HOUSE . . . . . No. 3600

The Commonwealth of Massachusetts

HOUSE OF REPRESENTATIVES, July 29, 2013.

The committee on Health Care Financing to whom was referred the Bill relative to pharmacy practice in the Commonwealth (House, No. 3548), reports recommending that the bill ought to pass with an amendment substituting therefor the accompanying bill (House, No. 3600) [Cost: Greater than $100,000.00].

For the committee,

STEVEN M. WALSH.

HOUSE . . . . . No. 3600

The Commonwealth of Massachusetts

In the Year Two Thousand Thirteen

An Act relative to Pharmacy Practice in the Commonwealth.

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 to the fund any money penalties collected under section 42 7/8 of chapter 112. Such funds shall be held separately and used by the commissioner in accordance with the requirements of said section.

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

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 11 members to the board. Members shall be residents of the commonwealth. The composition of the board shall be as follows: 6 registered pharmacists; 1 pharmacy technician; 1 representatives of the public with experience in health care service delivery, administration, or consumer advocacy, subject to the provisions of section 9B; 1 physician registered under chapter 112; 1 nurse registered under chapter 112; and 1 expert in patient safety and quality improvement.

(b) The 6 registered pharmacists 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 1 of the 6 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 and employed in an organization of 9 or fewer registered retail drugstores in the commonwealth under section 39 of chapter 112 and employing not more than 20 full-time pharmacists.

(d) At the time of appointment or reappointment to the board, at least 1 of the 6 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 in the employ of a retail drug organization operating 10 or more retail drug stores within the commonwealth under section 39 of chapter 112.

(e) At the time of appointment or reappointment to the board, at least 1 of the 6 registered pharmacist members shall have had at least 7 years of experience in a hospital setting in the commonwealth.

(f) At the time of appointment or reappointment to the board, at least 1 of the 6 registered pharmacist members shall have had at least 7 years of experience employed in a long-term care pharmacy setting.

(g) At the time of appointment or reappointment to the board, at least 1 of the 6 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 their employment.

(h) At the time of appointment or reappointment to the board, at least 1 of the 6 registered pharmacist members shall be employed in an academic or scholarly position with an institution of higher learning licensed under the laws of the commonwealth.

(i) Not more than 1 pharmacist in any 1 practice setting defined in subsections (c) to (g), inclusive, may serve on the board at any one 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 their 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 or 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, "public member" shall mean a person whose background and experience qualify them to act on the board in the public interest, including experience in health care service delivery, administration, or consumer advocacy, and who meets the provisions of paragraph (4) of subsection (a) of section 9B.

(m) Board members shall be appointed and shall serve for a term of 3 years from the first of the month following 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 one term.

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

SECTION 3. Section 23 of 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 chapter 13, as so appearing, is hereby amended by striking out, in line 1, the words “no more than six”.

SECTION 5. Chapter 13, as so appearing, is hereby further amended by inserting after section 25 the following section:-

Section 25A. As directed by the board, all inspecting agents shall be trained in United States Pharmacopeia/National Formulary chapters 797 and 795 as well as additional 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, 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.

All compounded 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 of the fact that the drug is either a sterile or non-sterile compounded drug preparation.

All sterile compounding pharmacies, as defined in section 39D of chapter 112, shall provide a telephone number, which shall be staffed during regular hours of operation and not less than 7 days and 56 hours per week, to foster communication between patients in the commonwealth and a pharmacist employed by the pharmacy with access to the patient's records. The phone number shall also be affixed to the container, alongside the label notifying prescribed users and practitioners of the fact that the drug is a compounded drug preparation.

SECTION 7. Section 51H of chapter 111, as so appearing, is hereby amended by striking out the definition "serious adverse drug event" and inserting in place thereof the following definition:-

"Serious adverse drug event", any untoward 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. Important medical occurrences associated with the use of a drug in humans that may not result in death, be life-threatening, or require hospitalization may be

considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

SECTION 8. Subsection (b) of section 51H of chapter 111, as so appearing, is hereby amended by adding the following sentence:- The facility who 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. Section 51H of 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 2 of chapter 111N, as so appearing, is hereby amended by striking out the first paragraph and inserting in place thereof the following paragraph:-

Notwithstanding any general or special law to the contrary, the department shall adopt a standard marketing code of conduct for all pharmaceutical compounding or manufacturing or medical device manufacturing companies that employ a person to sell or market prescription drugs or medical devices in the commonwealth. The marketing code of conduct shall be based on applicable legal standards and incorporate principles of health care including, without limitation; requirements that the activities of the pharmaceutical compounder or manufacturer or medical device manufacturer agents be intended to benefit patients, enhance the practice of medicine and not interfere with the independent judgment of health care practitioners. In promulgating

regulations for a marketing code of conduct, the department adopt regulations that shall be no less restrictive than the most recent version of the Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America and the Code on Interactions with Healthcare Professionals developed by the Advanced Medical Technology Association.

