mechanism. A price difference shall not be a significant difference to justify compounding.

Section 39H. (a) A specialty license to compound or sell compounded sterile drug preparations or compounded complex non-sterile drug preparations in the commonwealth shall not be renewed until each location where a licensee produces the sterile compounding drug preparations or compounded complex non-sterile drug preparations has been inspected by the board and found to be in compliance with this chapter and applicable regulations adopted by the board.

(b) The board shall conduct unannounced random and risk-based inspections of all sterile compounding pharmacies and compounded complex non-sterile drug preparation pharmacies licensed under this chapter to compound sterile drug preparations or compounded complex non-sterile drug preparations, as well as the compounded sterile drug preparations or compounded complex non-sterile drug preparations produced by these pharmacies.

(c) The board shall establish a list of procedural criteria to evaluate a sterile compounding pharmacy and a list of procedural criteria to evaluate a complex non-sterile compounding pharmacy at the time of the inspection. The procedural criteria shall contain a predetermined list of standards and safeguards upon which a sterile compounding pharmacy or

complex non-sterile compounding pharmacy, as applicable, shall be inspected, as well as a pre-determined yet alternating list of variable criteria. The pharmacies may be inspected without prior notice as to which subset of these variable criteria will be included in the inspection. The unannounced and random inspection of compounded sterile drug preparations shall include, at a minimum, testing for sterility of the products, conducted either on or off-site and the potency of the products. The unannounced and random inspection of a sterile compounding pharmacy, licensed under this chapter, shall include an inspection of the pharmacy's records regarding the manufacturer, supplier and point of origin of all materials and ingredients used in the pharmacy's sterile compounded drug preparations. All sterile compounding pharmacies licensed under this chapter shall be required to maintain such records as a condition of their specialty license to compound or sell sterile compounded drug preparations.

(d) The board shall, in consultation with the advisory committee, established by section 42C, develop a quality assurance procedure for sterile compounding pharmacies to adhere to including, but not limited to, procedures to enhance physical inspection, compounding accuracy checks and sterility testing. The board shall also, in consultation with the advisory committee, established by section 42C, develop a quality assurance procedure for complex non-sterile compounding pharmacies to adhere to including, but not limited to, procedures to enhance physical inspection and compounding accuracy checks.

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

(f) Sterile compounding pharmacies and complex non-sterile compounding pharmacies shall designate a manager of record who shall be responsible for the pharmacy's compliance with this chapter and shall:

(1) 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. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate office or manager of record.

(2) Certify the pharmacy's compliance with reasonable informational requests made by the board.

(3) Certify to the board that the manager of record has fulfilled continuing education requirements for sterile compounding and ensured that all pharmacy staff engaging in compounding have received the appropriate training and education required by law and regulations.

(4) Submit to the board the names and titles of all individuals employed by the pharmacy.

(g) The board shall establish regulations for all pharmacies intending to compound or dispense sterile or complex non-sterile drug preparations in the commonwealth. The board shall establish regulations in consultation with the advisory committee, established by section 42C. The regulations shall include, but not be limited to: (1) enhancing environmental monitoring procedures; (2) enhancing media fill testing procedures; (3) enhancing non-sterile active pharmaceutical ingredient controls; (4) enhancing procedures testing endotoxin and bioburden levels of compounded drug preparations; (5) enhancing procedures surrounding process validation and reproducibility of compounded drug preparations; (6) enhancing procedures related to end stage testing of compounded drug preparations; (7) enhancing procedures relating to the storage and beyond-use-dating of compounded drug preparations; (8) enhancing the physical inspection process for finished sterile compounded drug preparations; (9) developing effective formulation records for sterile compounding pharmacies; (10) developing effective compounding records for compounded drug preparations produced at sterile compounding pharmacies; and (11) developing effective procedures to maintain a preparation's quality and control after the compounded sterile or complex non-sterile drug preparation leaves the pharmacy. Said regulations shall not conflict with chapters 795 and 797 of the USP, but may be more expansive than those chapters of the USP.

Section 39I. (a) The board shall establish a procedure to license non-resident or out-of-state pharmacies located outside of the commonwealth that 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) The non-resident or out-of-state pharmacies shall designate a pharmacist in charge who shall register with the board and shall be responsible for the pharmacy's compliance with this section. The 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 designated pharmacist in charge shall:

(1) Disclose to the board the location, name and title of all principal managers and the name 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) 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) Maintain its records of all drugs dispensed to patients in the commonwealth and ensure 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 be authorized to prescribe, ship, mail, sell, transfer or dispense drug preparations in to the commonwealth unless

the drug preparations are produced in a pharmacy that has been granted a non-resident or out-of-state 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 compounded sterile or complex non-sterile drug preparations in the commonwealth unless the compounded sterile or complex non-sterile drug preparations are produced in a pharmacy or facility that has been granted a non-resident or out-of of-state compounded sterile or complex non-sterile drug preparations license pursuant to this section.

