

SENATE No. 2651

The Commonwealth of Massachusetts

—————
In the One Hundred and Ninety-Second General Court
(2021-2022)
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SENATE, February 3, 2022.

The committee on Senate Ways and Means to whom was referred the Senate Bill relative to pharmaceutical access, costs and transparency (Senate, No. 771), - reports, recommending that the same ought to pass with an amendment substituting a new draft with the same title (Senate, No. 2651).

For the committee,
Michael J. Rodrigues

SENATE No. 2651

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**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 shall not be used as the sole source of
289 information by the office of Medicaid, health insurance carriers, managed care organizations,
290 accountable care organizations, hospitals or pharmacies to determine whether to implement step
291 therapy or utilization management or whether a drug should be included in a formulary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

356 (j) The commission may assess a civil penalty to a manufacturer of not more than
357 \$500,000, in each instance, if the commission determines that the manufacturer: (i) willfully
358 neglected to file an access and affordability improvement plan with the commission under
359 subsection (a); (ii) failed to file an acceptable access and affordability improvement plan in good

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

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

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

383 recommendations shall be publicly posted on the commission’s website and provided to the
384 clerks of the house of representatives and senate, the joint committee on health care financing
385 and the house and senate committees on ways and means.

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

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

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

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

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

402 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
403 drug application approved under 21 U.S.C. 355(c) except for an authorized generic as defined by

404 42 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application
405 approved under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand
406 name drug based on available data resources such as Medi-Span.

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

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

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

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

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

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

441 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
442 1395w-3a(c)(6)(B).

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

446 SECTION 27. Said section 3 of said chapter 12C, as so appearing, is hereby further
447 amended by striking out, in line 24, the words “and payer” and inserting in place thereof the

448 following words:- , payer, pharmaceutical manufacturing company and pharmacy benefit
449 manager.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

606 2RRRRR. (a) There shall be a Prescription Drug Cost Assistance Trust Fund. The
607 secretary of health and human services shall administer the fund and shall make expenditures
608 from the fund, without further appropriation, to provide financial assistance to state residents to
609 lower the cost of prescription drugs. Money in the fund shall be spent to provide financial
610 assistance for prescription drugs used to treat: (i) chronic respiratory conditions, including, but
611 not limited to, chronic obstructive pulmonary disease and asthma; (ii) chronic heart conditions,
612 including, but not limited to, heart failure, coronary artery disease, hypertension and high blood
613 pressure; (iii) diabetes; and (iv) any other chronic condition identified by the department that
614 disproportionately impacts marginalized communities. For the purpose of this section
615 “prescription drug” shall include the prescription drug and any drug delivery device needed to
616 administer the drug that is not included as part of the underlying drug prescription.

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

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

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

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

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

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

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

644 defined in section 3B of chapter 176D; provided further, that “specialty pharmacy” shall not
645 include a mail service pharmacy.

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

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

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

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

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

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

673 (c) No pharmacy or pharmacist operating outside of the state shall prescribe, ship, mail,
674 sell, transfer or dispense drug preparations in the commonwealth unless that pharmacy has been
675 granted a specialty license pursuant to this section.

676 (d) The division of insurance may adopt any written policies or procedures or promulgate
677 regulations that the division determines are necessary to implement this section.

678 SECTION 43. Section 10C of chapter 118E of the General Laws, as appearing in the
679 2020 Official Edition, is hereby amended by adding the following sentence:-

680 Coverage for insulin under this section shall not be subject to any deductible or co-
681 insurance and any co-payment shall not exceed \$25 per 30-day supply, regardless of the amount
682 or type of insulin needed to fill an insured's prescription; provided, however, that nothing in this
683 section shall prevent the division and its contracted health insurers, health plans, health
684 maintenance organizations, behavioral health management firms and third-party administrators
685 under contract with the division, a Medicaid managed care organization or a primary care
686 clinician plan, from reducing the co-payments for insulin for a 30-day supply below the amount
687 specified in this section.

