

SENATE No. 2020

The Commonwealth of Massachusetts

In the One Hundred and Eighty-Ninth General Court
(2015-2016)

SENATE, September 28, 2015

The committee on Ways and Means to whom was committed the Senate Bill to improve the accessibility and affordability of naloxone and other pharmaceutical drugs of public health concern (Senate, No. 603) (the committee on Rules having recommended that the bill be amended by substituting a new draft with the same title (Senate, No. 2010)),-- reports recommending that the proposed Rules amendment be amended by substituting a new draft entitled "An Act relative to substance use prevention" (Senate, No. 2020) [Estimated cost: \$1,200,000] (Senator Keenan dissenting)

For the committee,
Karen E. Spilka

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An Act relative to substance use prevention.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Chapter 6 of the General Laws is hereby amended by inserting after section
2 116F the following section:-

3 Section 116G. The municipal police training committee may establish a course within the
4 recruit basic training curriculum for regional and municipal police training schools to train law
5 enforcement officers on the application of section 34A of chapter 94C and section 12FF of
6 chapter 112 and on responding to calls for assistance for drug-related overdoses.

7 The committee may periodically include within its in-service training curriculum a course
8 of instruction on the application of said section 34A of said chapter 94C and on responding to
9 calls for assistance for drug-related overdoses.

10 The executive office of public safety and security, in collaboration with the department of
11 public health, shall facilitate the collection and sharing of resources regarding the application of
12 said section 34A of said chapter 94C.

13 SECTION 2. Section 13 of chapter 17 of the General Laws, as appearing in the 2014
14 Official Edition, is hereby amended by adding the following subsection:-

15 (e) The commission shall also identify and publish a list of non-opioid drug products that
16 have been approved by the United States Food and Drug Administration that are effective pain
17 management alternatives and have a lesser potential for abuse than an opioid drug product
18 contained in schedules II and III of section 3 of chapter 94C.

19 The commission shall provide for distribution, including electronic distribution, of copies
20 of the list and revisions to the list among all prescribers and dispensers licensed to practice in the
21 commonwealth and to other appropriate individuals and shall supply a copy to any person on
22 request upon payment of the cost of printing.

23 The list shall be revised not less frequently than annually to include new pertinent
24 information on non-opioid drug products approved for inclusion or non-opioid drug products to
25 be deleted and to reflect current information as to the therapeutic efficacy of drugs and
26 pharmaceuticals.

27 SECTION 3. Section 14 of said chapter 17 is hereby repealed.

28 SECTION 4. Section 19 of said chapter 17, as appearing in the 2014 Official Edition, is
29 hereby amended by striking out, in lines 27 and 28, the words “and (6)” and inserting in place
30 thereof the following words:-

31 (6) provide information to the patient prior to discharge about the patient’s option to
32 voluntarily record a non-opiate directive under section 18B of chapter 94C; and

33 (7).

34 SECTION 5. Section 57 of chapter 71 of the General Laws, as so appearing, is hereby
35 amended by inserting after the word “results,” in line 15, the following words: - to screen pupils
36 for substance use disorders through a verbal screening tool approved by the department of public
37 health.

38 SECTION 6. The first paragraph of said section 57 of said chapter 71, as so appearing, is
39 hereby amended by inserting after the third sentence the following sentence:- Verbal substance
40 use disorder screenings shall be performed by nurses, physicians or other personnel approved by
41 the department of public health and shall be conducted at least once annually in grades 7 and 10.

42 SECTION 7. Said first paragraph of said section 57 of said chapter 71, as so appearing, is
43 hereby further amended by adding the following sentence:- A child or the child’s parent or
44 guardian may opt out of the verbal substance use disorder screening at any point prior to or
45 during the screening.

46 SECTION 8. Said section 57 of said chapter 71, as so appearing, is hereby further
47 amended by adding the following paragraph:-

48 Results of verbal substance use disorder screenings shall be reported to the department of
49 public health without identifying information not later than 30 days after completion of the
50 screening.

51 SECTION 9. Said chapter 71 is hereby further amended by inserting after section 57 the
52 following section:-

53 Section 57A. (a) As used in this section, the following words shall have the following
54 meanings unless the context clearly requires otherwise:

55 “Confidential information”, any statement, response or disclosure provided in
56 confidence by a child to a school employee during a verbal substance use disorder screening
57 under section 57.

58 “School employee”, a person who is employed or volunteers in a public school to
59 conduct the verbal substance use disorder screening under section 57.

60 (b) Except as required under state and federal law and as provided in this paragraph, a
61 school employee shall not disclose confidential information provided during a verbal substance
62 use disorder screening under section 57. Confidential information shall not be subject to
63 discovery or subpoena in any civil, criminal, legislative or administrative proceeding without the
64 prior written consent of the child or the child’s parent or guardian.

65 SECTION 10. Section 1 of chapter 94C of the General Laws, as appearing in the 2014
66 Official Edition, is hereby amended by inserting after the definition of “drug paraphernalia” the
67 following definition:-

68 “Extended-release long-acting opioid in a non-abuse deterrent form”, a drug that is: (i)
69 subject to the United States Food and Drug Administration’s Extended Release and Long-Acting
70 Opioid Analgesics Risk Evaluation and Mitigation Strategy; (ii) an opioid approved for medical
71 use but does not meet the requirements for listing as a drug with abuse-deterrent properties
72 pursuant to section 13 of chapter 17; and (iii) identified pursuant to said section 13 of said
73 chapter 17 as posing a heightened level of public health risk.

74 SECTION 11. Section 18 of said chapter 94C, as so appearing, is hereby amended by
75 striking out, in line 70, the words “A prescription” and inserting in place thereof the following
76 words:- Except as provided in section 18A, a prescription.

