

SENATE No. 771

The Commonwealth of Massachusetts

PRESENTED BY:

Cindy F. Friedman

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to pharmaceutical access, costs and transparency.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	
<i>Cindy F. Friedman</i>	<i>Fourth Middlesex</i>	
<i>Jason M. Lewis</i>	<i>Fifth Middlesex</i>	<i>3/2/2021</i>
<i>Joanne M. Comerford</i>	<i>Hampshire, Franklin and Worcester</i>	<i>3/2/2021</i>
<i>Michael O. Moore</i>	<i>Second Worcester</i>	<i>3/2/2021</i>
<i>Jack Patrick Lewis</i>	<i>7th Middlesex</i>	<i>2/26/2021</i>
<i>Peter Capano</i>	<i>11th Essex</i>	<i>3/5/2021</i>
<i>Patrick M. O'Connor</i>	<i>Plymouth and Norfolk</i>	<i>3/10/2021</i>
<i>Eric P. Lesser</i>	<i>First Hampden and Hampshire</i>	<i>3/12/2021</i>
<i>Walter F. Timilty</i>	<i>Norfolk, Bristol and Plymouth</i>	<i>3/18/2021</i>

SENATE No. 771

By Ms. Friedman, a petition (accompanied by bill, Senate, No. 771) of Cindy F. Friedman, Jason M. Lewis, Joanne M. Comerford, Michael O. Moore and other members of the General Court for legislation relative to pharmaceutical access, costs and transparency. Health Care Financing.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. 2409 OF 2019-2020.]

The Commonwealth of Massachusetts

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

An Act relative to pharmaceutical access, costs and transparency.

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

1 SECTION 1. Section 1 of chapter 6D of the General Laws, as appearing in the 2018
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 an authorized generic as defined by
8 42 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application

9 approved under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand
10 name drug based on available data resources such as Medi-Span.

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

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

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

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

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

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

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

38 “Pharmacy benefit manager”, a person, business or other entity, however organized, that
39 directly or through a subsidiary provides pharmacy benefit management services for prescription
40 drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-
41 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
42 management services shall include, but not be limited to, the processing and payment of claims
43 for prescription drugs; the performance of drug utilization review; the processing of drug prior
44 authorization requests; pharmacy contracting; the adjudication of appeals or grievances related to
45 prescription drug coverage contracts; formulary administration; drug benefit design; mail and
46 specialty drug pharmacy services; cost containment; clinical, safety and adherence programs for
47 pharmacy services and managing the cost of covered prescription drugs; provided further, that
48 “pharmacy benefit manager” shall include a health benefit plan that does not contract with a
49 pharmacy benefit manager and manages its own prescription drug benefits unless specifically
50 exempted by the commission.

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

53 “Pipeline drugs”, prescription drug products containing a new molecular entity for which
54 the sponsor has submitted a new drug application or biologics license application and received an
55 action date from the federal Food and Drug Administration.

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

58 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
59 1395w-3a(c)(6)(B).

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

62 Section 2A. The commission shall keep confidential all nonpublic clinical, financial,
63 strategic or operational documents or information provided or reported to the commission in
64 connection with any care delivery, quality improvement process, performance improvement
65 plan, early notification or access improvement plan activities authorized under sections 7, 10, 14,
66 15, 15A, 20 or 21 of this chapter or under section 2GGGG of chapter 29 and shall not disclose
67 the information or documents to any person without the consent of the payer, provider or
68 pharmaceutical manufacturing company providing or reporting the information or documents
69 under said sections 7, 10, 14, 15, 15A, 20 or 21 of this chapter or under said section 2GGGG of
70 said chapter 29, except in summary form in evaluative reports of such activities or when the
71 commission believes that such disclosure should be made in the public interest after taking into
72 account any privacy, trade secret or anticompetitive considerations. The confidential information
73 and documents shall not be public records and shall be exempt from disclosure under clause
74 Twenty sixth of section 7 of chapter 4 or section 10 of chapter 66.

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

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

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

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

86 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
87 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
88 appropriated by the general court for the expenses of the commission minus amounts collected
89 from: (i) filing fees; (ii) fees and charges generated by the commission's publication or
90 dissemination of reports and information; and (iii) federal matching revenues received for these
91 expenses or received retroactively for expenses of predecessor agencies. Pharmaceutical and
92 biopharmaceutical manufacturing companies and pharmacy benefit managers shall, in a manner
93 and distribution determined by the commission, pay to the commonwealth an amount of the
94 estimated expenses of the commission attributable to the commission’s activities under sections
95 8, 9, 15A, 20 and 21. A pharmacy benefit manager that is a surcharge payor subject to the

96 preceding paragraph and manages its own prescription drug benefits shall not be subject to
97 additional assessment under this paragraph

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

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

104 SECTION 15. Said section 8 of said chapter 6D, as so appearing, is hereby further
105 amended by striking out, in line 32, the words “and (xi)” and inserting in place thereof the
106 following words:- (xi) not less than 3 representatives of the pharmaceutical industry; (xii) at least
107 1 pharmacy benefit manager; and (xiii).

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

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

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

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

122 The report shall be based on the commission's analysis of information provided at the
123 hearings by witnesses, providers, provider organizations, payers, pharmaceutical manufacturing
124 companies and pharmacy benefit managers, registration data collected under section 11, data
125 collected or analyzed by the center under sections 8, 9, 10, and 10A of chapter 12C and any other
126 available information that the commission considers necessary to fulfill its duties under this
127 section as defined in regulations promulgated by the commission.

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

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

133 Section 15A. (a) A pharmaceutical manufacturing company shall provide early notice to
134 the commission in a manner described in this section for a: (i) pipeline drug; (ii) generic drug; or
135 (iii) biosimilar drug. The commission shall make non-confidential early notice information
136 available to the office of Medicaid or another agency, as the commission deems appropriate.

137 Early notice for a pipeline drug or biosimilar drug under this subsection shall be
138 submitted to the commission in writing not later than 60 days after receipt of the federal Food
139 and Drug Administration action date. Early notice for a generic drug under this subsection shall
140 be submitted to the commission in writing not later than 60 days before the generic drug's
141 effective date of distribution.

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

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

153 (b) A pharmaceutical manufacturing company shall provide early notice to the
154 commission if it plans to increase the wholesale acquisition cost of a: (i) brand-name drug by
155 more than 20 per cent per wholesale acquisition cost unit during any 12-month period; or (ii)
156 generic drug with a significant price increase as determined by the commission during any 12-
157 month period. The commission shall make non-confidential early notice information available to
158 the office of Medicaid or another agency, as the commission deems appropriate.

