

SENATE No. 2695

Senate, February 10, 2022 -- Text of the Senate Bill relative to pharmaceutical access, costs and transparency (being the text of Senate, No. 2651, printed as amended).

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-Second General Court
(2021-2022)**

An Act relative to pharmaceutical access, costs and transparency.

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

1 SECTION 1. Section 1 of chapter 6D of the General Laws, as appearing in the 2020
2 Official Edition, is hereby amended by inserting after the definition of “Alternative payment
3 methodologies or methods” the following 2 definitions:-

4 “Biosimilar”, a drug that is produced or distributed pursuant to a biologics license
5 application approved under 42 U.S.C. 262(k)(3).

6 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
7 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
8 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
9 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
10 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
11 application that was approved by the United States Secretary of Health and Human Services
12 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
13 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of

14 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
15 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
16 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
17 based on available data resources such as Medi-Span.

18 SECTION 2. Said section 1 of said chapter 6D, as so appearing, is hereby further
19 amended by inserting after the definition of “Disproportionate share hospital” the following
20 definition:-

21 “Early notice”, advanced notification by a pharmaceutical manufacturing company of a:
22 (i) new drug, device or other development coming to market; or (ii) a price increase, as described
23 in subsection (b) of section 15A.

24 SECTION 3. Said section 1 of said chapter 6D, as so appearing, is hereby further
25 amended by inserting after the definition of “Fiscal year” the following definition:-

26 “Generic drug”, a retail drug that is: (i) marketed or distributed pursuant to an
27 abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic
28 drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962
29 and was not originally marketed under a new drug application; or (iv) identified by the health
30 benefit plan as a generic drug based on available data resources such as Medi-Span.

31 SECTION 4. Said section 1 of said chapter 6D, as so appearing, is hereby further
32 amended by striking out, in line 189, the words “not include excludes ERISA plans” and
33 inserting in place thereof the following words:- include self-insured plans to the extent allowed
34 under the federal Employee Retirement Income Security Act of 1974.

35 SECTION 5. Said section 1 of said chapter 6D, as so appearing, is hereby further
36 amended by inserting after the definition of “Performance penalty” the following 2 definitions:-

37 “Pharmaceutical manufacturing company”, an entity engaged in the: (i) production,
38 preparation, propagation, compounding, conversion or processing of prescription drugs, directly
39 or indirectly, by extraction from substances of natural origin, independently by means of
40 chemical synthesis or by a combination of extraction and chemical synthesis; or (ii) packaging,
41 repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that
42 “pharmaceutical manufacturing company” shall not include a wholesale drug distributor licensed
43 under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said
44 chapter 112.

45 “Pharmacy benefit manager”, a person, business or other entity, however organized, that
46 directly or through a subsidiary provides pharmacy benefit management services for prescription
47 drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-
48 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
49 management services shall include, but not be limited to: (i) the processing and payment of
50 claims for prescription drugs; (ii) the performance of drug utilization review; (iii) the processing
51 of drug prior authorization requests; (iv) pharmacy contracting; (v) the adjudication of appeals or
52 grievances related to prescription drug coverage contracts; (vi) formulary administration; (vii)
53 drug benefit design; (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x)
54 clinical, safety and adherence programs for pharmacy services; and (xi) managing the cost of
55 covered prescription drugs; provided further, that “pharmacy benefit manager” shall include a
56 health benefit plan that does not contract with a pharmacy benefit manager and manages its own
57 prescription drug benefits unless specifically exempted by the commission.

58 SECTION 6. Said section 1 of said chapter 6D, as so appearing, is hereby further
59 amended by inserting after the definition of “Physician” the following definition:-

60 “Pipeline drug”, a prescription drug product containing a new molecular entity for which
61 the sponsor has submitted a new drug application or biologics license application and received an
62 action date from the United States Food and Drug Administration.

63 SECTION 7. Said section 1 of said chapter 6D, as so appearing, is hereby further
64 amended by adding the following definition:-

65 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
66 1395w-3a(c)(6)(B).

67 SECTION 8. Said chapter 6D is hereby further amended by striking out section 2A, as so
68 appearing, and inserting in place thereof the following section:-

69 Section 2A. The commission shall keep confidential all nonpublic clinical, financial,
70 strategic or operational documents or information provided or reported to the commission in
71 connection with any care delivery, quality improvement process, performance improvement
72 plan, early notification or access and affordability improvement plan activities authorized under
73 sections 7, 10, 14, 15, 15A, 20 or 21 of this chapter or under section 2GGGG of chapter 29 and
74 shall not disclose the information or documents to any person without the consent of the payer,
75 provider or pharmaceutical manufacturing company providing or reporting the information or
76 documents under said sections 7, 10, 14, 15, 15A, 20 or 21 of this chapter or under said section
77 2GGGG of said chapter 29, except in summary form in evaluative reports of such activities or
78 when the commission believes that such disclosure should be made in the public interest after
79 taking into account any privacy, trade secret or anticompetitive considerations. The confidential

80 information and documents shall not be public records and shall be exempt from disclosure
81 under clause Twenty-sixth of section 7 of chapter 4 or section 10 of chapter 66.

82 SECTION 9. Section 4 of said chapter 6D, as so appearing, is hereby amended by
83 striking out, in lines 6 and 7, the word “manufacturers” and inserting in place thereof the
84 following words:- manufacturing companies, pharmacy benefit managers.

85 SECTION 10. Section 6 of said chapter 6D, as so appearing, is hereby amended by
86 inserting after the word “center”, in line 1, the following words:- , pharmaceutical and
87 biopharmaceutical manufacturing company, pharmacy benefit manager.

88 SECTION 11. Said section 6 of said chapter 6D, as so appearing, is hereby further
89 amended by striking out, in lines 5 and 36, the figure “33” and inserting in place thereof, in each
90 instance, the following figure:- 25.

91 SECTION 12. Said section 6 of said chapter 6D, as so appearing, is hereby further
92 amended by adding the following paragraph:-

93 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
94 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
95 appropriated by the general court for the expenses of the commission minus amounts collected
96 from: (i) filing fees; (ii) fees and charges generated by the commission's publication or
97 dissemination of reports and information; and (iii) federal matching revenues received for these
98 expenses or received retroactively for expenses of predecessor agencies. Pharmaceutical and
99 biopharmaceutical manufacturing companies and pharmacy benefit managers shall, in a manner
100 and distribution determined by the commission, pay to the commonwealth an amount of the
101 estimated expenses of the commission attributable to the commission’s activities under sections

102 8, 9, 15A, 20 and 21. A pharmacy benefit manager that is a surcharge payor subject to the
103 preceding paragraph and manages its own prescription drug benefits shall not be subject to
104 additional assessment under this paragraph

105 SECTION 13. Section 8 of said chapter 6D, as so appearing, is hereby amended by
106 inserting after the word “organization”, in lines 6 and 7, the following words:- , pharmacy benefit
107 manager, pharmaceutical manufacturing company.

108 SECTION 14. Said section 8 of said chapter 6D, as so appearing, is hereby further
109 amended by inserting after the word “organizations”, in line 14, the following words:- ,
110 pharmacy benefit managers, pharmaceutical manufacturing companies.

111 SECTION 15. Said section 8 of said chapter 6D, as so appearing, is hereby further
112 amended by striking out, in line 32, the words “and (xi)” and inserting in place thereof the
113 following words:- (xi) not less than 3 representatives of the pharmaceutical industry; (xii) at least
114 1 representative of the pharmacy benefit management industry; and (xiii).

115 SECTION 16. Said section 8 of said chapter 6D, as so appearing, is hereby further
116 amended by striking out, in line 48, the first time it appears, the word “and”.

117 SECTION 17. Said section 8 of said chapter 6D, as so appearing, is hereby further
118 amended by inserting after the word “commission”, in line 59, the first time it appears, the
119 following words:- ; and (iii) in the case of pharmacy benefit managers and pharmaceutical
120 manufacturing companies, testimony concerning factors underlying prescription drug costs and
121 price increases including, but not limited to, the initial prices of drugs coming to market and
122 subsequent price increases, changes in industry profit levels, marketing expenses, reverse
123 payment patent settlements, the impact of manufacturer rebates, discounts and other price

124 concessions on net pricing, the availability of alternative drugs or treatments and any other
125 matters as determined by the commission.

126 SECTION 18. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is
127 hereby amended by striking out the second sentence and inserting in place thereof the following
128 2 sentences:-

129 The report shall be based on the commission's analysis of information provided at the
130 hearings by witnesses, providers, provider organizations, payers, pharmaceutical manufacturing
131 companies and pharmacy benefit managers, registration data collected under section 11, data
132 collected or analyzed by the center under sections 8, 9, 10 and 10A of chapter 12C and any other
133 available information that the commission considers necessary to fulfill its duties under this
134 section as defined in regulations promulgated by the commission. To the extent practicable, the
135 report shall not contain any data that is likely to compromise the financial, competitive or
136 proprietary nature of the information.

137 SECTION 19. Section 9 of said chapter 6D, as so appearing, is hereby amended by
138 inserting after the word "organization", in line 72, the following words:- , pharmacy benefit
139 manager, pharmaceutical manufacturing company.

140 SECTION 20. Said chapter 6D is hereby further amended by inserting after section 15
141 the following section:-

142 Section 15A. (a) A pharmaceutical manufacturing company shall provide early notice to
143 the commission in a manner described in this section for a: (i) pipeline drug; (ii) generic drug; or
144 (iii) biosimilar drug. The commission shall provide non-confidential information received under

145 this section to the office of Medicaid, the division of insurance and the group insurance
146 commission.

147 Early notice under this subsection shall be submitted to the commission in writing not
148 later than 30 days after receipt of the United States Food and Drug Administration approval date.

149 For each pipeline drug, early notice shall include a brief description of the: (i) primary
150 disease, health condition or therapeutic area being studied and the indication; (ii) route of
151 administration being studied; (iii) clinical trial comparators; and (iv) estimated date of market
152 entry. To the extent possible, information shall be collected using data fields consistent with
153 those used by the federal National Institutes of Health for clinical trials.

