

SENATE No. 1907

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

Commonwealth of Massachusetts

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In the Year Two Thousand Thirteen
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1 SECTION 1. Section 35X of chapter 10 of the General Laws, as appearing in the 2012
2 Official Edition, is hereby amended by adding the following subsection:—

3 (e) There shall be deposited into the fund any monetary penalties collected pursuant to
4 section 42D of chapter 112; provided, however, any monetary penalties collected shall be held
5 separately and used by the commissioner in accordance with the requirements of said section
6 42D.

7 SECTION 2. Chapter 13 of the General Laws is hereby amended by striking out section
8 22, as so appearing, and inserting in place thereof the following section: -

9 Section 22. (a) There shall be a board of registration in pharmacy, called the “board” in
10 this section and sections 23 to 25A, inclusive. The governor shall appoint 13 members to the
11 board who shall be residents of the commonwealth. No person who has been convicted of a
12 felony or other crime involving embezzlement, theft, fraud or perjury shall serve as a member of
13 the board. The board shall be comprised of: 8 registered pharmacists; 1 pharmacy technician; 1
14 representative of the public with experience in health care service delivery, administration or
15 consumer advocacy, subject to section 9B; 1 physician registered pursuant to chapter 112; 1
16 nurse registered pursuant to said chapter 112; and 1 expert in patient safety and quality
17 improvement.

18 (b) The 8 registered pharmacists of the board shall each have had at least 7 consecutive
19 years of experience in the practice of pharmacy and shall be currently employed in the practice
20 of pharmacy in the commonwealth at the time of appointment or reappointment.

21 (c) At the time of appointment or reappointment to the board, at least 2 of the 8 registered
22 pharmacist members shall be an independent pharmacist employed in the independent pharmacy
23 setting. For the purposes of this section, “independent pharmacist” shall mean a pharmacist
24 actively engaged in the business of retail pharmacy who is employed by an organization, which
25 is registered under section 39 of chapter 112, has 9 or fewer registered retail drugstores in the
26 commonwealth and employs not more than 20 full-time pharmacists.

27 (d) At the time of appointment or reappointment to the board, at least 2 of the 8 registered
28 pharmacist members shall be a chain pharmacist employed in the chain pharmacy setting. For the
29 purposes of this section, “chain pharmacist” shall mean a pharmacist employed by a retail drug
30 organization that operates 10 or more retail drug stores within the commonwealth and is
31 registered under section 39 of chapter 112.

32 (e) At the time of appointment or reappointment to the board, at least 1 of the 8 registered
33 pharmacist members shall have had at least 7 years of experience in a hospital setting within the
34 commonwealth.

35 (f) At the time of appointment or reappointment to the board, at least 1 of the 8 registered
36 pharmacist members shall have had at least 7 years of experience being employed in a long-term
37 care pharmacy setting.

38 (g) At the time of appointment or reappointment to the board, at least 1 of the 8 registered
39 pharmacist members shall have had at least 7 years of experience in the practice of compounding
40 sterile drug preparations, as defined in section 39D of chapter 112, and shall be engaged in
41 compounding sterile drug preparations as a routine function of the member’s employment.

42 (h) At the time of appointment or reappointment to the board, at least 1 of the 8 registered
43 pharmacist members shall be employed in an academic or scholarly position related to the
44 practice of pharmacy with an institution of higher learning licensed by the commonwealth.

45 (i) Not more than 1 pharmacist in any 1 practice setting defined in subsections (e) to (g),
46 inclusive, may serve on the board at any one time. Not more than 2 pharmacists in any 1 practice
47 setting defined in subsections (c) and (d) may serve on the board at any 1 time.

48 (j) At the time of appointment or reappointment to the board, the pharmacy technician
49 member shall have had at least 7 years of practical experience as a pharmacy technician and shall
50 actually be engaged in the practice of pharmacy as a routine function of the member's
51 employment.

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

56 (l) At the time of appointment or reappointment to the board, no member of the board
57 licensed to practice by the department of public health division of health professions licensure or
58 by the board of registration in medicine shall have had any type of disciplinary or enforcement
59 action taken against them by their respective licensing board, the federal Food and Drug
60 Administration or the federal Drug Enforcement Administration during the 10 years preceding
61 their appointment to the board.