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

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

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

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

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

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

178 “Eligible drug”, a (i) brand name drug or biologic, not including a biosimilar, that has a
179 launch wholesale acquisition cost of \$50,000 or more for a 1-year supply or full course of

180 treatment; (ii) biosimilar drug that has a launch wholesale acquisition cost that is not at least 15
181 per cent lower than the referenced brand biologic at the time the biosimilar is launched; or (iii)
182 public health essential drug, as defined in subsection (f) of section 13 of chapter 17, with a
183 significant price increase over a defined period of time as determined by the commission by
184 regulation or with a wholesale acquisition cost of \$25,000 or more for a 1-year supply or full
185 course of treatment.

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

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

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

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

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

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

202 (iii) a written, narrative description, suitable for public release, of factors that contributed
203 to reported changes in wholesale acquisition cost during the previous 5 calendar years; and

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

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

210 Any information, analyses or reports regarding an eligible drug review shall be provided
211 to the manufacturer. The commission shall consider any clarifications or data provided by the
212 manufacturer with respect to the eligible drug. The commission shall not base its determination
213 on the proposed value of the eligible drug solely on the analysis or research of an outside third
214 party. If the commission relies upon a third party to provide cost-effectiveness analysis or
215 research related to the proposed value of the eligible drug, such analysis or research shall also
216 include, but not be limited to: (i) a description of the methodologies and models used in its
217 analysis; (ii) any assumptions and potential limitations of research findings in the context of the
218 results; and (iii) outcomes for affected subpopulations that utilize the drug.

219 (d) If, after review of an eligible drug and after receiving information from the
220 manufacturer under subsections (b) or (e), the commission determines that the manufacturer's

221 pricing of the eligible drug does not substantially exceed the proposed value of the drug, the
222 commission shall notify the manufacturer, in writing, of its determination and shall evaluate
223 other ways to mitigate the eligible drug's cost in order to improve patient access to the eligible
224 drug. The commission may engage with the manufacturer and other relevant stakeholders,
225 including, but not limited to, patients, patient advocacy organizations, providers, provider
226 organizations and payers, to explore options for mitigating the cost of the eligible drug. Upon the
227 conclusion of a stakeholder engagement process under this subsection, the commission shall
228 issue recommendations on ways to reduce the cost of the eligible drug for the purpose of
229 improving patient access to the eligible drug. Recommendations may include, but not be limited
230 to: (i) an alternative payment plan or methodology; (ii) a bulk purchasing program; (iii) co-pay,
231 deductible, coinsurance or other cost-sharing restrictions; and (iv) a reinsurance program to
232 subsidize the cost of the eligible drug. The recommendations shall be publicly posted on the
233 commission's website and provided to the clerks of the house of representatives and senate, the
234 joint committee on health care financing and the house and senate committees on ways and
235 means.

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

241 (f) Not later than 60 days after receiving information from the manufacturer under
242 subsections (b) or (e), the commission shall confidentially issue a determination on whether the
243 manufacturer's pricing of an eligible drug substantially exceeds the commission's proposed

244 value of the drug. If the commission determines that the manufacturer's pricing of an eligible
245 drug substantially exceeds the proposed value of the drug, the commission shall confidentially
246 notify the manufacturer, in writing, of its determination and request the manufacturer to enter
247 into an access improvement plan under section 21.

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

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

259 (h) If the manufacturer fails to timely comply with the commission's request for records
260 under subsections (b) or (e), or otherwise knowingly obstructs the commission's ability to issue
261 its determination under subsection (f), including, but not limited to, by providing incomplete,
262 false or misleading information, the commission may impose appropriate sanctions against the
263 manufacturer, including reasonable monetary penalties not to exceed \$500,000, in each instance.
264 The commission shall seek to promote compliance with this section and shall only impose a civil
265 penalty on the manufacturer as a last resort.

266 (i) The commission shall adopt any written policies, procedures or regulations that the
267 commission determines are necessary to implement this section.

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

270 Upon providing written notice provided under subsection (f) of section 20, the
271 commission shall request that a manufacturer whose pricing of an eligible drug substantially
272 exceeds the commission's proposed value of the drug file an access improvement plan with the
273 commission. Not later than 45 days after receipt of a notice under subsection (f) of section 20, a
274 manufacturer shall: (i) file an access improvement plan; or (ii) provide written notice declining
275 the commission's request.

276 (b) An access improvement plan shall: (i) be generated by the manufacturer; (ii) identify
277 the reasons for the manufacturer's drug price; and (iii) include, but not be limited to, specific
278 strategies, adjustments and action steps the manufacturer proposes to implement to address the
279 cost of the eligible drug in order to improve patient access to the eligible drug. The proposed
280 access improvement plan shall include specific identifiable and measurable expected outcomes
281 and a timetable for implementation. The timetable for an access improvement plan shall not
282 exceed 18 months.

283 (c) The commission shall approve any access improvement plan that it determines: (i) is
284 reasonably likely to address the cost of an eligible drug in order to substantially improve patient
285 access to the eligible drug; and (ii) has a reasonable expectation for successful implementation.

286 (d) If the commission determines that the access improvement plan is unacceptable or
287 incomplete, the commission may provide consultation on the criteria that have not been met and

288 may allow an additional time period of not more than 30 calendar days for resubmission;
289 provided, however, that all aspects of the access improvement plan shall be proposed by the
290 manufacturer and the commission shall not require specific elements for approval.

291 (e) Upon approval of the proposed access improvement plan, the commission shall notify
292 the manufacturer to begin immediate implementation of the access improvement plan. Public
293 notice shall be provided by the commission on its website, identifying that the manufacturer is
294 implementing an access improvement plan; provided, that upon the successful completion of the
295 access improvement plan, the identity of the manufacturer shall be removed from the
296 commission's website. All manufacturers implementing an approved access improvement plan
297 shall be subject to additional reporting requirements and compliance monitoring as determined
298 by the commission. The commission shall provide assistance to the manufacturer in the
299 successful implementation of the access improvement plan.

300 (f) All manufacturers shall work in good faith to implement the access improvement plan.
301 At any point during the implementation of the access improvement plan the manufacturer may
302 file amendments to the access improvement plan, subject to approval of the commission.

303 (g) At the conclusion of the timetable established in the access improvement plan, the
304 manufacturer shall report to the commission regarding the outcome of the access improvement
305 plan. If the commission determines that the access improvement plan was unsuccessful, the
306 commission shall: (i) extend the implementation timetable of the existing access improvement
307 plan; (ii) approve amendments to the access improvement plan as proposed by the manufacturer;
308 (iii) require the manufacturer to submit a new access improvement plan; or (iv) waive or delay
309 the requirement to file any additional access improvement plans.

