

SENATE No. 2010

The Commonwealth of Massachusetts

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

SENATE, September 10, 2015

The committee on Rules, to whom was referred the Senate Bill to improve the accessibility and affordability of naloxone and other pharmaceutical drugs of public health concern (Senate, No. 603),-- reports, recommending that the same ought to pass with an amendment substituting a new draft with the same title (Senate, No. 2010).

For the committee,
Mark C. Montigny

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An Act to improve the accessibility and affordability of naloxone and other pharmaceutical drugs of public health concern.

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 116A the following section:-

3 Section 116A½. The municipal police training committee shall establish a course within
4 the recruit basic training curriculum for regional and municipal police training schools to train
5 law enforcement officers on the application of section 34A of chapter 94C.

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

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

11 (e) The commission shall also identify and publish a list of federally approved non-opioid
12 drugs that provide effective pain management alternatives and that have a lesser potential for

13 abuse than opioid drugs contained in schedules II and III of section 3 of chapter 94C, and shall
14 provide for distribution copies of such list and revisions thereto amongst physicians and
15 pharmacists licensed to practice within the commonwealth and to other appropriate individuals
16 and shall supply a copy to any person on request upon payment of the cost of printing.

17 SECTION 3. Section 19 of chapter 17 of the General Laws, as appearing in the 2014
18 Official Edition, is hereby amended by striking “and (6)” in lines 27 and 28, and inserting in
19 place thereof the following:-

20 (6) upon discharge, provide information to the patient about their option to voluntarily
21 record a non-opiate directive under section 18B of chapter 94C; and (7)

22 SECTION 4. Section 57 of Chapter 71 of the General Laws is hereby amended by
23 inserting after the word results, in line 11, the following words: - “including a substance use
24 screening using a validated tool,”

25 And by inserting after the word department., in line 21, the following words: -
26 “Substance use screenings shall be performed by nurses, physicians, or other personnel who are
27 approved by the department of public health for the purpose, and shall be conducted at least once
28 annually in grades 8 or 9, and 11.”

29 SECTION 5. Said Section 57 of Chapter 71 is further amended by inserting after the final
30 paragraph the following paragraph:-

31 “Substance use screening results shall not be recorded in any file subject to inspection
32 under Section 34E of Chapter 71. Results for all students shall be recorded without identifying

33 information and reported to the Department of Public Health no later than 30 days after
34 completion.”

35 SECTION 6. Section 1 of chapter 94C of the General Laws, as appearing in the 2014
36 Official Edition, is hereby amended by inserting after the definition of “drug paraphernalia” the
37 following definition:-

38 “Extended-release long-acting opioid”, a drug that is subject to the United States Food
39 and Drug Administration’s Extended-Release and Long-Acting Opioid Analgesics Risk
40 Evaluation and Mitigation Strategy; provided, however, that “extended-release long-acting
41 opioid” shall include any opioid in an extended-release form.

42 SECTION 7. Said section 1 of said chapter 94C, as so appearing, is hereby further
43 amended by inserting after the definition of “narcotic drug” the following definition:-

44 “Non-abuse deterrent opioid”, an opioid drug product that is approved for medical use
45 but does not meet the requirements for listing as a drug with abuse-deterrent properties pursuant
46 to section 13 of chapter 17; provided, however, that “non-abuse deterrent opioid” shall include
47 any opioid in a non-abuse deterrent form.

48 SECTION 8. Section 18 of said chapter 94C, as so appearing, is hereby amended by
49 striking out, in line 70, the words “A prescription” and inserting in place thereof the following
50 words:- “Except as further restricted by section 18A, a prescription”.

51 SECTION 9. Said section 18 of said chapter 94C, as so appearing, is hereby further
52 amended by adding the following subsection:-

53 (d^{3/4}) A prescription for a narcotic substance contained in schedule II or schedule III of
54 section 3 may be filled by the pharmacist in a lesser quantity of the substance than that quantity
55 indicated on the prescription if the person presenting the prescription requests the lesser quantity.
56 Within a reasonable time following a reduction in quantity, but not to exceed 7 days, the
57 pharmacist or a designee shall notify the prescribing practitioner of the reduction and of the
58 amount actually dispensed. The notification shall be conveyed by a notation in the interoperable
59 electronic health record of the patient as defined by section 1 of chapter 118I or, if the
60 pharmacist does not have the ability to make a notation in the patient's interoperable electronic
61 health record, by facsimile, electronic transmission or by making a notation in the patient's
62 record maintained by the pharmacy which shall be accessible to the practitioner by request. A
63 prescription filled in a lesser quantity pursuant to this subsection shall be considered a partial fill
64 and may subsequently be filled according to federal regulations applicable to partially filled
65 prescriptions; provided, however, that the subsequent fill shall occur at the pharmacy that
66 initially dispensed the partial fill. Nothing in this subsection shall be interpreted to conflict with
67 or supersede any other requirement established in this section for a prescription of a narcotic
68 substance or any requirements or conditions for drug substitutions established in chapter 112.