77 SECTION 12. Said section 18 of said chapter 94C, as so appearing, is hereby further
78 amended by striking out subsection (e) and inserting in place thereof the following subsection:-

79 (e) Practitioners who prescribe controlled substances, except veterinarians, shall be
80 required, as a prerequisite to obtaining or renewing their professional licenses, to complete
81 appropriate training relative to: (i) effective pain management; (ii) identification of patients at
82 risk for substance use disorders; (iii) counseling patients about the side effects, addictive nature
83 and proper storage and disposal of prescription medications; and (iv) appropriate prescription
84 quantities for prescription medications that have an increased risk of abuse. The boards of
85 registration for each professional license that requires this training shall develop the standards for
86 appropriate training programs.

87 SECTION 13. Said chapter 94C is hereby further amended by inserting after section 18
88 the following 2 sections:-

89 Section 18A. Prior to issuing an extended-release long-acting opioid in a non-abuse
90 deterrent form for outpatient use for the first time, a practitioner registered under section 7 shall:
91 (i) evaluate the patient's current condition, risk factors, history of substance abuse, if any, and
92 current medications; (ii) provide a statement that the prescription, in the prescriber's medical
93 opinion, is an appropriate course of treatment based on the medical need of the patient; (iii)
94 utilize the prescription drug monitoring program established under section 24A prior to issuing
95 the prescription; and (iv) in the event of long term pain management, enter into a pain
96 management treatment agreement with the patient that appropriately addresses the risk factors
97 for abuse or misuse of the prescribed substance under guidelines published by the department

98 and document the statement and the agreement, if applicable, in the patient's medical file and
99 interoperable electronic health record.

100 Section 18B. (a) The secretary of health and human services shall establish a voluntary
101 non-opiate directive form that shall indicate to all prescribers, health care providers and facilities
102 that an individual shall not be administered or offered a prescription or medication order for an
103 opiate. A person may execute and file a voluntary non-opiate directive form with a practitioner
104 registered under section 7 or other authority authorized by the secretary to accept the directive
105 for filing. A voluntary non-opiate directive form may be revoked by the participant for any
106 reason.

107 (b) The secretary shall promulgate regulations for the implementation of the voluntary
108 non-opiate directive form, which shall include, but need not be limited to:

109 (i) procedures to record the voluntary non-opiate directive form in the person's
110 interoperable electronic health record and in the prescription drug monitoring program
111 established under section 24A;

112 (ii) a standard form for the recording and transmission of the voluntary non-opiate
113 directive form, which shall include verification by a practitioner registered under said section 7
114 and which shall comply with the written consent requirements of the Public Health Service Act,
115 42 U.S.C. § 290dd-2(b), and 42 CFR Part 2; provided, however, that the form shall also provide
116 in plain language information on the process to revoke the directive;

117 (iii) requirements for an individual to appoint a duly authorized guardian or health care
118 proxy to override a previously recorded voluntary non-opiate directive form and circumstances
119 under which a treating practitioner registered under said section 7 may override a previously

120 recorded voluntary non-opiate directive form based on documented medical judgment which
121 shall be recorded in the patient's interoperable electronic health record;

122 (iv) provisions for a board of professional licensure to limit, condition, suspend or revoke
123 the license of, or to assess fines against, a licensed health care professional who knowingly or
124 recklessly fails to comply with a patient's voluntary non-opiate directive form;

125 (v) procedures to ensure that any recording, sharing or distribution of data relative to the
126 voluntary non-opiate directive form complies with all state and federal confidentiality laws; and

127 (vi) appropriate exemptions for emergency medical personnel.

128 (c) A written prescription that is presented at an outpatient pharmacy or a prescription
129 that is electronically transmitted to an outpatient pharmacy shall be presumed to be valid for the
130 purposes of this section and a pharmacist in an outpatient setting shall not be held in violation of
131 this section for dispensing a controlled substance in contradiction to a voluntary non-opiate
132 directive form, except upon evidence that the pharmacist acted knowingly against the voluntary
133 non-opiate directive form.

134 (d) No health care provider or employee of a health care provider acting in good faith
135 shall be subject to criminal or civil liability or be considered to have engaged in unprofessional
136 conduct for failing to offer or administer a prescription or medication order for an opiate under
137 the voluntary non-opiate directive form.

138 No person acting as an agent pursuant to a health care proxy shall be subject to criminal
139 or civil liability for making a decision under clause (iii) of subsection (b) in good faith.

140 SECTION 14. The second paragraph of section 21A of said chapter 94C, as appearing in
141 the 2014 Official Edition, is hereby amended by adding the following sentence:- A pharmacist or
142 a pharmacist's designee shall give notice to any person who presents for filling a prescription for
143 an opiate contained in schedule III of section 3 that the person may choose to receive a lesser
144 quantity of the prescribed substance than the quantity indicated on the prescription.

145 SECTION 15. Said chapter 94C is hereby further amended by inserting after section 24A
146 the following section:-

147 Section 24B. The department shall annually determine, through the prescription drug
148 monitoring system established under section 24A, the mean and median quantity and volume of
149 prescriptions for opiates contained in schedule II and schedule III of section 3 issued by
150 practitioners registered under section 7; provided, however, that mean and median prescription
151 quantities and volumes shall be determined within categories of practitioners of a similar
152 specialty or practice type as determined by the department.