154 For each pipeline drug, early notice shall include whether the drug has been designated
155 by the United States Food and Drug Administration: (i) as an orphan drug; (ii) for fast track; (iii)
156 as a breakthrough therapy; (iv) for accelerated approval; or (v) for priority review for a new
157 molecular entity; provided, however, that notwithstanding clause (v), submissions for drugs in
158 development that are designated as new molecular entities by the United States Food and Drug
159 Administration shall be provided as soon as practical upon receipt of the relevant designations.

160 For each generic drug, early notice shall include a copy of the drug label approved by the United
161 States Food and Drug Administration.

162 (b) A pharmaceutical manufacturing company shall provide early notice to the
163 commission if it plans to increase the wholesale acquisition cost of a: (i) brand-name drug by
164 more than 15 per cent per wholesale acquisition cost unit during any 12-month period; or (ii)
165 generic drug with a significant price increase as determined by the commission during any 12-

166 month period. The commission shall provide non-confidential information received under this
167 section to the office of Medicaid, the division of insurance and the group insurance commission.

168 Early notice under this subsection shall be submitted to the commission in writing not
169 less than 60 days before the planned effective date of the increase.

170 A pharmaceutical manufacturing company required to notify the commission of a price
171 increase under this subsection shall, not less than 30 days before the planned effective date of the
172 increase, report to the commission any information regarding the price increase that is relevant to
173 the commission including, but not limited to: (i) drug identification information; (ii) drug sales
174 volume information; (iii) wholesale price and related information for the drug; (iv) net price and
175 related information for the drug; (v) drug acquisition information, if applicable; (vi) revenue
176 from the sale of the drug; and (vii) manufacturer costs.

177 (c) The commission shall conduct an annual study of pharmaceutical manufacturing
178 companies subject to the requirements in subsections (a) and (b). The commission may contract
179 with a third-party entity to implement this section.

180 (d) Notwithstanding any general or special law to the contrary, information provided
181 under this section shall be protected as confidential and shall not be a public record under clause
182 Twenty-sixth of section 7 of chapter 4 or under chapter 66.

183 (e) If a pharmaceutical manufacturing company fails to timely comply with the
184 requirements under subsection (a) or subsection (b), or otherwise knowingly obstructs the
185 commission's ability to receive early notice under this section, including, but not limited to,
186 providing incomplete, false or misleading information, the commission may impose appropriate
187 sanctions against the manufacturer, including reasonable monetary penalties not to exceed

188 \$500,000, in each instance. The commission shall seek to promote compliance with this section
189 and shall only impose a civil penalty on the manufacturer as a last resort. Amounts collected
190 under this section shall be deposited into the Prescription Drug Cost Assistance Trust Fund
191 established in section 2RRRRR of chapter 29.

192 SECTION 21. Said chapter 6D is hereby further amended by adding the following 2
193 sections:-

194 Section 20. (a) As used in this section, the following words shall have the following
195 meanings unless the context clearly requires otherwise:

196 “Eligible drug”, (i) a brand name drug or biologic, not including a biosimilar, that has a
197 launch wholesale acquisition cost of \$50,000 or more for a 1-year supply or full course of
198 treatment; (ii) a biosimilar drug that has a launch wholesale acquisition cost that is not at least 15
199 per cent lower than the referenced brand biologic at the time the biosimilar is launched; (iii) a
200 public health essential drug, as defined in subsection (f) of section 13 of chapter 17, with a
201 significant price increase over a defined period of time as determined by the commission by
202 regulation or with a wholesale acquisition cost of \$25,000 or more for a 1-year supply or full
203 course of treatment; or (iv) other prescription drug products that may have a direct and
204 significant impact and create affordability challenges for the state’s health care system and
205 patients, as determined by the commission; provided, however, that the commission shall
206 promulgate regulations to establish the type of prescription drug products classified under clause
207 (iv) prior to classification of any such prescription drug product under said clause (iv).

208 “Manufacturer”, a pharmaceutical manufacturer of an eligible drug.

209 “Public health essential drug”, shall have the same meaning as defined in subsection (f)
210 of section 13 of chapter 17.

211 (b) The commission shall review the impact of eligible drug costs on patient access;
212 provided, however, that the commission may prioritize the review of eligible drugs based on
213 potential impact to consumers.

214 In order to conduct a review of eligible drugs, the commission may require a
215 manufacturer to disclose to the commission within a reasonable time period information relating
216 to the manufacturer’s pricing of an eligible drug. The disclosed information shall be on a
217 standard reporting form developed by the commission with the input of the manufacturers and
218 shall include, but not be limited to:

219 (i) a schedule of the drug’s wholesale acquisition cost increases over the previous 5
220 calendar years;

221 (ii) the manufacturer’s aggregate, company-level research and development and other
222 relevant capital expenditures, including facility construction, for the most recent year for which
223 final audited data are available;

224 (iii) a narrative description, absent proprietary information and written in plain language,
225 of factors that contributed to reported changes in wholesale acquisition cost during the previous 5
226 calendar years; and

227 (iv) any other information that the manufacturer wishes to provide to the commission or
228 that the commission requests.

229 (c) Based on the records furnished under subsection (b) and available information from
230 the center for health information and analysis or an outside third party, the commission shall
231 identify a proposed value for the eligible drug. The commission may request additional relevant
232 information that it deems necessary.

233 Any information, analyses or reports regarding an eligible drug review shall be provided
234 to the manufacturer. The commission shall consider any clarifications or data provided by the
235 manufacturer with respect to the eligible drug. The commission shall not base its determination
236 on the proposed value of the eligible drug solely on the analysis or research of an outside third
237 party and shall not employ a measure or metric that assigns a reduced value to the life extension
238 provided by a treatment based on a pre-existing disability or chronic health condition of the
239 individuals whom the treatment would benefit. If the commission relies upon a third party to
240 provide cost-effectiveness analysis or research related to the proposed value of the eligible drug,
241 such analysis or research shall also include, but not be limited to: (i) a description of the
242 methodologies and models used in its analysis; (ii) any assumptions and potential limitations of
243 research findings in the context of the results; and (iii) outcomes for affected subpopulations that
244 utilize the drug, including, but not limited to, potential impacts on individuals of marginalized
245 racial or ethnic groups, and on individuals with specific disabilities or health conditions who
246 regularly utilize the eligible drug.

247 (d) If, after review of an eligible drug and after receiving information from the
248 manufacturer under subsection (b) or subsection (e), the commission determines that the
249 manufacturer's pricing of the eligible drug does not substantially exceed the proposed value of
250 the drug, the commission shall notify the manufacturer, in writing, of its determination and shall
251 evaluate other ways to mitigate the eligible drug's cost in order to improve patient access to the

252 eligible drug. The commission may engage with the manufacturer and other relevant
253 stakeholders, including, but not limited to, patients, patient advocacy organizations, consumer
254 advocacy organizations, providers, provider organizations and payers, to explore options for
255 mitigating the cost of the eligible drug. Upon the conclusion of a stakeholder engagement
256 process under this subsection, the commission shall issue recommendations on ways to reduce
257 the cost of the eligible drug for the purpose of improving patient access to the eligible drug.
258 Recommendations may include, but shall not be limited to: (i) an alternative payment plan or
259 methodology; (ii) a bulk purchasing program; (iii) co-pay, deductible, coinsurance or other cost-
260 sharing restrictions; and (iv) a reinsurance program to subsidize the cost of the eligible drug. The
261 recommendations shall be publicly posted on the commission's website and provided to the
262 clerks of the house of representatives and senate, the joint committee on health care financing
263 and the house and senate committees on ways and means.

264 (e) If, after review of an eligible drug, the commission determines that the manufacturer's
265 pricing of the eligible drug substantially exceeds the proposed value of the drug, the commission
266 shall request that the manufacturer provide further information related to the pricing of the
267 eligible drug and the manufacturer's reasons for the pricing not later than 30 days after receiving
268 the request.

269 (f) Not later than 60 days after receiving information from the manufacturer under
270 subsection (b) or subsection (e), the commission shall confidentially issue a determination on
271 whether the manufacturer's pricing of an eligible drug substantially exceeds the commission's
272 proposed value of the drug. If the commission determines that the manufacturer's pricing of an
273 eligible drug substantially exceeds the proposed value of the drug, the commission shall

274 confidentially notify the manufacturer, in writing, of its determination and request the
275 manufacturer to enter into an access and affordability improvement plan under section 21.

276 (g) Records disclosed by a manufacturer under this section shall: (i) be accompanied by
277 an attestation that all information provided is true and correct; (ii) not be public records under
278 clause Twenty-sixth of section 7 of chapter 4 or chapter 66; and (iii) remain confidential;
279 provided, however, that the commission may produce reports summarizing any findings;
280 provided further, that any such report shall not be in a form that identifies specific prices charged
281 for or rebate amounts associated with drugs by a manufacturer or in a manner that is likely to
282 compromise the financial, competitive or proprietary nature of the information.

283 Any request for further information made by the commission under subsection (e) or any
284 determination issued or written notification made by the commission under subsection (f) shall
285 not be public records under said clause Twenty-sixth of said section 7 of said chapter 4 or said
286 chapter 66.

287 (h) The proposed value of an eligible drug as determined by the commission and the
288 commission's underlying analysis of the eligible drug is not intended to be used to determine
289 whether any individual patient receives prior authorization or approval for the eligible drug or is
290 subjected to step therapy or utilization management with regard to the eligible drug. The
291 proposed value and underlying analysis shall not be the predominant factor in determining
292 whether a drug is included in a formulary.

