

HOUSE No. 3458

The Commonwealth of Massachusetts

HOUSE OF REPRESENTATIVES, July 11, 2013.

The committee on Public Health to whom were referred the message from His Excellency the Governor recommending legislation relative to pharmacy practice in the Commonwealth (House, No. 39), the petition (accompanied by bill, Senate, No. 1040) of Thomas P. Kennedy for legislation to authorize the dispensing of compounded prescriptions for office and institutional settings without patient- specific prescriptions, and the petition (accompanied by bill, Senate, No. 1053) of Mark C. Montigny and Benjamin Swan for legislation to further regulate pharmacies, reports recommending that the accompanying bill (House, No. 3458) ought to pass.

For the committee,

JEFFREY SANCHEZ.

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:

1 SECTION 1. Chapter 13 of the General Laws is hereby amended by striking out section 22 and
2 inserting in place thereof the following sections: -

3 Section 22. (a) There shall be a board of registration in pharmacy, called the “board” in
4 this section and sections 23 to 25A inclusive. The governor shall appoint 11 members to the
5 board. Members shall be residents of the commonwealth. The composition of the board shall be
6 as follows: 6 registered pharmacists; 1 pharmacy technician; 1 representatives of the public with
7 experience in health care service delivery, administration, or consumer advocacy, subject to the
8 provisions of section 9B; 1 physician registered under chapter 112; 1 nurse registered under
9 chapter 112; and 1 expert in patient safety and quality improvement.

10 (b) The 6 registered pharmacists shall each have had at least 7 consecutive years of
11 experience in the practice of pharmacy and shall be currently employed in the practice of
12 pharmacy in the commonwealth at the time of appointment or reappointment.

13 (c) At the time of appointment or reappointment to the board, at least 1 of the 6 registered
14 pharmacist members shall be an independent pharmacist employed in the independent pharmacy
15 setting. For the purposes of this section “independent pharmacist” shall mean a pharmacist
16 actively engaged in the business of retail pharmacy and employed in an organization of 9 or
17 fewer registered retail drugstores in the commonwealth under section 39 of chapter 112 and
18 employing not more than 20 full-time pharmacists.

19 (d) At the time of appointment or reappointment to the board, at least 1 of the 6 registered
20 pharmacist members shall be a chain pharmacist employed in the chain pharmacy setting. For the
21 purposes of this section “chain pharmacist” shall mean a pharmacist in the employ of a retail
22 drug organization operating 10 or more retail drug stores within the commonwealth under
23 section 39 of chapter 112.

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

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

30 (g) At the time of appointment or reappointment to the board, at least 1 of the 6 registered
31 pharmacist members shall have had at least 7 years of experience in the practice of compounding
32 sterile drug preparations, as defined in section 39D of chapter 112, and shall be engaged in
33 compounding sterile drug preparations as a routine function of their employment.

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

37 (i) Not more than 1 pharmacist in any 1 practice setting defined in subsections (c) to (g),
38 inclusive, may serve on the board at any one time.

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

42 (k) At the time of appointment or reappointment to the board, no registered pharmacist or
43 pharmacy technician shall have had any type of disciplinary or enforcement action taken against
44 them by the board or the federal Food and Drug Administration or the federal Drug Enforcement
45 Administration during the 10 years preceding their appointment to the board.

46 (l) For the purposes of this section, “public member” shall mean a person whose
47 background and experience qualify them to act on the board in the public interest, including
48 experience in health care service delivery, administration, or consumer advocacy, and who meets
49 the provisions of paragraph (4) of subsection (a) of section 9B.

50 (m) Board members shall be appointed and shall serve for a term of 3 years from the first
51 of the month following appointment. No member may serve more than 2 consecutive terms on
52 the board. Members who have served the maximum number of consecutive terms shall be
53 eligible for reappointment after not serving for at least one term.

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

59 SECTION 2. Section 23 of chapter 13, as so appearing, is hereby amended by adding the
60 following paragraph:-

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

63 SECTION 3. Section 25 of chapter 13, as so appearing, is hereby amended by striking
64 out, in line 1, the words “no more than six”.

