

HOUSE No. 4235

The Commonwealth of Massachusetts

The committee of conference on the disagreeing votes of the two branches with reference to the Senate amendment (striking out all after the enacting clause and inserting in place thereof the text contained in Senate document numbered 1907) of the House Bill relative to pharmacy practice in the Commonwealth (House, No. 3672, amended), reports recommending passage of the accompanying bill (House, No. 4235). June 29, 2014.

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HOUSE No. 4235

The Commonwealth of Massachusetts

In the Year Two Thousand Fourteen

An Act relative to pharmacy practice in the Commonwealth.

Whereas, The deferred operation of this act would tend to defeat its purpose, which is to enhance forthwith the safety of drug compounding in the commonwealth, therefore, it is hereby declared to be an emergency law, necessary for the immediate preservation of the public health.

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. 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. Monetary penalties collected shall be held separately and used by
5 the commissioner in accordance with the requirements of said section 42D.

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

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

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

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

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

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

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

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

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

44 (i) Not more than 1 pharmacist in any 1 practice setting defined in subsections (e) and (f)
45 may serve on the board at any 1 time. Not more than 2 pharmacists in any 1 practice setting
46 defined in subsections (c) and (d) may serve on the board at any 1 time.

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

50 (k) At the time of appointment or reappointment to the board, no registered pharmacist or
51 pharmacy technician shall have had any type of disciplinary or enforcement action taken against

52 them by the board, the federal Food and Drug Administration or the federal Drug Enforcement
53 Administration during the 10 years preceding their appointment to the board.

54 (l) For the purposes of this section, “representative of the public” shall mean a person
55 whose background and experience qualifies that person to act on the board in the public interest,
56 including experience in health care service delivery, administration or consumer advocacy and
57 who meets the requirements of paragraph (4) of subsection (a) of section 9B.

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

64 (n) Board members shall be appointed and shall serve for a term of 3 years. The term
65 shall begin on the first day of the month following the member’s appointment. A member whose
66 term has expired shall continue in office until a successor is appointed. No member shall serve
67 more than 2 consecutive terms on the board. Members who have served the maximum number of
68 consecutive terms shall be eligible for reappointment after not serving for at least 1 term.

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

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

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

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

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

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

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

99 SECTION 6. Section 21 of chapter 94C of the General Laws, as appearing in the 2012
100 Official Edition, is hereby amended by adding the following 2 paragraphs:-

101 The labeling provisions of this section shall apply to the compounding and dispensing of
102 drugs on the oral or written prescription of a licensed and registered prescriber under section 9.
103 All drug preparations compounded, made or formulated by a pharmacy licensed by the board of
104 registration in pharmacy shall have affixed to their container by the compounding pharmacy a
105 label notifying prescribed users and practitioners that the drug is either a sterile or non-sterile
106 compounded drug preparation.

107 All pharmacies engaged in sterile or complex non-sterile compounding and licensed
108 under sections 39G to 39I, inclusive, of chapter 112 shall provide a telephone number to foster
109 communication between patients in the commonwealth and a pharmacist employed by the
110 pharmacy who has access to the patient’s records. The phone shall be staffed during regular
111 hours of operation every day and not less than 56 hours per week. The phone number shall be
112 affixed to the drug’s container, alongside the label notifying prescribed users and practitioners of
113 the fact that the drug is a compounded drug preparation. This paragraph shall not apply to an
114 institutional pharmacy licensed pursuant to section 39I of chapter 112 if the sterile drug
115 preparation compounded by such pharmacy is to be administered to an individual admitted as an
116 inpatient within the same hospital.

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

120 “Serious adverse drug event”, any untoward, preventable medical occurrence associated
121 with the use of a drug in humans that results in any of the following outcomes: (i) death; (ii) a
122 life-threatening outcome; (iii) inpatient hospitalization or prolongation of existing

123 hospitalization; (iv) a persistent or significant incapacity or substantial disruption of the ability to
124 conduct normal life functions; (v) a congenital anomaly or birth defect; or (vi) any other kind of
125 harm as determined by the department in regulation; provided, however, that adverse medical
126 occurrences directly associated with the use of a drug in humans that may not immediately result
127 in 1 of the outcomes listed in clauses (i) to (vi), inclusive, may be considered a serious adverse
128 drug event when they develop into or result in any of the outcomes listed in clauses (i) to (vi),
129 inclusive.

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

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

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

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

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

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

150 The board shall require each registered pharmacist seeking personal registration renewal
151 to complete continuing education requirements as a condition precedent to such renewal. No
152 registrant shall be eligible for renewal of a personal registration without completion of the
153 requisite number of contact hours for such renewal. A registrant seeking renewal of a personal
154 registration shall complete a minimum of 20 contact hours each calendar year of the 2 year
155 renewal cycle. Any pharmacist licensed by the commonwealth overseeing or directly engaged in
156 the practice of sterile compounding or practicing in a pharmacy licensed pursuant to section 39G
157 or 39I shall devote at least 5 of the 20 contact hours to the area of sterile compounding. Any
158 pharmacist licensed by the commonwealth overseeing or directly engaged in the practice of

159 complex non-sterile compounding or practicing in a pharmacy licensed pursuant to section 39H
160 shall devote at least 3 of the 20 contact hours to the area of complex non-sterile compounding.

