

SENATE No. 749

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>Rebecca L. Rausch</i>	<i>Norfolk, Worcester and Middlesex</i>	<i>1/24/2023</i>
<i>Susannah M. Whipps</i>	<i>2nd Franklin</i>	<i>1/27/2023</i>
<i>Joanne M. Comerford</i>	<i>Hampshire, Franklin and Worcester</i>	<i>1/27/2023</i>
<i>Jack Patrick Lewis</i>	<i>7th Middlesex</i>	<i>1/30/2023</i>
<i>Jason M. Lewis</i>	<i>Fifth Middlesex</i>	<i>1/31/2023</i>
<i>Patrick M. O'Connor</i>	<i>First Plymouth and Norfolk</i>	<i>2/8/2023</i>
<i>James B. Eldridge</i>	<i>Middlesex and Worcester</i>	<i>2/16/2023</i>
<i>Julian Cyr</i>	<i>Cape and Islands</i>	<i>2/23/2023</i>
<i>Patricia D. Jehlen</i>	<i>Second Middlesex</i>	<i>3/2/2023</i>
<i>Paul R. Feeney</i>	<i>Bristol and Norfolk</i>	<i>3/6/2023</i>

SENATE No. 749

By Ms. Friedman, a petition (accompanied by bill, Senate, No. 749) of Cindy F. Friedman, Rebecca L. Rausch, Susannah M. Whipps, Joanne M. Comerford 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. 771 OF 2021-2022.]

The Commonwealth of Massachusetts

—————
**In the One Hundred and Ninety-Third General Court
(2023-2024)**
—————

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. Chapter 6A of the General Laws is hereby amended by adding the
2 following section:-

3 Section 16DD. (a) The following terms shall have the following meanings, unless the
4 context clearly requires otherwise:

5 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
6 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
7 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
8 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
9 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug

10 application that was approved by the United States Secretary of Health and Human Services
11 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the 2
12 of 53 date of the enactment of the federal Drug Price Competition and Patent Term Restoration
13 Act of 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by
14 42 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application
15 approved under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand
16 name drug based on available data resources such as Medi-Span.

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

22 (b) Notwithstanding any general or special law to the contrary, there shall be a drug
23 access program, administered by the executive office of health and human services, for the
24 purpose of enhancing access to targeted high-value medications used to treat certain chronic
25 conditions. To implement the drug access program, the secretary of health and human services,
26 in consultation with the department of public health, the division of insurance, the health policy
27 commission, and the center for health information and analysis, shall identify one generic drug
28 and one brand name drug used to treat each of the following chronic conditions: (i) diabetes; (ii)
29 asthma; and (iii) heart conditions, including, but not limited to, hypertension and coronary artery
30 disease. In determining the one generic drug and one brand name drug used to treat each chronic
31 condition, the secretary shall consider whether the drug is:

32 (1) of clear benefit and strongly supported by clinical evidence to be cost-effective;

33 (2) likely to reduce hospitalizations or emergency department visits, or reduce future
34 exacerbations of illness progression, or improve quality of life;

35 (3) relatively low cost when compared to the cost of an acute illness or incident prevented
36 or delayed by the use of the service, treatment or drug;

37 (4) at low risk for overutilization, abuse, addiction, diversion or fraud; and

38 (5) widely utilized as a treatment for the chronic condition.

39 (c) The secretary of health and human services shall identify insulin as the drug used to
40 treat diabetes under the drug access program.

41 (d) Every two years, the secretary of health and human services, in consultation with the
42 health policy commission, the center for health information and analysis and the division of
43 insurance, shall evaluate the impact of the drug access program established in this section on
44 drug treatment adherence, incidence of related acute events, premiums and cost-sharing, overall
45 health, long-term health costs, and any other issues that the secretary may deem relevant. The
46 secretary may collaborate with an independent research organization to conduct such evaluation.
47 The secretary shall file a report of its findings with the clerks of the house of representatives and
48 senate, the chairs of the joint committee on public health, the chairs of the joint committee on
49 health care financing and the chairs of house and senate committees on ways and means.