65 SECTION 4. Chapter 13, as so appearing, is hereby further amended by inserting after
66 section 25 the following section:-

67 Section 25A. As directed by the board, all inspecting agents shall be trained in USP 797
68 and USP 795 as well as additional sterile compounding surveyor courses. This training shall
69 include, but not be limited to, programs offered free of charge by the National Association of
70 Boards of Pharmacy.

71 SECTION 5. Section 21 of chapter 94C, as appearing in the 2012 Official Edition, is
72 hereby amended by adding the following 3 paragraphs:

73 The labeling provisions of this section shall apply to the compounding and dispensing of
74 drugs on the oral or written prescription of a licensed and registered prescriber as defined under
75 section 9.

76 All compounded drug preparations compounded, made or formulated by a pharmacy
77 licensed by the board of registration in pharmacy shall have affixed to their container by the
78 compounding pharmacy a label notifying prescribed users and practitioners of the fact that the
79 drug is either a sterile or non-sterile compounded drug preparation.

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

86 SECTION 6. Section 51H of Chapter 111, as so appearing, is hereby amended by
87 inserting after the definition “Healthcare-associated infection”, the following definition:-

88 “Practitioner”, a licensed and registered prescriber, as defined under section 9 of chapter
89 94C.

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

93 “Serious adverse drug event”, any untoward medical occurrence associated with the use
94 of a drug in humans, whether or not considered drug related, that results in any of the following
95 outcomes: (i) death; (ii) a life-threatening outcome; (iii) inpatient hospitalization or prolongation
96 of existing hospitalization; (iv) a persistent or significant incapacity or substantial disruption of
97 the ability to conduct normal life functions; or (v) a congenital anomaly or birth defect.
98 Important medical occurrences associated with the use of a drug in humans that may not result in
99 death, be life-threatening, or require hospitalization may be considered serious when, based upon
100 appropriate medical judgment, they may jeopardize the patient or subject and may require
101 medical or surgical intervention to prevent one of the outcomes listed in this definition.

102 SECTION 8. Subsection (b) of section 51H of chapter 111, as so appearing, is hereby
103 amended by adding the following sentence:- The practitioner or other licensed healthcare
104 provider, who discovers a serious adverse drug event resulting from a patient’s use, consumption
105 or interaction with any pharmaceutical or drug preparation, shall report the event to the federal
106 Food and Drug Administration’s MedWatch Program, as well as the pharmacy from which the
107 drug was produced, compounded or dispensed in addition to all other reporting requirements.

108 SECTION 9. Section 51H of chapter 111, as so appearing, is hereby further amended by
109 inserting after the word “reduction”, in line 29, the following words:- “,the bureau of healthcare
110 safety and quality within the department and the board of registration in pharmacy.

111 SECTION 10. Section 2 of chapter 111N, as so appearing, is hereby amended by striking
112 out the first paragraph and inserting in place thereof the following paragraph:-

113 Notwithstanding any general or special law to the contrary, the department shall adopt a
114 standard marketing code of conduct for all pharmaceutical or medical device compounding or
115 manufacturing companies that employ a person to sell or market prescription drugs or medical
116 devices in the commonwealth. The marketing code of conduct shall be based on applicable legal
117 standards and incorporate principles of health care including, without limitation; requirements
118 that the activities of the pharmaceutical or medical device compounder or manufacturer agents
119 be intended to benefit patients, enhance the practice of medicine and not interfere with the
120 independent judgment of health care practitioners. In promulgating regulations for a marketing
121 code of conduct, the department adopt regulations that shall be no less restrictive than the most
122 recent version of the Code on Interactions with Healthcare Professionals developed by the
123 Pharmaceutical Research and Manufacturers of America and the Code on Interactions with
124 Healthcare Professionals developed by the Advanced Medical Technology Association.

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

128 SECTION 12. Section 24A of chapter 112 as so appearing, is hereby amended by striking
129 out the second paragraph and inserting in place thereof the following 3 paragraphs:-

130 The board shall require each registered pharmacist seeking personal registration renewal
131 to complete continuing education requirements as a condition precedent to such renewal. No
132 registrant shall be eligible for renewal of a personal registration without completion of the
133 requisite number of contact hours for such renewal. A registrant seeking renewal of a personal
134 registration must complete a minimum of 20 contact hours each calendar year of the 2-year
135 renewal cycle. Of the 20 contact hours effective for the renewal period beginning January 1,
136 2014 any pharmacist licensed by the commonwealth shall devote at least 5 of the 20 contact
137 hours in the area of sterile compounding

138 The board, in consultation with an advisory committee of industry experts as established
139 by section 42¾ of chapter 112, shall adopt further rules and regulations for a system of
140 continuing education, in addition to the aforementioned requirements listed in this section. The
141 board shall accept all conferences and programs from providers approved by the American
142 Council on Pharmaceutical Education meeting these requirements.