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

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

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

701 (a) For the purposes of this section, the term "pharmacy benefit manager" shall mean a
702 person, business or other entity, however organized, that directly or through a subsidiary
703 provides pharmacy benefit management services for prescription drugs and devices on behalf of
704 a health benefit plan sponsor, including, but not limited to, a self-insurance plan, labor union or
705 other third-party payer; provided, however, that pharmacy benefit management services shall
706 include, but not be limited to: (i) the processing and payment of claims for prescription drugs;
707 (ii) the performance of drug utilization review; (iii) the processing of drug prior authorization
708 requests; (iv) pharmacy contracting; (v) the adjudication of appeals or grievances related to
709 prescription drug coverage contracts; (vi) formulary administration; (vii) drug benefit design;

710 (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x) clinical, safety and
711 adherence programs for pharmacy services; and (xi) managing the cost of covered prescription
712 drugs; provided further, that “pharmacy benefit manager” shall include a health benefit plan that
713 does not contract with a pharmacy benefit manager and manages its own prescription drug
714 benefits unless specifically exempted.

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

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

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

726 Coverage for insulin under this section shall not be subject to any deductible or co-
727 insurance and any co-payment shall not exceed \$25 per 30-day supply, regardless of the amount
728 or type of insulin needed to fill an insured’s insulin prescription; provided, however, that nothing
729 in this section shall prevents a subscription certificate under an individual or group medical
730 service agreement that is issued or renewed within or without the commonwealth, from reducing
731 the co-payment for insulin for a 30-day supply below the amount specified in this section.

732 SECTION 48. The fourth paragraph of section 3B of chapter 176D of the General Laws,
733 as so appearing, is hereby amended by inserting after the second sentence the following
734 sentences:- A carrier shall not prohibit the dispensing of specialty drugs as defined by this
735 section that are included in its pharmaceutical drug benefits to insureds by any licensed
736 pharmacy; provided, however, that the pharmacy is able to comply with the special handling,
737 administration and monitoring requirements of the specialty drug. A carrier shall allow any
738 network pharmacy to provide specialty drugs if the pharmacy agrees to the same reimbursement
739 terms and conditions.

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

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

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

753 shall mean a prescription medication that requires special handling, administration or
754 monitoring.

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

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

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

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

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

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

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

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

778 “Cost-sharing”, an amount owed by a consumer under the terms of the consumer’s health
779 benefit plan .

780 “Negotiated price”, the amount that the health benefit plan or a pharmacy benefit
781 manager, as defined in section 1 of chapter 6D, would pay for a prescription medication at a
782 pharmacy under an agreement between the health benefit plan and the pharmacy.

783 “Usual and customary charge”, the lowest price that a provider charges or accepts from
784 any payer for the same quantity of a drug on the same date of service in the commonwealth,
785 including, but not limited to, the shelf price, sale price or advertised price for any drug including
786 an over-the-counter drug; provided, however, that if an insurer and the provider have a contract
787 that specified that the insurer will pay an average or similarly computed fixed amount for
788 multiple therapeutic categories of drugs with different acquisition costs, the fixed amount will
789 not be the provider’s usual and customary charge.

790 (b) A carrier, or an entity that manages or administrators benefits for a carrier, shall not
791 impose cost sharing, including co-pays, deductibles and coinsurance, on a member for a covered
792 prescription drug that exceeds the negotiated price or usual and customary charge, whichever is
793 lower.

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

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

798 Chapter 176X.

799 LICENSING AND REGULATION OF PHARMACY BENEFIT MANAGERS.

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

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

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

813 “Commissioner”, the commissioner of insurance.

814 “Division”, the division of insurance.

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

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

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

835 Section 2. (a) A person, business or other entity shall not establish or operate as a
836 pharmacy benefit manager without obtaining a license from the division pursuant to this section.

837 The division shall issue a pharmacy benefit manager license to a person, business or other entity
838 that demonstrates to the division that it has the necessary organization, background expertise and
839 financial integrity to maintain such a license. A pharmacy benefit manager license shall be valid
840 for a period of 3 years and shall be renewable for additional 3-year periods. Initial application
841 and renewal fees for the license shall be established pursuant to section 3B of chapter 7.

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

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

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

852 (e) The division shall develop an application for licensure of pharmacy benefit managers
853 that shall include, but not be limited to: (i) the name of the applicant or pharmacy benefit
854 manager; (ii) the address and contact telephone number for the applicant or pharmacy benefit
855 manager; (iii) the name and address of the agent of the applicant or pharmacy benefit manager
856 for service of process in the commonwealth; (iv) the name and address of any person with
857 management or control over the applicant or pharmacy benefit manager; and (v) any audited
858 financial statements specific to the applicant or pharmacy benefit manager. An applicant or

859 pharmacy benefit manager shall report to the division any material change to the information
860 contained in its application, certified by an officer of the pharmacy benefit manager, within 30
861 days of such a change.