SECTION 11. Section 24 of chapter 112 of the General Laws, as appearing in the 2012 Official Edition is hereby amended by striking out the word “forty-two”, in line 5, and inserting in place thereof the following word:- 42A.

SECTION 12. Section 24A of 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 must 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 shall devote at least 2 of the 20 contact hours in the area of sterile compounding; provided, however, that any pharmacist licensed by the commonwealth and practicing in a licensed specialty sterile compounding pharmacy shall devote at least 5 of the 20 contact hours in the area of sterile compounding.

The board, in consultation with an advisory committee of industry experts as established by section 42¾, shall adopt further rules and regulations for a system of continuing education, in

addition to the aforementioned requirements listed in this section. The board shall accept all conferences and programs from providers approved by the American Council on Pharmaceutical Education meeting these requirements.

The board shall conduct audits of randomly selected, renewed licenses. The board shall initiate such audits by sending those selected for an audit a request to provide documentation establishing completion of contact hour requirements. 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 contact hour requirements or fail to provide the requested documentation within 7 days of receiving a request shall be fined not more than $1000.

SECTION 13. Said chapter 112, as so appearing, is hereby further amended by inserting after section 25 the following section:-

Section 25A (a) The board shall submit an annual report to the joint committee on public health and joint committee on health care financing on or before December 31 detailing the investigatory and disciplinary actions conducted by the board; provided further, that the initial report 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 agencies that collaborated with the investigation; (5) the summary of and rationale for 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 or not the board reported the result of its investigation to another state board, federal agency or external entity.

(b) All relevant data collected, synthesized and analyzed under subsections (b) through (e), inclusive, of section 39D shall also be summarized and included in this report which the board shall compile and submit annually to the joint committee on public health, the joint committee on health care financing and the commissioner of public health on or before December 31 and shall make the compilation widely available, including by electronic means, to the public and all hospitals, pharmacies and health care providers doing business in the commonwealth.

SECTION 14. Section 32 of chapter 112 of the General Laws, as so appearing, is hereby amended by 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 the Boards of Pharmacy and the federal Food and Drug Administration.

SECTION 15. The second paragraph of section 39 of said chapter 112, as so appearing, is hereby amended by striking out the second sentence.

SECTION 16. Said section 39 of said chapter 112, as so appearing, is hereby amended by adding the following paragraph:-

The board of registration in pharmacy may establish specialty pharmacy licensure categories beyond those delineated in this section, and in sections 39A to C, inclusive, and in sections 39D ½ through 39G, through 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 under section 39, shall apply to a

pharmacy registered under this section and may establish regulations which shall apply only to a licensure category established under this provision. The licensure fee shall be determined annually by the secretary of administration and finance under section 3B of chapter 7.

SECTION 17. Chapter 112 of the General Laws, as so appearing, is hereby amended by striking out section 39D and inserting in place thereof the following 4 sections:-

Section 39D. (a) As used in this section and in sections 39D½ to 42A, 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 as defined in section 9 of chapter 94C.. The purpose of accountability documentation shall be to facilitate tracing of a drug preparation or compounded sterile drug preparation back to the sterile compounding pharmacy it was produced at, an individual who produced the drug, and the prescription order that generated the production or compounding of the drug preparation.

"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 the 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;

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

(4) if compounding does not include the preparation of commercially available, FDA-approved drug preparations. Compounded preparations that produce, 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 are not copies of commercially available preparations. Significant differences may include, but are not limited to, the removal of a dye for medical reasons, changes in strength, and changes in dosage form or delivery mechanism. Price differences are not a significant difference to justify compounding.

"Compounded sterile drug preparation", a biologic, diagnostic, drug, nutrient, or radiopharmaceutical that under USP 797 or the federal Food and Drug Administration's current good manufacturing practices, must be compounded using aseptic techniques. Such preparations may include, but are not limited to, implants, injectables, parenteral nutrition solutions, irrigation solutions, inhalation solution, intravenous solutions and ophthalmic preparations.

"cGMP" Current Good Manufacturing Practice regulations enforced by the federal Food and Drug Administration.