62 (m) Board members shall be appointed and shall serve for a term of 3 years. The term
63 shall begin on the first day of the month following the member's appointment. No member may
64 serve more than 2 consecutive terms on the board. Members who have served the maximum
65 number of consecutive terms shall be eligible for reappointment after not serving for at least 1
66 term.

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

72 (o) Chapters 268A and 268B shall apply to the members of the board; provided, however,
73 that the board shall establish a code of ethics for all members, investigative agents appointed
74 pursuant to section 25 and employees, which shall be more restrictive than said chapters 268A
75 and 268B. A copy of the code shall be filed with the state ethics commission. The code shall
76 include provisions reasonably necessary to carry out this section and any other laws pertaining to
77 the jurisdiction of the board including, but not limited to: (i) requiring the disclosure of any gifts
78 received by board members by any person or entity subject to the jurisdiction of the board; (ii)
79 prohibiting the participation by board members in a particular matter as defined in section 1 of
80 said chapter 268A that affects the financial interest of a relative within the third degree of
81 consanguinity or a person with whom the board member has a significant relationship as defined
82 in the code; and (iii) providing for recusal of a board member in a licensing decision due to a
83 potential conflict of interest.

84 SECTION 3. Section 23 of said chapter 13, as so appearing, is hereby amended by adding
85 the following paragraph:-

86 A member may serve up to 1 year as secretary and up to 1 year as president during any
87 single term.

88 SECTION 4. Section 25 of said chapter 13, as so appearing, is hereby amended by
89 striking out, in line 1, the words “no more than six”.

90 SECTION 5. Said chapter 13 is hereby further amended by inserting after section 25 the
91 following section:-

92 Section 25A. As directed by the board, all agents appointed pursuant to section 25 shall
93 be trained in chapters 795 and 797 of the United States Pharmacopeia and National Formulary as
94 well as additional sterile compounding and complex non-sterile compounding surveyor courses.
95 This training shall include, but not be limited to, programs offered free of charge by the National
96 Association of Boards of Pharmacy.

97 SECTION 6. Section 21 of chapter 94C of the General Laws, as appearing in the 2012
98 Official Edition, is hereby amended by adding the following 3 paragraphs:-

99 The labeling provisions of this section shall apply to the compounding and dispensing of
100 drugs on the oral or written prescription of a licensed and registered prescriber under section 9.
101 The label shall also notify prescribed users if the compounded preparation has not been tested or
102 approved by the federal Food and Drug Administration or if the compounded preparation does
103 not meet federal Food and Drug Administration good manufacturing guidelines. In such
104 instances, the label shall notify prescribed users to contact their prescribing health care
105 professional if the prescribed user has any questions.

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

110 All sterile compounding pharmacies and complex non-sterile compounding pharmacies,
111 as defined in section 39D of chapter 112, shall provide a telephone number to patients to foster
112 communication between patients in the commonwealth and a pharmacist employed by the
113 pharmacy who has access to the patient's records. The phone shall be staffed during regular
114 hours of operation every day and not less than 56 hours per week. The phone number shall be
115 affixed to the drug's container, alongside the label notifying prescribed users and practitioners of
116 the fact that the drug is a compounded drug preparation. This paragraph shall not apply to a
117 hospital pharmacy engaged in sterile compounding or complex non-sterile compounding.

118 SECTION 7. Subsection (a) of section 51H of chapter 111 of the General Laws, as so
119 appearing, is hereby amended by striking out the definition of "Serious adverse drug event" and
120 inserting in place thereof the following definition:-

121 "Serious adverse drug event", any preventable medical occurrence associated with the
122 use of a drug in humans, that results in any of the following outcomes: (i) death; (ii) a life-
123 threatening outcome; (iii) inpatient hospitalization or prolongation of existing hospitalization;
124 (iv) a persistent or significant incapacity or substantial disruption of the ability to conduct normal
125 life functions; (v) a congenital anomaly or birth defect; or (vi) any other kind of harm as
126 determined by the department in regulation.

127 SECTION 8. Subsection (b) of said section 51H of said chapter 111, as so appearing, is
128 hereby amended by adding the following sentence:- A facility that discovers a serious adverse
129 drug event resulting from a patient’s use, consumption or interaction with any pharmaceutical or
130 drug preparation, shall report the event to the federal Food and Drug Administration’s
131 MedWatch Program, as well as the pharmacy from which the drug was produced, compounded
132 or dispensed in addition to all other reporting requirements.