69 SECTION 10. Said chapter 94C is hereby further amended by inserting after section 18
70 the following section:-

71 Section 18A. For an opioid drug identified pursuant to said section 13 of said chapter 17
72 as posing a heightened level of public health risk, a practitioner prior to issuing an initial
73 prescription shall: (i) evaluate the patient's current condition, risk factors, history of substance
74 abuse, if any, and current medications; (ii) make a determination that other pain management
75 treatments, including drugs presenting a lower risk for abuse or misuse, are or would be

76 inadequate for the patient; (iii) utilize the prescription monitoring program prior to issuing the
77 prescription; and (iv) enter into a pain management treatment agreement with the patient that
78 appropriately addresses the risk factors for abuse or misuse of the prescribed substance under
79 guidelines published by the department and document the agreement in the patient's
80 interoperable electronic health record.

81 SECTION 11. Said Chapter 94C is hereby further amended by inserting the following
82 new section:-

83 Section 18B. (a) The secretary for health and human services shall establish a program
84 for persons to voluntarily record a non-opiate directive. A person, if they are in recovery from a
85 substance addiction or for any other reason, may request their own inclusion in the program,
86 which shall indicate to all practitioners and health care providers and facilities that the person
87 shall not be administered nor offered a prescription or medication order for an opiate substance.
88 A person recording such a directive may request in a manner determined by the secretary, and
89 the secretary shall comply with said request, for the deletion and expungement of their directive
90 for any reason.

91 (b) The secretary shall direct all agencies under his or her authority to promulgate
92 appropriate regulations for the implementation of this non-opiate directive program, which shall
93 include but need not be limited to:

94 (1) Procedures to record the directive in the person's interoperable electronic
95 health record and in the prescription monitoring program established under section 24A of
96 chapter 94C.

97 (2) A standard form for the recording and transmission of the directive, which
98 shall include verification by a physician, nurse practitioner or physician assistant licensed by the
99 Commonwealth, and which shall comply with the written consent requirements of 42 CFR Part
100 2. The form shall also present, in plain language, information on the process to request deletion
101 of the directive.

102 (3) Provisions for a duly authorized guardian or health care proxy to override a
103 previously recorded directive, and circumstances under which a treating clinician may override a
104 previously recorded directive based on documented medical judgment which shall be recorded in
105 the patient's interoperable electronic health record.

106 (4) Provisions for a board of professional licensure to limit, condition, suspend or
107 revoke the license of, or to assess fines against, a licensed health care professional who
108 knowingly or recklessly fails to comply with a patient's non-opiate directive.

109 (5) Procedures to ensure that any recording, sharing or distribution of data relative
110 to the non-opiate directive program complies with applicable laws and regulations regarding
111 privacy of health information.

112 (6) Appropriate exemptions from the requirement to comply with the directive,
113 based on emergency circumstances.

114 (c) A written prescription that is presented at a retail pharmacy, or a prescription that is
115 electronically transmitted to a retail pharmacy, shall be presumed to be valid for the purposes of
116 this section, and a pharmacist in a retail setting shall not be held in violation of this section for
117 dispensing a controlled substance in contradiction to a non-opiate directive, except upon
118 evidence that the pharmacist acted knowingly and negligently against the directive.

119 SECTION 12. The first paragraph of section 21 of said chapter 94C, as appearing in the
120 2014 Official Edition, is hereby amended by adding the following sentence:- If the dispensed
121 substance has a recommended or required expiration date, the label affixed by the pharmacist
122 shall have the expiration date displayed in a print size allowing not more than 10 characters per
123 inch.

124 SECTION 13. The second paragraph of section 21A of said chapter 94C, as so appearing,
125 is hereby amended by adding the following sentence:- A pharmacist shall give notice to any
126 person who presents for filling a new prescription for a narcotic substance contained in schedule
127 II or schedule III of section 3 of the option to receive a lesser quantity of the prescribed
128 substance than that quantity indicated on the prescription.

129 SECTION 14. Section 22 of said chapter 94C, as so appearing, is hereby amended by
130 adding the following subsection:-

131 (c) A practitioner who dispenses, by issuing a written prescription, an extended-release
132 long-acting opioid drug in a non-abuse deterrent form that has been identified pursuant to section
133 13 of chapter 17 as posing a heightened level of public health risk shall, in addition to the
134 requirements of subsection (a) and, in a manner set forth in department regulations, prepare
135 appropriate documentation of the medical need for the drug and a statement of the practitioner's
136 professional judgment that other treatments or drugs are not suitable for the patient. The
137 documentation shall be placed in the patient's medical file.

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

140 Section 24B. The department shall annually determine, through the electronic monitoring
141 system established pursuant to section 24A, the mean and median quantity and volume of
142 prescriptions for opiates contained in schedule II and schedule III of section 3 issued by
143 practitioners registered under section 7; provided, however, that mean and median prescription
144 quantities and volumes shall be determined within categories determined by the department of
145 practitioners of a similar specialty or practice type.