"Manager of record", a person, who, being licensed as a pharmacist, 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.

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

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

"Sterile compounding pharmacy", any pharmacy or facility, where a compounded sterile drug preparation is compounded or manufactured.

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

(b) Stores or pharmacies engaged in the drug business, as defined in section 37, 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 7 business days after discovery of the improper dispensing.

(c) The manager of record of a store or pharmacies shall report any serious adverse drug event, as defined in section 51H of chapter 111, occurring as result of patient interaction with any drug or pharmaceutical preparation manufactured, produced or compounded at their pharmacy, to the board, the federal Food and Drug Administration MedWatch Program and the Betsy Lehman Center for 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 that has been reported to the board of pharmacy, must 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 warn patients, consumers and pharmacies of any trends which could pose a danger to public health and safety. Data collected under this subsection shall be made available on the searchable website established under section 42 ½ .

(e) If a sterile compounding pharmacy believes that a compounded sterile drug preparation dispensed or distributed by such pharmacy is or may be defective in any way, the pharmacy shall immediately recall any such preparation. Any of the same preparation remaining in the possession of such 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 board of pharmacy inspectors within 7 days of the recall, and shall be kept on record for at least 2 years. Upon submission of the defective preparation log to a board of pharmacy inspector, the pharmacy shall work with the board of pharmacy to develop a corrective action plan that rectifies the error which resulted in a defective preparation.

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

Section 39D 1/2. (a) The board of registration in pharmacy 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 of registration in pharmacy under this section.

(b) The sterile compound drug preparations specialty license issued by the board shall be obtained in addition to and shall not replace any other permit or license a sterile compounding pharmacy holds. This license is non-transferable and shall be renewed annually. The fee for such renewal shall be determined annually by the secretary of administration and finance under section 3B of chapter 7.

(c) A pharmacy licensed by the commonwealth intending to compound sterile drug preparations as well as dispense sterile compounded drug preparations in or out of state, shall adhere to the most current standards established by USP, all chapters, when engaging in any form of sterile compounding, and shall obtain and hold a sterile compounded drug preparations

specialty license. Such pharmacies shall also adhere to the additional regulations promulgated by the board of pharmacy under subsection (h) of section 39F, in consultation with an advisory committee of industry experts as established by section 42¾ of chapter 112.

(d) A pharmacy licensed by the commonwealth that intends to compound and distribute sterile compounded drug preparations to pharmacies, wholesalers or prescribers in or out of the state in anticipation of a prescription, in volumes inconsistent with routinely observed volume patterns associated with patient-specific prescriptions, or 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. The manufacturer,s license is non-transferable and shall be renewed annually, at a fee which shall be determined annually by the secretary of administration and finance under section 3B of chapter 7.

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

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

(c) The board shall establish a list of procedural criteria on which a sterile compounding pharmacy will be evaluated at the time of inspection. The procedural criteria shall contain a pre-

determined list of standards and safeguards upon which a sterile compounding pharmacy shall be inspected, as well as a pre-determined yet alternating list of variable criteria upon which the pharmacy may be inspected without prior notice as to which subset of these variable criteria will be included in the inspection.

(d) The board shall, in consultation with an advisory committee of industry experts as established by section 42¾, 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.

(e) All sterile compounding pharmacies shall certify that they have undergone a lean manufacturing assessment, before they are eligible to receive a sterile compounding drug preparations license.

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

(g) Sterile compounding pharmacies shall designate a manager of record who shall be responsible for the pharmacy's compliance with this chapter and shall disclose to the board the following:

(1)The location, name and titles 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 1 month after any change of office, corporate office or manager of record.

(2) The pharmacy shall certify its compliance with reasonable informational requests made by the board.

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

(h) The board shall establish supplementary regulations, beyond those established by the current form of USP 797, for all pharmacies intending to compound or dispense sterile drug preparations in the commonwealth. The board shall establish such regulations in consultation with an advisory committee of industry experts as established by section 42¾ of chapter 112. The regulations shall include, but will 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 preparations quality and control after the compounded sterile drug preparation leaves the pharmacy.

Section 39G. (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 pertain to the practice of pharmacy. In establishing a procedure to license non-resident or out of statepharmacies, the board shall require that the licensing procedure of the state in which any non-resident or out of state pharmacy is located is equivalent to the licensing procedures applicable to Massachusetts pharmacies under this chapter.