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

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

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

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

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

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

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

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

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

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

206 SECTION 18. Said chapter 112 is hereby further amended by striking out section 39D, as
207 so appearing, and inserting in place thereof the following 6 sections:-

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

211 "Accountability documentation", physical documentation validating the lot numbers and
212 expiration dates or beyond-use dates of drugs or drug preparations with a patient drug
213 prescription order from a practitioner listed in section 9 of chapter 94C; provided, that
214 "accountability documentation" shall include evidence of receipt of patient-specific prescriptions
215 prior to dispensing in accordance with section 17 of said chapter 94C. The purpose of
216 accountability documentation shall be: to facilitate tracing of a complex non-sterile drug
217 preparation or sterile drug preparation back to the pharmacy where it was compounded; identify
218 the individual, pharmacy technician or automated compounding device that compounded the
219 complex non-sterile drug preparation or sterile drug preparation; and identify the prescription
220 order that generated the compounding of the complex non-sterile drug preparation or sterile drug
221 preparation.

222 "Beyond-use date", the date or time beyond which a drug preparation is not
223 recommended to be dispensed, administered, stored or transported; provided, that the "beyond-
224 use date" shall be determined from the date or time the drug preparation is compounded.

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

227 "Complex non-sterile compounding", engaging in the compounding of a complex non-
228 sterile drug preparation.

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

235 “Compounding”, the preparation, mixing, assembling, packaging or labeling of 1 or
236 more active ingredients with 1 or more other substances by or under the supervision of a licensed
237 pharmacist within a licensed pharmacy to create a final drug preparation that is formulated:

238 (1) for use on or for a patient as a result of a practitioner’s prescription order, based on
239 the relationship between the practitioner, patient and pharmacist in the course of routine
240 professional practice to meet the unique medical need of an individual patient by producing a
241 significant difference between the compounded drug preparation and a comparable commercially
242 available drug that is justified by a documented medical need as determined by the prescribing
243 practitioner including, but not limited to, the removal of a dye for medical reasons, a change in
244 strength, a change in dosage, form or delivery mechanism; provided, that a price difference shall
245 not be a significant difference to justify compounding;

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

248 (3) for the purpose of, or as an incident to, research, teaching or chemical analysis and
249 not for sale or dispensing.

250 Except as provided in clause (1), “compounding” shall not include the preparation of
251 commercially available, federal Food and Drug Administration approved drugs or drug
252 preparations.

253

254 “Institutional pharmacy”, the physical portion or satellite unit of an organization
255 including, but not limited to, hospitals, health maintenance organizations and clinic pharmacies,
256 whose primary purpose is to provide a physical environment for patients to obtain health care
257 services under the supervision of a licensed pharmacist and is authorized to dispense controlled
258 substances.

259 “Institutional sterile compounding pharmacy”, an institutional pharmacy that prepares a
260 sterile drug preparation.

261 “Manager of record” or “pharmacist in charge”, a licensed pharmacist who signs the
262 application for a pharmacy permit and assumes full legal responsibility for the operation of the
263 relevant pharmacy in a manner complying with the laws and regulations for the practice of

264 pharmacy and the sale and dispensing of controlled substances. The manager of record shall
265 personally supervise the pharmacy and pharmacy personnel as required by section 39.

266 “Non-resident pharmacy”, any pharmacy located outside of the commonwealth that
267 prescribes, ships, mails, sells or dispenses medications in the commonwealth.

268 “Pharmacy”, any entity engaged in the drug business, as defined in section 37, or that
269 engages in the practice of compounding to fulfill a practitioner prescription.

270 “Practitioner”, a person who, under section 9 of chapter 94C, may prescribe or dispense
271 controlled substances.

272 “Quality assurance”, a set of activities used to ensure that compounding processes lead,
273 with a high degree of assurance and certainty, to finished drug preparations meeting pre-
274 determined specifications and standards of quality.

275 “Retail complex non-sterile compounding pharmacy”, a retail pharmacy or facility that
276 prepares a complex non-sterile drug preparation.

277 “Retail sterile compounding pharmacy”, a retail pharmacy or facility that prepares a
278 sterile drug preparation.

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

280 “Sterile drug preparation”, a compounded biologic, diagnostic, drug, nutrient or
281 radiopharmaceutical, which under chapter 797 of the USP or the cGMP shall be compounded
282 using aseptic techniques; provided, that "sterile drug preparation" may include, but shall not
283 limited to, implants, injectables, parenteral nutrition solutions, irrigation solutions, inhalation
284 solution, intravenous solutions and ophthalmic preparations.

285 “USP”, the current edition of the United States Pharmacopeia and the National
286 Formulary.