(e) Out-of-state pharmacies holding an out-of-state license under this section shall be subject to the requirements of section 24A of chapter 94C; provided, however, that non-resident or out of state pharmacies shall not be eligible for any 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 or out-of-state pharmacy license for failure to comply with said section 24A.

SECTION 18A. Subsection (e) of section 39F of said chapter 112 is hereby repealed.

SECTION 18B. Subsection (e) of section 39G of said chapter 112 is hereby repealed.

SECTION 19. Section 41 of said chapter 112 is hereby repealed.

SECTION 19A. Section 42 of said chapter 112 is hereby repealed.

SECTION 20. Section 42A of chapter 112 of the General Laws, as appearing in the 2012 Official Edition, 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 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. These 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:

(1) copies of all enforcement action records of any pharmacy or pharmacist licensed by the department whether they are located within or without the commonwealth;

(2) copies of any records of serious adverse drug events, as defined in section 51H of chapter 111, reported to the board, pursuant to section 39D, and data related to the event 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 without the commonwealth;

(3) the names, locations and central points of contact for all licensed compounding pharmacies based in the commonwealth as well as licensed out-of-state pharmacies shipping compounded drugs into the commonwealth; and

(4) any other relevant information specified by the commissioner.

(c) The searchable website shall allow users to search electronically by field in a single search, 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 pharmacists 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 not be considered 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. There shall be an advisory committee to the board, which shall consist of the following members, to be appointed by the commissioner of public health: an expert in chapter 795 of the USP; an expert in chapter 797 of the USP; an expert in chapter 71 of the USP; an expert in cGMP for aseptic processing; an expert in pharmacoeconomics; an expert in clinical pharmacology; and a microbiologist. The advisory committee shall consist of additional members, as determined by the board, at least 1 of whom shall be a member of the public with experience in health care service delivery, administration or consumer advocacy.

The advisory committee shall advise the board regarding proposed regulations on quality assurance and the inspection and testing of compounded drug preparations. The advisory committee shall advise the board regarding proposed regulations to supplement the current form of chapters 795 and 797 of the USP. The advisory committee shall evaluate current trends in pharmacy in the commonwealth, as well as recommended improvements to pharmacy practice in the commonwealth. The advisory committee shall evaluate the volume and revenue of drug preparations generated by each licensed sterile compounding pharmacy in the commonwealth. The advisory committee shall study the feasibility of a centralized reporting system for serious adverse drug events and other serious reportable events which shall be administered by the department of public health for the purposes of allowing pertinent state agencies, providers, health systems, pharmacies, licensed compounding pharmacies and other relevant health care entities, as defined by the department of public health in regulation, to utilize this resource to further improve their internal quality initiatives and reduce patient safety concerns. 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.

The advisory committee shall investigate the causes of drug shortages and their relation to the market for compounded drugs in the commonwealth. The advisory committee shall

determine an approach to address potential drug shortages when a sufficient clinical need or a threat to public health and safety exists.

Section 42D. (a) The board of registration in pharmacy 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 regulations, 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, which were 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 provisions of law relied upon and shall accord 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 on the thirtieth day after notification to the licensee, or on the fifteenth day 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, there shall be a special commission to study and report on the feasibility of the establishment of central fill pharmacies in the commonwealth. The commission shall study and make recommendations relative to: (i) licensing central fill pharmacies for the purpose of compounding and distributing compounded drug preparations within a network of hospitals under common ownership; (ii) the current national use of central fill pharmacies; (iii) establishing a state-administered central fill pharmacy; (iv) recommendations for additional specialty licenses, pursuant to section 39 of chapter 112 of the General Laws, for alternate forms of central fill pharmacy licensure; (v) the projected resource allocation by the department of public health needed to implement the recommended licensure attributes; (vi) the projected resource allocation by the department needed to implement a state-administered central fill pharmacy for the purposes of compounding and distributing compounded drug preparations for hospitals in the commonwealth; and (vii) any additional recommendations related to staffing and appropriations necessary to carry out preceding recommendations.

The special commission shall consist of: the commissioner of the department of public health, or a designee, who shall serve as the chair of the committee; the co-chairs of the joint committee on public health; 1 member of the house of representatives who shall be appointed by the minority leader; 1 member of the senate who shall be appointed by the minority leader; and 7 members who shall be appointed by the governor, 1 of whom shall have experience with central fill pharmacies, 1 of whom shall be a representative of hospitals, 1 of whom shall be an expert in health economics, 1 of whom shall be a representative of pharmacy technicians, 1 of whom shall be an expert in pharmacy compounding, 1 of whom shall be a member of the public with experience in health care service delivery, regulation or consumer advocacy and 1 of whom shall be a licensed pharmacist.

The special commission shall report to the general court the results of its investigation and study and its recommendations, if any, together with drafts of legislation necessary to carry out its recommendations by filing the same with the clerks of the senate and house of representatives, who shall forward the same to the joint committee on public health and the house and senate committees on ways and means, not later than January 1, 2015.