(b) The non-resident or out of state pharmacies shall designate a pharmacist in charge who is licensed as a pharmacist in Massachusetts and is responsible for the pharmacy's compliance with this chapter and shall disclose to the board all of the following:

(1) The location, name and titles of all principal managers and the name and Massachusetts license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within one month after any change of office, corporate office, or manager of record.

(2) That it 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.

(3) That it maintains its records of all drugs dispensed to patients in the commonwealth, and that these records are readily available, upon 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 under this section.

(d) No pharmacy or pharmacist operating outside of the state shall be authorized to prescribe, ship, mail, sell, transfer or dispense sterile compounded drug preparations in the commonwealth unless the sterile compounded drug preparations are produced in a pharmacy that has been granted a non-resident or out of state sterile compounded drug preparations license under this section.

SECTION 18. Sections 41 and 42 of chapter 112 of the General Laws are hereby repealed.

SECTION 19. Chapter 112 of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after Section 42 the following 3 sections:-

Section 42 ½. (a) For the purpose of his section, the following words shall 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 at no charge to search for and obtain enforcement action records and serious adverse drug events records, as defined in section 51H of chapter 111, pertaining to pharmacies licensed by the commonwealth.

(b) The commissioner shall develop and operate a searchable website accessible by the public at no charge that 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, and data relative to such events collected and reported under 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 department whether within or without the commonwealth; and

(3) 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 shall provide to the commissioner all data that is required to be included in the searchable website no later than 30 days after the data becomes available to the department. 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 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 requirement of this section.

Section 42¾. There is hereby established an advisory committee to the board consisting of the following members to be appointed by the commissioner of the department of public health: an expert in United States Pharmacopeia chapter 795, an expert in United States Pharmacopeia 797, an expert in United States Pharmacopeia 71, an expert in federal current good manufacturing practices 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 of registration in pharmacy, if so deemed necessary to fulfill the duties that this committee is charged with. The advisory committee shall advise the board of pharmacy regarding proposed regulations on quality assurance and the inspection and testing of compounded drug preparations. The advisory committee shall also advise the board of

pharmacy regarding proposed regulations to supplement the current form of United States Pharmacopeia 797. The advisory committee shall also 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. Members of the advisory committee shall serve without compensation, and shall be free of any liability incurred by their proposed recommendation to the board of pharmacy. 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 of Massachusetts. The advisory committee shall determine an approach to address potential drug shortages when sufficient clinical need or a threat to public health and safety exist.

The advisory committee shall study the feasibility of a state-administered central fill pharmacy for the purposes of compounding and distributing compounded drug preparations for hospitals in the commonwealth.

Section 42 7/8. (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 under any general law that governs the practice of pharmacy.

(b) The board may assess a pharmacy licensed under 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 provisions of law relied upon and shall accord such person an opportunity for a hearing upon written request within 15 business days of the assessment. If after a hearing, or waiver thereof, 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 affected licensee, or on the fifteenth day after resolution of an administrative appeal, and deposited into the quality in health professions trust fund as established by section 35X of chapter 10. The attorney general shall recover any assessment due and payable brought in the name of the commonwealth in the superior court. Funds collected under subsection (b) shall be paid as described in subsection (c). Monetary penalties collected under this section and deposited in the quality in health professions trust fund administered by the department of public health 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 this fund, in consultation with the division, including the establishment of eligibility criteria, program requirements, and assessment and reporting processes.

SECTION 20. Section 42A of 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 the Boards of Pharmacy and the United States 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 such summary action; provided, however, that the board shall, within 7 days of such action, afford the holder of such license the opportunity of a hearing under chapter 30A. Any suspension imposed by the board or board president shall remain in effect until the conclusion of the proceedings including the 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: (1) 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 (2) 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. Section 187 of Chapter 149 of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by adding the word “pharmacy” after “community health agency” in the definition of “health care facility”.

SECTION 23. The board of registration in pharmacy, shall, in consultation with the department of public health and an advisory committee of industry experts as established by section 42¾ of chapter 112, promulgate regulations no later than 180 days after passage of this law pertaining to the inspections and testing of sterile compounding pharmacies, as well as the inspection and testing of compounded sterile drug preparations produced by relevant pharmacies, as required by section 39F of chapter 112 of the General Laws.

SECTION 24. 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 25. Notwithstanding any general or special law to the contrary, the board of pharmacy shall establish in regulation no later than180 days after passage of this law the requirements for specialty licensure, pursuant to section 39D ½ of chapter 112 of the General Laws, of pharmacies engaged in the practice of compounding sterile drug preparations consistent with pertinent United States Pharmacopeia Standards and General Chapters.