146 The department shall work in conjunction with the respective boards of licensure to
147 annually determine each practitioner's schedule II and schedule III opiate prescribing quantity
148 and volume, and the practitioner's standing with regard to the mean and median quantity and
149 volume for the practitioner's category of specialty or practice type; provided, however, that the
150 practitioner's standing shall be expressed as a percentile ranking for the practitioner within the
151 practitioner's category. Each practitioner whose prescribing exceeds said mean or median within
152 their category shall be sent notice of their percentile ranking in a manner determined by the
153 department. The ranking determined for each practitioner shall be distributed by the department
154 or by the relevant board of licensure only to the practitioner to which the information pertains
155 and this information shall be confidential, not considered a public record as defined in clause
156 Twenty-sixth of section 7 of chapter 4 and not subject to disclosure pursuant to chapter 66, not
157 admissible as evidence in a civil or criminal proceeding, and shall not be the sole basis for
158 investigation by a licensure board.

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

161 CHAPTER 94G

162 PROVISIONS CONCERNING PHARMACEUTICAL PRODUCT MANUFACTURERS

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

165 “Covered drug”, any brand or generic drug placed in schedule II or schedule III of section
166 3 of chapter 94C; provided, however, that “covered drug” shall also include benzodiazepines;
167 provided further, that “covered drug” shall not include: (i) drugs intended for use solely in
168 veterinary care; (ii) substances that are regulated as cosmetic products under the federal Food,
169 Drug and Cosmetic Act, 21 U.S.C. § 301 et. seq.; (iii) drugs that are compounded under a
170 specialty license pursuant to sections 39G to 39J, inclusive of chapter 112; (iv) hypodermic
171 needles, lancets or other sharps products subject to collection and disposal procedures
172 established in section 27A of chapter 94C; or (e) drugs approved and used primarily for
173 medication-assisted substance addiction treatment.

174 “Department”, the department of public health.

175 “Drug stewardship program”, a program financed by a pharmaceutical product
176 manufacturer or a group of manufacturers to collect, secure, transport and safely dispose of
177 unwanted drugs that complies with the requirements of this chapter.

178 “Pharmaceutical product manufacturer” or “manufacturer”, any entity that engages in the
179 manufacture of a controlled substance under a federal Food and Drug Administration
180 manufacturer’s license; provided, however, that “pharmaceutical product manufacturer” or
181 “manufacturer” shall not include a hospital pharmacy.

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

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

187 “Unwanted drug”, a covered drug that is no longer wanted or intended to be consumed or
188 that is abandoned, discarded or surrendered by the person to whom it was prescribed or any other
189 person; provided, however, that “unwanted drug” shall not apply to waste or unused products
190 from a pharmacy, hospital or health clinic or other commercial sources that the department may
191 determine by regulation to be a nonresidential source; provided further, that “unwanted drug”
192 shall include covered drugs that are voluntarily deposited at collection points co-located with a
193 law enforcement agency; and provided further, that “unwanted drug” shall not include drugs
194 seized by law enforcement officers in the course of their law enforcement duties.

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

196 Section 2. (a) Any pharmaceutical product manufacturer selling or distributing a covered
197 drug contained in schedule II or schedule III of section 3 of chapter 94C to consumers in the
198 commonwealth, whether directly or through a wholesaler, retailer or other agent, shall: (i)
199 operate a drug stewardship plan approved by the department individually or jointly with other
200 manufacturers; or (ii) enter into an agreement with a stewardship organization that shall operate a
201 drug stewardship plan approved by the department.

202 (b) The department shall establish a process to review applications for approval and re-
203 approval of a manufacturer’s drug stewardship plan and through this process the department

204 shall ensure that the scope and extent of each approved stewardship program is reasonably
205 related to the manufacturer's total sales of covered drugs in the commonwealth.

206 (c) Each operator of a drug stewardship program shall provide an annual written report
207 to the department describing the program's activities for the prior year and the volume and type
208 of unwanted drugs collected.

209 (d) The department shall review for re-approval each drug stewardship program, whether
210 operated by a manufacturer, a group of manufacturers or a stewardship organization, not less
211 frequently than every 3 years.

212 (e) The department shall publish and make publicly available a list and description of
213 each approved drug stewardship program and shall update this list at least bimonthly.

214 Section 3. An applicant seeking approval for a drug stewardship program shall provide,
215 in a manner and form determined by the department, information on how the program shall meet
216 the following minimum requirements:

217 (i) a collection system to provide convenient, ongoing collection services to all persons
218 seeking to dispose of an unwanted drug; provided, however, that the collection system may
219 accept any covered drug and any other prescription drug in a pill formulation regardless of its
220 schedule, brand or source of manufacture, shall offer reasonably frequent access to persons
221 across all geographic regions of the commonwealth and shall include any 2 or more of the
222 following: (A) a mail-back program that provides prepaid and preaddressed packaging for a
223 pharmacy to distribute when filling a prescription for a covered drug or upon request by a
224 consumer; (B) collection kiosks; (C) drop-off day events at regional locations; (D) distribution of
225 in-home disposal methods that render a product safe from misuse and that comply with

226 applicable controlled substance regulations and environmental safety regulations; and (E) any
227 other method recommended by the department or pursuant to federal Drug Enforcement
228 Administration guidelines;