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

136 SECTION 10. Section 1 of chapter 111N of the General Laws, as so appearing, is hereby
137 amended by inserting after the word “device”, in line 15, the following words:- compounding or.

138 SECTION 11. The first paragraph of section 2 of said chapter 111N, as so appearing, is
139 hereby amended by inserting after the first sentence the following sentence:- For the purposes of
140 this section, an entity that is involved in pharmaceutical compounding shall also be subject to
141 said marketing code of conduct.

142 SECTION 12. Section 24 of chapter 112 of the General Laws, as so appearing, is hereby
143 amended by striking out the words “twenty-five to forty-two”, in line 5, and inserting in place
144 thereof the following words:- 25 to 42D.

145 SECTION 13. Section 24A of said chapter 112, as so appearing, is hereby amended by
146 striking out the second paragraph and inserting in place thereof the following 3 paragraphs:-

147 The board shall require each registered pharmacist seeking personal registration renewal
148 to complete continuing education requirements as a condition precedent to such renewal. No
149 registrant shall be eligible for renewal of a personal registration without completion of the
150 requisite number of contact hours for such renewal. A registrant seeking renewal of a personal
151 registration shall complete a minimum of 20 contact hours each calendar year of the 2-year
152 renewal cycle. Of the 20 contact hours effective for the renewal period beginning January 1,
153 2014 any pharmacist licensed by the commonwealth overseeing or directly engaged in the
154 practice of sterile pharmaceutical compounding or practicing in a licensed specialty sterile

155 compounding pharmacy shall devote at least 5 of the 20 contact hours to the area of sterile
156 compounding. Of the 20 contact hours effective for the renewal period beginning January 1,
157 2014 any pharmacist licensed by the commonwealth overseeing or directly engaged in the
158 practice of complex non-sterile pharmaceutical compounding or practicing in a licensed specialty
159 complex non-sterile compounding pharmacy shall devote at least 3 of the 20 contact hours to the
160 area of complex non-sterile compounding.

161 The board, in consultation with the advisory committee, established by section 42C, shall,
162 in addition to the requirements listed in this section, adopt further rules and regulations for a
163 system of continuing education. The board shall accept all conferences and programs from
164 providers approved by the Accreditation Council for Pharmacy Education meeting these
165 requirements.

166 The board shall conduct audits of randomly selected renewed licenses. The board shall
167 initiate the audit by sending selected licensees a request to provide documentation, which
168 evidences the completion of the required contact hours. The name and date of licensees included
169 in an audit shall be posted on the board's website. Licensees who are not in compliance with the
170 contact hour requirements or fail to provide the requested documentation within 7 days of
171 receiving a request shall be fined not more than \$1,000.

172 SECTION 14. Said chapter 112 is hereby further amended by inserting after section 25
173 the following section:-

174 Section 25A. The board shall submit an annual report to the department of public health,
175 the joint committee on public health and the joint committee on health care financing on or
176 before December 31. The report shall detail the investigatory and disciplinary actions conducted
177 by the board and shall detail: (1) each complaint received by the board or initiated by the board;
178 (2) the date of the complaint; (3) the violation alleged; (4) the name of any state or federal
179 agency that collaborated with the investigation; (5) the summary of the final decision of the
180 board to: (i) dismiss the complaint, (ii) impose an informal sanction or penalty, (iii) impose a
181 formal sanction or penalty or (iv) amend a previously issued sanction or penalty; and (6) whether
182 the board reported the result of its investigation to another state board, federal agency or external
183 entity.

184 All relevant data collected and analyzed under subsections (b) through (e), inclusive, of
185 section 39D shall be summarized and included in the report. The report shall be made publicly
186 available, including by electronic means, to all hospitals, pharmacies and health care providers
187 doing business in the commonwealth. Said report shall be posted on the department of public
188 health's website.

189 SECTION 15. Section 32 of said chapter 112, as appearing in the 2012 Official Edition,
190 is hereby amended by adding the following paragraph:-

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

195 SECTION 16. The second paragraph of section 39 of said chapter 112, as so appearing, is
196 hereby amended by striking out the second sentence.