153 The department shall work in conjunction with the respective boards of licensure to
154 annually determine each practitioner's schedule II and schedule III opiate prescribing quantity
155 and volume and the practitioner's standing with regard to the mean and median quantity and
156 volume for the practitioner's category of specialty or practice type; provided, however, that the
157 practitioner's standing shall be expressed as a percentile ranking for the practitioner within the
158 practitioner's category. Each practitioner whose prescribing exceeds the mean or median within
159 the practitioner's category shall be sent notice of the practitioner's percentile ranking in a manner
160 determined by the department. The ranking determined for each practitioner shall be distributed
161 by the department or by the relevant board of licensure only to the practitioner to which the

162 information pertains and this information shall be confidential, not considered a public record as
163 defined in clause Twenty-sixth of section 7 of chapter 4, not subject to disclosure pursuant to
164 chapter 66, not admissible as evidence in a civil or criminal proceeding and shall not be the sole
165 basis for investigation by a licensure board.

166 The department shall also coordinate with the respective boards of licensure to make
167 resources available to prescribers regarding ways to change prescribing practices and incorporate
168 alternative pain management options into a prescriber's practice.

169 SECTION 16. The General Laws are hereby amended by inserting after chapter 94F the
170 following chapter:-

171 CHAPTER 94G

172 DRUG STEWARDSHIP PROGRAM

173 Section 1. As used in this chapter, the following words shall have the following meanings
174 unless the context clearly requires otherwise:-

175 "Covered drug", any brand name or generic opioid drug placed in schedule II or schedule
176 III of section 3 of chapter 94C; provided, however, that "covered drug" shall also include
177 benzodiazepines; provided further, that "covered drug" shall not include: (i) drugs intended for
178 use solely in veterinary care; (ii) substances that are regulated as cosmetic products under the
179 United States Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.; (iii) drugs that are
180 compounded under a specialty license pursuant to sections 39G to 39J, inclusive, of chapter 112;
181 (iv) hypodermic needles, lancets or other sharps products subject to collection and disposal

182 procedures established in section 27A of chapter 94C; or (v) drugs approved and used primarily
183 for medication-assisted substance addiction treatment.

184 “Department”, the department of public health.

185 “Drug stewardship program”, a program financed by a pharmaceutical product
186 manufacturer or a group of manufacturers to collect, secure, transport and safely dispose of
187 unwanted drugs.

188 “Pharmaceutical product manufacturer” or “manufacturer”, an entity that manufactures a
189 controlled substance under a United States Food and Drug Administration manufacturer’s
190 license; provided, however, that “pharmaceutical product manufacturer” or “manufacturer” shall
191 not include an institutional pharmacy, as defined in section 39D of chapter 112.

192 “Prescription drug”, any drug product which, pursuant to chapter 94C, may be dispensed
193 under a written prescription by an authorized prescriber.

194 “Stewardship organization”, an organization designated by a manufacturer or a group of
195 manufacturers to act as an agent on behalf of the manufacturer or the group of manufacturers to
196 implement and operate a drug stewardship program.

197 “Unwanted drug”, a covered drug: (i) that is no longer wanted or intended to be
198 consumed or that is abandoned, discarded, expired or surrendered by the person to whom it was
199 prescribed; or (ii) voluntarily deposited at collection points co-located with a law enforcement
200 agency; provided, however, that “unwanted drug” shall not include: (A) waste or unused drug
201 products from a pharmacy, hospital or health clinic or other commercial sources that the

202 department may determine by regulation to be a nonresidential source; or (B) drug products
203 seized by law enforcement officers in the course of their law enforcement duties.

204 “Wholesaler”, an entity licensed pursuant to section 36B of chapter 112.

205 Section 2. (a) Any pharmaceutical product manufacturer selling or distributing a covered
206 drug to consumers in the commonwealth, whether directly or through a wholesaler, retailer or
207 other agent, shall: (i) operate a drug stewardship plan approved by the department individually or
208 jointly with other manufacturers; or (ii) enter into an agreement with a stewardship organization
209 that shall operate a drug stewardship plan approved by the department.

210 (b) The department shall establish a process to review applications for approval and
211 renewal of a manufacturer’s drug stewardship plan and shall ensure that the scope and extent of
212 each approved stewardship program is reasonably related to the manufacturer’s total sales of
213 covered drugs in the commonwealth.

214 (c) Each operator of a drug stewardship program shall file an annual written report to the
215 department describing the program’s activities for the prior year and the volume and type of
216 unwanted drugs collected not later than March 1.

217 (d) The department shall review for renewal each drug stewardship program at least once
218 every 3 years.

219 (e) The department shall publish and make publicly available a list and description of
220 each approved drug stewardship program and shall update this list at least every 2 months.

221 (f) The department shall promulgate regulations to implement this chapter.

222 Section 3. A manufacturer or stewardship organization seeking approval for a drug
223 stewardship program shall submit, in a manner and form determined by the department, a plan
224 that meets, but is not limited to, the following requirements:

225 (i) a collection system to provide convenient, ongoing collection services to all persons
226 seeking to dispose of unwanted drugs; provided, however, that the collection system may accept
227 any covered drug and any other prescription drug in a pill formulation regardless of its schedule,
228 brand or source of manufacture; provided further, that the system shall offer reasonable access to
229 persons across all geographic regions; provided further, that the collection system shall include at
230 least 2 or more of the following: (A) a mail-back program that provides prepaid and
231 preaddressed packaging for a pharmacy to distribute when filling a prescription for a covered
232 drug or upon request by a consumer; (B) additional collection kiosks; (C) drop-off day events at
233 regional locations; (D) in-home disposal methods that render a product safe from misuse and that
234 comply with applicable controlled substance regulations and environmental safety regulations; or
235 (E) any other method recommended by the department or pursuant to United States Drug
236 Enforcement Administration guidelines;

237 (ii) adequate provisions for the security of unwanted drugs throughout the collection
238 process and the safety of any person involved in monitoring, staffing or servicing the
239 stewardship program;

240 (iii) a plan for public outreach and education about the drug stewardship program, which
241 shall include, but not be limited to, a plan for communicating information about the drug
242 products that may be disposed of through the program, a listing of all available collection
243 methods, participating collectors and locations, dates and hours of operation for all collection or