287 (b) A pharmacy shall inform the department of public health of any improper dispensing
288 of a prescription drug that results in serious injury or death, as defined by the department in
289 regulations, as soon as is reasonably and practically possible, but not later than 7 business days
290 after discovery of the improper dispensing.

291 (c) The manager of record of a pharmacy shall report any serious adverse drug event, as
292 defined in section 51H of chapter 111, occurring as a result of the patient’s interaction with any
293 drug or pharmaceutical manufactured, produced or compounded at the manager of record’s
294 pharmacy, to the board, the federal Food and Drug Administration MedWatch Program and the
295 Betsy Lehman center for patient safety and medical error reduction. This data shall be reported to
296 the board within 7 business days of the knowledge of any serious adverse drug event by any
297 pharmacy employee.

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

304 (e) If a pharmacy knows or should have reason to know that a drug preparation
305 compounded, dispensed or distributed by the pharmacy is or may be defective in any way, the
306 pharmacy shall immediately recall the drug preparation. Any of the same drug preparation
307 remaining in the possession of the pharmacy shall be located and segregated and shall not be
308 distributed or dispensed. A defective drug preparation log documenting the recalled drug
309 preparation shall be kept by the pharmacy including information on:

- 310 (1) the drug preparation name, potency and dosage form;
- 311 (2) the reason for the recall;
- 312 (3) the amount of the drug preparation made;
- 313 (4) the date that the drug preparation was made;
- 314 (5) the amount of the drug preparation dispensed or distributed;
- 315 (6) the actual drug preparation potency and dosage form; and
- 316 (7) any and all serious adverse drug events related to the drug preparation in question.

317 The defective drug preparation log shall be made available to the board within 7 days of
318 the recall and shall be kept on record for at least 10 years. Upon submission of the defective drug
319 preparation log to the board, the pharmacy shall work with the board to develop a corrective
320 action plan that rectifies the error that resulted in the defective drug preparation.

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

323 Section 39F. (a) A pharmacy shall not engage in sterile compounding nor shall a
324 pharmacy prescribe, ship, mail, sell, transfer or dispense sterile drug preparations in the
325 commonwealth unless the pharmacy has obtained a license from the board pursuant to section
326 39G, 39I or 39J.

327 (b) No pharmacy shall engage in complex non-sterile compounding nor shall a pharmacy
328 prescribe, ship, mail, sell, transfer or dispense complex non-sterile drug preparations in the
329 commonwealth unless the pharmacy has obtained a license from the board pursuant to section
330 39H or 39J.

331 (c) An entity that intends to compound and distribute a sterile drug preparation or a
332 complex non-sterile drug preparation to pharmacies, wholesalers or prescribers within or outside
333 of the commonwealth: (i) in anticipation of a prescription, (ii) in volumes inconsistent with
334 routinely observed volume patterns associated with patient-specific prescriptions or (iii) in the
335 absence of accountability documentation shall adhere to the most current standards established
336 under cGMP when engaging in any form of compounding. Such pharmacies shall obtain and
337 hold a manufacturer's license appropriate to this practice, from the federal Food and Drug
338 Administration, before engaging in any sterile compounding or complex non-sterile
339 compounding.

340 (d) A pharmacy shall not compound any drug preparations banned by the federal Food
341 and Drug Administration because of safety concerns.

342 Section 39G. (a)(1) The board shall establish a category of pharmacy licensure for retail
343 pharmacies engaged in sterile compounding. A retail sterile compounding pharmacy license
344 issued by the board shall be obtained in addition to and not in place of any other permit or
345 license a pharmacy holds.

346 (2) A retail sterile compounding pharmacy license shall be non-transferable and shall be
347 renewed annually. The fee for the renewal shall be determined annually by the secretary of
348 administration and finance pursuant to section 3B of chapter 7.

349 (3) A retail sterile compounding pharmacy license shall not be renewed until each
350 location where a licensee compounds sterile drug preparations has been inspected by the board
351 and found to be in compliance with this chapter and regulations adopted by the board. The board
352 shall conduct unannounced random and risk-based inspections of retail sterile compounding
353 pharmacies licensed under this chapter, as well as the sterile drug preparations compounded by
354 these pharmacies.

355 (4) A retail sterile compounding pharmacy licensed by the commonwealth shall adhere to
356 the most current standards established by USP, all chapters, when engaging in any form of sterile
357 compounding. Such pharmacy shall also adhere to the additional regulations promulgated by the
358 board pursuant to subsection (c).

359 (5) All retail sterile compounding pharmacies shall report to the board, on an annual
360 basis, a list of prescriptions dispensed within and outside of the commonwealth, as well as the
361 volume of these prescriptions. A retail sterile compounding pharmacy that ships compounded
362 drug preparations outside of the commonwealth shall, in addition to the requirements in this
363 section, report to the board the names of the states to which the pharmacy has shipped sterile
364 drug preparations.

365 (6) A retail sterile compounding pharmacy license shall not be renewed until the licensee
366 certifies that their employees have been trained in lean concepts, which are tools that assist in the

367 identification and steady elimination of waste and promote continuous improvement in quality
368 and efficiency.