229 (ii) adequate provisions for the security of the unwanted drugs throughout the collection
230 process and the safety of any persons involved in monitoring, staffing or servicing the
231 stewardship program;

232 (iii) a program for public outreach and education about the drug stewardship program,
233 which shall include a plan for communicating information about the drug products that may be
234 disposed of through the program, a listing of all available collection methods, participating
235 collectors and the locations, dates and hours of operation for all collection or drop-off locations,
236 educational information on the environmental, health and addiction risks posed by unused or
237 improperly disposed prescription drugs and a means of communication to receive public
238 comments and questions about the program;

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

243 (v) provisions by the manufacturer, group of manufacturers or stewardship organization
244 operating the program that provide incentives to consumers to return unused drugs;

245 (vi) an attestation that the program shall comply with all applicable state and federal
246 requirements for the collection, security, transport and disposal of drugs, including any

247 requirements established by rule or regulation of the federal Drug Enforcement Administration
248 or the federal Environmental Protection Agency; and

249 (vii) other requirements as may be established by regulation by the department for the
250 safe and effective administration of a drug stewardship program.

251 Section 4. (a) Any pharmaceutical product manufacturer that sells or distributes a covered
252 drug in the commonwealth and has not submitted an application for approval under section 2
253 shall receive an initial notice from the department informing the manufacturer of the
254 requirements to comply with this chapter. Any manufacturer in receipt of an initial notice shall
255 submit an application for approval under said section 2 within 180 calendar days.

256 (b) Upon becoming aware that a pharmaceutical product manufacturer has discontinued
257 its drug stewardship program or has altered the program such that the program no longer fulfills
258 the requirements of this chapter, the department shall send a notice of noncompliance to the
259 manufacturer. Any manufacturer in receipt of a notice of noncompliance shall take all required
260 corrective steps to reestablish compliance with this chapter within 30 days or submit a written
261 appeal of the notice of noncompliance to the department.

262 (c) If, after consideration of an appeal or after the manufacturer submits no appeal in the
263 prescribed time period, the department determines that the manufacturer has continued to violate
264 this chapter, the department shall assess the manufacturer an initial penalty of not more than
265 \$150,000 and a further penalty of not more than \$10,000 for each subsequent day that the
266 manufacturer continues to violate this chapter.

267 (d) Assessments collected pursuant to this section shall be deposited in the Substance
268 Abuse Services Fund established in section 2I of chapter 111.

269 (e) The department shall report any persistent violations of this chapter to the attorney
270 general who may protect consumers in the health care market under this chapter or any other
271 law.

272 Section 5. (a) The requirements established by the department pursuant to this chapter
273 may exceed, but shall not conflict with, any obligations which may be imposed on a
274 manufacturer by a federally-approved Risk Evaluation and Mitigation Strategy.

275 (b) Nothing in this chapter shall require a retail pharmacy or a pharmacist practicing in a
276 retail setting to participate in the collection, securing, transport or disposal of prescription drug
277 products.

278 (c) No stewardship program developed by a manufacturer or stewardship organization
279 may require a pharmacy in the commonwealth to participate in the collection, securing, transport
280 or disposal of unwanted drugs or provide a space for or maintain a collection kiosk within a retail
281 pharmacy unless the pharmacy licensee provides written consent.

282 (d) The department shall promulgate regulations to implement this chapter.

283 SECTION 17. Chapter 112 of the General Laws is hereby amended by inserting after
284 section 5M the following section:-

285 Section 5N. The board shall by regulation establish qualifications, standards and criteria
286 not less stringent than credentialing criteria by the American Academy for Pain Management,
287 and a process by which licensed physicians may apply, for certification as a pain management
288 specialist and periodic renewal of the certification. This section shall not be construed to prohibit
289 any duly licensed health care practitioner who did not receive certification under this section

290 from engaging in pain management treatment and services within the scope of the practitioner's
291 license.

292 SECTION 18. Chapter 112 of the General Laws is hereby amended by inserting after
293 section 24G the following section:-

294 Section 24H. Notwithstanding any general or special law to the contrary. The board shall
295 establish a rehabilitation program designed to assist its registered pharmacists, pharmacy interns
296 and pharmacy technicians, whose competency has been impaired because of substance abuse
297 disorders, to return to practice. Such program shall be designed in such a manner so that the
298 public health and safety will not be endangered.

299 (b) The rehabilitation program shall: (1) serve as a voluntary alternative to traditional
300 disciplinary actions; (2) establish criteria for the acceptance, denial, or termination of registered
301 pharmacists, pharmacy interns and pharmacy technicians in said program; and (3) establish an
302 outreach program to help identify registered pharmacists, pharmacy interns and pharmacy
303 technicians who are substance abusers and to educate them about said rehabilitation program.

304 Only those registered pharmacists, pharmacy interns and pharmacy technicians who have
305 requested rehabilitation and supervision shall participate in said program.