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

314 (i) An access improvement plan under this section shall remain confidential in
315 accordance with section 2A.

316 (j) The commission may assess a civil penalty to a manufacturer of not more than
317 \$500,000, in each instance, if the commission determines that the manufacturer: (i) willfully
318 neglected to file an access improvement plan with the commission under subsection (a); (ii)
319 failed to file an acceptable access improvement plan in good faith with the commission; (iii)
320 failed to implement the access improvement plan in good faith; or (iv) knowingly failed to
321 provide information required by this section to the commission or knowingly falsified the
322 information. The commission shall seek to promote compliance with this section and shall only
323 impose a civil penalty as a last resort.

324 (k) If a manufacturer declines to enter into an access improvement plan under this
325 section, the commission may publicly post the proposed value of the eligible drug, hold a public
326 hearing on the proposed value of the eligible drug and solicit public comment. The manufacturer
327 shall appear and testify at any hearing held on the eligible drug's proposed value. Upon the
328 conclusion of a public hearing under this subsection, the commission shall issue
329 recommendations on ways to reduce the cost of an eligible drug for the purpose of improving
330 patient access to the eligible drug. The recommendations shall be publicly posted on the
331 commission's website and provided to the clerks of the house of representatives and senate, the

332 joint committee on health care financing and the house and senate committees on ways and
333 means.

334 If a manufacturer is deemed to not be acting in good faith to develop an acceptable or
335 complete access improvement plan, the commission may publicly post the proposed value of the
336 eligible drug, hold a public hearing on the proposed value of the eligible drug and solicit public
337 comment. The manufacturer shall appear and testify at any hearing held on the eligible drug's
338 proposed value. Upon the conclusion of a public hearing under this subsection, the commission
339 shall issue recommendations on ways to reduce the cost of an eligible drug for the purpose of
340 improving patient access to the eligible drug. The recommendations shall be publicly posted on
341 the commission's website and provided to the clerks of the house of representatives and senate,
342 the joint committee on health care financing and the house and senate committees on ways and
343 means.

344 Before making a determination that the manufacturer is not acting in good faith, the
345 commission shall send a written notice to the manufacturer that the commission shall deem the
346 manufacturer to not be acting in good faith if the manufacturer does not submit an acceptable
347 access improvement plan within 30 days of receipt of notice; provided, however, that the
348 commission shall not send a notice under this paragraph within 120 calendar days from the date
349 that the commission issued its request that the manufacturer enter into the access improvement
350 plan.

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

352 SECTION 22. Section 1 of chapter 12C of the General Laws, as appearing in the 2018
353 Official Edition, is hereby amended by inserting after the definition of “Ambulatory surgical
354 center services” the following 3 definitions:-

355 “Average manufacturer price”, the average price paid to a manufacturer for a drug in the
356 commonwealth by a wholesaler for drugs distributed to pharmacies and by a pharmacy that
357 purchases drugs directly from the manufacturer.

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

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

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

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

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

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

384 “Pharmacy benefit manager”, a person, business or other entity, however organized, that,
385 directly or through a subsidiary, provides pharmacy benefit management services for prescription
386 drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-
387 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
388 management services shall include, but not be limited to, the processing and payment of claims
389 for prescription drugs; the performance of drug utilization review; the processing of drug prior
390 authorization requests; pharmacy contracting; the adjudication of appeals or grievances related to
391 prescription drug coverage contracts; formulary administration; drug benefit design; mail and
392 specialty drug pharmacy services; cost containment; clinical, safety and adherence programs for
393 pharmacy services and managing the cost of covered prescription drugs; provided further, that
394 “pharmacy benefit manager” shall include a health benefit plan that does not contract with a

395 pharmacy benefit manager and manages its own prescription drug benefits unless specifically
396 exempted by the commission.

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

399 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
400 1395w-3a(c)(6)(B).

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

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

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

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

416 SECTION 30. The first paragraph of section 7 of said chapter 12C, as so appearing, is
417 hereby amended by adding the following sentence:-

418 Each pharmaceutical and biopharmaceutical manufacturing company and pharmacy
419 benefit manager shall pay to the commonwealth an amount for the estimated expenses of the
420 center and for the other purposes described in this chapter.

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

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

426 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
427 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
428 appropriated by the general court for the expenses of the center minus amounts collected from:
429 (i) filing fees; (ii) fees and charges generated by the commission's publication or dissemination
430 of reports and information; and (iii) federal matching revenues received for these expenses or
431 received retroactively for expenses of predecessor agencies. Pharmaceutical and
432 biopharmaceutical manufacturing companies and pharmacy benefit managers shall, in a manner
433 and distribution determined by the center, pay to the commonwealth an amount of the estimated
434 expenses of the center attributable to the center’s activities under sections 3, 10A, 12 and 16. A
435 pharmacy benefit manager that is a surcharge payor subject to the preceding paragraph and
436 manages its own prescription drug benefits shall not be subject to additional assessment under
437 this paragraph.

438 SECTION 33. Said chapter 12C, as so appearing, is hereby further amended by inserting
439 after section 10 the following section:-

440 Section 10A. (a) The center shall promulgate the regulations necessary to ensure the
441 uniform reporting of information from pharmaceutical manufacturing companies that enables the
442 center to analyze: (i) year-over-year changes in wholesale acquisition cost and average
443 manufacturer price for prescription drug products; (ii) year-over-year trends in net expenditures;
444 (iii) net expenditures on subsets of biosimilar, brand name and generic drugs identified by the
445 center; (iv) trends in estimated aggregate drug rebates, discounts or other remuneration paid or
446 provided by a pharmaceutical manufacturing company to a pharmacy benefit manager,
447 wholesaler, distributor, health carrier client, health plan sponsor or pharmacy in connection with
448 utilization of the pharmaceutical drug products offered by the pharmaceutical manufacturing
449 company; (v) discounts provided by a pharmaceutical manufacturing company to a consumer in
450 connection with utilization of the pharmaceutical drug products offered by the pharmaceutical
451 manufacturing company, including any discount, rebate, product voucher, coupon or other
452 reduction in a consumer's out-of-pocket expenses including co-payments and deductibles under
453 section 3 of chapter 175H; (vi) research and development costs as a percentage of revenue; (vii)
454 annual marketing and advertising costs, identifying costs for direct-to-consumer advertising;
455 (viii) annual profits over the most recent 5-year period; (ix) cost disparities between prices
456 charged to purchasers in the commonwealth and purchasers outside of the United States; and (x)
457 any other information deemed necessary by the center.