369 (b) A retail sterile compounding pharmacy shall designate a manager of record who shall:

370 (i) disclose to the board the location, name and title of all principal managers and the
371 name and Massachusetts license number of the designated manager of record;

372 (ii) certify the retail sterile compounding pharmacy's compliance with reasonable
373 informational requests made by the board;

374 (iii) certify to the board that the manager of record has fulfilled continuing education
375 requirements for sterile compounding and ensured that all pharmacy staff has received the
376 appropriate training and education required by law and regulation before engaging in
377 compounding;

378 (iv) submit to the board the names and titles of all individuals employed by the
379 pharmacy; and

380 (v) annually, and within 30 days after any change of office, corporate office or manager
381 of record, file a report containing the information disclosed under clause (i).

382 (c)(1) The board shall establish a list of procedural criteria on which a retail sterile
383 compounding pharmacy shall be evaluated at the time of inspection. The procedural criteria shall
384 contain a predetermined list of standards and safeguards upon which a retail sterile compounding
385 pharmacy shall be inspected, as well as a predetermined yet alternating list of variable criteria
386 upon which the pharmacy may be inspected without prior notice as to which subset of these
387 variable criteria shall be included in the inspection.

388 (2) The board shall develop a quality assurance procedure for retail sterile compounding
389 pharmacies to adhere to including, but not limited to, procedures to enhance physical inspection,
390 compounding accuracy checks and sterility testing.

391 (3) The board shall establish supplementary regulations for all retail sterile compounding
392 pharmacies intending to compound or dispense sterile drug preparations in the commonwealth.
393 The regulations shall include, but not be limited to: (i) enhancing environmental monitoring
394 procedures; (ii) enhancing media fill testing procedures; (iii) enhancing non-sterile active
395 pharmaceutical ingredient controls; (iv) enhancing procedures testing endotoxin and bioburden
396 levels of sterile drug preparations; (v) enhancing procedures surrounding process validation and
397 reproducibility of sterile drug preparations; (vi) enhancing procedures related to end stage testing
398 of sterile drug preparations; (vii) enhancing procedures relating to the storage and beyond-use-
399 dating of sterile drug preparations; (viii) enhancing the physical inspection process for finished
400 sterile drug preparations; (ix) developing effective formulation records for retail sterile
401 compounding pharmacies; (x) developing effective compounding records for sterile drug

402 preparations produced at retail sterile compounding pharmacies; and (xi) developing effective
403 procedures to maintain a drug preparation's quality and control after the sterile drug preparation
404 leaves the retail sterile compounding pharmacy.

405 (4) The board shall promulgate regulations for the administration of paragraphs (1), (2)
406 and (3) of this subsection, provided that no such regulation shall exempt a retail sterile
407 compounding pharmacy from compliance with the most current standards established by USP,
408 all chapters.

409 Section 39H. (a)(1) The board shall establish a category of pharmacy licensure for retail
410 pharmacies engaged in complex non-sterile compounding. A retail complex non-sterile
411 compounding pharmacy license issued by the board shall be obtained in addition to and not in
412 place of any other permit or license a pharmacy holds.

413 (2) A retail complex non-sterile compounding pharmacy license shall be non-transferable
414 and shall be renewed annually. The fee for the renewal shall be determined annually by the
415 secretary of administration and finance pursuant to section 3B of chapter 7.

416 (3) A retail complex non-sterile compounding pharmacy license shall not be renewed
417 until each location where a licensee compounds complex non-sterile drug preparations has been
418 inspected by the board and found to be in compliance with this chapter and regulations adopted
419 by the board. The board shall conduct unannounced random and risk-based inspections of all
420 retail complex non-sterile compounding pharmacies licensed under this chapter, as well as the
421 complex non-sterile drug preparations compounded by these pharmacies.

422 (4) A retail complex non-sterile compounding pharmacy licensed by the commonwealth
423 shall adhere to the most current standards established by USP, all chapters, when engaging in
424 any form of complex non-sterile compounding. Such pharmacy shall also adhere to the
425 additional regulations promulgated by the board pursuant to subsection (c).

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

432 (6) A retail complex non-sterile compounding pharmacy license shall not be renewed
433 until the licensee certifies that their employees have been trained in lean concepts, which are
434 tools that assist in the identification and steady elimination of waste and promote continuous
435 improvement in quality and efficiency.

436 (b) A retail complex non-sterile compounding pharmacy shall designate a manager of
437 record who shall:

438 (i) disclose to the board the location, name and title of all principal managers and the
439 name and Massachusetts license number of the designated manager of record; (ii) certify the
440 retail complex non-sterile compounding pharmacy's compliance with reasonable informational
441 requests made by the board;

442 (iii) certify to the board that the manager of record has fulfilled continuing education
443 requirements for complex non-sterile compounding and ensured that all pharmacy staff has
444 received the appropriate training and education required by law and regulations before engaging
445 in compounding; and

446 (iv) submit to the board the names and titles of all individuals employed by the
447 pharmacy; and

448 (v) annually, and within 30 days after any change of office, corporate office or manager
449 of record, file a report containing the information disclosed under clause (i)..