293 (i) If the manufacturer fails to timely comply with the commission's request for records
294 under subsection (b) or subsection (e), or otherwise knowingly obstructs the commission's
295 ability to issue its determination under subsection (f), including, but not limited to, by providing

296 incomplete, false or misleading information, the commission may impose appropriate sanctions
297 against the manufacturer, including reasonable monetary penalties not to exceed \$500,000, in
298 each instance. The commission shall seek to promote compliance with this section and shall only
299 impose a civil penalty on the manufacturer as a last resort. Penalties collected under this
300 subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established
301 in section 2RRRRR of chapter 29.

302 (j) The commission shall adopt any written policies, procedures or regulations that the
303 commission determines are necessary to implement this section.

304 Section 21. (a) The commission shall establish procedures to assist manufacturers in
305 filing and implementing an access and affordability improvement plan.

306 Upon providing written notice provided under subsection (f) of section 20, the
307 commission shall request that a manufacturer whose pricing of an eligible drug substantially
308 exceeds the commission's proposed value of the drug file an access and affordability
309 improvement plan with the commission. Not later than 45 days after receipt of a notice under
310 said subsection (f) of said section 20, a manufacturer shall: (i) file an access and affordability
311 improvement plan; or (ii) provide written notice declining the commission's request.

312 (b) An access and affordability improvement plan shall: (i) be generated by the
313 manufacturer; (ii) identify the reasons for the manufacturer's drug price; and (iii) include, but not
314 be limited to, specific strategies, adjustments and action steps the manufacturer proposes to
315 implement to address the cost of the eligible drug in order to improve the accessibility and
316 affordability of the eligible drug for patients and the state's health system. The proposed access
317 and affordability improvement plan shall include specific identifiable and measurable expected

318 outcomes and a timetable for implementation. The timetable for an access and affordability
319 improvement plan shall not exceed 18 months.

320 (c) The commission shall approve any access and affordability improvement plan that it
321 determines: (i) is reasonably likely to address the cost of an eligible drug in order to substantially
322 improve the accessibility and affordability of the eligible drug for patients and the state's health
323 system; and (ii) has a reasonable expectation for successful implementation.

324 (d) If the commission determines that the proposed access and affordability improvement
325 plan is unacceptable or incomplete, the commission may provide consultation on the criteria that
326 have not been met and may allow an additional time period of not more than 30 calendar days for
327 resubmission; provided, however, that all aspects of the access plan shall be proposed by the
328 manufacturer and the commission shall not require specific elements for approval.

329 (e) Upon approval of the proposed access and affordability improvement plan, the
330 commission shall notify the manufacturer to begin immediate implementation of the access and
331 affordability improvement plan. Public notice shall be provided by the commission on its
332 website, identifying that the manufacturer is implementing an access and affordability
333 improvement plan; provided, however, that upon the successful completion of the access and
334 affordability improvement plan, the identity of the manufacturer shall be removed from the
335 commission's website. All manufacturers implementing an approved access improvement plan
336 shall be subject to additional reporting requirements and compliance monitoring as determined
337 by the commission. The commission shall provide assistance to the manufacturer in the
338 successful implementation of the access and affordability improvement plan.

339 (f) All manufacturers shall work in good faith to implement the access and affordability
340 improvement plan. At any point during the implementation of the access and affordability
341 improvement plan, the manufacturer may file amendments to the access improvement plan,
342 subject to approval of the commission.

343 (g) At the conclusion of the timetable established in the access and affordability
344 improvement plan, the manufacturer shall report to the commission regarding the outcome of the
345 access and affordability improvement plan. If the commission determines that the access and
346 affordability improvement plan was unsuccessful, the commission shall: (i) extend the
347 implementation timetable of the existing access and affordability improvement plan; (ii) approve
348 amendments to the access and affordability improvement plan as proposed by the manufacturer;
349 (iii) require the manufacturer to submit a new access and affordability improvement plan; or (iv)
350 waive or delay the requirement to file any additional access and affordability improvement plans.

351 (h) The commission shall submit a recommendation for proposed legislation to the joint
352 committee on health care financing if the commission determines that further legislative
353 authority is needed to assist manufacturers with the implementation of access and affordability
354 improvement plans or to otherwise ensure compliance with this section. The recommendation
355 shall be publicly posted on the commission's website.

356 (i) An access and affordability improvement plan under this section shall remain
357 confidential in accordance with section 2A.

358 (j) The commission may assess a civil penalty to a manufacturer of not more than
359 \$500,000, in each instance, if the commission determines that the manufacturer: (i) willfully
360 neglected to file an access and affordability improvement plan with the commission under

361 subsection (a); (ii) failed to file an acceptable access and affordability improvement plan in good
362 faith with the commission; (iii) failed to implement the access and affordability improvement
363 plan in good faith; or (iv) knowingly failed to provide information required by this section to the
364 commission or knowingly falsified the information. The commission shall seek to promote
365 compliance with this section and shall only impose a civil penalty as a last resort. Penalties
366 collected under this subsection shall be deposited into the Prescription Drug Cost Assistance
367 Trust Fund established in section 2RRRRR of chapter 29.

368 (k) If a manufacturer declines to enter into an access and affordability improvement plan
369 under this section, the commission may publicly post the proposed value of the eligible drug,
370 hold a public hearing on the proposed value of the eligible drug and solicit public comment. The
371 manufacturer shall appear and testify at the public hearing held on the eligible drug's proposed
372 value. Upon the conclusion of a public hearing under this subsection, the commission shall issue
373 recommendations on ways to reduce the cost of an eligible drug for the purpose of improving
374 patient access to the eligible drug. The recommendations shall be publicly posted on the
375 commission's website and provided to the clerks of the house of representatives and senate, the
376 joint committee on health care financing and the house and senate committees on ways and
377 means.

378 If a manufacturer is deemed to not be acting in good faith to develop an acceptable or
379 complete access and affordability improvement plan, the commission may publicly post the
380 proposed value of the eligible drug, hold a public hearing on the proposed value of the eligible
381 drug and solicit public comment. The manufacturer shall appear and testify at any hearing held
382 on the eligible drug's proposed value. Upon the conclusion of a public hearing under this
383 subsection, the commission shall issue recommendations on ways to reduce the cost of an

384 eligible drug for the purpose of improving patient access to the eligible drug. The
385 recommendations shall be publicly posted on the commission’s website and provided to the
386 clerks of the house of representatives and senate, the joint committee on health care financing
387 and the house and senate committees on ways and means.

388 Before making a determination that the manufacturer is not acting in good faith, the
389 commission shall send a written notice to the manufacturer that the commission shall deem the
390 manufacturer to not be acting in good faith if the manufacturer does not submit an acceptable
391 access and affordability improvement plan within 30 days of receipt of notice; provided,
392 however, that the commission shall not send a notice under this paragraph within 120 calendar
393 days from the date that the commission issued its request that the manufacturer enter into the
394 access and affordability improvement plan.

395 (l) The commission shall promulgate regulations necessary to implement this section.

396 SECTION 22. Section 1 of chapter 12C of the General Laws, as appearing in the 2020
397 Official Edition, is hereby amended by inserting after the definition of “Ambulatory surgical
398 center services” the following 3 definitions:-

399 “Average manufacturer price”, the average price paid to a manufacturer for a drug in the
400 commonwealth by a: (i) wholesaler for drugs distributed to pharmacies; and (ii) pharmacy that
401 purchases drugs directly from the manufacturer.

402 “Biosimilar”, a drug that is produced or distributed pursuant to a biologics license
403 application approved under 42 U.S.C. 262(k)(3).

404 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
405 drug application approved under 21 U.S.C. 355(c) except for an authorized generic as defined by
406 42 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application
407 approved under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand
408 name drug based on available data resources such as Medi-Span.

409 SECTION 23. Said section 1 of said chapter 12C, as so appearing, is hereby further
410 amended by inserting after the definition of “General health supplies, care or rehabilitative
411 services and accommodations” the following definition:-

412 “Generic drug”, a retail drug that is: (i) marketed or distributed pursuant to an
413 abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic as
414 defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962 that
415 was not originally marketed under a new drug application; or (iv) identified by the health benefit
416 plan as a generic drug based on available data resources such as Medi-Span.

417 SECTION 24. Said section 1 of said chapter 12C, as so appearing, is hereby further
418 amended by inserting after the definition of “Patient-centered medical home” the following 2
419 definitions:-

420 “Pharmaceutical manufacturing company”, an entity engaged in the: (i) production,
421 preparation, propagation, compounding, conversion or processing of prescription drugs, directly
422 or indirectly, by extraction from substances of natural origin, independently by means of
423 chemical synthesis or by a combination of extraction and chemical synthesis; or (ii) packaging,
424 repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that
425 “pharmaceutical manufacturing company” shall not include a wholesale drug distributor licensed

426 under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said
427 chapter 112.

428 “Pharmacy benefit manager”, a person, business or other entity, however organized, that,
429 directly or through a subsidiary, provides pharmacy benefit management services for prescription
430 drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-
431 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
432 management services shall include, but not be limited to: (i) the processing and payment of
433 claims for prescription drugs; (ii) the performance of drug utilization review; (iii) the processing
434 of drug prior authorization requests; (iv) pharmacy contracting; (v) the adjudication of appeals or
435 grievances related to prescription drug coverage contracts; (vi) formulary administration; (vii)
436 drug benefit design; (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x)
437 clinical, safety and adherence programs for pharmacy services; and (xi) managing the cost of
438 covered prescription drugs; provided further, that “pharmacy benefit manager” shall include a
439 health benefit plan that does not contract with a pharmacy benefit manager and manages its own
440 prescription drug benefits unless specifically exempted by the commission.

441 SECTION 25. Said section 1 of said chapter 12C, as so appearing, is hereby further
442 amended by adding the following definition:-

443 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
444 1395w-3a(c)(6)(B).

445 SECTION 26. Section 3 of said chapter 12C, as so appearing, is hereby amended by
446 inserting after the word “organizations”, in lines 13 and 14, the following words:- ,
447 pharmaceutical manufacturing companies, pharmacy benefit managers.