458 The center shall require the submission of available data and other information from
459 pharmaceutical manufacturing companies including, but not limited to: (i) changes in wholesale
460 acquisition costs and average manufacturer prices for prescription drug products as identified by

461 the center; (ii) aggregate, company-level research and development costs to the extent
462 attributable to a specific product and other relevant capital expenditures for the most recent year
463 for which final audited data are available for prescription drug products as identified by the
464 center; (iii) annual marketing and advertising expenditures; and (iv) a description, suitable for
465 public release, of factors that contributed to reported changes in wholesale acquisition costs and
466 average manufacturer prices for prescription drug products as identified by the center.

467 (b) The center shall promulgate the regulations necessary to ensure the uniform reporting
468 of information from pharmacy benefit managers that enables the center to analyze: (i) trends in
469 estimated aggregate drug rebates and other drug price reductions, if any, provided by a pharmacy
470 benefit manager to a health carrier client or health plan sponsor or passed through from a
471 pharmacy benefit manager to a health carrier client or health plan sponsor in connection with
472 utilization of the drugs offered through the pharmacy benefit manager and a measure of lives
473 covered by each health carrier client or health plan sponsor; (ii) pharmacy benefit manager
474 practices with regard to drug rebates and other drug price reductions, if any, provided by a
475 pharmacy benefit manager to a health carrier client or to the consumer or passed through from a
476 pharmacy benefit manager to a health carrier client or to the consumer; and (iii) any other
477 information deemed necessary by the center.

478 The center shall require the submission of available data and other information from
479 pharmacy benefit managers including, but not limited to: (i) the amount of all rebates that the
480 pharmacy benefit manager received from all pharmaceutical manufacturing companies for all
481 health carrier clients in the aggregate and for each health carrier client individually; (ii) the
482 administrative fees that the pharmacy benefit manager received from all health carrier clients in
483 the aggregate and for each health carrier client individually; (iii) the aggregate amount of all

484 retained rebates that the pharmacy benefit manager received from all pharmaceutical
485 manufacturing companies and did not pass through to the pharmacy benefit manager's health
486 carrier clients; (iv) the aggregate amount of rebates a pharmacy benefit manager: (A) retains
487 based on its contractual arrangement with its client; and (B) passes through to its clients; and (v)
488 the percentage of contracts that a pharmacy benefit manager holds where the pharmacy benefit
489 manager: (A) retains all rebates; (B) passes all rebates through to the client; and (C) shares
490 rebates with the client.

491 (c) Except as specifically provided otherwise by the center or under this chapter, data
492 collected by the center pursuant to this section from pharmaceutical manufacturing companies
493 and pharmacy benefit managers shall not be a public record under clause Twenty-sixth of section
494 7 of chapter 4 or under chapter 66.

495 SECTION 34. Said chapter 12C, as so appearing, is hereby further amended by striking
496 out section 11 and inserting in place thereof the following section:-

497 Section 11. The center shall ensure the timely reporting of information required under
498 sections 8, 9, 10 and 10A. The center shall notify payers, providers, provider organizations,
499 pharmacy benefit managers and pharmaceutical manufacturing companies of any applicable
500 reporting deadlines. The center shall notify, in writing, a private health care payer, provider,
501 provider organization, pharmacy benefit manager or pharmaceutical manufacturing company that
502 it has failed to meet a reporting deadline and that failure to respond within 2 weeks of the receipt
503 of the notice may result in penalties. The center may assess a penalty against a private health care
504 payer, provider, provider organization, pharmacy benefit manager or pharmaceutical
505 manufacturing company that fails, without just cause, to provide the requested information

506 within 2 weeks following receipt of the written notice required under this section of not more
507 than \$2,000 per week for each week of delay after the 2-week period following receipt of the
508 written notice. Amounts collected under this section shall be deposited in the Healthcare
509 Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

510 SECTION 35. Section 12 of said chapter 12C, as so appearing, is hereby amended by
511 striking out, in line 2, the words “and 10” and inserting in place thereof the following words:- ,
512 10 and 10A.

513 SECTION 36. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby
514 amended by striking out the first sentence and inserting in place thereof the following sentence:-
515 The center shall publish an annual report based on the information submitted under: (i) sections
516 8, 9, 10 and 10A concerning health care provider, provider organization, private and public
517 health care payer, pharmaceutical manufacturing company and pharmacy benefit manager costs
518 and cost and price trends; (ii) section 13 of chapter 6D relative to market power reviews; and (iii)
519 section 15 of said chapter 6D relative to quality data.

520 SECTION 37. Section 13 of chapter 17 of the General Laws, as so appearing, is hereby
521 amended by adding the following subsection:-

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

524 “Public health essential drug”, a prescription drug, biologic or biosimilar approved by the
525 federal Food and Drug Administration that: (i) appears on the Model List of Essential Medicines
526 most recently adopted by the World Health Organization; or (ii) is deemed an essential medicine
527 by the commission due to its efficacy in treating a life-threatening health condition or a chronic

528 health condition that substantially impairs an individual's ability to engage in activities of daily
529 living or because limited access to a certain population would pose a public health challenge.

530 The commission shall identify and publish a list of public health essential prescription
531 drugs. The list shall be updated not less than annually and be made publicly available on the
532 department's website; provided, however, that the commission may provide an interim listing of
533 a public health essential drug prior to an annual update. The commission shall also notify and
534 forward a copy of the list to the health policy commission established under chapter 6D.

535 SECTION 38. Chapter 29 of the General Laws, as appearing in the 2018 Official Edition,
536 is hereby amending by inserting after section 2CCCCC the following section:-

537 2DDDDD. (a) There shall be a Prescription Drug Cost Assistance Trust Fund. The
538 secretary of health and human services, as trustee, shall administer the fund and shall make
539 expenditures from the fund, without further appropriation, to provide financial assistance to state
540 residents for the cost of prescription drugs through the prescription drug cost assistance program
541 established under section 238 of chapter 111.

542 The fund shall consist of: (1) revenue generated from the assessment established under
543 chapter 63D; (2) revenue from appropriations or other money authorized by the general court and
544 specifically designated to be credited to the fund; and (3) funds from public or private sources,
545 including, but not limited to, gifts, grants, donations, rebates and settlements received by the
546 commonwealth that are specifically designated to be credited to the fund. An amount equal to the
547 total receipts from the assessments established under chapter 63D shall be transferred from the
548 General Fund to the Prescription Drug Cost Assistance Trust Fund before the end of each fiscal

549 year. Money remaining in the fund at the close of a fiscal year shall not revert to the General
550 Fund and shall be available for expenditure in the following fiscal year.