450 (c)(1) The board shall establish a list of procedural criteria on which a retail complex
451 non-sterile compounding pharmacy shall be evaluated at the time of inspection. The procedural
452 criteria shall contain a predetermined list of standards and safeguards upon which a retail
453 complex non-sterile compounding pharmacy shall be inspected, as well as a predetermined yet
454 alternating list of variable criteria upon which the pharmacy may be inspected without prior
455 notice as to which subset of these variable criteria shall be included in the inspection.

456 (2) The board shall develop a quality assurance procedure for retail complex non-sterile
457 compounding pharmacies to adhere to including, but not limited to, procedures to enhance
458 physical inspection and compounding accuracy checks.

459 (3) The board shall establish supplementary regulations for all retail complex non-sterile
460 compounding pharmacies intending to compound or dispense complex non-sterile drug
461 preparations in the commonwealth. The regulations shall include, but not be limited to: (i)
462 enhancing non-sterile active pharmaceutical ingredient controls; (ii) enhancing procedures
463 surrounding process validation and reproducibility of complex non-sterile drug preparations; (iii)
464 enhancing procedures related to end stage testing of complex non-sterile drug preparations; (iv)
465 enhancing procedures relating to the storage and beyond-use-dating of complex non-sterile drug
466 preparations; (v) developing effective formulation records for retail complex non-sterile
467 compounding pharmacies; and (vi) developing effective procedures to maintain a drug
468 preparation's quality and control after the complex non-sterile drug preparation leaves the retail
469 complex non-sterile compounding pharmacy.

470 (4) The board shall promulgate regulations for the administration of paragraphs (1), (2)
471 and (3) of this subsection, provided that no such regulation shall exempt a retail complex non-
472 sterile compounding pharmacy from compliance with the most current standards established by
473 USP, all chapters.

474 Section 39I. (a) (1) The board shall establish a category of pharmacy licensure for
475 institutional pharmacies engaged in sterile compounding. An institutional sterile compounding
476 pharmacy license issued by the board shall be obtained in addition to and not in place of any
477 other permit or license an entity operating an institutional pharmacy holds.

478 (2) An institutional sterile compounding pharmacy license shall be non-transferable and
479 shall be renewed annually. The fee for the renewal shall be determined annually by the secretary
480 of administration and finance pursuant to section 3B of chapter 7.

481 (3) An institutional sterile compounding pharmacy license shall be valid only for the
482 premises and shall list the specific locations on the premises where a licensee compounds sterile
483 drug preparations.

484 (4) The license shall not be renewed until each location where a licensee compounds
485 sterile drug preparations has been inspected by the board and found to be in compliance with this
486 chapter and regulations adopted by the board. The board shall conduct unannounced random and
487 risk-based inspections of all institutional sterile compounding pharmacies licensed under this
488 chapter, as well as the sterile drug preparations compounded by such pharmacies.

489 (5) An institutional sterile compounding pharmacy licensed by the commonwealth shall
490 adhere to the most current standards established by USP, all chapters, when engaging in any
491 form of sterile compounding. Such pharmacy shall also adhere to the additional regulations
492 promulgated by the board pursuant to subsection (c).

493 (6) All institutional sterile compounding pharmacies shall report to the board, on an
494 annual basis, a list of prescriptions dispensed within and outside of the commonwealth, as well
495 as the volume of these prescriptions. An institutional sterile compounding pharmacy that ships
496 compounded drug preparations outside of the commonwealth shall, in addition to the
497 requirements in this section, report to the board the names of the states to which the pharmacy
498 has shipped sterile drug preparations.

499 (7) The license shall not be renewed until the licensee certifies that their employees
500 engaged in sterile compounding have been trained in lean concepts, which are tools that assist in
501 the identification and steady elimination of waste and promote continuous improvement in
502 quality and efficiency.

503 (b) An institutional sterile compounding pharmacy shall designate a manager of record
504 who shall:

505 (i) disclose to the board the name, title and Massachusetts license number of all licensed
506 pharmacists managing or supervising a specific location on the premises where a licensee
507 compounds sterile drug preparations; (ii) certify the institutional sterile compounding pharmacy's
508 compliance with reasonable informational requests made by the board;

509 (iii) certify to the board that the manager of record has fulfilled continuing education
510 requirements for sterile compounding and ensured that all pharmacy staff has received the
511 appropriate training and education required by law and regulations before engaging in
512 compounding; and

513 (iv) submit to the board the names and titles of all individuals employed by the licensee
514 engaged in sterile compounding;

515 (v) annually, and within 30 days after any change of office, corporate office or manager
516 of record, file a report containing the information disclosed under clause (i)..

517 (c)(1) The board shall establish a list of procedural criteria on which an institutional
518 sterile compounding pharmacy shall be evaluated at the time of inspection. The procedural
519 criteria shall contain a predetermined list of standards and safeguards upon which a institutional
520 sterile compounding pharmacy shall be inspected, as well as a predetermined yet alternating list
521 of variable criteria upon which the pharmacy may be inspected without prior notice as to which
522 subset of these variable criteria shall be included in the inspection.