197 SECTION 17. Said section 39 of said chapter 112, as so appearing, is hereby further
198 amended by adding the following paragraph:-

199 The board may establish specialty pharmacy licensure categories beyond those delineated
200 in this section, and in sections 39A to 39C, inclusive, and in sections 39F to 39I, inclusive,
201 through the promulgation of regulations as the board, in consultation with the commissioner of
202 public health, deems necessary. The board shall determine which regulations, applicable to a
203 retail drug business registered pursuant to section 39, shall apply to a pharmacy registered
204 pursuant to this section and may establish regulations that shall only apply to a licensure
205 category established pursuant to this paragraph. The licensure fee shall be determined annually
206 by the secretary of administration and finance, under section 3B of chapter 7.

207 SECTION 18. Said chapter 112 is hereby further amended by striking out section 39D, as
208 so appearing, and inserting in place thereof the following 5 sections:-

209 Section 39D. (a) As used in this section and in sections 39F to 42D, inclusive, the
210 following words shall, unless the context clearly requires otherwise, have the following
211 meanings:-

212 “Accountability documentation”, physical documentation validating the lot numbers and
213 expiration dates of drugs or preparations with a patient drug prescription order from a
214 practitioner listed in section 9 of chapter 94C. The purpose of accountability documentation shall
215 be to: facilitate the tracing of a compounded complex non-sterile drug preparation or
216 compounded sterile drug preparation back to the compounding pharmacy where it was produced;
217 identify the individual, pharmacy technician or automated compounding device that produced the
218 drug; and identify the prescription order that generated the production or compounding of the
219 drug preparation.

220 “Complex non-sterile compounding”, engaging in the compounding of complex non-
221 sterile drug preparation.

222 “Complex non-sterile compounding pharmacy”, any retail or hospital pharmacy or
223 facility where a compounded complex non-sterile drug preparation is compounded or
224 manufactured.

225 “Compounded complex non-sterile drug preparation”, a compounded preparation which
226 requires special training, a special environment or special facilities or equipment or the use of
227 compounding techniques and procedures that may present an elevated risk to the compounder or
228 the patient, as defined by the board through regulation; provided, that the regulations
229 promulgated by the board, which are applicable to this definition, shall be consistent with the
230 category of complex non-sterile compounding described in chapter 795 of the USP.

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

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

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

241 routine professional practice to meet the unique medical need of an individual patient of the
242 practitioner;

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

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

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

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

252 “Manager of record”, a licensed pharmacist who signs the application for a pharmacy
253 permit and assumes full legal responsibility for the operation of the relevant pharmacy in a
254 manner complying with the laws and regulations for the practice of pharmacy and the sale and
255 dispensing of controlled substances. The manager of record shall personally supervise the
256 pharmacy and pharmacy personnel as required by section 39.

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

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

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

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

266 “USP ”, the most recent edition of the United States Pharmacopeia and National
267 Formulary.

268 (b) A store or pharmacy engaged in the drug business shall inform the department of
269 public health of any improper dispensing of prescription drugs that results in serious injury or
270 death, as defined by the department in regulations, as soon as is reasonably and practically
271 possible, but not later than 3 business days after discovery of the improper dispensing.

272 (c) The manager of record of a store or pharmacy shall report any serious adverse drug
273 event, as defined in section 51H of chapter 111, occurring as a result of patient interaction with
274 any drug or pharmaceutical preparation manufactured, produced or compounded at the manager
275 of record’s pharmacy, to the federal Food and Drug Administration MedWatch Program and the
276 Betsy Lehman center for patient safety and medical error reduction. The manager of record of a
277 store or pharmacy shall report to the board any serious adverse drug event, as defined in section
278 51H of chapter 111, occurring as a result of patient interaction with any drug or pharmaceutical
279 preparation manufactured, produced or compounded at the manager of record’s store or
280 pharmacy that is suspected to be caused by the drug preparation, drug compounding or other
281 pharmacist error. This data shall be reported to the board within 3 business days of the
282 knowledge of any serious adverse drug event by any pharmacy employee.

283 (d) All data concerning serious adverse drug events reported to the board shall be
284 collected, synthesized and analyzed by the board in a traceable and easily navigable database
285 format using information technology. The board shall use the data to track trends in serious
286 adverse drug events and to warn patients, consumers and pharmacies of any trends which could
287 pose a danger to public health and safety. Data collected pursuant to this subsection shall be
288 made available on the searchable website established pursuant to section 42B.