143 The board shall also conduct an audit of randomly selected, renewed licenses. Individuals
144 selected for an audit will be mailed a request from the board of pharmacy to provide documented
145 proof of completion of contact hour requirements. The name and date of licensees included in
146 this audit shall be posted on the board website. Pharmacists in violation of this requirement will
147 be fined no more than \$1000.

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

150 Section 25A (a) The board shall submit an annual report to the joint committee on public
151 health and joint committee on health care finance on or before December 31 detailing the
152 investigatory and disciplinary actions conducted by the board; provided further, that the initial
153 report shall detail (1) each complaint received by the board or initiated by the board; (2) the date
154 of the complaint; (3) the violation alleged; (4) the name of any state or federal agencies that
155 collaborated with the investigation (5) the summary of and rationale for the final decision of the
156 board to; (i) dismiss the complaint, (ii) impose an informal sanction or penalty, (iii) impose a
157 formal sanction or penalty or (iv) amend a previously issued sanction or penalty; and (6) whether
158 or not the board reported the result of its investigation to another state board, federal agency or
159 external entity.

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

167 SECTION 14. Section 32 of chapter 112 of the General Laws, as so appearing, is hereby
168 amended by the following paragraph:-

169 The board shall participate in any national data reporting system which provides
170 information on individual pharmacies, pharmacists and pharmacy technicians including, but not
171 limited to, relevant databases maintained by the National Association of the Boards of Pharmacy
172 and the federal Food and Drug Administration.

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

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

177 The board of registration in pharmacy may establish specialty pharmacy licensure
178 categories beyond those delineated in this section, and in sections 39A to C, inclusive, and in
179 sections 39E and 39F, through promulgation of regulation as deemed necessary by the board in
180 consultation with the commissioner of public health. The board shall determine which
181 regulations, applicable to a retail drug business registered under section 39 shall apply to a
182 pharmacy registered under this section and may establish regulations which shall apply only to a
183 licensure category established under this provision. The licensure fee shall be determined
184 annually by the commissioner of the administration under section 3B of chapter 7.

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

187 Section 39D. (a) As used in this section and in sections 39D½ to 42A, inclusive, the
188 following words shall, unless the context clearly requires otherwise, have the following
189 meanings:-

190 “Accountability documentation”, physical documentation validating the lot numbers and
191 expiration dates of drugs or products with a patient drug prescription order from a physician
192 licensed to practice medicine in the commonwealth. The purpose of accountability
193 documentation shall be to facilitate tracing of a drug preparation or compounded sterile drug
194 preparation back to the sterile compounding pharmacy it was produced at, an individual who
195 produced the drug, and the prescription order that generated the production or compounding of
196 the drug preparation.

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

200 (1) formulated for use on or for the patient as a result of a practitioner’s prescription drug
201 order or initiative, based on the relationship between the practitioner, patient, and pharmacist in

202 the course of routine professional practice, to meet the unique medical need of an individual
203 patient of the practitioner;

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

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

208 (4) if compounding does not include the preparation of commercially available, FDA-
209 approved drug preparations. Compounded preparations that produce, for the patient, a significant
210 difference between the compounded drug and the comparable commercially available drug
211 preparation as determined, by the prescriber, as necessary for the medical best interest of the
212 patient are not copies of commercially available preparations. Significant differences may
213 include, but are not limited to, the removal of a dye for medical reasons, changes in strength, and
214 changes in dosage form or delivery mechanism. Price differences are not a significant difference
215 to justify compounding.

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

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

223 “Manager of record”, a person, who, being licensed as a pharmacist, signs the application
224 for a pharmacy permit and assumes full legal responsibility for the operation of the relevant
225 pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and
226 the sale and dispensing of controlled substances. The manager of record shall personally
227 supervise the pharmacy and pharmacy personnel as required by section 39.