551 SECTION 39. The General Laws, as appearing in the 2018 Official Edition, are hereby
552 amended by inserting after chapter 63C the following chapter:-

553 Chapter 63D. ASSESSMENT ON THE MANUFACTURE AND SALE OF CERTAIN
554 PHARMACEUTICALS DISTRIBUTED IN THE COMMONWEALTH.

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

557 “Commissioner”, the commissioner of revenue.

558 “Person”, any natural person or legal entity.

559 “Secretary”, the secretary of health and human services.

560 Section 2. (a) Any person who manufactures and sells prescription drugs, as defined in
561 section 1 of chapter 94C, directly or through another person, for distribution in the
562 commonwealth, shall pay an assessment, which shall be proportionate to the person’s percent of
563 total prescription drug sales generated by all persons for prescription drugs distributed in the
564 commonwealth during the previous calendar year. The amount of the assessment that each
565 person is required to pay shall be determined by the secretary, in collaboration with the
566 commissioner; provided, that the total amount assessed across all persons shall not exceed
567 \$200,000,000 in any calendar year.

568 (b) A person who manufactures and sells prescription drugs, directly or through another
569 person, for distribution in the commonwealth shall file a return, as provided in section 4,

570 declaring total sales of all prescription drugs, directly or through another person, for distribution
571 in the commonwealth during the previous calendar year.

572 Section 3. The assessment under section 2 shall apply for any calendar year only to a
573 person whose total sales of all prescription drugs, directly or through another person, for
574 distribution in the commonwealth were more than \$250,000 in the calendar year for which the
575 assessment is imposed.

576 Section 4. Any person subject to the assessment under section 2 shall file a return with
577 the commissioner and shall pay the assessment for the previous calendar year annually, by
578 March 1, subject to such reasonable extensions of time for filing as the commissioner may allow.
579 The return shall set out the person's total sales of all prescription drugs, directly or through
580 another person, for distribution in the commonwealth in the immediately preceding calendar year
581 and shall provide such other information as the commissioner may require.

582 Section 5. The commissioner may disclose information contained in returns filed under
583 this chapter to the secretary for purposes of verifying that a filer's sales are properly declared and
584 that all reporting is otherwise correct. Return information so disclosed shall remain confidential
585 and shall not be public record.

586 Section 6. The commissioner shall annually submit a report to the clerks of the senate and
587 house of representatives, the chairs of the joint committee on ways and means and the chairs of
588 the joint committee on health care financing, which shall include: (1) the total amount assessed
589 across all persons and deposited in the Prescription Drug Cost Assistance Trust Fund established
590 under section 2DDDDD of chapter 29 in the previous calendar year; and (2) the assessment
591 amount that each person was required to pay in the previous calendar year.

592 Section 7. The commissioner, in consultation with the secretary, shall promulgate
593 regulations or issue other guidance for the implementation and enforcement of this chapter.

594 SECTION 40. Chapter 94C of the General Laws, as appearing in the 2018 Official
595 Edition, is hereby amended by inserting after section 21B the following section:-

596 Section 21C. (a) For the purposes of this section, the following words shall have the
597 following meanings unless the context clearly requires otherwise:

598 “Cost-sharing”, amounts owed by a consumer under the terms of the consumer’s health
599 benefit plan as defined in section 1 of chapter 176O or as required by a pharmacy benefit
600 manager as defined in section 1 of chapter 6D.

601 “Pharmacy retail price”, the amount an individual would pay for a prescription
602 medication at a pharmacy if the individual purchased that prescription medication at that
603 pharmacy without using a health benefit plan as defined in section 1 of chapter 176O or any
604 other prescription medication benefit or discount.

605 (b) A pharmacy shall provide the consumer, at the point of sale, the current pharmacy
606 retail price and the applicable cost-sharing amount for each prescription medication the
607 consumer is purchasing; provided, however, that the lower cost prescription medication is clearly
608 indicated. The consumer shall affirm by signature in writing that the pharmacy has provided this
609 price information and an opportunity for counseling. The pharmacy shall charge the consumer
610 the applicable cost-sharing amount or the current pharmacy retail price for that prescription
611 medication, as directed by the consumer.

612 A pharmacy shall post a notice informing consumers that a consumer may request, at the
613 point of sale, the current pharmacy retail price for each prescription medication the consumer
614 intends to purchase.

615 (c) A contract shall not: (i) prohibit a pharmacist from complying with this section; or (ii)
616 impose a penalty on the pharmacist or pharmacy for complying with this section; provided,
617 however, that a pharmacist shall submit a claim to the consumer's health benefit plan or its
618 pharmacy benefit manager if the pharmacist has knowledge that the prescription medication is
619 covered under the consumer's health benefit plan.

620 SECTION 41. Chapter 111 of the General Laws shall hereby be amended by adding the
621 following section:-

622 Section 238. (a) The department shall establish and administer a prescription drug cost
623 assistance program, which shall be funded by the Prescription Drug Cost Assistance Trust Fund
624 established in section 2DDDDD of chapter 29. The program shall provide financial assistance for
625 prescription drugs used to treat: (1) chronic respiratory conditions, including, but not limited to,
626 chronic obstructive pulmonary disease and asthma; (2) chronic heart conditions, including, but
627 not limited to, heart failure, coronary artery disease, hypertension and high blood pressure; (3)
628 diabetes; and (4) any other chronic condition identified by the department that disproportionately
629 impacts people of color or is a risk factor for increased COVID-19 complications; provided, that
630 for paragraphs (1) and (3), "prescription drug" shall include the prescription drug and any drug
631 delivery device needed to administer the drug that is not included as part of the underlying drug
632 prescription. Such financial assistance shall cover the full cost of any co-payment, co-insurance
633 or deductible for the prescription drug for an individual who is eligible for the program.

634 (b) An individual shall be eligible for the program if the individual: (1) is a resident of
635 Massachusetts; (2) has a current prescription from a health care provider for a drug that is used to
636 treat a chronic condition listed in subsection (a); (3) has a family income equal to or less than
637 500 per cent of the federal poverty level; and (4) is not enrolled in MassHealth.

638 (c) The department shall create an application process, which shall be available
639 electronically and in hard copy form, to determine whether an individual meets the program
640 eligibility requirements under subsection (b). Upon receipt of such application, the department
641 shall determine an applicant's eligibility and notify the applicant of the department's
642 determination within 10 business days. If necessary for its determination, the department may
643 request additional information from the applicant; provided, that the department shall notify the
644 applicant within 5 business days of receipt of the original application as to what specific
645 additional information is being requested. If additional information is being requested, the
646 department shall, within 3 business days of receipt of the additional information, determine
647 whether the applicant is eligible for the program and notify the applicant of the department's
648 determination.