289 (e) If a sterile compounding pharmacy or complex non-sterile compounding pharmacy
290 knows or should have reason to know that a compounded sterile drug preparation or
291 compounded complex non-sterile drug preparation dispensed or distributed by the pharmacy is or
292 may be defective in any way, the pharmacy shall immediately recall the preparation. Any of the
293 same preparation remaining in the possession of the pharmacy shall be located and segregated,

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

- 296 (1) the preparation name, potency and dosage form;
- 297 (2) the reason for the recall;
- 298 (3) the amount of the preparation made;
- 299 (4) the date that the preparation was made;
- 300 (5) the amount of the preparation dispensed or distributed;
- 301 (6) the actual preparation potency and dosage form; and
- 302 (7) any and all serious adverse drug events related to the drug in question.

303 The defective preparation log shall be made available to the board within 7 days of the
304 recall. Defective preparation logs shall be kept on record by the board indefinitely and shall be
305 kept on record by the pharmacy for at least 10 years. Upon submission of the defective
306 preparation log to the board, the pharmacy shall work with the board to develop a corrective
307 action plan that rectifies the error that resulted in the defective preparation.

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

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

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

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

324 (b) A sterile compounded drug preparations specialty license issued by the board shall be
325 obtained in addition to and not in place of any other permit or license a sterile compounding
326 pharmacy holds. The license shall be non-transferable and shall be renewed annually. The fee for
327 the renewal shall be determined annually by the secretary of administration and finance pursuant
328 to section 3B of chapter 7.

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

333 (d) A pharmacy licensed by the commonwealth that intends to compound and distribute
334 compounded sterile drug preparations to pharmacies, wholesalers or prescribers in or out of the
335 commonwealth: (i) in anticipation of a prescription, in volumes inconsistent with routinely
336 observed volume patterns associated with patient-specific prescriptions, or (ii) in the absence of
337 accountability documentation, shall adhere to the most current standards established under
338 cGMP when engaging in any form of sterile compounding. Such pharmacies shall obtain and
339 hold a manufacturer's license appropriate to this practice, from the federal Food and Drug
340 Administration, before engaging in any sterile compounding and shall notify the board of the
341 acquisition, renewal or revocation of the license, as applicable, within 30 days of the action.

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

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

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

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

360 (b) A complex non-sterile compounded drug preparations specialty license issued by the
361 board shall be obtained in addition to and not in place of any other permit or license a sterile
362 compounding pharmacy holds. The license shall be non-transferable and shall be renewed
363 annually. The fee for the renewal shall be determined annually by the secretary of administration
364 and finance pursuant to section 3B of chapter 7.

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

370 (d) A pharmacy licensed by the commonwealth that intends to compound and distribute
371 compounded complex non-sterile drug preparations to pharmacies, wholesalers or prescribers in
372 or out of the commonwealth: (i) in anticipation of a prescription in volumes inconsistent with
373 routinely observed volume patterns associated with patient-specific prescriptions, or (ii) in the
374 absence of accountability documentation shall adhere to the most current standards established
375 under cGMP when engaging in complex non-sterile compounding. Such pharmacies shall obtain
376 and hold a manufacturer's license appropriate to this practice, from the federal Food and Drug
377 Administration, before engaging in any complex non-sterile compounding and shall notify the

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

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

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

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

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

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

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

418 (d) The board shall, in consultation with the advisory committee, established by section
419 42C, develop a quality assurance procedure for sterile compounding pharmacies to adhere to
420 including, but not limited to, procedures to enhance physical inspection, compounding accuracy
421 checks and sterility testing. The board shall also, in consultation with the advisory committee,
422 established by section 42C, develop a quality assurance procedure for complex non-sterile
423 compounding pharmacies to adhere to including, but not limited to, procedures to enhance
424 physical inspection and compounding accuracy checks.

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

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

435 (1) Disclose to the board the location, name and title of all principal managers and the
436 name and Massachusetts license number of the designated manager of record. A report
437 containing this information shall be made on an annual basis and within 30 days after any change
438 of office, corporate office or manager of record.

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

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

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

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

463 Section 39I. (a) The board shall establish a procedure to license non-resident or out-of-
464 state pharmacies located outside of the commonwealth that prescribe, ship, mail, sell or dispense
465 medications in the commonwealth, that pertains to the practice of pharmacy. The board shall also
466 take steps to ensure that all shipments of pharmaceuticals from in-state pharmacies to out-of-
467 state destinations are in compliance with the licensing procedures applicable to pharmacies in the
468 commonwealth.