244 drop-off locations, educational information on the environmental, health and addiction risks
245 posed by unused or improperly disposed prescription drug products and a means of
246 communication to receive public comments and questions about the program;

247 (iv) a plan for the manufacturer, group of manufacturers or stewardship organization that
248 provides the operational and administrative costs associated with the program; provided,
249 however, that no point-of-sale, point-of-collection, processing fees or other drug cost increases
250 may be charged to individual consumers to recoup program costs;

251 (v) incentives provided by the manufacturer, group of manufacturers or stewardship
252 organization to consumers to return unwanted drugs;

253 (vi) an attestation that the program shall comply with all applicable state and federal
254 requirements for the collection, security, transport and disposal of drug products, including any
255 requirements established by rule or regulation of either the United States Drug Enforcement
256 Administration or the United States Environmental Protection Agency; and

257 (vii) any other requirements established by the department for the safe and effective
258 administration of a drug stewardship program.

259 Section 4. (a) The department shall send a notice to a pharmaceutical product
260 manufacturer that sells or distributes a covered drug in the commonwealth that has not submitted
261 an application for approval under section 2 informing the manufacturer of the requirements to
262 comply with this chapter. Any manufacturer in receipt of a notice shall submit an application for
263 approval under said section 2 within 180 calendar days of receipt of the initial notice.

264 (b) Upon becoming aware that a pharmaceutical product manufacturer has discontinued
265 its drug stewardship program or has altered the program such that the program no longer fulfills
266 the requirements of this chapter, the department shall send a notice of noncompliance to the
267 manufacturer. A manufacturer in receipt of a notice of noncompliance shall take all required
268 corrective steps to reestablish compliance with this chapter or submit a written appeal of the
269 notice of noncompliance to the department within 30 days of receipt of the notice of
270 noncompliance.

271 (c) If, after consideration of an appeal or if the manufacturer does not appeal within 30
272 days of receipt of the notice of noncompliance, the department determines that the manufacturer
273 has continued to violate this chapter, the department shall assess the manufacturer an initial
274 penalty of not more than \$150,000 and a further penalty of not more than \$10,000 for each
275 subsequent day that the manufacturer continues to violate this chapter.

276 (d) Assessments collected pursuant to this section shall be deposited in the Substance
277 Abuse Services Fund established in section 2I of chapter 111; provided, however, that not more
278 than 3 per cent of assessments collected pursuant to this section shall be expended to support the
279 administration of the drug stewardship program.

280 (e) The department shall report any persistent violations of this chapter to the attorney
281 general who may enforce this chapter.

282 Section 5. (a) The requirements established by the department pursuant to this chapter
283 may exceed, but shall not conflict with, any obligations imposed on a manufacturer by a Risk
284 Evaluation and Mitigation Strategy approved by the United States Food and Drug
285 Administration.

286 (b) Nothing in this chapter shall require a retail pharmacy or a pharmacist practicing in a
287 retail setting to participate in the collection, securing, transport or disposal of unwanted drugs.

288 (c) No stewardship program shall require an outpatient pharmacy in the commonwealth
289 to participate in the collection, securing, transport or disposal of unwanted drugs or to provide a
290 space for or to maintain a collection kiosk within an outpatient pharmacy unless the pharmacy
291 certifies, in writing, that this participation is voluntary.

292 Section 6. There shall be a prescription drug awareness program administered by the
293 department. The program shall be open to all manufacturers of covered drugs. A manufacturer
294 who opts into the program shall be exempt from sections 2 to 5, inclusive.

295 Each participating manufacturer shall pay an assessment which shall be collected by the
296 department and deposited into the Prescription Drug Awareness Trust Fund established in
297 section 2J of chapter 111.

298 A participating manufacturer's assessment shall be paid over 3 calendar years according
299 to a payment schedule established by the department and shall be based on a sliding scale not
300 less than \$10,000 per year but not to exceed \$100,000 per year. The assessment shall be based on
301 the ratio of the average volume of covered drugs sold by the manufacturer over the previous 3
302 calendar years to the total volume of covered drugs sold in the commonwealth for the same 3
303 calendar year period. For the purposes of this section, "volume" shall mean the number of pills,
304 capsules or other unit of a covered drug prescribed and entered into the prescription drug
305 monitoring program established under section 24A of chapter 94C. Any funds unexpended from
306 an assessment at the end of the 3-year assessment period shall be applied as a credit to a

307 manufacturer's assessment for the subsequent 3-year period. This assessment shall not be passed
308 on to the consumer or a health insurance carrier.

309 Not more than 9 months prior to the date of the first assessment payment, the department
310 shall provide each manufacturer with a projected assessment amount and schedule. The
311 manufacturer shall have 90 days from the receipt of the projected assessment to notify the
312 department of its acceptance of the assessment and that it is opting into the program. Upon
313 receiving notice of acceptance, the department shall enter the manufacturer into the program and
314 provide an assessment schedule to the manufacturer.

315 SECTION 17. Chapter 111 of the General Laws is hereby amended by inserting after
316 section 2I the following section:-

317 Section 2J. (a) There shall be established and set upon the books of the commonwealth a
318 Prescription Drug Awareness Trust Fund to be expended, without further appropriation, by the
319 department. The commissioner shall, as trustee, administer the fund. The fund shall consist of
320 revenues collected by the commonwealth, including: (i) assessments collected by the department
321 as part of the prescription drug awareness program established in section 6 of chapter 94G; (ii)
322 any revenue from appropriations or other monies authorized by the general court and specifically
323 designated to be credited to the fund; (iii) any funds from public and private sources, including
324 gifts, grants and donations to provide awareness and education about prescription drug use; (iv)
325 any interest earned on these revenues; and (v) any funds provided from other sources. Money
326 remaining in the fund at the end of a fiscal year shall not revert to the General Fund.
327 Notwithstanding mandatory deductions for indirect costs, not more than 1% of any assessment
328 shall be used to support the administration costs of the program, including fringe benefits.

