

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 adoption 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

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:

1 SECTION 1. Chapter 13 of the General Laws, as appearing in the 2010 Official Edition,
2 is hereby amended by striking out section 22 and inserting in place thereof the following
3 section:-

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

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

18 (b) At the time of appointment or reappointment to the board, at least 1 of the 4 registered
19 pharmacists shall be an independent pharmacist employed in the independent pharmacy setting
20 and at least 1 of such 4 members shall be a chain pharmacist employed in a chain pharmacy
21 setting. For the purposes of this section, “independent pharmacist” shall mean a pharmacist

22 actively engaged in the business of retail pharmacy and employed in an organization of 9 or
23 fewer registered retail drug stores in the commonwealth under the provisions of section 39 of
24 chapter 112 and employing not more than 20 full time pharmacists and “chain pharmacist” shall
25 mean a pharmacist in the employ of a retail drug organization operating 10 or more retail drug
26 stores in the commonwealth under section 39 of chapter 112.

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

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

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

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

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

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

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

48 Section 39E. Sterile Compounding Pharmacy Licensure

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

107 Section 39F. Patient Warning Labels on Compounded Drug Products

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

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

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

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

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

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

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

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

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

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

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

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

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

151 “Department”, the Department of Public Health including the Board of Registration in
152 Pharmacy.

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

155 “Commissioner”, the Commissioner of Public Health.

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

158 regulation by the compounding pharmacy or pharmacist. Said records shall include, but not be
159 limited to, consent decrees or judgments entered into between the Department and a licensed
160 compounding pharmacy or pharmacist as a result of a charge or complaint filed by the
161 Department against a compounding pharmacy or pharmacist for a statutory or regulatory
162 violation or infraction or any other type of voluntary resolution of a charge or complaint filed by
163 the Department.

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

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

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

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

177 (3) any other relevant information specified by the Commissioner

178 (c) The searchable website shall allow users to search electronically by field in a single
179 search, aggregate the data, and download information yielded by a search. The website shall,
180 among other things, permit users to search by a particular compounding pharmacy or
181 pharmacists or by a specific compounded medication.

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

184 (e) The Commissioner shall update the searchable website as new data becomes
185 available. All agencies or boards of the Department shall provide to the Commissioner all data
186 that is required to be included in the searchable website no later than 30 days after the data
187 becomes available to the Department. The Commissioner shall provide guidance to agency or
188 board heads to ensure compliance with this section.

189 (f) This section shall not be construed to require the disclosure of (1) information of
190 patients or users of medication that is confidential under state or federal law.

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