306 (c) The board shall appoint one or more rehabilitation evaluation committees consisting
307 of at least seven members, two of whom shall be registered pharmacists with demonstrated
308 experience in the field of substance use disorders; one of whom shall be a medical doctor
309 experienced in the treatment of substance use disorders; one of whom shall be a pharmacy
310 technician with demonstrated experience in the field of substance use disorders; one of whom
311 shall be a registered pharmacist who has recovered from drug or alcohol addiction and has been

312 drug and alcohol free for a minimum of five years; and two of whom shall be representatives of
313 the public who are knowledgeable about the field of substance abuse or mental health. Each
314 committee shall elect a chairperson and a vice chairperson. The members of the committee shall
315 serve for such terms as the board shall determine but in no case shall such term exceed four
316 years. All members of the committee who are pharmacists shall hold licenses as pharmacists in
317 the commonwealth for the duration of their terms and each member of the committee who is a
318 pharmacy technician must be registered in the commonwealth for the duration of their term. No
319 board member may serve on a committee.

320 (d) The board shall employ a pharmacist specialist with demonstrated professional
321 expertise in the field of substance abuse disorders to serve as supervisor of participants in the
322 rehabilitation program. Such supervisor shall serve as a liaison among the board, the committee,
323 approved treatment programs and providers, and licensees. All information obtained by a
324 supervisor pursuant to this section shall be exempt from disclosure and shall be confidential
325 subject to the provisions of subsections (f) and (g).

326 (e) All rehabilitation evaluation committee findings shall be submitted to the board as
327 recommendations and shall be subject to final approval of the board. Each committee shall have
328 the following duties and responsibilities:

329 (1) To evaluate, according to the guidelines prescribed by the board, those
330 registered pharmacists, pharmacy interns or pharmacy technicians who request participation in
331 the program and to consider the recommendations of the pharmacist specialist supervisor in the
332 admission of the registered pharmacist, pharmacy intern or pharmacy technician to the
333 rehabilitation program.

334 (2) To review and designate those treatment facilities and services to which
335 rehabilitation program participants may be referred.

336 (3) To receive and review information concerning a registered pharmacist,
337 pharmacy intern or pharmacy technician participating in the program.

338 (4) To consider in the case of each rehabilitation program participant whether the
339 pharmacist, pharmacy intern or registered pharmacy technician may with safety continue or
340 resume their respective practices.

341 (5) To call meetings as necessary to consider the requests of registered
342 pharmacists, pharmacy interns or pharmacy technicians to participate in the rehabilitation
343 program, and to consider reports regarding rehabilitation program participants.

344 (6) To prepare reports to be submitted to the board.

345 (7) To set forth in writing for each rehabilitation program participant an
346 individualized rehabilitation program with requirements for supervision and surveillance.

347 (8) To provide information to pharmacists, pharmacy interns or pharmacy
348 technicians requesting participation in the program.

349 (f) Each registered pharmacist, pharmacy intern or pharmacy technician who requests
350 participation in a rehabilitation program shall agree to cooperate with the rehabilitation program
351 recommended by a rehabilitation evaluation committee and approved by the board. Any failure
352 to comply with the provisions of a rehabilitation program may result in termination of the
353 participant from the rehabilitation program. The name and license number of a registered

354 pharmacist, pharmacy intern or pharmacy technician terminated for failure to comply with the
355 provisions of a rehabilitation program shall be reported to the board.

356 (g) After a committee in its discretion has determined that a registered pharmacist,
357 pharmacy intern or pharmacy technician has been rehabilitated and the rehabilitation program is
358 completed, the board shall seal all records pertaining to the registered pharmacist, pharmacy
359 intern or pharmacy technician's participation in the rehabilitation program. No record shall be
360 sealed sooner than five years from the participant's date of entry into the rehabilitation program.
361 All board and committee records and records of a proceeding pertaining to the rehabilitation of a
362 pharmacist, pharmacy intern or pharmacy technician in the rehabilitation program shall be kept
363 confidential and are not subject to discovery.

364 (h) Within 180 days of passage of this act, the commissioner of public health shall report
365 on which allied health professionals ought to be incorporated into the rehabilitation program
366 established in this section. The commissioner shall file recommendations, as well as any
367 recommended policy changes to effectuate those recommendations, with the chairs of the joint
368 committee on public health, the joint committee on health care financing, the house and senate
369 committees on ways and means, and the house and senate committees on rules.

370 SECTION 19. Chapter 175 of the General Laws, as appearing in the 2014 Official
371 Edition, is hereby amended by inserting after said section 47GG the following section:-

372 Section 47HH. Any policy, contract, agreement, plan or certificate of insurance issued,
373 delivered or renewed within the commonwealth, which is considered creditable coverage under
374 section 1 of chapter 111M, shall provide, for any covered drug that is a narcotic substance
375 contained in schedule II or schedule III of section 3 of chapter 94C and that is subject to cost

376 sharing, a schedule that allows for adjustments and reductions in the cost sharing when a person
377 requests a prescription filled in a lesser quantity pursuant to section 18 of said chapter 94C.