329 (b) All expenditures from the fund shall support initiatives to encourage public and
330 professional awareness of the potential for the abuse of prescription drugs and to reduce the
331 number of unwanted drugs in the commonwealth including, but not limited to: (i) evidence-based
332 outreach and education programs designed to provide information on the therapeutic and cost
333 effective utilization of prescription drugs for physicians, pharmacists and other health care
334 professionals authorized to prescribe and dispense prescription drugs; (ii) public education and
335 outreach on the dangers of prescription drug addiction; (iii) providing grants to law enforcement
336 agencies interested in providing controlled substance collection boxes or drug take back days;
337 (iv) school programs; (v) safe prescription drug disposal education; and (vi) providing grants to
338 cities and towns in the commonwealth to engage in activities that support the purposes of the
339 fund.

340 (c) Not later than March 1 of each year, the commissioner shall report to the executive
341 office for administration and finance, the joint committee on mental health and substance abuse
342 and the house and senate committees on ways and means including, but not limited to: (i) an
343 itemized accounting of the way funds were spent in the previous calendar year; (ii) descriptions
344 of the programs and activities supported by the fund; (iii) the amount of assessments deposited
345 into the fund by each participant; and (iv) goals for the fund over the 3 calendar year assessment
346 period.

347 SECTION 18. Section 3 of chapter 111E of the General Laws is hereby repealed.

348 SECTION 19. Chapter 112 of the General Laws is hereby amended by inserting after
349 section 12EE the following section:-

350 Section 12FF. Any person who, in good faith, attempts to render emergency care by
351 administering naloxone or other opioid antagonist as defined in section 19B of chapter 94C to a
352 person reasonably believed to be experiencing an opiate-related overdose shall not be liable for
353 acts or omissions, other than gross negligence or willful or wanton misconduct, resulting from
354 the attempt to render this emergency care.

355 SECTION 20. Said chapter 112 is hereby further amended by inserting after section 24G
356 the following section:-

357 Section 24H. (a) The board of registration in pharmacy shall establish a rehabilitation
358 program for registered pharmacists, pharmacy interns and pharmacy technicians who have a
359 substance use issue.

360 (b) The rehabilitation program shall: (i) serve as a voluntary alternative to traditional
361 disciplinary actions; (ii) establish criteria for the acceptance, denial or termination of registered
362 pharmacists, pharmacy interns and pharmacy technicians in the program; and (iii) establish an
363 outreach program to identify registered pharmacists, pharmacy interns and pharmacy technicians
364 who may have a substance use disorder and to provide education about the rehabilitation
365 program.

366 Only a registered pharmacist, pharmacy intern or pharmacy technician who has requested
367 rehabilitation and supervision shall be eligible to participate in the program.

368 (c) The board shall appoint a rehabilitation evaluation committee consisting of 7
369 members, 2 of whom shall be registered pharmacists with demonstrated experience in the field of
370 substance use disorders, 1 of whom shall be a medical doctor with experience in the treatment of
371 substance use disorders, 1 of whom shall be a pharmacy technician with demonstrated

372 experience in the field of substance use disorders, 1 of whom shall be a registered pharmacist
373 who has recovered from drug or alcohol addiction and has been drug and alcohol free for a
374 minimum of 5 years and 2 of whom shall be representatives of the public who are knowledgeable
375 about substance use disorders or mental health. The committee shall elect a chairperson and a
376 vice chairperson. Members of the committee shall serve for terms of 4 years. At the time of
377 appointment or reappointment to the committee, no member of the committee who is licensed to
378 practice by the department of public health, division of professional licensure or by the board of
379 registration in medicine shall have had any type of disciplinary or enforcement action taken
380 against them by their respective licensing board, the United States Food and Drug
381 Administration or the United States Drug Enforcement Administration during the 5 years
382 preceding their appointment to the committee. No member of the board shall serve on the
383 committee.

384 (d) The board shall employ a pharmacist supervisor with demonstrated professional
385 expertise in the field of substance use disorders to oversee participants in the rehabilitation
386 program. The supervisor shall serve as a liaison among the board, the committee, approved
387 treatment programs and providers and participants. Any information obtained by a supervisor
388 pursuant to this section shall be exempt from disclosure and shall be confidential, subject to
389 subsections (f) and (g).

390 (e) All rehabilitation evaluation committee findings shall be submitted to the board as
391 recommendations and shall be subject to final approval of the board. The committee shall have
392 the following duties and responsibilities:

393 (i) to evaluate, according to guidelines established by the board, registered pharmacists,
394 pharmacy interns or pharmacy technicians who request to participate in the program and
395 consider the recommendations of the pharmacist supervisor regarding the admission of a
396 registered pharmacist, pharmacy intern or pharmacy technician into the program;

397 (ii) to review and designate treatment facilities and services to which participants may be
398 referred;

399 (iii) to receive and review information concerning a participant in the program;

400 (iv) to consider, for each participant, whether the participant may continue or may resume
401 practice within the full scope of the participant's the license;

402 (v) to call meetings as necessary to review the request of a registered pharmacist,
403 pharmacy intern or pharmacy technician to participate in the program and review reports
404 regarding participants;

405 (vi) to prepare reports to be submitted to the board;

406 (vii) to provide each participant with an individualized rehabilitation plan with
407 requirements for supervision and surveillance; and

408 (viii) to provide information to pharmacists, pharmacy interns or pharmacy technicians
409 who request to participate in the program.