862 (f) The division may suspend, revoke, refuse to issue or renew or place on probation a
863 pharmacy benefit manager license for cause, which shall include, but not be limited to: (i) the
864 applicant or pharmacy benefit manager engaging in fraudulent activity that is found by a court of
865 law to be a violation of state or federal law; (ii) the division receiving consumer complaints that
866 justify an action under this chapter to protect the health, safety and interests of consumers; (iii)
867 the applicant or pharmacy benefit manager failing to pay an application or renewal fee for a
868 license; (iv) the applicant or pharmacy benefit manager failing to comply with reporting
869 requirements of the center under section 10A of chapter 12C; or (v) the applicant pharmacy
870 benefit manager's failing to comply with a requirement of this chapter.

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

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

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

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

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

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

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

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

902 (d) Not later than 60 days following completion of the examination, the examiner in
903 charge shall file with the commissioner a verified written report of examination under oath.
904 Upon receipt of the verified report, the commissioner shall transmit the report to the pharmacy
905 benefit manager examined with a notice that shall afford the pharmacy benefit manager
906 examined a reasonable opportunity of not more than 30 days to make a written submission or
907 rebuttal with respect to any matters contained in the examination report. Within 30 days of the
908 end of the period allowed for the receipt of written submissions or rebuttals, the commissioner
909 shall consider and review the reports together with any written submissions or rebuttals and any
910 relevant portions of the examiner's work papers and enter an order:

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

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

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

922 (e) Notwithstanding any general or special law to the contrary, including clause Twenty
923 sixth of section 7 of chapter 4 and chapter 66, the records of any such audit, examination or other

924 inspection and the information contained in the records, reports or books of any pharmacy
925 benefit manager examined pursuant to this section shall be confidential and open only to the
926 inspection of the commissioner, or the examiners and assistants. Access to such confidential
927 material may be granted by the commissioner to law enforcement officials of the commonwealth
928 or any other state or agency of the federal government at any time if the agency or office
929 receiving the information agrees in writing to keep such material confidential. Nothing in this
930 subsection shall be construed to prohibit the required production of such records, and
931 information contained in the reports of such company or organization before any court of the
932 commonwealth or any master or auditor appointed by any such court, in any criminal or civil
933 proceeding, affecting such pharmacy benefit manager, its officers, partners, directors or
934 employees. The final report of any such audit, examination or any other inspection by or on
935 behalf of the division of insurance shall be a public record.

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

942 The interim and final report shall include, but not be limited to: (i) rates of insulin
943 utilization; (ii) an analysis of the use of insulin, broken down by patient demographics,
944 geographic region and insulin delivery device; (iii) annual plan costs and member premiums; (iv)
945 the average price of insulin; (v) the average insulin price net of rebates or discounts received by
946 or accrued directly or indirectly by health insurance carriers; (vi) average and total out-of-pocket

947 expenditures on insulin delivery devices and glucose monitoring tests that are not included as
948 part of an insulin prescription; (vii) an analysis of the impact of capping co-payments and
949 eliminating deductible and co-insurance requirements for insulin on patient access to and cost of
950 care by patient demographics and geographic region; (viii) additional funding sources for the
951 Prescription Drug Cost Assistance Trust Fund established in section 2RRRRR of chapter 29 of
952 the General Laws; and (ix) any barriers to accessing insulin for individuals with diabetes and
953 policy recommendations for resolving such barriers. The interim report, including any
954 recommendations for expanding access to insulin for individuals with diabetes, shall be filed
955 with the clerks of the house of representatives and senate, the joint committee on public health,
956 the joint committee on health care financing and the house and senate committees on ways and
957 means not later than 18 months after the effective date of this act. The final report, including any
958 recommendations for expanding access to insulin for individuals with diabetes, shall be filed
959 with the clerks of the house of representatives and senate, the joint committee on public health,
960 the joint committee on health care financing and the house and senate committees on ways and
961 means not later than 3 years after the effective date of this act.