378 SECTION 20. Chapter 176A of the General Laws, as appearing in the 2014 Official
379 Edition, is hereby amended by inserting after said section 8II the following section:-

380 Section 8JJ. Any contract between a subscriber and the corporation under an individual
381 or group hospital service plan which is delivered, issued or renewed within the commonwealth
382 shall provide, for any covered drug that is a narcotic substance contained in schedule II or
383 schedule III of section 3 of chapter 94C and that is subject to cost sharing, a schedule that allows
384 for adjustments and reductions in the cost sharing when a person requests a prescription filled in
385 a lesser quantity pursuant to section 18 of said chapter 94C.

386 SECTION 21. Chapter 176B of the General Laws, as appearing in the 2014 Official
387 Edition, is hereby amended by inserting after said section 4II the following section:-

388 Section 4JJ. Any subscription certificate under an individual or group medical service
389 agreement delivered, issued or renewed within the commonwealth shall provide, for any covered
390 drug that is a narcotic substance contained in schedule II or schedule III of section 3 of chapter
391 94C and that is subject to cost sharing, a schedule that allows for adjustments and reductions in
392 the cost sharing when a person requests a prescription filled in a lesser quantity pursuant to
393 section 18 of said chapter 94C.

394 SECTION 22. Chapter 176G of the General Laws, as appearing in the 2014 Official
395 Edition, is hereby amended by inserting after said section 4AA the following section:-

396 Section 4BB. An individual or group health maintenance contract that is issued or
397 renewed shall provide, for any covered drug that is a narcotic substance contained in schedule II
398 or schedule III of section 3 of chapter 94C and that is subject to cost sharing, a schedule that
399 allows for adjustments and reductions in the cost sharing when a person requests a prescription
400 filled in a lesser quantity pursuant to section 18 of said chapter 94C.

401 SECTION 23. Said Chapter 175, as so appearing, is hereby further amended by inserting
402 after section 47HH the following section:-

403 Section 47II. (a) Any policy, contract, agreement, plan or certificate of insurance issued,
404 delivered or renewed within the commonwealth, which is considered creditable coverage under
405 section 1 of chapter 118M, shall provide for:

406 (1) a plan for the minimum coverage and provision of adequate access to pain
407 management services that provide alternatives to narcotic substance prescribing, as established
408 pursuant to section 2 of chapter 176O; and

409 (2) a plan, developed based on clinical evidence and in consultation with health
410 care practitioners, for reasonable controls and safeguards on potentially addictive opiate
411 prescription drugs, which may include, but need not be limited to (i) restricting individual
412 beneficiaries, based on excessive prescribed quantities or other signs of risk, to obtaining
413 prescriptions only from a limited number of providers and pharmacies, provided that
414 beneficiaries restricted under such programs must be appropriately notified and have rights to
415 appeal; (ii) establishing prior authorization requirements and other administrative safeguards on
416 the prescribing of drugs identified pursuant to section 13 of chapter 17 as posing a heightened
417 risk to the public health; (iii) requirements that beneficiaries provide informed consent prior to

418 receiving an opiate prescription, based on clinically accurate information about the risks and
419 benefits of opiate drugs; (iv) volume thresholds for new prescriptions, above which the carrier
420 may require treatment agreements, pain management consultations, or other authorization
421 requirements.

422 (b) The plans described in paragraphs (1) and (2) shall be subject to approval, and shall
423 be a component of carrier accreditation by the division of insurance, pursuant to section 2 of
424 chapter 176O. In its review, the division shall consider the adequacy of access to pain
425 management services, and any carrier policies which may create unduly preferential coverage to
426 opiate prescribing over other pain management modalities.

427 (c) Each carrier shall distribute educational materials to providers within their networks
428 about the plans described in paragraphs (1) and (2) and shall post information about said plans on
429 their public websites.

430 SECTION 24. Said Chapter 176A, as so appearing, is hereby further amended by
431 inserting after section 87JJ the following section:-

432 Section 8KK. Any contract between a subscriber and the corporation under an individual
433 or group hospital service plan which is delivered, issued or renewed within the commonwealth
434 shall provide for:

435 (1) a plan for the minimum coverage and provision of adequate access to pain
436 management services that provide alternatives to narcotic substance prescribing, as established
437 pursuant to section 2 of chapter 176O; and

438 (2) a plan, developed based on clinical evidence and in consultation with health care
439 practitioners, for reasonable controls and safeguards on potentially addictive opiate prescription
440 drugs, which may include, but need not be limited to (i) restricting individual beneficiaries,
441 based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only
442 from a limited number of providers and pharmacies, provided that beneficiaries restricted under
443 such programs must be appropriately notified and have rights to appeal; (ii) establishing prior
444 authorization requirements and other administrative safeguards on the prescribing of drugs
445 identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health;
446 (iii) requirements that beneficiaries provide informed consent prior to receiving an opiate
447 prescription, based on clinically accurate information about the risks and benefits of opiate
448 drugs; (iv) volume thresholds for new prescriptions, above which the carrier may require
449 treatment agreements, pain management consultations, or other authorization requirements.