410 (f) A registered pharmacist, pharmacy intern or pharmacy technician who requests to
411 participate in the program shall agree to cooperate with the individualized rehabilitation plan
412 recommended by the rehabilitation evaluation committee and approved by the board. Any failure
413 to comply with the rehabilitation program may result in termination of the participant from the

414 rehabilitation program. The committee shall report to the board the name and license number of a
415 registered pharmacist, pharmacy intern or pharmacy technician terminated from the program for
416 failure to comply with the provisions of an individualized rehabilitation plan.

417 (g) After the committee, in its discretion, has determined that a registered pharmacist,
418 pharmacy intern or pharmacy technician has successfully completed an individualized
419 rehabilitation plan through the program, the board shall seal all records pertaining to the
420 participation of the registered pharmacist, pharmacy intern or pharmacy technician in the
421 program. No record shall be sealed sooner than 5 years from the participant's date of entry into
422 the program. All board and committee records and records of a participant's involvement in the
423 program shall be kept confidential and shall not be subject to discovery or subpoena in any civil,
424 criminal, legislative or administrative proceeding without the prior written consent of the
425 participant.

426 SECTION 21. Chapter 175 of the General Laws is hereby amended by inserting after
427 section 47GG the following section:-

428 Section 47HH. (a) Any policy, contract, agreement, plan or certificate of insurance
429 issued, delivered or renewed within the commonwealth, which is considered creditable coverage
430 under section 1 of chapter 111M, shall provide for:

431 (i) a plan for the minimum coverage and adequate access to pain management services
432 that provide alternatives to narcotic substance prescribing as established pursuant to section 2 of
433 chapter 176O; and

434 (ii) a plan developed based on clinical evidence and in consultation with health care
435 practitioners for reasonable controls and safeguards on potentially addictive opiate prescription

436 drugs which may include, but need not be limited to: (A) restricting individual
437 beneficiaries, based on excessive prescribed quantities or other signs of risk, to obtaining
438 prescriptions only from a limited number of providers and pharmacies provided that beneficiaries
439 restricted under these programs shall be appropriately notified and have rights to appeal; (B)
440 establishing administrative safeguards on the prescribing of drugs identified pursuant to section
441 13 of chapter 17 as posing a heightened risk to the public health; (C) requirements that
442 beneficiaries provide informed consent prior to receiving opiate prescriptions based on clinically
443 accurate information about the risks and benefits of opiate drugs; or (D) volume thresholds for
444 new prescriptions above which the carrier may require treatment agreements, pain management
445 consultations or other authorization requirements.

446 (b) The plans described in clauses (i) and (ii) of subsection (a) shall be subject to
447 approval and shall be a component of carrier accreditation by the division of insurance pursuant
448 to section 2 of chapter 176O. In its review, the division shall consider the adequacy of access to
449 pain management services and any carrier policies which may create unduly preferential
450 coverage to prescribing opiates over other pain management modalities.

451 (c) Each carrier shall distribute educational materials to providers within their networks
452 about the plans described in clauses (i) and (ii) of subsection (a) and shall post information about
453 the plans on its public website.

454 SECTION 22. Chapter 176A of the General Laws is hereby amended by inserting after
455 section 8II the following section:-

456 Section 8JJ. (a) Any contract between a subscriber and the corporation under an
457 individual or group hospital service plan which is delivered, issued or renewed within the
458 commonwealth shall provide for:

459 (i) a plan for the minimum coverage and adequate access to pain management services
460 that provide alternatives to narcotic substance prescribing as established pursuant to section 2 of
461 chapter 176O; and

462 (ii) a plan developed based on clinical evidence and in consultation with health care
463 practitioners for reasonable controls and safeguards on potentially addictive opiate prescription
464 drugs which may include, but need not be limited to (A) restricting individual beneficiaries,
465 based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only
466 from a limited number of providers and pharmacies provided that beneficiaries restricted under
467 these programs shall be appropriately notified and have rights to appeal; (B) establishing
468 administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter
469 17 as posing a heightened risk to the public health; (C) requirements that beneficiaries provide
470 informed consent prior to receiving an opiate prescription based on clinically accurate
471 information about the risks and benefits of opiate drugs; or (D) volume thresholds for new
472 prescriptions above which the carrier may require treatment agreements, pain management
473 consultations or other authorization requirements.

474 (b) The plans described in clauses (i) and (ii) of subsection (a) shall be subject to
475 approval and shall be a component of carrier accreditation by the division of insurance pursuant
476 to section 2 of chapter 176O. In its review, the division shall consider the adequacy of access to

477 pain management services and any carrier policies which may create unduly preferential
478 coverage to prescribing opiates over other pain management modalities.

479 (c) Each carrier shall distribute educational materials to providers within their networks
480 about the plans described in clauses (i) and (ii) of subsection (a) and shall post information about
481 the plans on its public website.

482 SECTION 23. Chapter 176B of the General Laws is hereby amended by inserting after
483 section 4II the following section:-

484 Section 4JJ. (a) Any subscription certificate under an individual or group medical service
485 agreement delivered, issued or renewed within the commonwealth shall provide for:

486 (i) a plan for the minimum coverage and adequate access to pain management services
487 that provide alternatives to narcotic substance prescribing as established pursuant to section 2 of
488 chapter 176O; and

489 (ii) a plan developed based on clinical evidence and in consultation with health care
490 practitioners for reasonable controls and safeguards on potentially addictive opiate prescription
491 drugs which may include, but need not be limited to (A) restricting individual beneficiaries,
492 based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only
493 from a limited number of providers and pharmacies provided that beneficiaries restricted under
494 such programs shall be appropriately notified and have rights to appeal; (B) establishing
495 administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter
496 17 as posing a heightened risk to the public health; (C) requirements that beneficiaries provide
497 informed consent prior to receiving an opiate prescription based on clinically accurate
498 information about the risks and benefits of opiate drugs; or (D) volume thresholds for new

499 prescriptions above which the carrier may require treatment agreements, pain management
500 consultations or other authorization requirements.

