SENATE DOCKET, NO. 1733 FILED ON: 1/18/2013

SENATE . . . . . No. 1053

The Commonwealth of Massachusetts

PRESENTED BY:

Mark C. Montigny

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:

An Act Relative to the further regulation of pharmacies.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Mark C. Montigny	*Second Bristol and Plymouth*
Benjamin Swan	*11th Hampden*

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SENATE . . . . . No. 1053

By Mr. Montigny, a petition (accompanied by bill, Senate, No. 1053) of Mark C. Montigny and Benjamin Swan for legislation to further regulate pharmacies. Public Health.

The Commonwealth of Massachusetts

In the Year Two Thousand Thirteen

An Act Relative to the further regulation of pharmacies.

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. Chapter 13 of the General Laws, as appearing in the 2010 Official Edition, is hereby amended by striking out section 22 and inserting in place thereof the following section:-

Section 22. (a) There shall be a board of registration in pharmacy, in the following 3 sections called the board, consisting of 15 persons, who shall be residents of the commonwealth. The governor shall appoint the 15 members to the board. 4 of the members of the board shall be registered pharmacists. One member of the board shall be a registered pharmacy technician. One member of the board shall be a physician registered pursuant to chapter 112. One member shall be a nurse practitioner licensed pursuant to chapter 112. One member shall be a physician's assistant licensed pursuant to chapter 112. One member shall be an expert in drug safety and quality improvement. One member shall be a nurse licensed pursuant to chapter 112. Five members shall be representatives of the public. Al least one of the public's 5 representatives shall have experience in health care service delivery and another shall have experience in consumer advocacy.

(a) The 4 registered pharmacists shall each have at least 10 years of experience in the practice of pharmacy. At least two of the 4 pharmacists shall be currently employed in the practice of pharmacy in the Commonwealth at time of appointment or reappointment.

(b) At the time of appointment or reappointment to the board, at least 1 of the 4 registered pharmacists shall be an independent pharmacist employed in the independent pharmacy setting and at least 1 of such 4 members shall be a chain pharmacist employed in a chain 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 drug stores in the commonwealth under the provisions of section 39 of chapter 112 and employing not more than 20 full time pharmacists and “chain pharmacist’ shall mean a pharmacist in the employ of a retail drug organization operating 10 or more retail drug stores in the commonwealth under section 39 of chapter 112.

(c) At the time of appointment or reappointment to the board, at least 1 of the 4 registered pharmacists shall be a pharmacist employed in an academic or scholarly position with an institution of higher learning licensed under the laws of the commonwealth.

(d) At the time of appointment or reappointment to the board, at least 1 of the 4 registered pharmacists shall have had at least five years of experience in a hospital, long term care or sterile compounding pharmacy setting.

(e) At the time of appointment or reappointment to the board, no registered pharmacist shall have had any type of disciplinary or enforcement action taken against them by the board or the federal food and drug administration during the 10 years preceding their appointment to the board.

(f) board members shall be appointed and serve for a term of 3 years from the first of the month following appointment. No board member shall serve more than 2 consecutive terms.

(g) Any member of the board may be removed by the governor or his designee, after notice and hearing, for neglect of duty, misconduct, malfeasance, misfeasance in office or for loss of their professional license if the same is required for their appointment to the board.

(h) The board shall maintain a registry, accessible to the public, of the names and addresses of the employer(s) of each member of the board and the same information shall be available to the public on the web site of the board. Each board member shall be required to provide such information to the board and to update the same as required.

SECTION 2. Chapter 112 of the General Laws , as appearing in the 2010 Official edition, is hereby amended by inserting after section 39D the following:-

Section 39E. Sterile Compounding Pharmacy Licensure

(a) A pharmacy shall not compound sterile compound drug products, including but not limited to sterile injectable drug products in the Commonwealth unless the pharmacy has obtained a Sterile Products specialty license from the board of registration in pharmacy pursuant to this section. The license issued by the board of registration shall be renewed yearly and is not transferrable.

(b) A specialty license to compound sterile drug products may only be issued for a location that is licensed as a pharmacy. Moreover, the specialty license to compound sterile

compounded drug products may only be issued to the owner of the pharmacy license at that location. A specialty license to compound sterile drug products may not be issued until the location is inspected by the board of registration and found in compliance with this Chapter and the regulations adopted by the board of registration.

(c) A specialty license to compound sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this chapter and the regulations adopted by the board of registration.

(d) Pharmacies operated by entities that are licensed by the board of registration and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation organizations approved by the Board of Registration, shall be presumed to be qualified for the specialty license for compounding sterile drug products under this section.

(e) The reconstitution of a sterile powder shall not require the specialty license pursuant to this section provided:

(1) The sterile powder was obtained from a manufacturer that has federal FDA approval

(2) The drug is reconstituted for administration to patients by a healthcare professional licensed to administer drugs by an injection.

(f) A nonresident pharmacy may not compound sterile drug products including sterile injectable drug products for shipment or sale into the Commonwealth without a specialty license issued by the board of registration in pharmacy pursuant to this section. The license shall be renewed annually and shall not be transferrable.

(g) A license to compound sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Moreover, the specialty license to compound sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound sterile drug products may not be issued or renewed until the board of registration receives the following from the nonresident pharmacy:

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board of registration, in the prior 12 months documenting the pharmacy's compliance with board of registration regulations regarding the compounding sterile drug products.