SECTION 25. The department of public health shall identify pharmacies engaged in moderate non-sterile compounding through self-attestations, validation of those self-attestations and inspection. The department shall also provide a report on its findings to the general court. Such report shall be filed with the clerks of the senate and house of representatives who shall forward the same to the joint committee on public health and the house and senate committees on ways and means, not later than July 1, 2014.

SECTION 26. The department of public health, in consultation with the advisory committee, shall study the status of moderate non-sterile compounding and make recommendations on the feasibility, costs and implementation of licensure for moderate non-sterile compounding. The report shall provide the following information: (i) the staffing and resource needs for the licensure of moderate non-sterile compounding pharmacies; (ii) the current levels of moderate non-sterile compounding pharmacies in the state; (iii) proposed licensure structures; and (iv) projected costs of such licensure. The department shall provide its findings in a report to be filed with the clerks of the senate and house of representatives, who shall forward the same to the joint committee on public health and the house and senate committees on ways and means, not later than January 1, 2015.

SECTION 27. The board of registration in pharmacy, shall, in consultation with the department of public health and the advisory committee, established by section 42C of chapter 112 of the General Laws, consider and review current operational practices in place at hospital pharmacies and recommend any necessary exemptions for a hospital pharmacy to ensure consistency with pertinent federal and state statutory and regulatory requirements related to hospital pharmacies engaged in compounding under a sterile compounding pharmacy or a complex non-sterile compounding pharmacy specialty license, or both.

The board, in consultation with department of public health and the advisory committee, shall promulgate regulations based on these considerations and recommendations, not later than July 1, 2015. The board, in consultation with the department of public health and the advisory committee, shall promulgate regulations, requiring a hospital pharmacy to affix a label, to the maximum extent feasible, to notify prescribed users and practitioners that the drug is either a sterile or non-sterile compounded drug preparation.

SECTION 28. The department of public health shall review the practice of providing samples of compounded drugs as provided under chapter 111N of the General Laws and provide recommendations for any specific amendments as related to the provisions set forth under said chapter 111N. The department shall report to the general court the results of its study and its recommendations, if any, together with drafts of legislation necessary to carry its recommendations, by filing the same with the clerks of the senate and house of representatives, who shall forward the same to the joint committee on public health and the house and senate committees on ways and means, not later than January 1, 2015.

SECTION 28A. The advisory committee, established by section 42C of chapter 112 of the General Laws, in consultation with the board of registration in pharmacy and the department of public health, shall study the criteria used to test compounded sterile drug preparations, as defined under section 39D of said chapter 112, including, but not limited to, the feasibility of unannounced and random inspections of sterile compounding pharmacies for the efficacy of compounded sterile drug preparations. The advisory committee shall submit its findings in a report, together with any drafts of legislation necessary to carry out its recommendations, 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 not later than August 15, 2014.

SECTION 29. Notwithstanding any general or special law to the contrary, the initial report, as required by section 25A of chapter 112 of the General Laws shall detail the investigatory and disciplinary actions conducted by the board of registration in pharmacy from September 1, 2012 through December 1, 2013.

SECTION 29A. The board of registration in pharmacy shall, in consultation with the department of public health and the advisory committee, established by section 42C of chapter 112 of the General Laws, study the merits of establishing specialty pharmacy certificates of registration for those persons already actively registered as a pharmacist. Said study shall consider issuing to those registered pharmacists qualified by experience, knowledge and integrity specialty licenses for those specialties delineated in sections 39 to 39C, inclusive, of said chapter 112 and in sections 39F to 39G, inclusive, of said chapter 112 or any other specialty area deemed appropriate. Said study shall consider the appropriate scope of practice for pharmacists engaged in said specialties and the development of a system requiring specialty pharmacy certificates of registration to practice within a specialty delineated in one or any of the specialties in said sections 39 to 39C, inclusive, of said chapter 112 or said sections 39F to 39G, inclusive, of said chapter 112.

The board, in consultation with the department of public health and the advisory committee, shall report to the general court the results of its recommendations, if any, together with drafts of legislation necessary to carry its recommendations, by filing said report and recommendations with the clerks of the house of representatives and senate and the joint committee on public health not later than December 31, 2014.

SECTION 30. The department of public health shall promulgate regulations as necessary to implement sections 24A, 39D, 39F, 39G, 39H and 42A of chapter 112 of the General Laws not later than 180 days after the passage of this act.

SECTION 31. Sections 18A and 18B shall take effect July 1, 2015.

SECTION 32. Unless otherwise provided this act shall take effect 180 days after its passage.

SECTION 33. Sections 27, 28A, 29A and 30 shall take effect upon the passage of this act.

SECTION 34. Section 42C of chapter 112 of the General Laws shall take effect upon the passage of this act.