501 (b) The plans described in clauses (i) and (ii) of subsection (a) shall be subject to
502 approval and shall be a component of carrier accreditation by the division of insurance pursuant
503 to section 2 of chapter 176O. In its review, the division shall consider the adequacy of access to
504 pain management services and any carrier policies which may create unduly preferential
505 coverage to prescribing opiates over other pain management modalities.

506 (c) Each carrier shall distribute educational materials to providers within their networks
507 about the plans described in clauses (i) and (ii) of subsection (a) and shall post information about
508 the plans on its public website.

509 SECTION 24. Chapter 176G of the General Laws is hereby amended by inserting after
510 section 4AA the following section:-

511 Section 4BB. (a) Any individual or group health maintenance contract that is issued or
512 renewed shall provide for:

513 (i) a plan for the minimum coverage and adequate access to pain management services
514 that provide alternatives to narcotic substance prescribing as established pursuant to section 2 of
515 chapter 176O; and

516 (ii) a plan developed based on clinical evidence and in consultation with health care
517 practitioners for reasonable controls and safeguards on potentially addictive opiate prescription
518 drugs which may include, but need not be limited to (A) restricting individual beneficiaries,
519 based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only

520 from a limited number of providers and pharmacies provided that beneficiaries restricted under
521 such programs shall be appropriately notified and have rights to appeal; (B) establishing other
522 administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter
523 17 as posing a heightened risk to the public health; (C) requirements that beneficiaries provide
524 informed consent prior to receiving an opiate prescription based on clinically accurate
525 information about the risks and benefits of opiate drugs; or (D) volume thresholds for new
526 prescriptions above which the carrier may require treatment agreements, pain management
527 consultations or other authorization requirements.

528 (b) The plans described in clauses (i) and (ii) of subsection (a) shall be subject to
529 approval and shall be a component of carrier accreditation by the division of insurance pursuant
530 to section 2 of chapter 176O. In its review, the division shall consider the adequacy of access to
531 pain management services and any carrier policies which may create unduly preferential
532 coverage to prescribing opiates over other pain management modalities.

533 (c) Each carrier shall distribute educational materials to providers within their networks
534 about the plans described in clauses (i) and (ii) of subsection (a) and shall post information about
535 said plans on its public website.

536 SECTION 25. Section 2 of chapter 176O of the General Laws, as appearing in the 2014
537 Official Edition, is hereby amended by striking out, in lines 8 and 9, the words “and (5)” and
538 inserting in place thereof the following words:- (5) prescription drug safety and access to pain
539 management; and (6).

540 SECTION 26. Said chapter 176O is hereby further amended by inserting after section 6
541 the following section:-

542 Section 6A. (a) Each carrier shall provide for:

543 (i) a plan for the minimum coverage and adequate access to pain management services
544 that provide alternatives to narcotic substance prescribing as established pursuant to section 2;
545 and

546 (ii) a plan developed based on clinical evidence and in consultation with health care
547 practitioners for reasonable controls and safeguards on potentially addictive opiate prescription
548 drugs which may include, but need not be limited to: (A) restricting individual
549 beneficiaries, based on excessive prescribed quantities or other signs of risk, to obtaining
550 prescriptions only from a limited number of providers and pharmacies provided that beneficiaries
551 restricted under such programs shall be appropriately notified and have rights to appeal; (B)
552 establishing administrative safeguards on the prescribing of drugs identified pursuant to section
553 13 of chapter 17 as posing a heightened risk to the public health; (C) requirements that
554 beneficiaries provide informed consent prior to receiving an opiate prescription based on
555 clinically accurate information about the risks and benefits of opiate drugs; or (D) volume
556 thresholds for new prescriptions above which the carrier may require treatment agreements, pain
557 management consultations or other authorization requirements.

558 (b) The plans described in clauses (i) and (ii) of subsection (a) shall be subject to
559 approval and shall be a component of carrier accreditation by the division pursuant to section 2.
560 In its review, the division shall consider the adequacy of access to pain management services and
561 any carrier policies which may create unduly preferential coverage to prescribing opiates over
562 other pain management modalities.

563 (c) Each carrier shall distribute educational materials to providers within their networks
564 about the plans described in clauses (i) and (ii) of subsection (a) and shall post information about
565 the plans on its public website.

566 SECTION 27. Section 7 of said chapter 176O, as appearing in the 2014 Official Edition,
567 is hereby amended by striking out, in line 59, the word “and”.

568 SECTION 28. Said section 7 of said chapter 176O, as so appearing, is hereby further
569 amended by inserting after the word “age”, in line 68, the following words:- ; and

570 (5) a report detailing for the previous calendar year the total number of: (i) medical or
571 surgical claims submitted to the carrier; (ii) medical or surgical claims denied by the carrier; (iii)
572 mental health or substance use disorder claims submitted to the carrier; (iv) mental health or
573 substance use disorder claims denied by the carrier; and (v) medical or surgical claims and
574 mental health or substance use disorder claims denied by the carrier because: (A) the insured
575 failed to obtain pre-treatment authorization or referral for services; (B) the service was not
576 medically necessary; (C) the service was experimental or investigational; (D) the insured was not
577 covered or eligible for benefits at the time services occurred; (E) the carrier does not cover the
578 service or the provider under the insured’s plan; (F) duplicate claims had been submitted; (G)
579 incomplete claims had been submitted; (H) coding errors had occurred; or (I) of any other
580 specified reason.