523 (2) The board shall develop a quality assurance procedure for institutional sterile
524 compounding pharmacies to adhere to including, but not limited to, procedures to enhance
525 physical inspection, compounding accuracy checks and sterility testing.

526 (3) The board shall establish supplementary regulations for all institutional sterile
527 compounding pharmacies intending to compound or dispense sterile drug preparations in the
528 commonwealth. The regulations shall include, but not be limited to: (i) enhancing environmental
529 monitoring procedures; (ii) enhancing media fill testing procedures; (iii) enhancing non-sterile
530 active pharmaceutical ingredient controls; (iv) enhancing procedures testing endotoxin and
531 bioburden levels of compounded drug preparations; (v) enhancing procedures surrounding
532 process validation and reproducibility of compounded drug preparations; (vi) enhancing
533 procedures related to end stage testing of sterile drug preparations; (vii) enhancing procedures
534 relating to the storage and beyond-use-dating of sterile drug preparations; (viii) enhancing the
535 physical inspection process for finished sterile drug preparations; (ix) developing effective
536 formulation records for institutional sterile compounding pharmacies; (x) developing effective
537 compounding records for drug preparations compounded by institutional sterile compounding
538 pharmacies; and (xi) developing effective procedures to maintain a drug preparation's quality
539 and control after the sterile drug preparation leaves the institutional sterile compounding
540 pharmacy.

541 (4) The board shall review current regulations applicable to institutional pharmacies and
542 shall promulgate regulations for the administration of paragraphs (1), (2) and (3) of this
543 subsection appropriate to the practice setting of entities subject to an institutional sterile
544 compounding pharmacy license and which minimize regulatory and reporting duplication;
545 provided, that no such regulation shall exempt an institutional sterile compounding pharmacy
546 from compliance with the most current standards established by USP, all chapters.

547 Section 39J. (a) The board shall establish a procedure to license non-resident pharmacies,
548 which prescribe, ship, mail, sell or dispense medications in the commonwealth, that pertains to
549 the practice of pharmacy. The board shall also take steps to ensure that all shipments of
550 pharmaceuticals from in-state pharmacies to out-of-state destinations are in compliance with the
551 licensing procedures applicable to pharmacies in the commonwealth.

552 (b) A non-resident pharmacy shall designate a pharmacist in charge who shall register
553 with the board and shall be responsible for the pharmacy's compliance with this chapter. Such
554 pharmacist in charge shall be licensed and in good standing with the state board of registration in
555 pharmacy in which the pharmacy is located.

556 (1) The designated pharmacist in charge shall disclose to the board the location, name
557 and title of all principal managers and the name and Massachusetts license number of the
558 designated pharmacist in charge, if applicable, and a letter from the in-state board of registration
559 of pharmacy certifying that the pharmacist in charge is in good standing with the in-state board
560 of registration. The designated pharmacist in charge shall submit a report containing this
561 information and a copy of the certifying letter of good standing on an annual basis and within 30
562 days after any change of office, corporate office or manager of record.

563 (2) The designated pharmacist in charge shall certify to the board that the pharmacy
564 maintains, at all times, a current unrestricted license, permit or registration to conduct the
565 pharmacy in compliance with the laws and regulations of the jurisdiction in which it is licensed
566 to practice. The pharmacy shall certify its compliance with reasonable informational requests
567 made by the board. The pharmacy shall also notify the board of any enforcement or disciplinary
568 action taken against the pharmacy regardless of the state in which the enforcement action is
569 taken.

570 (3) The designated pharmacist in charge shall certify to the board that the pharmacy
571 maintains records of all drugs dispensed to patients in the commonwealth, and that these records
572 are readily available, upon the request of the board. A list of drugs dispensed in the
573 commonwealth shall be sent to the board annually.

574 (c) No pharmacy or pharmacist operating outside of the state shall prescribe, ship, mail,
575 sell, transfer or dispense drug preparations in the commonwealth unless the drug preparations are
576 produced in a pharmacy that has been granted a non-resident license pursuant to this section.

577 (d) No pharmacy or pharmacist operating outside of the commonwealth shall be
578 authorized to prescribe, ship, mail, sell, transfer or dispense sterile drug preparations or complex
579 non-sterile drug preparations in the commonwealth unless the sterile drug preparations or
580 complex non-sterile drug preparations are compounded in a pharmacy that has been granted a
581 non-resident sterile compounding license or non-resident complex non-sterile compounding
582 license pursuant to this section.

583 (d) Non-resident pharmacies holding a non-resident pharmacy license under this section
584 shall be subject to the requirements of section 24A of chapter 94C; provided, however, that non-
585 resident pharmacies shall not be eligible for a waiver under said section 24A. An application for
586 licensure under this section shall not be approved unless the applicant has demonstrated the
587 ability to comply with said section 24A. The board may revoke a non-resident pharmacy license
588 for failure to comply with said section 24A.