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

967 The report shall include, but not be limited to: (i) information on the differential between
968 medication list price and price net of rebates for plans offered and the impact of those
969 differentials on member premiums; (ii) the relationship between medication list price and

970 member cost-sharing requirements; (iii) the impact of medication price changes over time on
971 premium and out-of-pocket costs in plans authorized under section 3 of chapter 176J of the
972 General Laws offered through the commonwealth health insurance connector authority; (iv)
973 trends in changes in medication list price and price net of rebates by health plan; (v) an analysis
974 of the impact of member out-of-pocket costs on medication utilization and member experience;
975 and (vi) an analysis of the impact of medication list price and price net of rebates on member
976 formulary access to medications. Data collected under this subsection shall be protected as
977 confidential and shall not be a public record under clause Twenty-sixth of section 7 of chapter 4
978 or under chapter 66 of the General Laws.

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

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

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

992 The commission shall consist of: the commissioner of public health or a designee, who
993 shall serve as chair; the executive director of the group insurance commission or a designee; the
994 chief of pharmacy of the state office for pharmacy services; the MassHealth director of
995 pharmacy; the secretary of technology services and security; and 8 members appointed by the
996 commissioner of public health, 2 of whom shall be health care economists, 1 of whom shall be
997 an expert in health law and policy innovation, 1 of whom shall be an academic with relevant
998 expertise in the field, 1 of whom shall be the chief executive officer of a licensed hospital in the
999 commonwealth, 1 of whom shall be a representative of the Massachusetts Association of Health
1000 Plans, Inc., 1 of whom shall be a representative of Blue Cross Blue Shield of Massachusetts, Inc.
1001 and 1 of whom shall be a member of the public with experience with health care and consumer
1002 protection.

1003 The commission shall hold not less than 3 public hearings in different geographic areas of
1004 the commonwealth, accept input from the public and solicit expert testimony from individuals
1005 representing health insurance carriers, pharmaceutical companies, independent and chain
1006 pharmacies, hospitals, municipalities, health care practitioners, health care technology
1007 professionals, community health centers, substance abuse disorder providers, public health
1008 educational institutions and other experts identified by the commission.

1009 The commission shall consider: (i) the process by which the commonwealth could make
1010 bulk purchases of pharmaceutical products with a significant public health benefit and the
1011 potential for significant health care cost savings to consumers; (ii) the process by which both
1012 governmental and nongovernmental entities may participate in a collaborative to purchase
1013 pharmaceutical products with a significant public health benefit and the potential for significant
1014 health care cost savings; (iii) the feasibility of developing an electronic information interchange

1015 system to exchange bulk purchase price information with partnering states; (iv) potential sources
1016 of funding available to implement bulk purchases; (v) potential cost savings of bulk purchases to
1017 the commonwealth or other participating nongovernmental entities; (vi) the feasibility of
1018 partnering with the federal government and or other states in the New England region; and (vii)
1019 any other factors that the commission deems relevant.

1020 The commission shall file a report of its analysis, along with any recommended
1021 legislation, if any, to the clerks of the senate and house of representatives, the house and senate
1022 committees on ways and means, the joint committee on health care financing, the joint
1023 committee on public health, the joint committee on elder affairs and the joint committee on
1024 mental health, substance abuse and recovery not later than September 1, 2023.

1025 SECTION 59. (a) As used in this section, the following words shall have the following
1026 meanings, unless the context clearly requires otherwise:

1027 “Chain pharmacist”, a pharmacist employed by a retail drug organization operating not
1028 less than 10 retail drug stores within the commonwealth under section 39 of chapter 112 of the
1029 General Laws.

1030 “Independent pharmacist”, a pharmacist actively engaged in the business of retail
1031 pharmacy and employed in an organization of not more than 9 registered retail drugstores in the
1032 commonwealth under said section 39 of said chapter 112 that employs not more than a total of
1033 20 full-time pharmacists.

1034 (b) There shall be a task force to: (i) review the drug supply chain including, but not
1035 limited to: (A) plan and pharmacy benefit manager reimbursements to pharmacies; (B)
1036 wholesaler or pharmacy service administrative organization prices to pharmacies; and (C) drug