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

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

233 “Sterile compounding pharmacy”, any pharmacy or facility, where a compounded sterile
234 drug preparations is compounded or manufactured

235 “USP/NF”, the current edition of the United States Pharmacopeia/National Formulary.

236 (b) Stores or pharmacies engaged in the drug business, as defined in section 37, shall
237 inform the department of public health of any improper dispensing of prescription drugs that
238 results in serious injury or death, as defined by the department in regulations, as soon as is
239 reasonably and practically possible, but not later than 7 working days after discovery of the
240 improper dispensing.

241 (c) The manager of record of a store or pharmacies shall report any serious adverse drug
242 event, as defined in section 51H of chapter 111, occurring as result of patient interaction with
243 any drug or pharmaceutical preparation manufactured, produced or compounded at their
244 pharmacy, to the board, the FDA MedWatch Program and the Betsy Lehman Center for medical
245 error reduction. This data shall be reported to the board within 7 days of the knowledge of any
246 serious adverse drug event by any pharmacy employee.

247 (d) All data concerning serious adverse drug events that has been reported to the board of
248 pharmacy, must be collected, synthesized and analyzed in a traceable and easily navigable
249 database format using information technology. Data shall be used to track trends in serious
250 adverse drug events, and warn patients, consumers and pharmacies of any trends which could
251 pose a danger to public health and safety.

252 (e) If a sterile compounding pharmacy believes that their compounded sterile drug
253 preparation is defective in any way, the pharmacy shall recall any preparation dispensed or
254 distributed. Any preparation remaining in the outlet shall be isolated, and shall not be distributed
255 or dispensed to anybody. An accurate log of the recalled preparation shall be kept by the
256 pharmacy including information on:

257 (1) intended preparation name, potency, dosage form;

258 (2) the reason for the recall;

259 (3) the amount of preparation made;

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

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

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

263 (7) any and all serious adverse drug events related to the drug in question. The defective
264 preparation log shall be made available to board of pharmacy inspectors within 7 days of the
265 recall, and shall be kept on record for at least 2 years. Upon submission of the defective
266 preparation log to a board of pharmacy inspector, the pharmacy shall work with the board of
267 pharmacy to develop a corrective action plan that rectifies the error which resulted in a defective
268 preparation.

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

271 Section 39D 1/2. (a) A pharmacy shall not engage in sterile compounding, nor shall a
272 pharmacy prescribe, ship, mail, sell, transfer or dispense sterile compounded drug preparations in
273 the commonwealth unless the pharmacy has obtained a sterile compounded drug preparations
274 specialty license from the board of registration in pharmacy under this section.

275 (b) The sterile compound drug preparations specialty license issued by the board shall be
276 obtained in addition to and shall not replace any other permit or license a sterile compounding
277 pharmacy holds. This license is non-transferable and shall be renewed annually. The fee for such
278 renewal, shall be determined annually by the commissioner of the administration under section
279 3B of chapter 7

280 (c) A pharmacy licensed by the commonwealth intending to compound sterile drug
281 preparations as well as distribute sterile compounded drug preparations to pharmacies,
282 wholesalers or prescribers into or out of state, according to the definition established by this
283 chapter, shall adhere to the most current standards established by USP 797 when engaging in any
284 form of sterile compounding, and shall obtain and hold a sterile compounded drug preparations
285 specialty license appropriate to the definition of this practice. Such pharmacies shall also adhere
286 to the additional regulations promulgated by the board of pharmacy, in consultation with an
287 advisory committee of industry experts as established by section 42³/₄ of chapter 112., under
288 subsection (h) of section 39F.

289 (d) A pharmacy licensed by the commonwealth, intending to compound sterile drug
290 preparations, and with the additional intent to distribute sterile compounded drug preparations to
291 pharmacies, wholesalers or prescribers into or out of the state in anticipation of a prescription, in
292 volumes inconsistent with routinely observed volume patterns associated with patient-specific
293 prescriptions, or in the absence of accountability documentation, shall adhere to the most current
294 standards established by FDA cGMP when engaging in any form of sterile compounding.
295 Furthermore such pharmacies must obtain and hold a manufactures license appropriate to this
296 definition of practice, from the federal Food and Drug Administration, before engaging in any
297 sterile compounding. The manufacturers license is non-transferable and shall be renewed
298 annually, at a fee which shall be determined annually by the commissioner of the administration
299 under section 3B of chapter 7.