469 (b) The non-resident or out-of-state pharmacies shall designate a pharmacist in charge
470 who shall register with the board and shall be responsible for the pharmacy's compliance with
471 this section. The pharmacist in charge shall be licensed and in good standing with the state board
472 of registration in pharmacy in which the pharmacy is located. The designated pharmacist in
473 charge shall:

474 (1) Disclose to the board the location, name and title of all principal managers and the
475 name of the designated pharmacist in charge, if applicable, and a letter from the in-state board of
476 registration of pharmacy certifying that the pharmacist in charge is in good standing with the in-
477 state board of registration. The designated pharmacist in charge shall submit a report containing
478 this information and a copy of the certifying letter of good standing on an annual basis and
479 within 30 days after any change of office, corporate office or manager of record.

480 (2) Certify to the board that the pharmacy maintains, at all times, a current unrestricted
481 license, permit or registration to conduct the pharmacy in compliance with the laws and
482 regulations of the jurisdiction in which it is licensed to practice. The pharmacy shall certify its
483 compliance with reasonable informational requests made by the board. The pharmacy shall also
484 notify the board of any enforcement or disciplinary action taken against the pharmacy regardless
485 of the state in which the enforcement action is taken.

486 (3) Maintain its records of all drugs dispensed to patients in the commonwealth and
487 ensure that these records are readily available, upon the request of the board. A list of drugs
488 dispensed in the commonwealth shall be sent to the board annually.

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

491 the drug preparations are produced in a pharmacy that has been granted a non-resident or out-of-
492 state license pursuant to this section.

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

499 (e) Out-of-state pharmacies holding an out-of-state license under this section shall be
500 subject to the requirements of section 24A of chapter 94C; provided, however, that non-resident
501 or out of state pharmacies shall not be eligible for any waiver under said section 24A. An
502 application for licensure under this section shall not be approved unless the applicant has
503 demonstrated the ability to comply with said section 24A. The board may revoke a non-resident
504 or out-of-state pharmacy license for failure to comply with said section 24A.

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

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

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

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

509 SECTION 20. Section 42A of chapter 112 of the General Laws, as appearing in the 2012
510 Official Edition, is hereby amended by inserting after the first paragraph the following
511 paragraph:-

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

516 SECTION 21. Said section 42A of said chapter 112, as so appearing, is hereby further
517 amended by adding the following 2 paragraphs:-

518 The board or board president may, without holding a hearing, suspend or refuse to renew
519 a pharmacy license if the board or board president finds reasonable cause to believe that the
520 health, safety or welfare of the public warrants the summary action; provided, however, that the
521 board shall, within 7 days of such action, afford the licensee the opportunity of a hearing
522 pursuant to chapter 30A. Any suspension imposed by the board or board president shall remain
523 in effect until the conclusion of the proceedings, including any judicial review thereof, unless
524 sooner dissolved by a court of competent jurisdiction or withdrawn by the board.

525 If, based upon evidence, the board or board president determines that a registrant or
526 licensee, or the preparations prepared by a registrant or licensee are an immediate threat to the
527 public health, safety or welfare, the board or board president may: (i) issue a cease and desist
528 notice or quarantine notice requiring the cessation or restriction of any and all pharmacy
529 operations and prohibiting the use of medications prepared by or in possession of a pharmacy; or
530 (ii) issue a cease and desist notice or quarantine notice placing non-disciplinary restrictions on a
531 board registrant or licensee, to the extent necessary to avert a continued threat, pending final
532 investigation results. The board shall promulgate regulations pertaining to the issuance of cease
533 and desist and quarantine notices.

534 SECTION 22. Said chapter 112 is hereby further amended by inserting after section 42A
535 the following 3 sections:-

536 Section 42B. (a) For the purpose of this section, the following words shall, unless the
537 context clearly requires otherwise, have the following meanings:-

538 “Enforcement action records”, any documents issued by the department of public health
539 to a pharmacy or pharmacist relating to an infraction or violation of a state or federal statute or
540 regulation by the pharmacy or pharmacist. These records shall include, but not be limited to,
541 consent decrees or judgments entered into between the department and a licensed pharmacy or
542 pharmacist as a result of a charge or complaint filed by the department against a pharmacy or
543 pharmacist for a statutory or regulatory violation or infraction or any other type of voluntary
544 resolution of a charge or complaint filed by the department.