450 (b) The plans described in paragraphs (1) and (2) shall be subject to approval, and shall
451 be a component of carrier accreditation by the division of insurance, pursuant to section 2 of
452 chapter 176O. In its review, the division shall consider the adequacy of access to pain
453 management services, and any carrier policies which may create unduly preferential coverage to
454 opiate prescribing over other pain management modalities.

455 (c) Each carrier shall distribute educational materials to providers within their networks
456 about the plans described in paragraphs (1) and (2) and shall post information about said plans on
457 their public websites.

458 SECTION 25. Said Chapter 176B, as so appearing, is hereby further amended by
459 inserting after section 4JJ the following section:- Section 4KK. Any subscription certificate

460 under an individual or group medical service agreement delivered, issued or renewed within the
461 commonwealth shall provide for:

462 (1) a plan for the minimum coverage and provision of adequate access to pain
463 management services that provide alternatives to narcotic substance prescribing, as established
464 pursuant to section 2 of chapter 176O; and

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

477 (b) The plans described in paragraphs (1) and (2) shall be subject to approval, and shall
478 be a component of carrier accreditation by the division of insurance, pursuant to section 2 of
479 chapter 176O. In its review, the division shall consider the adequacy of access to pain
480 management services, and any carrier policies which may create unduly preferential coverage to
481 opiate prescribing over other pain management modalities.

482 (c) Each carrier shall distribute educational materials to providers within their networks
483 about the plans described in paragraphs (1) and (2) and shall post information about said plans on
484 their public websites.

485 SECTION 26. Said Chapter 176G, as so appearing, is hereby further amended by
486 inserting after section 4BB the following section:-

487 Section 4CC. Any individual or group health maintenance contract that is issued or
488 renewed shall provide for:

489 (1) a plan for the minimum coverage and provision of adequate access to pain
490 management services that provide alternatives to narcotic substance prescribing, as established
491 pursuant to section 2 of chapter 176O; and

492 (2) a plan, developed based on clinical evidence and in consultation with health care
493 practitioners, for reasonable controls and safeguards on potentially addictive opiate prescription
494 drugs, which may include, but need not be limited to (i) restricting individual beneficiaries,
495 based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only
496 from a limited number of providers and pharmacies, provided that beneficiaries restricted under
497 such programs must be appropriately notified and have rights to appeal; (ii) establishing prior
498 authorization requirements and other administrative safeguards on the prescribing of drugs
499 identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health;
500 (iii) requirements that beneficiaries provide informed consent prior to receiving an opiate
501 prescription, based on clinically accurate information about the risks and benefits of opiate
502 drugs; (iv) volume thresholds for new prescriptions, above which the carrier may require
503 treatment agreements, pain management consultations, or other authorization requirements.

504 (b) The plans described in paragraphs (1) and (2) shall be subject to approval, and shall
505 be a component of carrier accreditation by the division of insurance, pursuant to section 2 of
506 chapter 176O. In its review, the division shall consider the adequacy of access to pain
507 management services, and any carrier policies which may create unduly preferential coverage to
508 opiate prescribing over other pain management modalities.

509 (c) Each carrier shall distribute educational materials to providers within their networks
510 about the plans described in paragraphs (1) and (2) and shall post information about said plans on
511 their public websites.

512 SECTION 27. Section 2 of chapter 176O of the General Laws, as appearing in the 2014
513 Official Edition, is hereby amended by striking out, in lines 8 and 9, the words “and (5)” and
514 inserting in place thereof the following words:-

515 (5) prescription drug safety and access to pain management; and

516 (6)

517 SECTION 28. Chapter 176O of the General Laws, as appearing in the 2014 Official
518 Edition, is hereby further amended by inserting after section 6 the following section:-

519 Section 6A. Each carrier, as defined in section 1, shall provide for:

520 (1) a plan for the minimum coverage and provision of adequate access to pain
521 management services that provide alternatives to narcotic substance prescribing, as established
522 pursuant to section 2; and

523 (2) a plan, developed based on clinical evidence and in consultation with health care
524 practitioners, for reasonable controls and safeguards on potentially addictive opiate prescription

525 drugs, which may include, but need not be limited to (i) restricting individual beneficiaries,
526 based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only
527 from a limited number of providers and pharmacies, provided that beneficiaries restricted under
528 such programs must be appropriately notified and have rights to appeal; (ii) establishing prior
529 authorization requirements and other administrative safeguards on the prescribing of drugs
530 identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health;
531 (iii) requirements that beneficiaries provide informed consent prior to receiving an opiate
532 prescription, based on clinically accurate information about the risks and benefits of opiate
533 drugs; (iv) volume thresholds for new prescriptions, above which the carrier may require
534 treatment agreements, pain management consultations, or other authorization requirements.

535 (b) The plans described in paragraphs (1) and (2) shall be subject to approval, and shall
536 be a component of carrier accreditation by the division, pursuant to section 2. In its review, the
537 division shall consider the adequacy of access to pain management services, and any carrier
538 policies which may create unduly preferential coverage to opiate prescribing over other pain
539 management modalities.

540 (c) Each carrier shall distribute educational materials to providers within their networks
541 about the plans described in paragraphs (1) and (2) and shall post information about said plans on
542 their public websites.