448 SECTION 27. Said section 3 of said chapter 12C, as so appearing, is hereby further
449 amended by striking out, in line 24, the words “and payer” and inserting in place thereof the
450 following words:- , payer, pharmaceutical manufacturing company and pharmacy benefit
451 manager.

452 SECTION 28. Section 5 of said chapter 12C, as so appearing, is hereby amended by
453 striking out, in lines 11 and 12, the words “and public health care payers” and inserting in place
454 thereof the following words:- , public health care payers, pharmaceutical manufacturing
455 companies and pharmacy benefit managers.

456 SECTION 29. Said section 5 of said chapter 12C, as so appearing, is hereby further
457 amended by striking out, in line 15, the words “and affected payers” and inserting in place
458 thereof the following words:- affected payers, affected pharmaceutical manufacturing companies
459 and affected pharmacy benefit managers.

460 SECTION 30. The first paragraph of section 7 of said chapter 12C, as so appearing, is
461 hereby amended by adding the following sentence:- Each pharmaceutical and biopharmaceutical
462 manufacturing company and pharmacy benefit manager shall pay to the commonwealth an
463 amount for the estimated expenses of the center and for the other purposes described in this
464 chapter.

465 SECTION 31. Said section 7 of said chapter 12C, as so appearing, is hereby further
466 amended by striking out, in lines 8 and 42, the figure “33” and inserting in place thereof, in each
467 instance, the following figure:- 25.

468 SECTION 32. Said section 7 of said chapter 12C, as so appearing, is hereby further
469 amended by adding the following paragraph:-

470 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
471 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
472 appropriated by the general court for the expenses of the center minus amounts collected from:
473 (i) filing fees; (ii) fees and charges generated by the commission's publication or dissemination
474 of reports and information; and (iii) federal matching revenues received for these expenses or
475 received retroactively for expenses of predecessor agencies. Pharmaceutical and
476 biopharmaceutical manufacturing companies and pharmacy benefit managers shall, in a manner
477 and distribution determined by the center, pay to the commonwealth an amount of the estimated
478 expenses of the center attributable to the center's activities under sections 3, 10A, 12 and 16. The
479 assessed amount shall be based on business conducted in the commonwealth by the
480 pharmaceutical and biopharmaceutical manufacturing company and pharmacy benefit manager.
481 A pharmacy benefit manager that is also a surcharge payor subject to the preceding paragraph
482 and manages its own prescription drug benefits shall not be subject to additional assessment
483 under this paragraph.

484 SECTION 33. Said chapter 12C is hereby further amended by inserting after section 10
485 the following section:-

486 Section 10A. (a) The center shall promulgate the regulations necessary to ensure the
487 uniform reporting of information from pharmaceutical manufacturing companies to enable the
488 center to analyze: (i) year-over-year changes in wholesale acquisition cost and average
489 manufacturer price for prescription drug products; (ii) year-over-year trends in net expenditures;
490 (iii) net expenditures on subsets of biosimilar, brand name and generic drugs identified by the
491 center; (iv) trends in estimated aggregate drug rebates, discounts or other remuneration paid or
492 provided by a pharmaceutical manufacturing company to a pharmacy benefit manager,

493 wholesaler, distributor, health carrier client, health plan sponsor or pharmacy in connection with
494 utilization of the pharmaceutical drug products offered by the pharmaceutical manufacturing
495 company; (v) discounts provided by a pharmaceutical manufacturing company to a consumer in
496 connection with utilization of the pharmaceutical drug products offered by the pharmaceutical
497 manufacturing company, including any discount, rebate, product voucher, coupon or other
498 reduction in a consumer's out-of-pocket expenses including co-payments and deductibles under
499 section 3 of chapter 175H; (vi) research and development costs as a percentage of revenue; (vii)
500 annual marketing and advertising costs, identifying costs for direct-to-consumer advertising;
501 (viii) annual profits over the most recent 5-year period; (ix) disparities between prices charged to
502 purchasers in the commonwealth and purchasers outside of the United States; and (x) any other
503 information deemed necessary by the center.

504 The center shall require the submission of available data and other information from
505 pharmaceutical manufacturing companies including, but not limited to: (i) wholesale acquisition
506 costs and average manufacturer prices for prescription drug products as identified by the center;
507 (ii) true net typical prices charged to pharmacy benefits managers by payor type for prescription
508 drug products identified by the center, net of any rebate or other payments from the manufacturer
509 to the pharmacy benefits manager and from the pharmacy benefits manager to the manufacturer;
510 (iii) aggregate, company-level research and development costs to the extent attributable to a
511 specific product and other relevant capital expenditures for the most recent year for which final
512 audited data is available for prescription drug products as identified by the center; (iv) annual
513 marketing and advertising expenditures; and (v) a description, absent proprietary information and
514 written in plain language, of factors that contributed to reported changes in wholesale acquisition

515 costs, net prices and average manufacturer prices for prescription drug products as identified by
516 the center.

517 (b) The center shall promulgate the regulations necessary to ensure the uniform reporting
518 of information from pharmacy benefit managers to enable the center to analyze: (i) trends in
519 estimated aggregate drug rebates and other drug price reductions, if any, provided by a pharmacy
520 benefit manager to a health carrier client or health plan sponsor or passed through from a
521 pharmacy benefit manager to a health carrier client or health plan sponsor in connection with
522 utilization of drugs in the commonwealth offered through the pharmacy benefit manager and a
523 measure of lives covered by each health carrier client or health plan sponsor in the
524 commonwealth; (ii) pharmacy benefit manager practices with regard to drug rebates and other
525 drug price reductions, if any, provided by a pharmacy benefit manager to a health carrier client
526 or health plan sponsor or to consumers in the commonwealth or passed through from a pharmacy
527 benefit manager to a health carrier client or health plan sponsor or to consumers in the
528 commonwealth; and (iii) any other information deemed necessary by the center.

529 The center shall require the submission of available data and other information from
530 pharmacy benefit managers including, but not limited to: (i) true net typical prices charged by
531 pharmacy benefits managers for prescription drug products identified by the center, net of any
532 rebate or other payments from the manufacturer to the pharmacy benefits manager and from the
533 pharmacy benefits manager to the manufacturer; (ii) the amount of all rebates that the pharmacy
534 benefit manager received from all pharmaceutical manufacturing companies for all health carrier
535 clients in the aggregate and for each health carrier client or health plan sponsor individually,
536 attributable to patient utilization in the commonwealth; (iii) the administrative fees that the
537 pharmacy benefit manager received from all health carrier clients or health plan sponsors in the

538 aggregate and for each health carrier client or health plans sponsors individually; (iv) the
539 aggregate amount of all retained rebates that the pharmacy benefit manager received from all
540 pharmaceutical manufacturing companies and did not pass through to each pharmacy benefit
541 manager's health carrier client or health plan sponsor individually; (v) the aggregate amount of
542 rebates a pharmacy benefit manager: (A) retains based on its contractual arrangement with each
543 health plan client or health plan sponsor individually; and (B) passes through to each health care
544 client individually; (vi) the percentage of contracts that a pharmacy benefit manager holds where
545 the pharmacy benefit manager: (A) retains all rebates; (B) passes all rebates through to the client;
546 and (C) shares rebates with the client; and (vii) other information as determined by the center,
547 including, but not limited to, pharmacy benefit manager practices related to spread pricing,
548 administrative fees, claw backs and formulary placement.

549 (c) Except as specifically provided otherwise by the center or under this chapter, data
550 collected by the center pursuant to this section from pharmaceutical manufacturing companies
551 and pharmacy benefit managers shall not be a public record under clause Twenty-sixth of section
552 7 of chapter 4 or under chapter 66.

553 SECTION 34. Said chapter 12C is hereby further amended by striking out section 11, as
554 appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

555 Section 11. The center shall ensure the timely reporting of information required under
556 sections 8, 9, 10 and 10A. The center shall notify private health care payers, providers, provider
557 organizations, pharmacy benefit managers, pharmaceutical manufacturing companies and their
558 parent organization and other affiliates of any applicable reporting deadlines. The center shall
559 notify, in writing, a private health care payer, provider, provider organization, pharmacy benefit

560 manager or pharmaceutical manufacturing company, and their parent organization and other
561 affiliates, that has failed to meet a reporting deadline of such failure and that failure to respond
562 within 2 weeks of the receipt of the notice may result in penalties. The center may assess a
563 penalty against a private health care payer, provider, provider organization, pharmacy benefit
564 manager or pharmaceutical manufacturing company, and their parent organization and other
565 affiliates, that fails, without just cause, to provide the requested information, including subsets of
566 the requested information, within 2 weeks following receipt of the written notice required under
567 this section, of not more than \$2,000 per week for each week of delay after the 2-week period
568 following receipt of the notice. Amounts collected under this section shall be deposited in the
569 Healthcare Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

570 SECTION 35. Section 12 of said chapter 12C, as so appearing, is hereby amended by
571 striking out, in line 2, the words “and 10” and inserting in place thereof the following words:- ,
572 10 and 10A.

573 SECTION 36. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby
574 amended by striking out the first sentence and inserting in place thereof the following sentence:-
575 The center shall publish an annual report based on the information submitted under: (i) sections
576 8, 9, 10 and 10A concerning health care provider, provider organization, private and public
577 health care payer, pharmaceutical manufacturing company and pharmacy benefit manager costs
578 and cost and price trends; (ii) section 13 of chapter 6D relative to market power reviews; and (iii)
579 section 15 of said chapter 6D relative to quality data.

580 SECTION 37. Said section 16 of said chapter 12C, as so appearing, is hereby further
581 amended by striking out, in line 18, the words “in the aggregate”.