649 If the department determines that an applicant is not eligible for the program, the
650 department shall notify the applicant and shall include in the department's notification the
651 specific reasons why the applicant is not eligible. The applicant may appeal this determination to
652 the department within 30 days of receiving such notification.

653 If the department determines that an applicant is eligible for the program, the department
654 shall provide the applicant with a prescription drug cost assistance program identification card,
655 which shall clearly indicate that the department has determined that the applicant is eligible for

656 the program; provided, that the program identification card shall include, at a minimum: (1) the
657 applicant's full name, and (2) the full name of the prescription drug that the applicant is eligible
658 to receive under the program without having to pay a co-payment, co-insurance or deductible.
659 An applicant's program identification card shall be valid for 12 months and shall be renewable
660 upon a redetermination of program eligibility.

661 (d) An individual with a valid program identification card issued under subsection (c)
662 may present such card at any pharmacy in the commonwealth and, upon presentation of such
663 card, the pharmacy shall fill the individual's prescription and provide the prescribed drug to the
664 individual without requiring the individual to pay a co-payment, co-insurance or deductible;
665 provided, that the pharmacy shall be reimbursed for its costs by the Prescription Drug Cost
666 Assistance Trust Fund established in section 2DDDDD of chapter 29, in a manner determined by
667 the department, in an amount equal to what the pharmacy would have received had the individual
668 been required to pay a co-payment, co-insurance or deductible.

669 (e) The department, in collaboration with the division of insurance and board of
670 registration in pharmacy, shall develop and implement a plan to educate consumers, pharmacists,
671 providers, hospitals and insurers regarding eligibility for and enrollment in the program under
672 this section. The plan shall include, but not be limited to, appropriate staff training, notices
673 provided to consumers at the pharmacy, and a designated website with information for
674 consumers, pharmacists and other health care professionals. The plan shall be developed in
675 consultation with groups representing consumers, pharmacists, providers, hospitals and insurers.

676 (f) The department shall compile a report detailing information about the program from
677 the previous calendar year. The report shall include: (1) the number of applications received,

678 approved, denied and appealed; (2) the total number of applicants approved, and the number of
679 applicants approved broken down by race, gender, age range and income level; (3) a list of all
680 prescription drugs that qualify for the program under subsection (b) and a list of prescription
681 drugs that applicants actually received financial assistance for; and (4) the total cost savings
682 received by all approved applicants, and the cost savings broken down by race, gender, age range
683 and income level. The report shall be submitted annually, by March 1, to the clerks of the senate
684 and house of representatives, the chairs of the joint committee on ways and means and the chairs
685 of the joint committee on health care financing.

686 (g) The department shall promulgate regulations or issue other guidance for the
687 implementation and enforcement of this section.

688 SECTION 42. Section 226 of chapter 175 of the General Laws, as appearing in the 2018
689 Official Edition, is hereby amended by striking out subsection (a) and inserting in place thereof
690 the following subsection:-

691 (a) For the purposes of this section, the term “pharmacy benefit manager” shall mean a
692 person, business or other entity, however organized, that, directly or through a subsidiary,
693 provides pharmacy benefit management services for prescription drugs and devices on behalf of
694 a health benefit plan sponsor, including, but not limited to, a self-insurance plan, labor union or
695 other third-party payer; provided, however, that pharmacy benefit management services shall
696 include, but not be limited to, the processing and payment of claims for prescription drugs, the
697 performance of drug utilization review, the processing of drug prior authorization requests,
698 pharmacy contracting, the adjudication of appeals or grievances related to prescription drug
699 coverage contracts, formulary administration, drug benefit design, mail and specialty drug

700 pharmacy services, cost containment, clinical, safety and adherence programs for pharmacy
701 services and managing the cost of covered prescription drugs; provided further, that “pharmacy
702 benefit manager” shall include a health benefit plan that does not contract with a pharmacy
703 benefit manager and manages its own prescription drug benefits unless specifically exempted.

704 SECTION 43. Section 2 of Chapter 176O of the General Laws, as so appearing, is hereby
705 amended by adding the following subsection:-

706 (i) At least annually, a carrier that contracts with a pharmacy benefit manager shall
707 coordinate an audit of the operations of the pharmacy benefit manager to ensure compliance with
708 this chapter and to examine the pricing and rebates applicable to prescription drugs that are
709 provided to the carrier’s covered persons.

710 SECTION 44. Said chapter 176O of the General Laws is hereby further amended by
711 inserting after section 22 the following section:-

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

715 SECTION 45. The General Laws are hereby amended by inserting after chapter 176W
716 the following chapter:-

717 Chapter 176X. LICENSING AND REGULATION OF PHARMACY BENEFIT
718 MANAGERS.

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

721 “Carrier”, an insurer licensed or otherwise authorized to transact accident or health
722 insurance under chapter 175, a nonprofit hospital service corporation organized under chapter
723 176A, a non-profit medical service corporation organized under chapter 176B, a health
724 maintenance organization organized under chapter 176G and an organization entering into a
725 preferred provider arrangement under chapter 176I; provided, however, that the term “carrier”
726 shall not include an employer purchasing coverage or acting on behalf of its employees or the
727 employees of any subsidiary or affiliated corporation of the employer; provided further, that
728 unless otherwise noted the term “carrier” shall not include any entity to the extent it offers a
729 policy, certificate or contract that provides coverage solely for dental care services or vision care
730 services.

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

732 “Commissioner”, the commissioner of insurance.

733 “Division”, the division of insurance.

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

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

741 “Pharmacy benefit manager”, a person, business or other entity, however organized, that,
742 directly or through a subsidiary, provides pharmacy benefit management services for prescription
743 drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-
744 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
745 management services shall include, but not be limited to, the processing and payment of claims
746 for prescription drugs, the performance of drug utilization review, the processing of drug prior
747 authorization requests, pharmacy contracting, the adjudication of appeals or grievances related to
748 prescription drug coverage contracts, formulary administration, drug benefit design, mail and
749 specialty drug pharmacy services, cost containment, clinical, safety and adherence programs for
750 pharmacy services and managing the cost of covered prescription drugs; provided further, that
751 “pharmacy benefit manager” shall not include a health benefit plan unless otherwise specified by
752 the division.