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

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

306 (c) The board shall establish a list of procedural criteria by which a sterile compounding
307 pharmacy can expect to be evaluated on at the time of inspection. The procedural criteria shall
308 contain a pre-determined list of constant standards and safeguards upon which a sterile
309 compounding pharmacy can be assured to be inspected on, as well as a pre-determined yet
310 alternating list of variable criteria upon which the pharmacy can be inspected on, with no prior
311 assurance as to which subset of these variable criteria will be included in the inspection process.

312 (d) The board shall, in consultation with an advisory committee of industry experts as
313 established by section 42¾ of chapter 112, develop a quality assurance procedure for sterile
314 compounding pharmacies to adhere to including, but not limited to procedures to enhance:
315 physical inspection, compounding accuracy checks, sterility testing.

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

319 (f) All sterile compounding pharmacies shall report to the board, on an annual basis, a list
320 of prescriptions dispensed within and out of the state, as well as the volume of prescriptions
321 dispensed within and out of the state. All sterile compounding pharmacies intending to ship their
322 compounded drug preparations out of the state, shall in addition to the requirements in this
323 section, report to which states they have shipped their compounded preparations.

324 (g) Resident sterile compounding pharmacies shall require a manager of record to be
325 responsible for the pharmacy's compliance with this chapter and shall disclose to the board all of
326 the following:

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

331 (2) The pharmacy shall certify its compliance with reasonable informational requests
332 made by the board, in the course of honoring its charge to protect the public health of the citizens
333 of the commonwealth.

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

338 (h) The board shall establish supplementary regulations, beyond those established by the
339 current form of USP 797 for all pharmacies intending to compound sterile drug preparations in
340 the commonwealth . The board shall establish these supplementary regulations in consultation

341 with an advisory committee of industry experts as established by section 42¾ of chapter 112.,
342 The regulations shall include, but will not be limited to: (1) enhancing environmental monitoring
343 procedures, (2) enhancing media fill testing procedures, (3) enhancing non-sterile active
344 pharmaceutical ingredient controls, (4) enhancing procedures testing endotoxin and bioburden
345 levels of compounded drug preparations, (5) enhancing procedures surrounding process
346 validation and reproducibility of compounded drug preparations, (6) enhancing procedures
347 related to end stage testing of compounded drug preparations, (7) enhancing procedures relating
348 to the storage and beyond-use-dating of compounded drug preparations, (8) enhancing the
349 physical inspection process for finished sterile compounded drug preparations, (9) developing
350 effective formulation records for sterile compounding pharmacies, (10) developing effective
351 compounding records for compounded drug preparations produced at sterile compounding
352 pharmacies, (11) developing effective procedures to maintain preparations quality and control
353 after the compounded sterile drug preparation leaves the pharmacy.

354 Section 39G. (a) The board shall establish a procedure to license non-resident or out-of-
355 state pharmacies located outside of the commonwealth that prescribe, ship, mail, sell or dispense
356 medications into the commonwealth, that pertain to the practice of pharmacy. In establishing a
357 procedure to license non-resident or out-of-state pharmacies, the board shall ensure that the
358 licensing procedure is equivalent to licensing procedure established by this legislation, for
359 pharmacies licensed to operate in the commonwealth.

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

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

367 (2) That it maintains, at all times, a current unrestricted license, permit or registration to
368 conduct the pharmacy in compliance with the laws and regulations of the jurisdiction in which it
369 is licensed to practice. The pharmacy must also certify its compliance with reasonable
370 informational requests made by the board, in the course of honoring its charge to protect the
371 public health of the citizens of the commonwealth.

372 (3) That it maintains its records of all drugs dispensed to patients in the commonwealth,
373 and makes these records readily retrievable, upon request of the board. This list shall be updated
374 annually, and sent to the board proactively.

375 (c) No pharmacy or pharmacist operating outside of the state shall be authorized to
376 prescribe, ship, mail, sell, transfer or dispense drug preparations in to the commonwealth unless

377 the drug preparations are produced in a pharmacy that has been granted a non-resident license by
378 the board.