582 SECTION 38. Said section 16 of said chapter 12C, as so appearing, is hereby further
583 amended by inserting after the second paragraph the following paragraph:-

584 As part of its annual report, the center shall report on prescription drug utilization
585 and spending for pharmaceutical drugs provided in an outpatient setting or sold in a retail setting
586 for private and public health care payers, including, but not limited to, information sufficient to
587 show (i) highest utilization drugs; (ii) drugs with the greatest increases in utilization; (iii) drugs
588 that are most impactful on plan spending, net of rebates; and (iv) drugs with the highest year-
589 over-year price increases, net of rebates.

590 SECTION 39. Section 13 of chapter 17 of the General Laws, as so appearing, is hereby
591 amended by adding the following subsection:-

592 (f) As used in this subsection, the following words shall have the following meanings
593 unless the context clearly requires otherwise:

594 “Public health essential drug”, a prescription drug, biologic or biosimilar approved by the
595 United States Food and Drug Administration that: (i) appears on the Model List of Essential
596 Medicines most recently adopted by the World Health Organization; or (ii) is deemed an
597 essential medicine by the commission due to its efficacy in treating a life-threatening health
598 condition or a chronic health condition that substantially impairs an individual’s ability to engage
599 in activities of daily living or because limited access to a certain population would pose a public
600 health challenge.

601 The commission shall identify and publish a list of public health essential prescription
602 drugs. The list shall be updated not less than annually and be made publicly available on the
603 department’s website; provided, however, that the commission may provide an interim listing of

604 a public health essential drug prior to an annual update. The commission shall notify and forward
605 a copy of the list to the health policy commission established under chapter 6D.

606 SECTION 40. Chapter 29 of the General Laws is hereby amending by inserting after
607 section 2QQQQQ the following section:-

608 2RRRRR. (a) There shall be a Prescription Drug Cost Assistance Trust Fund. The
609 secretary of health and human services shall administer the fund and shall make expenditures
610 from the fund, without further appropriation, to provide financial assistance to state residents to
611 lower the cost of prescription drugs. Money in the fund shall be spent to provide financial
612 assistance for prescription drugs used to treat: (i) chronic respiratory conditions, including, but
613 not limited to, chronic obstructive pulmonary disease and asthma; (ii) chronic heart conditions,
614 including, but not limited to, heart failure, coronary artery disease, hypertension and high blood
615 pressure; (iii) diabetes; and (iv) any other chronic condition identified by the department that
616 disproportionately impacts marginalized communities. For the purpose of this section
617 “prescription drug” shall include the prescription drug and any drug delivery device needed to
618 administer the drug that is not included as part of the underlying drug prescription. The secretary
619 shall seek to maximize available federal reimbursements for money spent from the fund.

620 The fund shall consist of: (i) revenue from appropriations or other money authorized by
621 the general court and specifically designated to be credited to the fund; and (ii) funds from public
622 or private sources, including, but not limited to, gifts, grants, donations, rebates and settlements
623 received by the commonwealth that are specifically designated to be credited to the fund. Money
624 remaining in the fund at the close of a fiscal year shall not revert to the General Fund and shall
625 be available for expenditure in the following fiscal year.

626 (b) Annually, not later than March 1, the secretary shall report on the activities detailing
627 the funds expenditures from the previous calendar year. The report shall include: (i) the number
628 of individuals who received financial assistance from the fund; (ii) the breakdown of fund
629 recipients by race, gender, age range, geographic region and income level; (iii) a list of all
630 prescription drugs that were covered by money from the fund; and (iv) the total cost savings
631 received by all fund recipients and the cost savings broken down by race, gender, age range and
632 income level. The report shall be submitted to the clerks of the senate and house of
633 representatives, senate and house committees on ways and means and the joint committee on
634 health care financing.

635 (c) The secretary shall promulgate regulations or issue other guidance for the expenditure
636 of the funds under this section.

637 SECTION 41. Section 17G of chapter 32A of the General Laws, as appearing in the 2020
638 Official Edition, is hereby amended by adding the following sentence:-

639 Coverage for insulin under this section shall not be subject to any deductible or co-
640 insurance and any co-payment shall not exceed \$25 per 30-day supply, regardless of the amount
641 or type of insulin needed to fill an insured's prescription; provided, however, that nothing in this
642 section shall prevent the commission and its contracted health benefit plans from reducing the
643 co-payment for insulin for a 30-day supply below the amount specified in this section.

644 SECTION 42. Chapter 112 of the General Laws is hereby amended by inserting after
645 section 39J the following section:-

646 Section 39K. (a) For the purposes of this section, a "specialty pharmacy" may include
647 any pharmacy in the commonwealth engaged in the dispensing of specialty medications as

648 defined by the board; provided, however, that “specialty pharmacy” shall not include a mail
649 service pharmacy.

650 The board shall establish a procedure to license specialty pharmacies which prescribe,
651 ship, mail, sell or dispense specialty medications in the commonwealth. The board shall take
652 steps to ensure that all shipments of pharmaceutical drugs from in-state pharmacies to out-of-
653 state destinations are in compliance with the licensing procedures applicable to pharmacies in the
654 commonwealth.

655 (b)(1) A specialty pharmacy shall designate a pharmacist in charge who shall register
656 with the board and shall be responsible for the pharmacy’s compliance with this chapter. Such
657 pharmacist in charge shall be licensed and in good standing with the competent board of
658 registration in pharmacy in the jurisdiction where the pharmacy is located.

659 (2) The designated pharmacist in charge shall disclose to the board the location, name
660 and title of all principal managers and the name and applicable in-state board of registration
661 license number of the designated pharmacist in charge, if applicable, and a letter from the board
662 of registration of pharmacy certifying that the pharmacist in charge is in good standing with the
663 applicable in-state board of registration. The designated pharmacist in charge shall submit a
664 report containing this information and a copy of the certifying letter of good standing annually
665 and within 30 days after any change of office, corporate office or manager of record.

666 (3) The designated pharmacist in charge shall certify to the board that the pharmacy
667 maintains, at all times, a current unrestricted license, permit or registration to conduct the
668 pharmacy in compliance with the laws and regulations of the jurisdiction in which the designated
669 pharmacist in charge is licensed to practice. The pharmacy shall certify its compliance with

670 reasonable informational requests made by the board and shall notify the board of any
671 enforcement or disciplinary action taken against the pharmacy regardless of the state in which
672 the enforcement action is taken.

673 (4) Annually, the designated pharmacist in charge shall certify to the board that the
674 pharmacy maintains records of all drugs dispensed to patients in the commonwealth, and that
675 these records are readily available, upon the request of the board. Annually, the designated
676 pharmacist in charge shall send to the board a list of drugs dispensed in the commonwealth.

677 (c) No pharmacy or pharmacist operating outside of the commonwealth shall prescribe,
678 ship, mail, sell, transfer or dispense specialty medication preparations in the commonwealth
679 unless that pharmacy has been granted a specialty license pursuant to this section.

680 (d) The board shall adopt written policies or procedures or promulgate regulations that
681 the board determines are necessary to implement this section; provided, however, that the board
682 shall define the term “specialty medication” for the purposes of this section.

683 SECTION 43. Section 10C of chapter 118E of the General Laws, as appearing in the
684 2020 Official Edition, is hereby amended by adding the following sentence:-

685 Coverage for insulin under this section shall not be subject to any deductible or co-
686 insurance and any co-payment shall not exceed \$25 per 30-day supply, regardless of the amount
687 or type of insulin needed to fill an insured’s prescription; provided, however, that nothing in this
688 section shall prevent the division and its contracted health insurers, health plans, health
689 maintenance organizations, behavioral health management firms and third-party administrators
690 under contract with the division, a Medicaid managed care organization or a primary care

691 clinician plan, from reducing the co-payments for insulin for a 30-day supply below the amount
692 specified in this section.

693 SECTION 44. Section 47N of chapter 175 of the General Laws, as so appearing, is
694 hereby amended by adding the following paragraph:-

695 Coverage for insulin under this section shall not be subject to any deductible or co-
696 insurance and any co-payment shall not exceed \$25 per 30-day supply, regardless of the amount
697 or type of insulin needed to fill an insured's insulin prescription; provided, however, that nothing
698 in this section shall prevent an individual policy of accident and sickness insurance issued under
699 section 108 that provides hospital expense and surgical expense insurance or a group blanket or
700 general policy of accident and sickness insurance issued under section 110 that provides hospital
701 expense and surgical expense insurance that is issued or renewed within or without the
702 commonwealth, from reducing the co-payment for insulin for a 30-day supply below the amount
703 specified in this section.

704 SECTION 45. Section 226 of said chapter 175, as so appearing, is hereby amended by
705 striking out subsection (a) and inserting in place thereof the following subsection:-

706 (a) For the purposes of this section, the term "pharmacy benefit manager" shall mean a
707 person, business or other entity, however organized, that directly or through a subsidiary
708 provides pharmacy benefit management services for prescription drugs and devices on behalf of
709 a health benefit plan sponsor, including, but not limited to, a self-insurance plan, labor union or
710 other third-party payer; provided, however, that pharmacy benefit management services shall
711 include, but not be limited to: (i) the processing and payment of claims for prescription drugs;
712 (ii) the performance of drug utilization review; (iii) the processing of drug prior authorization

713 requests; (iv) pharmacy contracting; (v) the adjudication of appeals or grievances related to
714 prescription drug coverage contracts; (vi) formulary administration; (vii) drug benefit design;
715 (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x) clinical, safety and
716 adherence programs for pharmacy services; and (xi) managing the cost of covered prescription
717 drugs; provided further, that “pharmacy benefit manager” shall include a health benefit plan that
718 does not contract with a pharmacy benefit manager and manages its own prescription drug
719 benefits unless specifically exempted.

720 SECTION 46. Section 8P of chapter 176A of the General Laws, as so appearing, is
721 hereby amended by adding the following paragraph:-

722 Coverage for insulin under this section shall not be subject to any deductible or co-
723 insurance and any co-payment shall not exceed \$25 per 30-day supply, regardless of the amount
724 or type of insulin needed to fill an insured’s insulin prescription; provided, however, that nothing
725 in this section shall prevent a contract between a subscriber and the corporation under an
726 individual or group hospital service plan that is delivered, issued or renewed within or without
727 the commonwealth, from reducing the co-payment for insulin for a 30-day supply below the
728 amount specified in this section.