753 Section 2. (a) A person, business or other entity shall not establish or operate as a
754 pharmacy benefit manager in the commonwealth without obtaining a license from the division
755 pursuant to this section. The division shall issue a pharmacy benefit manager license to a person,
756 business or other entity that demonstrates to the division that it has the necessary organization,
757 background expertise and financial integrity to maintain such a license. A pharmacy benefit
758 manager license shall be valid for a period of 3 years and shall be renewable for additional 3-
759 year periods. Initial application and renewal fees for the license shall be established pursuant to
760 section 3B of chapter 7.

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

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

766 (d) The division may issue or renew a license subject to restrictions in order to protect the
767 interests of consumers. Such restrictions may include limiting the type of services that a license
768 holder may provide, limiting the activities in which the license holder may be engaged or
769 addressing conflicts of interest between pharmacy benefit managers and health plan sponsors.

770 (e) The division shall develop an application for licensure that shall include, but not be
771 limited to: (i) the name of the pharmacy benefit manager; (ii) the address and contact telephone
772 number for the pharmacy benefit manager; (iii) the name and address of the pharmacy benefit
773 manager's agent for service of process in the commonwealth; (iv) the name and address of each
774 person with management or control over the pharmacy benefit manager; and (v) any audited
775 financial statements specific to the pharmacy benefit manager. A pharmacy benefit manager
776 shall report to the division any material change to the information contained in its application,
777 certified by an officer of the pharmacy benefit manager, within 30 days of such a change.

778 (f) The division may suspend, revoke, refuse to issue or renew or place on probation a
779 pharmacy benefit manager license for cause, which shall include, but not be limited to: (i) the
780 pharmacy benefit manager engaging in fraudulent activity that constitutes a violation of state or
781 federal law; (ii) the division receiving consumer complaints that justify an action under this
782 chapter to protect the health, safety and interests of consumers; (iii) the pharmacy benefit
783 manager failing to pay an application or renewal fee for a license; (iv) the pharmacy benefit
784 manager failing to comply with reporting requirements of the center under section 10A of

785 chapter 12C; or (v) the pharmacy benefit manager failing to comply with a requirement of this
786 chapter.

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

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

796 (g) If a person, business or other entity performs the functions of a pharmacy benefit
797 manager in violation of this chapter, the person, business or other entity shall be subject to a fine
798 of \$5,000 per day for each day that the person, business or other entity is found to be in violation.

799 (h) A pharmacy benefit manager shall be required to submit to periodic audits by a carrier
800 licensed under chapters 175, 176A, 176B or 176G if the pharmacy benefit manager has entered
801 into a contract with the carrier to provide pharmacy benefit services to the carrier or its members.
802 The division may direct or provide specifications for such audits.

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

807 SECTION 46. Notwithstanding any general or special law to the contrary, there shall be a
808 4-year program to assess the public health utilization and cost impacts of capping co-pays and
809 eliminating deductible and co-insurance requirements for insulin for individuals with diabetes.
810 To implement the program any policy, contract or certificate of health insurance subject to
811 chapters 32A, 118E, 175, 176A, 176B, 176G or 176Q of the General Laws that is delivered,
812 issued or renewed from January 1, 2022 to December 31, 2025, inclusive, shall provide coverage
813 for insulin for the treatment of diabetes. Such coverage shall not be subject to any deductible or
814 co-insurance and any co-pay shall not exceed \$25 per month per insulin prescription.

815 The center for health information and analysis shall collect, analyze and evaluate data at
816 the start of the program and annually thereafter, including, but not limited to: (i) rates of insulin
817 utilization; (ii) average monthly out-of-pocket insulin costs; (iii) annual plan costs and member
818 premiums; (iv) the average price of insulin, net of rebates or discounts received by or accrued
819 directly or indirectly by health insurance carriers; and (v) average and total out-of-pocket
820 expenditures on insulin delivery devices that are not included as part of an insulin prescription.
821 The center shall file an interim 2-year report and a final 4-year report assessing the program's
822 impact on insulin utilization, member premiums and insulin costs and providing data on
823 expenditures on insulin delivery devices separate from insulin prescriptions. The reports shall be
824 filed with the clerks of the house of representatives and senate, the joint committee on public
825 health, the joint committee on health care financing and the house and senate committees on
826 ways and means not later than March 1, 2024 and March 1, 2026, respectively.

827 SECTION 47. (a) Notwithstanding any general or special laws to the contrary, the
828 commonwealth health insurance connector authority, in consultation with the division of
829 insurance, shall report to the joint committee on health care financing and the house and senate

830 committees on ways and means not later than January 15, 2023 on the impact of pharmaceutical
831 pricing on health care costs and outcomes for ConnectorCare and non-group and small group
832 plans offered through the connector and its members.

833 The report shall include, but not be limited to: (i) information on the differential between
834 medication list price and price net of rebates for plans offered and the impact of those
835 differentials on member premiums; (ii) the relationship between medication list price and
836 member cost-sharing requirements; (iii) the impact of medication price changes over time on
837 premium and out-of-pocket costs in plans authorized under section 3 of chapter 176J of the
838 General Laws offered through the commonwealth health insurance connector authority; (iv)
839 trends in changes in medication list price and price net of rebates by health plan; (v) an analysis
840 of the impact of member out-of-pocket costs on medication utilization and health outcomes; and
841 (vi) an analysis of the impact of medication list price and price net of rebates on member
842 formulary access to medications. Data collected under this subsection shall be protected as
843 confidential and shall not be a public record under clause Twenty-sixth of section 7 of chapter 4
844 of the General Laws or under chapter 66 of the General Laws.

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

850 SECTION 48. Notwithstanding any general or special law to the contrary, there shall be a
851 special commission to examine the feasibility of: (i) establishing a system for the bulk

852 purchasing and distribution of pharmaceutical products with a significant public health benefit
853 and the potential for significant health care cost savings for consumers through overall increased
854 purchase capacity; and (ii) making bulk purchase pricing information available to purchasers in
855 other states.

856 The commission shall consist of: the commissioner of public health or a designee, who
857 shall serve as chair; the executive director of the group insurance commission or a designee; the
858 chief of pharmacy of the state office for pharmacy services; the MassHealth pharmacy director;
859 the secretary of technology services and security; and 7 members to be appointed by the
860 commissioner of public health, 2 of whom shall be health care economists, 1 of whom shall be
861 an expert in health law and policy innovation, 1 of whom shall be an academic with relevant
862 expertise in the field, 1 of whom shall be the chief executive officer of a licensed hospital in the
863 commonwealth, 1 of whom shall be a representative of health insurance carriers and 1 of whom
864 shall be a member of the public with experience with health care and consumer protection.