379 (d) No pharmacy or pharmacist operating outside of the state shall be authorized to
380 prescribe, ship, mail, sell, transfer or dispense sterile compounded drug preparations into the
381 commonwealth unless the sterile compounded drug preparations are produced in a pharmacy that
382 has been granted a sterile compounded drug preparations non-resident license by the board.

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

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

387 Section 42 ½ (a) For the purpose of his section, the following words shall have the
388 following meanings:

389 “Enforcement action records”, any documents issued by the department of public health
390 to a pharmacy or pharmacist for an infraction or violation of a state or federal statute or
391 regulation by the pharmacy or pharmacist. These records shall include, but not be limited to,
392 consent decrees or judgments entered into between the department and a licensed pharmacy or
393 pharmacist as a result of a charge or complaint filed by the department against a pharmacy or
394 pharmacist for a statutory or regulatory violation or infraction or any other type of voluntary
395 resolution of a charge or complaint filed by the department.

396 “Searchable website”, a website that allows the public at no cost to search for and obtain
397 enforcement action records and serious adverse drug events records, as defined in section 51H of
398 chapter 111, pertaining to pharmacies licensed by the commonwealth

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

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

403 (2) copies of any records of serious adverse drug events, as defined in section 51H of
404 chapter 111, suffered by a patient or user of medications as a result of their use of medication
405 prepared, made or constituted by a pharmacy or pharmacist licensed by the department whether
406 within or without the commonwealth.

407 (3) any other relevant information specified by the commissioner.

408 (c) The searchable website shall allow users to search electronically by field in a single
409 search, parse, query or aggregate the data, and download information yielded by a search. The

410 website shall, among other things, permit users to search by a particular pharmacy or pharmacists
411 or by a specific medication.

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

414 (e) The commissioner shall update the searchable website as new data becomes available.
415 All agencies or boards of the department shall provide to the commissioner all data that is
416 required to be included in the searchable website no later than 30 days after the data becomes
417 available to the department. The commissioner shall provide guidance to agency or board heads
418 to ensure compliance with this section.

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

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

425 Section 42³/₄. There is hereby established an advisory committee to the board consisting
426 of the following members to be appointed by the commissioner of the department of public
427 health: an expert in United States Pharmacopeia chapter 795, an expert in United States
428 Pharmacopeia 797, and expert in United States Pharmacopeia 71, an expert in federal current
429 good manufacturing practices for aseptic processing, an expert in pharmacoeconomics, an expert
430 in clinical pharmacology, a microbiologist. The advisory committee shall consist of additional
431 members, as determined by the board of registration in pharmacy, if so deemed necessary to
432 fulfill the duties that this committee is charged with. The advisory committee shall advise the
433 board of pharmacy regarding proposed regulations surrounding quality assurance and the
434 inspection and testing of compounded drug products. The advisory committee shall also advise
435 the board of pharmacy regarding proposed regulations to supplement the current form of USP
436 797. The advisory committee shall also evaluate current trends in pharmacy in the
437 commonwealth, as well as recommended improvements to pharmacy practice in the
438 commonwealth. Furthermore the advisory committee shall evaluate the volume and revenue of
439 drug preparations generated by each licensed sterile compounding pharmacy in the
440 commonwealth. Members of the advisory committee shall serve without compensation, and shall
441 be free of any liability incurred by their proposed recommendation to the board of pharmacy.
442 The advisory committee shall be provided support services by the department of public health.

443 The advisory committee to the board is charged with investigating the causes of drug
444 shortages and their relation to the market for compounded drugs in the state of Massachusetts.
445 The advisory committee shall determine an approach to address potential drug shortages when
446 sufficient clinical need or a threat to public health and safety exist.

447 The advisory committee to the board is charged with studying the feasibility of a state
448 administered central fill pharmacy for the purposes of compounding and distributing
449 compounded drug preparations for hospitals in the Commonwealth.

450 Section 42 7/8. (a) The board may assess a licensed pharmacy a penalty of not more than
451 \$25,000 for each violation of regulations or administrative rules established under any general
452 law that governs the practice of pharmacy.