1037 manufacturer prices to pharmacies; (ii) review ways to recognize the unique challenges of small
1038 and independent pharmacies; (iii) identify methods to increase pricing transparency throughout
1039 the supply chain; (iv) make recommendations on the use of multiple maximum allowable costs
1040 lists and their frequency of use for mail order products; (v) review the utilization of maximum
1041 allowable costs lists or similar reimbursement structures established by a pharmacy benefit
1042 manager or payer; (vi) review the availability of drugs to independent and chain pharmacies on
1043 the maximum allowable cost list or any similar reimbursement structures established by a
1044 pharmacy benefit manager or payer; (vii) review the pharmacy acquisition cost from national or
1045 regional wholesalers that serve pharmacies compared to the reimbursement amount provided
1046 through a maximum allowable cost list or any similar reimbursement structures established by a
1047 pharmacy benefit manager or payer and the conditions under which an adjustment to a
1048 reimbursement is appropriate; (viii) review the timing of pharmacy purchases of products and the
1049 relative risk of list price changes related to the timing of dispensing the products; (ix) assess
1050 ways to increase transparency for chain and independent pharmacists to understand the
1051 methodology used by a pharmacy benefit manager or payer to develop a maximum allowable
1052 cost list or any similar reimbursement structure established by the pharmacy benefit manager or
1053 payer; (x) assess the prevalence and appropriateness of pharmacy benefit managers requiring, or
1054 using financial incentives or penalties to incentivize, customer use of pharmacies with whom the
1055 pharmacy benefit manager has an ownership or financial interest; (xi) examine the impact of the
1056 merger or consolidation of pharmacy benefit managers and health carrier clients on drug costs;
1057 (xii) review current appeals processes for a chain or independent pharmacist to request an
1058 adjustment on a reimbursement subject to a maximum allowable cost list or any similar
1059 reimbursement structure established by a pharmacy benefit manager or payer; and (xiii) evaluate

1060 the effect of differences between pharmacy benefit manager payments to pharmacies and charges
1061 made to health carrier clients on drug price.

1062 (c) The task force shall consist of: the commissioner of insurance or a designee, who shall
1063 serve as chair; and 6 members to be appointed by the commissioner, 2 of whom shall be
1064 independent pharmacists employed in the independent pharmacy setting or representatives of
1065 independent pharmacies, 2 of whom shall be chain pharmacists employed in the chain pharmacy
1066 setting or representatives of chain pharmacies and 2 of whom shall be representatives of a
1067 pharmacy benefit managers or payers who manage their own pharmacy benefit services. If more
1068 than 1 independent pharmacist is appointed, each appointee shall represent a distinct practice
1069 setting. If more than 1 chain pharmacist is appointed, each appointee shall represent a distinct
1070 practice setting. A pharmacy benefit manager or payer appointed to the task force shall not be
1071 co-owned or have any ownership relationship with any other payer, pharmacy benefit manager or
1072 chain pharmacist also appointed to the task force.

1073 (d) The commissioner shall file the task force's findings with the clerks of the house of
1074 representatives and the senate, the joint committee on health care financing and the house and
1075 senate committees on ways and means not later than December 1, 2023.

1076 SECTION 60. The health policy commission shall consult with relevant stakeholders,
1077 including, but not limited to, consumers, consumer advocacy organizations, organizations
1078 representing people with disabilities and chronic health conditions, providers, provider
1079 organizations, payers, pharmaceutical manufacturers, pharmacy benefit managers and health care
1080 economists and other academics, to assist in the development and periodic review of regulations
1081 to implement section 20 of chapter 6D of the General Laws, including, but not limited to: (i)

1082 establishing the criteria and processes for identifying the proposed value of an eligible drug as
1083 defined in said section 20 of said chapter 6D; and (ii) determining the appropriate price increase
1084 for a public health essential drug as described within the definition of eligible drug in said
1085 section 20 of said chapter 6D.

1086 The commission shall hold its first public outreach not more than 45 days after the
1087 effective date of this act and shall, to the extent possible, ensure fair representation and input
1088 from a diverse array of stakeholders.

1089 SECTION 61. Notwithstanding subsection (b) of section 15A of chapter 6D of the
1090 General Laws, for the purposes of providing early notice under said section 15A of said chapter
1091 6D, the health policy commission shall determine a significant price increase for a generic drug
1092 to be defined as a generic drug priced at \$100 or more per wholesale acquisition cost unit that
1093 increases in cost by 100 per cent or more during any 12-month period.

1094 SECTION 62. Section 61 is hereby repealed.

1095 SECTION 63. Sections 21 and 39 shall take effect on July 1, 2023.

1096 SECTION 64. Sections 41, 43, 44, 46, 47 and 51 shall take effect January 1, 2023.

1097 SECTION 65. Section 42 shall take effect on December 15, 2022.

1098 SECTION 66. Section 53 shall take effect on July 1, 2023.

1099 SECTION 67. Section 55 shall take effect on March 30, 2023.

1100 SECTION 68. Section 62 shall take effect on January 1, 2024.