865 The commission shall hold not less than 3 public hearings in different geographic areas of
866 the commonwealth, accept input from the public and solicit expert testimony from individuals
867 representing: health insurance carriers, pharmaceutical companies, independent and chain
868 pharmacies, hospitals, municipalities, health care practitioners, health care technology
869 professionals, community health centers, substance abuse disorder providers, public health
870 educational institutions and other experts as identified by the commission.

871 The commission shall consider: (i) the process by which the commonwealth could make
872 bulk purchases of pharmaceutical products with a significant public health benefit and the
873 potential for significant health care cost savings to consumers; (ii) the process by which both

874 governmental and nongovernmental entities may participate in a collaborative to purchase
875 pharmaceutical products with a significant public health benefit and the potential for significant
876 health care cost savings; (iii) the feasibility of developing an electronic information interchange
877 system to exchange bulk purchase price information with partnering states; (iv) potential sources
878 of funding available to implement bulk purchases; (v) potential cost savings of bulk purchases to
879 the commonwealth or other participating nongovernmental entities; (vi) the feasibility of
880 partnering with the federal government and or other states in the New England region; and (vii)
881 any other factors that the commission deems relevant.

882 Not later than September 1, 2022, the commission shall file a report of its analysis, along
883 with any recommended legislation, if any, to the clerks of the senate and house of
884 representatives, the house and senate committees on ways and means, the joint committee on
885 health care financing, the joint committee on public health, the joint committee on elder affairs
886 and the joint committee on mental health, substance abuse and recovery.

887 SECTION 49. (a) As used in this section, the following words shall have the following
888 meanings unless context clearly requires otherwise:

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

892 “Independent pharmacist”, a pharmacist actively engaged in the business of retail
893 pharmacy and employed in an organization of not more than 9 registered retail drugstores in the
894 commonwealth under said section 39 of said chapter 112 that employs not more than a total of
895 20 full-time pharmacists. I think we could potentially add this to the mission of the task force.

896 (b) There shall be a task force to: (i) review the drug supply chain including, but not
897 limited to: (A) plan and pharmacy benefit manager reimbursements to pharmacies; (B)
898 wholesaler or pharmacy service administrative organization prices to pharmacies; and (C) drug
899 manufacturer prices to pharmacies; (ii) review ways to recognize the unique challenges of small
900 and independent pharmacies; (iii) identify methods to increase pricing transparency throughout
901 the supply chain; (iv) make recommendations on the use of multiple maximum allowable costs
902 lists and their frequency of use for mail order products; (v) review the utilization of maximum
903 allowable costs lists or similar reimbursement structures established by a pharmacy benefit
904 manager or payer; (vi) review the availability of drugs to independent and chain pharmacies on
905 the maximum allowable cost list or any similar reimbursement structures established by a
906 pharmacy benefit manager or payer; (vii) review the pharmacy acquisition cost from national or
907 regional wholesalers that serve pharmacies compared to the reimbursement amount provided
908 through a maximum allowable cost list or any similar reimbursement structures established by a
909 pharmacy benefit manager or payer and the conditions under which an adjustment to a
910 reimbursement is appropriate; (viii) review the timing of pharmacy purchases of products and the
911 relative risk of list price changes related to the timing of dispensing the products; (ix) assess
912 ways to increase transparency for chain and independent pharmacists to understand the
913 methodology used by a pharmacy benefit manager or payer to develop a maximum allowable
914 cost list or any similar reimbursement structure established by the pharmacy benefit manager or
915 payer; (x) assess the prevalence and appropriateness of pharmacy benefit managers requiring, or
916 using financial incentives or penalties to incentivize, customer use of pharmacies with whom the
917 pharmacy benefit manager has an ownership or financial interest; (xi) examine the impact of the
918 merger or consolidation of pharmacy benefit managers and health carrier clients on drug costs;

919 (xii) review current appeals processes for a chain or independent pharmacist to request an
920 adjustment on a reimbursement subject to a maximum allowable cost list or any similar
921 reimbursement structure established by a pharmacy benefit manager or payer; and (xiii) evaluate
922 the effect of differences between pharmacy benefit manager payments to pharmacies and charges
923 made to health carrier clients on drug price.

924 (c) The task force shall consist of: the commissioner of insurance or a designee, who shall
925 serve as chair; and 6 members to be appointed by the commissioner, 2 of whom shall be either
926 independent pharmacists employed in the independent pharmacy setting or representatives of
927 independent pharmacies, 2 of whom shall be chain pharmacists employed in the chain pharmacy
928 setting or representatives of chain pharmacies and 2 of whom shall be representatives of a
929 pharmacy benefit managers or payers who manage their own pharmacy benefit services. If more
930 than 1 independent pharmacist is appointed to the task force, each appointee shall represent a
931 distinct practice setting and if more than 1 chain pharmacist is appointed to the task force, each
932 appointee shall represent a distinct practice setting. A pharmacy benefit manager or payer
933 appointed to the task force shall not be co-owned or have any ownership relationship with any
934 other payer, pharmacy benefit manager or chain pharmacist also appointed to the task force.

935 (d) The commissioner shall file the task force's findings with the clerks of the house of
936 representatives and the senate, the joint committee on health care financing and the house and
937 senate committees on ways and means not later than December 1, 2022.

938 SECTION 50. The health policy commission shall consult with relevant stakeholders,
939 including, but not limited to, consumers, consumer advocacy organizations, organizations
940 representing people with disabilities and chronic health conditions, providers, provider

941 organizations, payers, pharmaceutical manufacturers, pharmacy benefit managers and health care
942 economists and other academics, to assist in the development and periodic review of regulations
943 to implement section 20 of chapter 6D of the General Laws, including, but not limited to: (i)
944 establishing the criteria and processes for identifying the proposed value of an eligible drug as
945 defined in said section 20 of said chapter 6D; and (ii) determining the appropriate price increase
946 for a public health essential drug as described within the definition of eligible drug in said
947 section 20 of said chapter 6D.

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

951 SECTION 51. Notwithstanding subsection (b) of section 15A of chapter 6D of the
952 General Laws, for the purposes of providing early notice under said section 15A of said chapter
953 6D, the health policy commission shall determine a significant price increase for a generic drug
954 to be defined as a generic drug priced at \$100 or more per wholesale acquisition cost unit that
955 increases in cost by 100 per cent or more during any 12-month period.

956 SECTION 52. Section 51 is hereby repealed.

957 SECTION 53. Section 21 and 37 shall take effect on July 1, 2023.

958 SECTION 54. Section 52 shall take effect on January 1, 2024.