453 (b) The board may assess a pharmacy licensed under chapter 112, ordered to correct a
454 violation of regulations or administrative rules established under any general law that governs
455 the practice of pharmacy, a penalty of not more than \$1,000 for each violation for each day the
456 violation continues to exist beyond the date prescribed for correction.

457 (c) Upon making an assessment, the board shall give the licensee notice of the matters
458 alleged and the provisions of law relied upon and shall accord such person an opportunity for a
459 hearing upon written request within 15 business days of the assessment. If after a hearing, or
460 waiver thereof, the board determines that cause exists, the board shall make an appropriate
461 assessment. The affected licensee shall pay such assessment except to the extent that, upon
462 judicial review, the reviewing court may reverse the final decision of the board.

463 (d) An assessment made under this section shall be collected on the thirtieth day after
464 notification to the affected licensee, or on the fifteenth day after resolution of an administrative
465 appeal, and deposited into the quality in health professions trust fund as established by section 10
466 of chapter 35x. The attorney general shall recover any assessment due and payable brought in the
467 name of the commonwealth in the superior court. Funds collected under section 42B shall be
468 paid as described in procedures established under chapter 112 section 42C.

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

471 The board shall participate in any national data reporting system which provides
472 information on individual pharmacies, pharmacists and pharmacy technicians including, but not
473 limited to, relevant databases maintained by the National Association of the Boards of Pharmacy
474 and the United States Food and Drug Administration

475 SECTION 21. Said section 42A of said chapter 112, as so appearing, is hereby further
476 amended by adding the following 3 paragraphs:

477 The board or board president may, without holding a hearing, suspend, or refuse to renew
478 a registrant's license if the board or board president finds, through reasonable cause, that the
479 health, safety, or welfare of the public warrants such summary action; provided, however, that
480 the board shall, within 7 days of such summary action, afford the registrant the opportunity of a
481 hearing under chapter 30A. Any suspension imposed by the board or board president shall

482 remain in effect until the conclusion of the proceedings including the judicial review thereof,
483 unless sooner dissolved by a court of competent jurisdiction or withdrawn by the board.

484 If, based upon evidence, the board or board president determines that a registrant or
485 licensee or the preparations prepared by a registrant or licensee are an immediate threat to the
486 public health, safety, or welfare, the board or board president may: (1) issue a cease and desist
487 notice or quarantine notice requiring the cessation or restriction of any and all pharmacy
488 operations, and prohibiting the use of medications prepared by or in possession of a pharmacy; or
489 (2) issue a cease and desist notice or quarantine notice placing non-disciplinary restrictions on a
490 board registrant or licensee, to the extent necessary to avert a continued threat, pending final
491 investigation results. The board shall promulgate regulations pertaining to the issuance of cease
492 and desist and quarantine notices.

493 Monetary penalties collected under section 42A shall be deposited into the quality in
494 health profession trust administered by the department of public health to support initiatives such
495 as patient safety and quality improvement programs for organizations under the jurisdiction of
496 health professions licensure board, training for board staff, and to offset the costs of board
497 business, including investigation, enforcement activities and investments in health information
498 technology. The board shall promulgate regulations for the administration of this fund, in
499 consultation with all health professions licensure boards, including the establishment of
500 eligibility criteria, program requirements, and assessment and reporting processes.

501 SECTION 22. Section 187 of Chapter 149 of the General Laws, as appearing in the 2012
502 Official Edition, is hereby amended by adding the word “pharmacy” after “community health
503 agency” in the definition of “health care facility”.

504 SECTION 23. The board of registration in pharmacy, shall, in consultation with the
505 department of public health and an advisory committee of industry experts as established by
506 section 42³/₄ of chapter 112., promulgate regulations no later than 180 days after passage of this
507 law pertaining to the inspections and testing of sterile compounding pharmacies, as well as the
508 inspection and testing of compounded sterile drug preparations produced by relevant pharmacies,
509 as required by section 39F of chapter 112 of the General Laws.

510 SECTION 24. Notwithstanding any general or special law to the contrary, the initial
511 report, as required by section 25A of chapter 112 of the General Laws shall detail the
512 investigatory and disciplinary actions conducted by the board of registration in pharmacy from
513 September 1, 2012 through December 1, 2013.