729 SECTION 47. Section 4S of chapter 176B of the General Laws, as so appearing, is
730 hereby amended by adding the following sentence:-

731 Coverage for insulin under this section shall not be subject to any deductible or co-
732 insurance and any co-payment shall not exceed \$25 per 30-day supply, regardless of the amount
733 or type of insulin needed to fill an insured’s insulin prescription; provided, however, that nothing
734 in this section shall prevents a subscription certificate under an individual or group medical

735 service agreement that is issued or renewed within or without the commonwealth, from reducing
736 the co-payment for insulin for a 30-day supply below the amount specified in this section.

737 SECTION 48. The fourth paragraph of section 3B of chapter 176D of the General Laws,
738 as so appearing, is hereby amended by inserting after the second sentence the following 2
739 sentences:- A carrier shall not prohibit the dispensing of specialty medications that are included
740 in its pharmaceutical drug benefits to insureds by any pharmacy licensed under section 39K of
741 chapter 112. A carrier shall allow any network pharmacy to provide specialty medications if the
742 pharmacy agrees to the same reimbursement terms and conditions.

743 SECTION 49. Said section 3B of said chapter 176D, as so appearing, is hereby further
744 amended by striking out the fifth paragraph and inserting in place thereof the following
745 paragraph:-

746 A carrier shall allow any network pharmacy to provide mail order prescriptions if the
747 pharmacy agrees to the same reimbursement terms and conditions. A carrier shall not impose: (i)
748 any agreement, terms or conditions on the network pharmacy that are more restrictive than those
749 imposed on the participating mail order pharmacy; (ii) any terms or restrictions on network
750 pharmacies that are designed to exclude them from providing mail order prescriptions; or (iii) a
751 co-payment fee or other cost-sharing condition on any insured who elects to purchase mail order
752 prescription drugs from a network pharmacy that is not also imposed on the insured's mail order
753 pharmacy.

754 SECTION 50. The eighth paragraph of said section 3B of said chapter 176D, as so
755 appearing, is hereby amended by adding the following sentence:- The term "specialty

756 medication” shall mean a specialty medication as defined pursuant to section 39K of chapter
757 112.

758 SECTION 51. Section 4H of chapter 176G of the General Laws, as so appearing, is
759 hereby amended by adding the following paragraph:-

760 Coverage for insulin under this section shall not be subject to any deductible or co-
761 insurance and any co-payment shall not exceed \$25 per 30-day supply, regardless of the amount
762 or type of insulin needed to fill an insured’s insulin prescription; provided, however, that nothing
763 in this section shall prevent any individual or group health maintenance contract that is issued or
764 renewed within or without the commonwealth, from reducing the co-payment for insulin for a
765 30-day supply below the amount specified in this section.

766 SECTION 52. Section 2 of chapter 176O of the General Laws, as so appearing, is hereby
767 amended by adding the following subsection:-

768 (i) Every 3 years, a carrier that contracts with a pharmacy benefit manager shall
769 coordinate an audit of the operations of the pharmacy benefit manager to ensure compliance with
770 this chapter and to examine the pricing and rebates applicable to prescription drugs that are
771 provided to the carrier’s covered persons.

772 SECTION 53. Said chapter 176O is hereby further amended by inserting after section 22
773 the following section:-

774 Section 22A. Notwithstanding any other general or special law to the contrary, each
775 carrier shall require that a pharmacy benefit manager receive a license from the division under
776 chapter 176X as a condition of contracting with that carrier.

777 SECTION 54. Said chapter 176O is hereby further amended by adding the following
778 section:-

779 Section 30. (a) For the purposes of this section, the following words shall have the
780 following meanings unless the context clearly requires otherwise:

781 “Cost-sharing”, an amount owed by an individual under the terms of the individual’s
782 health benefit plan.

783 “Pharmacy retail price”, the amount an individual would pay for a prescription
784 medication at a pharmacy if the individual purchased that prescription medication at that
785 pharmacy without using a health benefit plan or any other prescription medication benefit or
786 discount.

787 (b) At the point of sale, a pharmacy shall charge an individual the: (i) appropriate cost-
788 sharing amount; or (ii) pharmacy retail price, whichever is the lowest; provided, however, that a
789 carrier, or an entity that manages or administers benefits for a carrier, shall not require an
790 individual to make a payment for a prescription drug at the point of sale in an amount that
791 exceeds the lesser of the: (a) individual’s cost share; or (b) pharmacy retail price.

792 (c) A contract shall not: (i) prohibit a pharmacist from complying with this section; or (ii)
793 impose a penalty on the pharmacist or pharmacy for complying with this section.

794 SECTION 55. The General Laws are hereby amended by inserting after chapter 176W
795 the following chapter:-

796 Chapter 176X.

797 LICENSING AND REGULATION OF PHARMACY BENEFIT MANAGERS.

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

800 “Carrier”, an insurer licensed or otherwise authorized to transact accident or health
801 insurance under chapter 175, a nonprofit hospital service corporation organized under chapter
802 176A, a non-profit medical service corporation organized under chapter 176B, a health
803 maintenance organization organized under chapter 176G and an organization entering into a
804 preferred provider arrangement under chapter 176I; provided, however, that the term “carrier”
805 shall not include an employer purchasing coverage or acting on behalf of its employees or the
806 employees of any subsidiary or affiliated corporation of the employer; provided further, that
807 unless otherwise provided, the term “carrier” shall not include any entity to the extent it offers a
808 policy, certificate or contract that provides coverage solely for dental care services or vision care
809 services.

810 “Center”, the center for health information and analysis established in chapter 12C.

811 “Commissioner”, the commissioner of insurance.

812 “Division”, the division of insurance.

813 “Health benefit plan”, a contract, certificate or agreement entered into, offered or issued
814 by a carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care
815 services; provided, however, that the commissioner may by regulation define other health
816 coverage as a “health benefit plan” for the purposes of this chapter.

817 “Pharmacy”, a physical or electronic facility under the direction or supervision of a
818 registered pharmacist that is authorized to dispense prescription drugs and has entered into a
819 network contract with a pharmacy benefit manager or a carrier.

820 “Pharmacy benefit manager”, a person, business or other entity, however organized, that
821 directly or through a subsidiary provides pharmacy benefit management services for prescription
822 drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-
823 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
824 management services shall include, but not be limited to: (i) the processing and payment of
825 claims for prescription drugs; (ii) the performance of drug utilization review; (iii) the processing
826 of drug prior authorization requests; (iv) pharmacy contracting; (v) the adjudication of appeals or
827 grievances related to prescription drug coverage contracts; (vi) formulary administration; (vii)
828 drug benefit design; (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x)
829 clinical, safety and adherence programs for pharmacy services; and (xi) managing the cost of
830 covered prescription drugs; provided further, that “pharmacy benefit manager” shall not include
831 a health benefit plan unless otherwise specified by the division.

832 Section 2. (a) A person, business or other entity shall not establish or operate as a
833 pharmacy benefit manager without obtaining a license from the division pursuant to this section.
834 The division shall issue a pharmacy benefit manager license to a person, business or other entity
835 that demonstrates to the division that it has the necessary organization, background expertise and
836 financial integrity to maintain such a license. A pharmacy benefit manager license shall be valid
837 for a period of 3 years and shall be renewable for additional 3-year periods. Initial application
838 and renewal fees for the license shall be established pursuant to section 3B of chapter 7.

839 (b) A license granted pursuant to this section and any rights or interests therein shall not
840 be transferable.

841 (c) A person, business or other entity licensed as a pharmacy benefit manager shall
842 submit data and reporting information to the center according to the standards and methods
843 specified by the center pursuant to section 10A of chapter 12C.

844 (d) The division may issue or renew a license pursuant to this section, subject to
845 restrictions in order to protect the interests of consumers. Such restrictions may include: (i)
846 limiting the type of services that a license holder may provide; (ii) limiting the activities in which
847 the license holder may be engaged; or (iii) addressing conflicts of interest between pharmacy
848 benefit managers and health plan sponsors.

849 (e) The division shall develop an application for licensure of pharmacy benefit managers
850 that shall include, but not be limited to: (i) the name of the applicant or pharmacy benefit
851 manager; (ii) the address and contact telephone number for the applicant or pharmacy benefit
852 manager; (iii) the name and address of the agent of the applicant or pharmacy benefit manager
853 for service of process in the commonwealth; (iv) the name and address of any person with
854 management or control over the applicant or pharmacy benefit manager; and (v) any audited
855 financial statements specific to the applicant or pharmacy benefit manager. An applicant or
856 pharmacy benefit manager shall report to the division any material change to the information
857 contained in its application, certified by an officer of the pharmacy benefit manager, within 30
858 days of such a change.

859 (f) The division may suspend, revoke, refuse to issue or renew or place on probation a
860 pharmacy benefit manager license for cause, which shall include, but not be limited to: (i) the

861 applicant or pharmacy benefit manager engaging in fraudulent activity that is found by a court of
862 law to be a violation of state or federal law; (ii) the division receiving consumer complaints that
863 justify an action under this chapter to protect the health, safety and interests of consumers; (iii)
864 the applicant or pharmacy benefit manager failing to pay an application or renewal fee for a
865 license; (iv) the applicant or pharmacy benefit manager failing to comply with reporting
866 requirements of the center under section 10A of chapter 12C; or (v) the applicant pharmacy
867 benefit manager's failing to comply with a requirement of this chapter.

868 The division shall provide written notice to the applicant or pharmacy benefit manager
869 and advise in writing of the reason for any suspension, revocation, refusal to issue or renew or
870 placement on probation of a pharmacy benefit manager license under this chapter. A copy of the
871 notice shall be forwarded to the center. The applicant or pharmacy benefit manager may make
872 written demand upon the division within 30 days of receipt of such notification for a hearing
873 before the division to determine the reasonableness of the division's action. The hearing shall be
874 held pursuant to chapter 30A.