(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(h) Nonresident pharmacies that are licensed by licensing agency in the jurisdiction in which the pharmacy resides and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation organizations approved by the board of registration shall be presumed to be qualified for the nonresident specialty license for compounding sterile compounded drug products under this section.

(i) The board of registration shall establish regulations no later than 180 days after passage of this law to carry out the requirements of this section including the formulation of the requirements for the specialty licenses under this section.

(j) Licensure fees for the specialty licenses under this section shall be determined annually by the commissioner of administration under section 3B of chapter 7. All monies received by the commonwealth from such licensure fees shall not be deposited in the general fund of the Commonwealth but shall be placed into a Compounding Pharmacy Inspection trust fund or account to be administered by the department of public health to support inspections and other oversight or enforcement actions towards compounding pharmacies. The board of registration shall promulgate regulations for the administration of said fund, in consultation with the department of public health.

SECTION 3. Chapter 112 of the General Laws, as appearing in the 2010 Official Edition, is hereby amended by inserting after section 39E the following:-

Section 39F. Patient Warning Labels on Compounded Drug Products

(i) All compounded drug products compounded, made or formulated by a compounding pharmacy licensed by the board of registration shall have affixed to their container by the compounding pharmacy a warning label notifying prescribed users of the compounded drug products, at a minimum, that such compounded drug products are not federal food and drug administration tested or approved, that the compounded drug products do not meet federal food and drug administration good manufacturing guidelines, that there may be adverse health effects or risks from using the compounded drug product and that the user should consult their prescribing healthcare provider about such risks.

(b) The board of registration shall establish in regulation no later than 180 days after passage of this law, the requirements for the warning labels called for by this section.

SECTION 4. Chapter 112, as appearing in the 2012 Official Edition, is hereby amended by inserting after section 39F the following:-

Section 39G. Inspection and Testing of Sterile Compounded Drug Products

(a) There shall be periodic and random inspection of all compounding pharmacies licensed under this chapter to compound sterile compounded drug products. There shall also be periodic and random testing of sterile compounded drug products compounded by, made or

formulated by compounding pharmacies licensed under this chapter to compound sterile compounded drug products. Such testing shall include, but not be limited to, testing for sterility of products, the potency of products and the efficacy of products. The board of registration, in consultation with the department of public health, shall promulgate regulations no later than 180 days after passage of this law pertaining to the inspections and testing required by this section.

(b) As part of any periodic and random inspection of compounding pharmacies of all compounding pharmacies licensed under this chapter to compound sterile drug products under this section, the board of registration shall inspect the records of all such licensed compounding pharmacies regarding the manufacturer, supplier and point of origin of all ingredients used in compounding sterile compounded drug products and all such licensed compounded pharmacies shall be required as a condition of their license to have and maintain such records.

SECTION 5. Chapter 112 of the General Laws, as so appearing in the 2010 Official Edition is amended by inserting after section 39G, the following:-

(a) Section 39H. (a) The compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal Drug Administration approved products is prohibited.

(b) (b) Notwithstanding the above, there shall be sufficient documentation within the prescription record of a compounding pharmacy of the specific medical need for a particular variation of a commercially available drug product. Any alteration, change or modification to the contents of a commercially over the counter product shall require a prescription from an authorized prescriber.

(c) (c) The compounding of any drug product to be sold without a prescription is prohibited.

SECTION 6. Chapter 112 of the General Laws, as appearing in the 2010 Official Edition, is hereby amended by inserting after Section 42A the following:-

Section 42B. (a) As used in this section, the following words shall, unless the context clearly requires otherwise, have the following meanings:-

"Department", the Department of Public Health including the Board of Registration in Pharmacy.

"Searchable website", a website that allows the public at no cost to search for, obtain and aggregate the information identified in subsection (b).

"Commissioner", the Commissioner of Public Health.

"Enforcement action records", any documents issued by the Department to a compounding pharmacy or pharmacist for an infraction or violation of a state or federal statute or

regulation by the compounding pharmacy or pharmacist. Said records shall include, but not be limited to, consent decrees or judgments entered into between the Department and a licensed compounding pharmacy or pharmacist as a result of a charge or complaint filed by the Department against a compounding 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.

"Adverse consequences records', any documents or reports maintained by the Department that pertain to any adverse physical reaction or effect suffered by a patient or user of a compounded medication as a result of the use, ingestion or injection of such compounded medication prepared, made or constituted by a compounding pharmacy or pharmacists licensed by the Department.

(b) The commissioner shall develop and operate a searchable website accessible by the public at no cost that includes:

(1) copies of all enforcement action records of any compounding pharmacy or pharmacist licensed by the Department whether they are located within or without the Commonwealth.

(2) copies of any records of adverse consequences suffered by a patient or user of compounded medications as a result of their use of compounded medication prepared, made or constituted by a compounding pharmacy or pharmacist licensed by the Department whether within or without the Commonwealth.

(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, aggregate the data, and download information yielded by a search. The website shall, among other things, permit users to search by a particular compounding pharmacy or pharmacists or by a specific compounded medication.

(d) The searchable website shall include and retain information for each fiscal year for not less than ten (10) fiscal years.

(e) The Commissioner 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 (1) 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.