545 “Searchable website”, a website that allows the public to search for and obtain, at no
546 charge, enforcement action records and records of serious adverse drug events, as defined in

547 section 51H of chapter 111, pertaining to pharmacies licensed by the commonwealth and other
548 relevant information related to pharmacy licensure.

549 (b) The commissioner of public health shall develop and operate a searchable website,
550 which includes:

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

553 (2) copies of any records of serious adverse drug events, as defined in section 51H of
554 chapter 111, reported to the board, pursuant to section 39D, and data related to the event suffered
555 by a patient or user of medications as a result of their use of medication prepared, made or
556 constituted by a pharmacy or pharmacist licensed by the board whether within or without the
557 commonwealth;

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

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

562 (c) The searchable website shall allow users to search electronically by field in a single
563 search, parse, query or aggregate the data and download information yielded by a search. The
564 website shall permit users to search by a particular pharmacy or pharmacists or by a specific
565 medication.

566 (d) The searchable website shall include and retain information for not less than 10 years.

567 (e) The commissioner of public health shall update the searchable website as new data
568 becomes available. All agencies or boards of the department of public health shall provide to the
569 commissioner all data that is required to be included in the searchable website, not later than 30
570 days after the data becomes available to them. The commissioner shall provide guidance to
571 agency or board heads to ensure compliance with this section.

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

574 (g) The commissioner of public health shall not be considered in compliance with this
575 section if the data required for the searchable website is not available in a searchable and
576 aggregate manner or if the public is redirected to other government websites, unless each of
577 those websites complies with the requirements of this section.

578 Section 42C. There shall be an advisory committee to the board, which shall consist of
579 the following members, to be appointed by the commissioner of public health: an expert in
580 chapter 795 of the USP; an expert in chapter 797 of the USP; an expert in chapter 71 of the USP;
581 an expert in cGMP for aseptic processing; an expert in pharmacoeconomics; an expert in clinical
582 pharmacology; and a microbiologist. The advisory committee shall consist of additional
583 members, as determined by the board, at least 1 of whom shall be a member of the public with
584 experience in health care service delivery, administration or consumer advocacy.

585 The advisory committee shall advise the board regarding proposed regulations on quality
586 assurance and the inspection and testing of compounded drug preparations. The advisory
587 committee shall advise the board regarding proposed regulations to supplement the current form
588 of chapters 795 and 797 of the USP. The advisory committee shall evaluate current trends in
589 pharmacy in the commonwealth, as well as recommended improvements to pharmacy practice in
590 the commonwealth. The advisory committee shall evaluate the volume and revenue of drug
591 preparations generated by each licensed sterile compounding pharmacy in the commonwealth.
592 The advisory committee shall study the feasibility of a centralized reporting system for serious
593 adverse drug events and other serious reportable events which shall be administered by the
594 department of public health for the purposes of allowing pertinent state agencies, providers,
595 health systems, pharmacies, licensed compounding pharmacies and other relevant health care
596 entities, as defined by the department of public health in regulation, to utilize this resource to
597 further improve their internal quality initiatives and reduce patient safety concerns. Members of
598 the advisory committee shall serve without compensation and shall be free of any liability
599 incurred by their proposed recommendations to the board. The department of public health shall
600 provide the advisory committee with support services.

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

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

605 Section 42D. (a) The board of registration in pharmacy may assess a licensed pharmacy a
606 penalty of not more than \$25,000 for each violation of regulations or administrative rules
607 established pursuant to any general law that governs the practice of pharmacy. The board,
608 through regulations, shall ensure that any fine levied is commensurate with the severity of the
609 violation.

610 (b) The board may assess a pharmacy licensed pursuant to this chapter and ordered to
611 correct a violation of regulations or administrative rules, which were established under any
612 general law that governs the practice of pharmacy, a penalty of not more than \$1,000 for each
613 violation for each day the violation continues to exist beyond the date prescribed for correction.

614 (c) Upon making an assessment, the board shall give the licensee notice of the matters
615 alleged and the provisions of law relied upon and shall accord the licensee an opportunity for a
616 hearing upon a written request within 15 business days of the assessment. If after a hearing, or if
617 the licensee waives the licensee's right to a hearing, the board determines that cause exists, the
618 board shall make an appropriate assessment. The affected licensee shall pay such assessment,
619 except to the extent that, upon judicial review, the reviewing court may reverse the final decision
620 of the board.