875 The division shall not suspend or cancel a license unless the division has first afforded
876 the pharmacy benefit manager an opportunity for a hearing pursuant to said chapter 30A.

877 (g) If a person, business or other entity performs the functions of a pharmacy benefit
878 manager in violation of this chapter, the person, business or other entity shall be subject to a fine
879 of \$5,000 per day for each day that the person, business or other entity is found to be in violation.
880 Penalties collected under this subsection shall be deposited into the Prescription Drug Cost
881 Assistance Trust Fund established in section 2RRRRR of chapter 29.

882 (h) A pharmacy benefit manager licensed under this section shall notify a health carrier
883 client in writing of any activity, policy, practice contract or arrangement of the pharmacy benefit
884 manager that directly or indirectly presents any conflict of interest with the pharmacy benefit
885 manager's relationship with or obligation to the health carrier client.

886 (i) The division shall adopt any written policies, procedures or regulations that the
887 division determines are necessary to implement this section.

888 Section 3. (a) The commissioner may make an examination of the affairs of a pharmacy
889 benefit manager when the commissioner deems prudent but not less frequently than once every 3
890 years. The focus of the examination shall be to ensure that a pharmacy benefit manager is able to
891 meet its responsibilities under contracts with carriers licensed under chapters 175, 176A, 176B,
892 or 176G. The examination shall be conducted according to the procedures set forth in subsection
893 (6) of section 4 of chapter 175.

894 (b) The commissioner, a deputy or an examiner may conduct an on-site examination of
895 each pharmacy benefit manager in the commonwealth to thoroughly inspect and examine its
896 affairs.

897 (c) The charge for each such examination shall be determined annually according to the
898 procedures set forth in subsection (6) of section 4 of chapter 175.

899 (d) Not later than 60 days following completion of the examination, the examiner in
900 charge shall file with the commissioner a verified written report of examination under oath.
901 Upon receipt of the verified report, the commissioner shall transmit the report to the pharmacy
902 benefit manager examined with a notice that shall afford the pharmacy benefit manager
903 examined a reasonable opportunity of not more than 30 days to make a written submission or

904 rebuttal with respect to any matters contained in the examination report. Within 30 days of the
905 end of the period allowed for the receipt of written submissions or rebuttals, the commissioner
906 shall consider and review the reports together with any written submissions or rebuttals and any
907 relevant portions of the examiner's work papers and enter an order:

908 (i) adopting the examination report as filed with modifications or corrections and, if the
909 examination report reveals that the pharmacy benefit manager is operating in violation of this
910 section or any regulation or prior order of the commissioner, the commissioner may order the
911 pharmacy benefit manager to take any action the commissioner considered necessary and
912 appropriate to cure such violation;

913 (ii) rejecting the examination report with directions to examiners to reopen the
914 examination for the purposes of obtaining additional data, documentation or information and re-
915 filing pursuant to the above provisions; or

916 (iii) calling for an investigatory hearing with not less than 20 days' notice to the
917 pharmacy benefit manager for purposes of obtaining additional documentation, data, information
918 and testimony.

919 (e) Notwithstanding any general or special law to the contrary, including clause Twenty
920 sixth of section 7 of chapter 4 and chapter 66, the records of any such audit, examination or other
921 inspection and the information contained in the records, reports or books of any pharmacy
922 benefit manager examined pursuant to this section shall be confidential and open only to the
923 inspection of the commissioner, or the examiners and assistants. Access to such confidential
924 material may be granted by the commissioner to law enforcement officials of the commonwealth
925 or any other state or agency of the federal government at any time if the agency or office

926 receiving the information agrees in writing to keep such material confidential. Nothing in this
927 subsection shall be construed to prohibit the required production of such records, and
928 information contained in the reports of such company or organization before any court of the
929 commonwealth or any master or auditor appointed by any such court, in any criminal or civil
930 proceeding, affecting such pharmacy benefit manager, its officers, partners, directors or
931 employees. The final report of any such audit, examination or any other inspection by or on
932 behalf of the division of insurance shall be a public record, shall be posted on the division's
933 website and shall be submitted to the clerks of the senate and the house of representatives.

934 SECTION 56. Notwithstanding any general or special law to the contrary, the health
935 policy commission, in consultation with the center for health information and analysis, the
936 executive office of health and human services and the division of insurance, shall produce
937 interim and final reports on the use of insulin in the commonwealth and the effects of capping
938 copayments and eliminating deductible and co-insurance requirements for insulin for individuals
939 with diabetes on health care access and system cost.

940 The interim and final report shall include, but not be limited to: (i) rates of insulin
941 utilization; (ii) an analysis of the use of insulin, broken down by patient demographics,
942 geographic region and insulin delivery device; (iii) annual plan costs and member premiums; (iv)
943 the average price of insulin; (v) the average insulin price net of rebates or discounts received by
944 or accrued directly or indirectly by health insurance carriers; (vi) average and total out-of-pocket
945 expenditures on insulin delivery devices and glucose monitoring tests that are not included as
946 part of an insulin prescription; (vii) an analysis of the impact of capping co-payments and
947 eliminating deductible and co-insurance requirements for insulin on patient access to and cost of
948 care by patient demographics and geographic region; (viii) additional funding sources for the

949 Prescription Drug Cost Assistance Trust Fund established in section 2RRRRR of chapter 29 of
950 the General Laws; and (ix) any barriers to accessing insulin for individuals with diabetes and
951 policy recommendations for resolving such barriers. The interim report, including any
952 recommendations for expanding access to insulin for individuals with diabetes, shall be filed
953 with the clerks of the house of representatives and senate, the joint committee on public health,
954 the joint committee on health care financing and the house and senate committees on ways and
955 means not later than 18 months after the effective date of this act. The final report, including any
956 recommendations for expanding access to insulin for individuals with diabetes, shall be filed
957 with the clerks of the house of representatives and senate, the joint committee on public health,
958 the joint committee on health care financing and the house and senate committees on ways and
959 means not later than 3 years after the effective date of this act.

960 SECTION 57. (a) Notwithstanding any general or special law to the contrary, the
961 commonwealth health insurance connector authority, in consultation with the division of
962 insurance, shall report on the impact of pharmaceutical pricing on health care costs and outcomes
963 for ConnectorCare and non-group and small group plans offered through the connector and its
964 members.

965 The report shall include, but not be limited to: (i) information on the differential between
966 medication list price and price net of rebates for plans offered and the impact of those
967 differentials on member premiums; (ii) the relationship between medication list price and
968 member cost-sharing requirements; (iii) the impact of medication price changes over time on
969 premium and out-of-pocket costs in plans authorized under section 3 of chapter 176J of the
970 General Laws offered through the commonwealth health insurance connector authority; (iv)
971 trends in changes in medication list price and price net of rebates by health plan; (v) an analysis

972 of the impact of member out-of-pocket costs on medication utilization and member experience;
973 and (vi) an analysis of the impact of medication list price and price net of rebates on member
974 formulary access to medications. Data collected under this subsection shall be protected as
975 confidential and shall not be a public record under clause Twenty-sixth of section 7 of chapter 4
976 or under chapter 66 of the General Laws.

977 The report shall be submitted to the joint committee on health care financing and the
978 house and senate committees on ways and means not later than July 1, 2024.

979 (b) In fiscal year 2023, the amount required to be paid pursuant to the last paragraph of
980 section 6 of chapter 6D of the General Laws shall be increased by \$500,000; provided, however,
981 that said \$500,000 shall be provided to the commonwealth health insurance connector authority
982 not later than October 14, 2022 for data collection and analysis costs associated with the report
983 required by this section.

984 SECTION 58. Notwithstanding any general or special law to the contrary, there shall be a
985 special commission to examine the feasibility of: (i) establishing a system for the bulk
986 purchasing and distribution of pharmaceutical products with a significant public health benefit
987 and the potential for significant health care cost savings for consumers through overall increased
988 purchase capacity; and (ii) making bulk purchase pricing information available to purchasers in
989 other states.

990 The commission shall consist of: the commissioner of public health or a designee, who
991 shall serve as chair; the executive director of the group insurance commission or a designee; the
992 chief of pharmacy of the state office for pharmacy services; the MassHealth director of
993 pharmacy; the secretary of technology services and security; and 9 members to be appointed by

994 the commissioner of public health, 2 of whom shall be health care economists, 1 of whom shall
995 be an expert in health law and policy innovation, 1 of whom shall be an academic with relevant
996 expertise in the field, 1 of whom shall be a representative from a community health center, 1 of
997 whom shall be the chief executive officer of a hospital licensed in the commonwealth, 1 of
998 whom shall be a representative of the Massachusetts Association of Health Plans, Inc., 1 of
999 whom shall be a representative of Blue Cross Blue Shield of Massachusetts, Inc. and 1 of whom
1000 shall be a member of the public with experience with health care and consumer protection.

1001 The commission shall hold not less than 3 public hearings in different geographic areas of
1002 the commonwealth, accept input from the public and solicit expert testimony from individuals
1003 representing health insurance carriers, pharmaceutical companies, independent and chain
1004 pharmacies, hospitals, municipalities, health care practitioners, health care technology
1005 professionals, community health centers, substance abuse disorder providers, public health
1006 educational institutions and other experts identified by the commission.

1007 The commission shall consider: (i) the process by which the commonwealth could make
1008 bulk purchases of pharmaceutical products with a significant public health benefit and the
1009 potential for significant health care cost savings to consumers; (ii) the process by which both
1010 governmental and nongovernmental entities may participate in a collaborative to purchase
1011 pharmaceutical products with a significant public health benefit and the potential for significant
1012 health care cost savings; (iii) the feasibility of developing an electronic information interchange
1013 system to exchange bulk purchase price information with partnering states; (iv) potential sources
1014 of funding available to implement bulk purchases; (v) potential cost savings of bulk purchases to
1015 the commonwealth or other participating nongovernmental entities; (vi) the feasibility of

1016 partnering with the federal government and or other states in the New England region; and (vii)
1017 any other factors that the commission deems relevant.