589 SECTION 19. Said chapter 112 is hereby further amended by striking out sections 41 and
590 42, as so appearing.

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

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

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

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

606 If, based upon evidence, the board or board president determines that a registrant or
607 licensee or the drug preparations prepared by a registrant or licensee are an immediate threat to
608 the public health, safety or welfare, the board or board president may: (i) issue a cease and desist
609 notice or quarantine notice requiring the cessation or restriction of any and all pharmacy
610 operations and prohibiting the use of medications prepared by or in possession of a pharmacy; or
611 (ii) issue a cease and desist notice or quarantine notice placing non-disciplinary restrictions on a
612 board registrant or licensee, to the extent necessary to avert a continued threat, pending final

613 investigation results. The board shall promulgate regulations pertaining to the issuance of cease
614 and desist and quarantine notices.

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

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

619 “Enforcement action records”, any documents issued by the department of public health
620 to a pharmacy or pharmacist relating to an infraction or violation of a state or federal statute or
621 regulation by the pharmacy or pharmacist; provided, that enforcement action records shall
622 include, but not be limited to, consent decrees or judgments entered into between the department
623 and a licensed pharmacy or pharmacist as a result of a charge or complaint filed by the
624 department against a pharmacy or pharmacist for a statutory or regulatory violation or infraction
625 or any other type of voluntary resolution of a charge or complaint filed by the department.

626 “Searchable website”, a website that allows the public to search for and obtain, at no
627 charge, enforcement action records and records of serious adverse drug events, as defined in
628 section 51H of chapter 111, pertaining to pharmacies licensed by the commonwealth and other
629 relevant information related to pharmacy licensure.

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

632 (i) copies of all enforcement action records of any pharmacy or pharmacist licensed by
633 the department whether they are located within or outside of the commonwealth;

634 (ii) copies of any records of serious adverse drug events, as defined in section 51H of
635 chapter 111, and data relative to such events collected and reported pursuant to section 39D,
636 suffered by a patient or user of medications as a result of their use of medication prepared, made
637 or constituted by a pharmacy or pharmacist licensed by the board whether within or outside of
638 the commonwealth;

639 (iii) the names, locations and central points of contact for all licensed compounding
640 pharmacies based in the commonwealth as well as licensed non-resident pharmacies shipping
641 compounded drugs into the commonwealth; and

642 (iv) any other relevant information specified by the commissioner.

643 (c) The searchable website shall allow users to search electronically by field in a single
644 search and shall allow users to parse, query or aggregate the data and download information
645 yielded by a search. The website shall permit users to search by a particular pharmacy or
646 pharmacist or by a specific medication.

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

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

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

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

659 Section 42C. (a) There shall be an advisory committee to the board. The committee shall
660 consist of the commissioner of public health or a designee and 7 members who shall be
661 appointed by the commissioner: 1 of whom shall be an expert in chapter 71 of the USP; 1 of
662 whom shall be an expert in chapter 795 of the USP; 1 of whom shall be an expert in chapter 797
663 of the USP; 1 of whom shall be an expert in cGMP for aseptic processing; 1 of whom shall be an
664 expert in pharmacoeconomics; 1 of whom shall be an expert in clinical pharmacology; and 1 of
665 whom shall be a microbiologist. At the request of the board, the commissioner may appoint
666 additional members knowledgeable in the fields of pharmaceutical compounding, pharmaceutical
667 manufacturing, pharmacy, medicine or related specialties.

668 (b) Each member of the advisory committee appointed by the commissioner shall serve
669 for a term of 3 years; provided, however, that additional members shall serve for a term
670 determined by the commissioner not to exceed 3 years. Any person appointed to fill a vacancy
671 on the committee shall serve for only the unexpired term of the member who vacated. Members
672 shall be eligible for reappointment. A member of the committee appointed by the commissioner
673 may be removed by the commissioner for cause. Members of the committee shall serve without
674 compensation and shall be free of any liability incurred by their proposed recommendations to
675 the board. The advisory committee shall meet at least semi-annually but may meet as often as
676 the members or the board shall determine or at such other intervals as established by the
677 commissioner to fulfill its duties. The department shall provide the advisory committee with
678 support services necessary to complete needed research and analysis and enable the committee to
679 make effective recommendations. Any recommendation made by the advisory committee shall
680 be posted on the department of public health's website and a copy shall be transmitted to the
681 clerks of the senate and house of representatives, who shall forward the report to the joint
682 committee on public health and the joint committee on health care financing.

683 (c) The advisory committee shall evaluate the practice of pharmacy across all settings and
684 recommend to the board any new or revised regulations and policies necessary to improve the
685 delivery of pharmacy services in the commonwealth. The committee shall advise the board: on
686 the establishment of specialty pharmacy licensure categories; on the development of quality
687 assurance, inspection and testing procedures applicable to compounding; on the application of
688 accountability documentation requirements in licensed sterile pharmacies and complex non-
689 sterile pharmacies; the development of regulations to supplement the USP, all chapters; and any
690 other area as requested by the board.