581 SECTION 29. Section 13 of said chapter 176O, as so appearing, is hereby amended by
582 adding the following subsection:-

583 (e) For any grievance involving a denial of coverage or a denial of preauthorization for
584 mental health services, including behavioral health and substance use disorder services, the

585 carrier shall provide to the insured and the insured's authorized representative, if any, in addition
586 to all other notices required under this chapter, a statement certifying and specifically describing:

587 (i) that the denial of coverage by the carrier, the carrier's utilization review organization
588 or other subcontracted entity complies with applicable state parity requirements for providing
589 coverage on a nondiscriminatory basis under chapter 80 of the acts of 2000; and

590 (ii) the quantitative and non-quantitative treatment limitations applied during review,
591 including both the initial review of the claim and the review of the internal grievance, and how
592 these treatment limitations comply with state and federal parity regulations, including those
593 codified at 42 U.S.C. § 300gg-26 and regulations implemented pursuant to section 8K of chapter
594 26.

595 SECTION 30. Within 180 days after the effective date of this act, the commissioner of
596 public health shall provide a report on the feasibility of the creation of programs similar to the
597 program established in section 20 for other health professional boards of registration. The
598 commissioner shall file the report, along with any recommendations to effectuate the findings,
599 with the chairs of the joint committee on public health, the chairs of the joint committee on
600 health care financing, the chairs of the house and senate committees on ways and means and the
601 chairs of the house and senate committees on rules.

602 SECTION 31. The department of public health shall promulgate regulations to classify
603 gabapentin and its chemical equivalents as "additional drugs" for the purposes of section 24A of
604 chapter 94C of the General Laws.

605 SECTION 32. The first distribution to individual practitioners of the prescribing trends
606 and profiles set forth in section 15 shall occur not later than March 1, 2017. The department of

607 public health shall establish educational resources on prescribing practices and alternative pain
608 management options not later than March 1, 2017.

609 SECTION 33. (a) There shall be a special commission to examine the feasibility of
610 establishing a pain management access program, with the goal of increasing access to pain
611 management for patients in need of comprehensive pain management resources.

612 (b) The commission shall review: (i) the development of a referral process to make pain
613 management specialists accessible to primary care providers, including a process similar to the
614 Massachusetts child psychiatry access project; (ii) the establishment of a pain management
615 specialty certification through the board of registration in medicine to refer a primary care
616 provider through the referral system described in clause (i); (iii) ways to incorporate a full
617 spectrum of pain management methods into provider care practices including, but not limited to,
618 acupuncture, exercise and other non-pharmaceutical interventions; (iv) the current coverage of
619 pain management through commercial and public insurers; and (v) ways to ensure a full
620 spectrum of pain management interventions are covered through commercial and public
621 insurance health plans.

622 (c) The special commission shall consist of the following members or their designees: the
623 secretary of health and human services, who shall serve as co-chair; the chancellor of the
624 University of Massachusetts medical school, who shall serve as co-chair; the assistant director of
625 Medicaid; the commissioner of the group insurance commission; the commissioner of insurance;
626 the executive director of the health policy commission; the executive director of the center for
627 health information and analysis; the commissioner of public health; the chair of the board of
628 registration in medicine; the chair of the board of registration in nursing; 1 representative of the

629 Massachusetts Association of Health Plans, Inc.; 1 representative of the Massachusetts Medical
630 Society; 1 representative of the Massachusetts Hospital Association, Inc.; 1 representative of the
631 Massachusetts Pain Initiative; and 6 members who shall be appointed by the governor, 1 of
632 whom shall be an oncologist, 1 of whom shall be a physician, 1 of whom shall be an advanced
633 practice nurse, 1 of whom shall be a health economist, 1 of whom shall be a physician
634 specializing in pain management and 1 of whom shall be a professor of medicine.

635 (d) The special commission shall file an initial report of its recommendations and drafts
636 of proposed legislation or regulations, if any, on clauses (i) and (ii) of subsection (b) with the
637 clerks of the house of representatives and the senate, the chairs of the joint committee on health
638 care financing, the chairs of the joint committee on mental health and substance abuse, the chairs
639 of the joint committee on public health and the chairs of the house and senate committees on
640 ways and means not later than November 1, 2016. The special commission shall file a final
641 report providing a full report regarding said subsection (b) not later than November 1, 2017.

642 SECTION 34. The department of public health and the bureau of substance abuse
643 services, in consultation with the division of insurance, shall recommend a universal intake form
644 to streamline the administrative process for intake of a behavioral health or substance use
645 disorder patient. The form shall: (i) ensure adequate recordkeeping; (ii) lessen the current
646 documentation burden for providers of behavioral health or substance use disorder services; (iii)
647 be available in electronic form. The form may be incorporated by all payers of behavioral health
648 and substance use disorder services. The department shall hold not fewer than 4 public hearings
649 on the development of the universal intake form. The department shall post the universal intake
650 form on its website not later than March 1, 2016.

651 SECTION 35. Notwithstanding any general or special law to the contrary, the attorney
652 general shall seek a letter not later than 30 days from the effective date of this act from the
653 United States Drug Enforcement Administration providing guidance on whether it is a violation
654 of 21 U.S.C. § 829 and 21 C.F.R. 1306.13 if a pharmacist dispenses an amount less than the
655 prescribed amount of a schedule II drug included in section 3 of chapter 94C of the General
656 Laws on a valid prescription.

657 SECTION 36. Section 2 shall take effect March 1, 2016.

658 SECTION 37. Sections 4, 15, 31 and proposed section 18B of chapter 94C of the General
659 Laws shall take effect December 1, 2016.

660 SECTION 38. Sections 16, 17, 21 to 24, inclusive, and section 26 shall take effect
661 January 1, 2017.