621 (d) An assessment made under this section shall be due on the thirtieth day after
622 notification to the licensee, or on the fifteenth day after resolution of an administrative appeal.
623 The attorney general shall recover any assessment due and payable brought in the name of the
624 commonwealth in the superior court. Funds collected pursuant to subsection (b) shall be paid as
625 described in subsection (c). Assessments collected pursuant to this section shall be deposited in
626 the Quality in Health Professions Trust Fund, established by section 35X of chapter 10, and shall
627 be used to support initiatives such as: patient safety and quality improvement programs for
628 organizations under the jurisdiction of the division of health professions licensure; training for
629 board and division staff; and to offset the costs of board business, including investigation,
630 enforcement activities and investments in health information technology. The board shall
631 promulgate regulations for the administration of the fund, in consultation with the division,

632 including the establishment of eligibility criteria, program requirements and assessment and
633 reporting processes.

634 SECTION 23. Section 187 of chapter 149 of the General Laws, as appearing in the 2012
635 Official Edition, is hereby amended by inserting after the word “community health agency”, in
636 line 6, the following word:- , pharmacy.

637 SECTION 24. Notwithstanding any general or special law to the contrary, there shall be a
638 special commission to study and report on the feasibility of the establishment of central fill
639 pharmacies in the commonwealth. The commission shall study and make recommendations
640 relative to: (i) licensing central fill pharmacies for the purpose of compounding and distributing
641 compounded drug preparations within a network of hospitals under common ownership; (ii) the
642 current national use of central fill pharmacies; (iii) establishing a state-administered central fill
643 pharmacy; (iv) recommendations for additional specialty licenses, pursuant to section 39 of
644 chapter 112 of the General Laws, for alternate forms of central fill pharmacy licensure; (v) the
645 projected resource allocation by the department of public health needed to implement the
646 recommended licensure attributes; (vi) the projected resource allocation by the department
647 needed to implement a state-administered central fill pharmacy for the purposes of compounding
648 and distributing compounded drug preparations for hospitals in the commonwealth; and (vii) any
649 additional recommendations related to staffing and appropriations necessary to carry out
650 preceding recommendations.

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

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

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

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

682 SECTION 27. The board of registration in pharmacy, shall, in consultation with the
683 department of public health and the advisory committee, established by section 42C of chapter
684 112 of the General Laws, consider and review current operational practices in place at hospital
685 pharmacies and recommend any necessary exemptions for a hospital pharmacy to ensure
686 consistency with pertinent federal and state statutory and regulatory requirements related to
687 hospital pharmacies engaged in compounding under a sterile compounding pharmacy or a
688 complex non-sterile compounding pharmacy specialty license, or both.

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

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

703 SECTION 28A. The advisory committee, established by section 42C of chapter 112 of
704 the General Laws, in consultation with the board of registration in pharmacy and the department
705 of public health, shall study the criteria used to test compounded sterile drug preparations, as
706 defined under section 39D of said chapter 112, including, but not limited to, the feasibility of
707 unannounced and random inspections of sterile compounding pharmacies for the efficacy of
708 compounded sterile drug preparations. The advisory committee shall submit its findings in a
709 report, together with any drafts of legislation necessary to carry out its recommendations, to the
710 clerks of the senate and house of representatives, who shall forward the report to the joint
711 committee on public health and the joint committee on health care financing not later than
712 August 15, 2014.

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

717 SECTION 29A. The board of registration in pharmacy shall, in consultation with the
718 department of public health and the advisory committee, established by section 42C of chapter
719 112 of the General Laws, study the merits of establishing specialty pharmacy certificates of
720 registration for those persons already actively registered as a pharmacist. Said study shall
721 consider issuing to those registered pharmacists qualified by experience, knowledge and integrity
722 specialty licenses for those specialties delineated in sections 39 to 39C, inclusive, of said chapter
723 112 and in sections 39F to 39G, inclusive, of said chapter 112 or any other specialty area deemed
724 appropriate. Said study shall consider the appropriate scope of practice for pharmacists engaged
725 in said specialties and the development of a system requiring specialty pharmacy certificates of
726 registration to practice within a specialty delineated in one or any of the specialties in said
727 sections 39 to 39C, inclusive, of said chapter 112 or said sections 39F to 39G, inclusive, of said
728 chapter 112.

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

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

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

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

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

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