691 (d) The advisory committee shall evaluate the volume and revenue of drug preparations
692 generated by each licensed sterile compounding complex non-sterile compounding pharmacy
693 and pharmacy in the commonwealth, provided, that any item of information which is
694 confidential or privileged in nature or under any other law shall not be regarded as a public
695 record. Nothing in this section shall authorize the committee to obtain individually identifiable
696 patient information.

697 (e) The advisory committee shall monitor existing or potential shortages of medically
698 necessary drug products and recommend to the board options available to the commonwealth to
699 mitigate the impact of drug shortages on patients and providers when a sufficient clinical need or
700 a threat to public health and safety exists.

701

702 Section 42D. (a) The board may assess a licensed pharmacy a penalty of not more than
703 \$25,000 for each violation of regulations or administrative rules established pursuant to any
704 general law that governs the practice of pharmacy. The board, through regulation, shall ensure
705 that any fine levied is commensurate with the severity of the violation.

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

710 (c) Upon making an assessment, the board shall give the licensee notice of the matters
711 alleged and the law relied upon and shall afford the licensee an opportunity for a hearing upon a
712 written request within 15 business days of the assessment. If after a hearing, or if the licensee
713 waives the licensee's right to a hearing, the board determines that cause exists, the board shall
714 make an appropriate assessment. The affected licensee shall pay such assessment except to the
715 extent that, upon judicial review, the reviewing court may reverse the final decision of the board.

716 (d) An assessment made under this section shall be due 30 days after notification to the
717 affected licensee, or 15 days after resolution of an administrative appeal. The attorney general
718 shall recover any assessment due and payable brought in the name of the commonwealth in the

719 superior court. Funds collected pursuant to subsection (b) shall be paid as described in subsection
720 (c). Assessments collected pursuant to this section shall be deposited in the Quality in Health
721 Professions Trust Fund established by section 35X of chapter 10 and shall be used to support
722 initiatives such as: patient safety and quality improvement programs for organizations under the
723 jurisdiction of the division of health professions licensure; training for board and division staff;
724 and to offset the costs of board business, including investigation, enforcement activities and
725 investments in health information technology. The board shall promulgate regulations for the
726 administration of the fund, in consultation with the division, including the establishment of
727 eligibility criteria, program requirements and assessment and reporting processes.

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

731 SECTION 24. Notwithstanding any general or special law to the contrary, the department
732 of public health, in consultation with the board of registration in pharmacy and the advisory
733 committee established by section 42C of chapter 112 of the General Laws, shall conduct an
734 investigation of emerging models of coordinated, remote and shared pharmacy services,
735 including but not limited to: central fill pharmacies; central processing pharmacies; outsourcing
736 facilities; and telepharmacy. The department shall also issue a report indicating its support for or
737 opposition to the adoption of certain pharmacy models in the commonwealth and identifying
738 those elements of said models that should be promoted in support of the commonwealth’s efforts
739 to promote efficient, cost-effective and patient-centered health care in community settings and
740 within integrated care systems. The report shall also include recommendations for appropriate
741 regulations and standards of practice necessitated by said models to ensure compliance with state
742 and federal pharmacy practice restrictions to safeguard patient safety in dispensing. The
743 department shall file the report on its investigation, including its recommendations and drafts of
744 any legislation, if necessary, by filing the same with the clerks of the senate and house of
745 representatives who shall forward a copy of the report to the joint committee on public health
746 and the joint committee on health care financing not later than December 31, 2015.

747 SECTION 25. Notwithstanding any general or special law to the contrary, the board of
748 registration in pharmacy may issue a 1-time provisional license for a period of not more than 1
749 year to an applicant for an initial pharmacy license issued pursuant to sections 39G to 39J,
750 inclusive, of chapter 112 of the General Laws, which is not in full compliance with applicable
751 requirements but which the board finds is in substantial compliance with such requirements and
752 demonstrates potential for achieving full compliance within the provisional licensure period. A
753 provisional license issued to a pharmacy shall not be extended or renewed.

754 SECTION 26. The board of registration in pharmacy shall, in consultation with the
755 department of public health and not later than December 31, 2014, promulgate regulations

756 establishing the requirements for specialty licensure pursuant to sections 39G, 39H and 39J of
757 chapter 112 of the General Laws.

758 SECTION 27. The board of registration in pharmacy shall, in consultation with the
759 department of public health and not later than June 30, 2015, promulgate regulations establishing
760 the requirements for specialty licensure pursuant to sections 39I of chapter 112 of the General
761 Laws.

762 SECTION 28. Section 18 shall take effect on December 31, 2014; provided, however,
763 that section 39I of chapter 112 of the General Laws shall take effect on June 30, 2015.

764 SECTION 29. Section 42C of chapter 112 of the General Laws and sections 24, 26 and
765 27 shall take effect upon the passage of this act.

766 SECTION 30. Unless otherwise provided, this act shall take effect 90 days after the
767 effective date.