543 SECTION 29. Subsection (b) of section 7 of said chapter 176O, as so appearing, is
544 hereby amended by striking out, in lines 59 to 68, inclusive, the words “and (4) a report
545 detailing, for the previous calendar year, the total number of; (i) filed grievances, grievances that
546 were approved internally, grievances that were denied internally, and grievances that were

547 withdrawn before resolution; and (ii) external appeals pursued after exhausting the internal
548 grievance process and the resolution of all such external appeals. The report shall identify for
549 each such category, to the extent such information is available, the demographics of such
550 insured, which shall include, but need not be limited to, race, gender and age” and inserting in
551 place thereof the following 2 clauses:-

552 (4) a report detailing for the previous calendar year the total number of: (i) filed
553 grievances, grievances that were approved internally, grievances that were denied internally and
554 grievances that were withdrawn before resolution; and (ii) external appeals pursued after
555 exhausting the internal grievance process and the resolution of all external appeals; provided,
556 however, that the report shall identify for each category, to the extent information is available,
557 the demographics of the insured, which shall include, but need not be limited to, race, gender and
558 age; and

559 (5) a report detailing for the previous calendar year the total number of: (i) medical or
560 surgical claims submitted to the carrier; (ii) medical or surgical claims denied by the carrier; (iii)
561 mental health or substance use disorder claims submitted to the carrier; (iv) mental health or
562 substance use disorder claims denied by the carrier; (v) medical or surgical claims and mental
563 health or substance use disorder claims denied by the carrier because: (A) pre-treatment
564 authorization or referral for services was not obtained; (B) the service was not medically
565 necessary; (C) the service was experimental or investigational; (D) the insured was not covered
566 or eligible for benefits at the time services occurred; (E) the service or the provider was not
567 covered; (F) duplicate claims had been submitted; (G) incomplete claims had been submitted;
568 (H) coding errors had occurred; and (I) of any other specified reason.

569 SECTION 30. Section 13 of said chapter 176O, as so appearing, is hereby amended by
570 adding the following subsection:-

571 (e) For any grievance involving a denial of coverage or a denial of preauthorization for
572 mental health services, including behavioral health and substance use disorder services, the
573 carrier shall provide to the insured and the insured's authorized representative, if any, in addition
574 to all other notices required under this chapter, a statement certifying and specifically describing:

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

578 (ii) the quantitative and non-quantitative treatment limitations applied during
579 review, including both the initial review of the claim and the review of the internal grievance,
580 and how these treatment limitations comply with state and federal parity regulations, including
581 those codified at 42 U.S.C. § 300gg-26 and regulations implemented pursuant to section 8K of
582 chapter 26 of the General Laws; and

583 (iii) that the carrier's claim processing and utilization review methods complied
584 with the parity requirements set forth in clauses (i) and (ii).

585 SECTION 31. Section 4 of chapter 258 of the General Laws, as so appearing, is hereby
586 amended by adding the following paragraph:-

587 No civil action shall be brought and no liability for damages shall be assessed against a
588 public employee, including any first responder or law enforcement personnel, for rendering or
589 attempting to render emergency care in good faith by administering naloxone or a similar opioid

590 antagonist, as defined in section 19B of chapter 94C, to an individual who has or reasonably
591 appears to have suffered a drug-related overdose.

592 SECTION 32. Within 90 days of the effective date of this act, the department of public
593 health shall promulgate regulations to classify the drugs commercially referred to as gabapentin,
594 Neurontin and other chemical equivalents as “additional drugs” for the purposes of section 24A
595 of chapter 94C of the General Laws.

596 SECTION 33. The first distribution to individual practitioners of the prescribing trends
597 and profiles set forth in section 15 shall occur not later than January 1, 2017.

598 SECTION 34. There shall be a special commission to examine the feasibility of
599 establishing a Massachusetts pain management access program, with the goal of increasing
600 access to pain management by allowing primary care providers to arrange pain management
601 consultations and temporary services by specialists certified under section 5N of chapter 111 of
602 the General Laws for their patients in need of comprehensive non-opiate pain management
603 resources.

604 If the special commission determines that the program is feasible and suitable,
605 recommendations for establishing the program shall include recommended policies for funding
606 the program, including consideration of commercial payer, public payer and federal
607 reimbursement possibilities, and may also include, but need not be limited to, consideration of
608 pilot programs and a timeline for full implementation. The special commission shall examine in
609 its review similar service models in other specialty fields, including the Massachusetts Child
610 Psychiatry Access Program.

611 The special commission shall consist of: the secretary of health and human services or a
612 designee, who shall serve as co-chair; the chancellor of the University of Massachusetts Medical
613 School or a designee, who shall serve as co-chair; a representative of the Massachusetts Medical
614 Society; a representative of the Massachusetts Hospital Association, Inc.; a representative of the
615 Massachusetts Pain Initiative; and other members as determined by the co-chairs.

616 The special commission shall file a report of its recommendations and drafts of proposed
617 legislation or regulations, if any, with the clerks of the house of representatives and the senate
618 not later than January 1, 2017.