1018 The commission shall file a report of its analysis, along with any recommended
1019 legislation, if any, to the clerks of the senate and house of representatives, the house and senate
1020 committees on ways and means, the joint committee on health care financing, the joint
1021 committee on public health, the joint committee on elder affairs and the joint committee on
1022 mental health, substance abuse and recovery not later than September 1, 2023.

1023 SECTION 59. (a) As used in this section, the following words shall have the following
1024 meanings, unless the context clearly requires otherwise:

1025 “Chain pharmacist”, a pharmacist employed by a retail drug organization operating not
1026 less than 10 retail drug stores within the commonwealth under section 39 of chapter 112 of the
1027 General Laws.

1028 “Independent pharmacist”, a pharmacist actively engaged in the business of retail
1029 pharmacy and employed in an organization of not more than 9 registered retail drugstores in the
1030 commonwealth under said section 39 of said chapter 112 that employs not more than a total of
1031 20 full-time pharmacists.

1032 (b) There shall be a task force to: (i) review the drug supply chain including, but not
1033 limited to: (A) plan and pharmacy benefit manager reimbursements to pharmacies; (B)
1034 wholesaler or pharmacy service administrative organization prices to pharmacies; and (C) drug
1035 manufacturer prices to pharmacies; (ii) review ways to recognize the unique challenges of small
1036 and independent pharmacies; (iii) identify methods to increase pricing transparency throughout
1037 the supply chain; (iv) make recommendations on the use of multiple maximum allowable costs

1038 lists and their frequency of use for mail order products; (v) review the utilization of maximum
1039 allowable costs lists or similar reimbursement structures established by a pharmacy benefit
1040 manager or payer; (vi) review the availability of drugs to independent and chain pharmacies on
1041 the maximum allowable cost list or any similar reimbursement structures established by a
1042 pharmacy benefit manager or payer; (vii) review the pharmacy acquisition cost from national or
1043 regional wholesalers that serve pharmacies compared to the reimbursement amount provided
1044 through a maximum allowable cost list or any similar reimbursement structures established by a
1045 pharmacy benefit manager or payer and the conditions under which an adjustment to a
1046 reimbursement is appropriate; (viii) review the timing of pharmacy purchases of products and the
1047 relative risk of list price changes related to the timing of dispensing the products; (ix) assess
1048 ways to increase transparency for chain and independent pharmacists to understand the
1049 methodology used by a pharmacy benefit manager or payer to develop a maximum allowable
1050 cost list or any similar reimbursement structure established by the pharmacy benefit manager or
1051 payer; (x) assess the prevalence and appropriateness of pharmacy benefit managers requiring, or
1052 using financial incentives or penalties to incentivize, customer use of pharmacies with whom the
1053 pharmacy benefit manager has an ownership or financial interest; (xi) examine the impact of the
1054 merger or consolidation of pharmacy benefit managers and health carrier clients on drug costs;
1055 (xii) review current appeals processes for a chain or independent pharmacist to request an
1056 adjustment on a reimbursement subject to a maximum allowable cost list or any similar
1057 reimbursement structure established by a pharmacy benefit manager or payer; and (xiii) evaluate
1058 the effect of differences between pharmacy benefit manager payments to pharmacies and charges
1059 made to health carrier clients on drug price.

1060 (c) The task force shall consist of: the commissioner of insurance or a designee, who shall
1061 serve as chair; and 6 members to be appointed by the commissioner, 2 of whom shall be
1062 independent pharmacists employed in the independent pharmacy setting or representatives of
1063 independent pharmacies, 2 of whom shall be chain pharmacists employed in the chain pharmacy
1064 setting or representatives of chain pharmacies and 2 of whom shall be representatives of a
1065 pharmacy benefit managers or payers who manage their own pharmacy benefit services. If more
1066 than 1 independent pharmacist is appointed, each appointee shall represent a distinct practice
1067 setting. If more than 1 chain pharmacist is appointed, each appointee shall represent a distinct
1068 practice setting. A pharmacy benefit manager or payer appointed to the task force shall not be
1069 co-owned or have any ownership relationship with any other payer, pharmacy benefit manager or
1070 chain pharmacist also appointed to the task force.

1071 (d) The commissioner shall file the task force's findings with the clerks of the house of
1072 representatives and the senate, the joint committee on health care financing and the house and
1073 senate committees on ways and means not later than December 1, 2023.

1074 SECTION 60. The health policy commission shall consult with relevant stakeholders,
1075 including, but not limited to, consumers, consumer advocacy organizations, organizations
1076 representing people with disabilities and chronic health conditions, providers, provider
1077 organizations, payers, pharmaceutical manufacturers, pharmacy benefit managers and health care
1078 economists and other academics, to assist in the development and periodic review of regulations
1079 to implement section 20 of chapter 6D of the General Laws, including, but not limited to: (i)
1080 establishing the criteria and processes for identifying the proposed value of an eligible drug as
1081 defined in said section 20 of said chapter 6D; and (ii) determining the appropriate price increase

1082 for a public health essential drug as described within the definition of eligible drug in said
1083 section 20 of said chapter 6D.

1084 The commission shall hold its first public outreach not more than 45 days after the
1085 effective date of this act and shall, to the extent possible, ensure fair representation and input
1086 from a diverse array of stakeholders.

1087 SECTION 61. Notwithstanding subsection (b) of section 15A of chapter 6D of the
1088 General Laws, for the purposes of providing early notice under said section 15A of said chapter
1089 6D, the health policy commission shall determine a significant price increase for a generic drug
1090 to be defined as a generic drug priced at \$100 or more per wholesale acquisition cost unit that
1091 increases in cost by 100 per cent or more during any 12-month period.

1092 SECTION 62. Section 61 is hereby repealed.

1093 SECTION 63. For the purposes of this section, “epinephrine injector” shall include an
1094 auto-injector approved by the United States Food and Drug Administration for the administration
1095 of epinephrine and a prefilled syringe approved by the United States Food and Drug
1096 Administration for the administration of epinephrine that contains a pre-measured dose of
1097 epinephrine that is equivalent to the dosages used in an auto-injector.

1098 Notwithstanding any general or special law to the contrary, the center for health
1099 information and analysis shall provide a cost estimate review and evaluation of coverage for
1100 medically-necessary appropriate weight-based dosage epinephrine injectors for persons 18 years
1101 of age or under; provided, however, that coverage shall not be subject to any deductible, co-
1102 insurance or co-pay; provided further, that the review and evaluation shall include an estimate of
1103 costs to the commonwealth under 45 C.F.R. 155.170.

1104 The review and evaluation shall be posted on the center’s website and shall be filed with
1105 the clerks of the senate and the house of representatives and the house and senate committees on
1106 ways and means not later than June 30, 2022.

1107 SECTION 64. The health policy commission, in consultation with the department of
1108 public health, the office of Medicaid, the group insurance commission and the division of
1109 insurance, shall study and analyze health insurance payer, including public and private payer,
1110 specialty pharmacy networks in the commonwealth. The study shall include: (i) a description of
1111 the type of specialty medications most often provided by specialty pharmacies; (ii) the impact of
1112 existing health insurance payers’ specialty pharmacy networks on patient access, availability of
1113 clinical support, continuity of care, safety, quality, cost sharing and health care costs; and (iii)
1114 any recommendations for increasing patient access to and choice of specialty medications,
1115 maintaining high-quality specialty pharmacy standards and meeting the commonwealth’s health
1116 care cost containment goals.

1117 The commission shall submit a report of its findings and recommendations to the clerks
1118 of the senate and house of representatives, the senate and house committees on ways and means,
1119 the joint committee on health care financing and the joint committee on public health not later
1120 than July 1, 2023.

1121 SECTION 65. The regulations required by subsection (d) of section 39K of chapter 112
1122 of the General Laws shall be promulgated not later than December 31, 2022.

1123 SECTION 66. The department of public health, in consultation with the attorney general,
1124 district attorneys, patient advocates, health care practitioners and other relevant stakeholders,
1125 shall analyze the effectiveness and sufficiency of the marketing code of conduct rules established

1126 pursuant to chapter 111N of the General Laws. The department's analysis shall include, but not
1127 be limited to: (i) an evaluation of the reports, compliance information and data required under
1128 sections 2A, 5 and 6 of said chapter 111N; (ii) a comparison of the marketing code of conduct
1129 rules with similar rules established in other states; (iii) a review of any enforcement actions taken
1130 for violations of said chapter 111N; (iv) a review of opioid marketing practices and direct impact
1131 upon increased substance abuse disorders and related deaths; and (v) an assessment of the need,
1132 and recommendations for implementation, for further requirements to ensure marketing
1133 activities by pharmaceutical and medical device manufacturers do not influence prescribing
1134 patterns in a manner that adversely affects patient care, which shall include, but not be limited to,
1135 requiring the licensing of all pharmaceutical and medical device representatives, including
1136 pharmaceutical or medical device manufacturer agents, as defined in section 1 of said chapter
1137 111N. The department shall file a report of its findings with the clerks of the senate and house of
1138 representatives, the joint committee on public health, the joint committee on health care
1139 financing, the senate committee on steering and policy and the senate and house committees on
1140 ways and means not later than May 1, 2022.

1141 SECTION 67. Sections 21 and 39 shall take effect on July 1, 2023.

1142 SECTION 68. Sections 41, 43, 44, 46, 47 and 51 shall take effect January 1, 2023.

1143 SECTION 69. Section 42 shall take effect on April 1, 2023.

1144 SECTION 70. Section 53 shall take effect on July 1, 2023.

1145 SECTION 71. Section 55 shall take effect on March 30, 2023.

1146 SECTION 72. Section 62 shall take effect on January 1, 2024.