50 (e) The secretary, in consultation with the division of insurance, shall promulgate rules
51 and regulations necessary to implement this section.

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

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

57 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
58 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
59 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
60 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
61 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
62 application that was approved by the United States Secretary of Health and Human Services
63 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
64 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
65 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
66 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
67 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
68 based on available data resources such as Medi-Span.

69 SECTION 3. Said section 1 of said chapter 6D, as so appearing, is hereby further
70 amended by inserting after the definition of “Disproportionate share hospital” the following
71 definition:-

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

75 SECTION 4. Said section 1 of said chapter 6D, as so appearing, is hereby further
76 amended by inserting after the definition of “Fiscal year” the following definition:-

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

82 SECTION 5. Said section 1 of said chapter 6D, as so appearing, is hereby further
83 amended by striking out, in line 189, the words “not include excludes ERISA plans” and
84 inserting in place thereof the following words:- include self-insured plans to the extent allowed
85 under the federal Employee Retirement Income Security Act of 1974.

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

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

94 under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said
95 chapter 112.

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

109 SECTION 7. Said section 1 of said chapter 6D, as so appearing, is hereby further
110 amended by inserting after the definition of “Physician” the following definition:-

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

114 SECTION 8. Said section 1 of said chapter 6D, as so appearing, is hereby further
115 amended by adding the following definition:-

116 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
117 1395w-3a(c)(6)(B).

118 SECTION 9. Said chapter 6D is hereby further amended by striking out section 2A, as so
119 appearing, and inserting in place thereof the following section:-

120 Section 2A. The commission shall keep confidential all nonpublic clinical, financial,
121 strategic or operational documents or information provided or reported to the commission in
122 connection with any care delivery, quality improvement process, performance improvement
123 plan, early notification or access and affordability improvement plan activities authorized under
124 sections 7, 10, 14, 15, 15A, 20 or 21 of this chapter or under section 2GGGG of chapter 29 and
125 shall not disclose the information or documents to any person without the consent of the payer,
126 provider or pharmaceutical manufacturing company providing or reporting the information or
127 documents under said sections 7, 10, 14, 15, 15A, 20 or 21 of this chapter or under said section
128 2GGGG of said chapter 29, except in summary form in evaluative reports of such activities or
129 when the commission believes that such disclosure should be made in the public interest after
130 taking into account any privacy, trade secret or anticompetitive considerations. The confidential
131 information and documents shall not be public records and shall be exempt from disclosure
132 under clause Twenty-sixth of section 7 of chapter 4 or under chapter 66.

133 SECTION 10. Section 4 of said chapter 6D, as so appearing, is hereby amended by
134 striking out, in lines 7 and 8, the word “manufacturers” and inserting in place thereof the
135 following words:- manufacturing companies, pharmacy benefit managers,.

136 SECTION 11. Section 6 of said chapter 6D, as so appearing, is hereby amended by
137 inserting after the word “center”, in line 1, the following words:- , pharmaceutical and
138 biopharmaceutical manufacturing company, pharmacy benefit manager.

139 SECTION 12. Said section 6 of said chapter 6D, as so appearing, is hereby further
140 amended by striking out, in lines 5 and 36, the figure “33” and inserting in place thereof, in each
141 instance, the following figure:- 25.

142 SECTION 13. Said section 6 of said chapter 6D, as so appearing, is hereby further
143 amended by adding the following paragraph:-

144 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
145 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
146 appropriated by the general court for the expenses of the commission minus amounts collected
147 from: (i) filing fees; (ii) fees and charges generated by the commission's publication or
148 dissemination of reports and information; and (iii) federal matching revenues received for these
149 expenses or received retroactively for expenses of predecessor agencies. Pharmaceutical and
150 biopharmaceutical manufacturing companies and pharmacy benefit managers shall, in a manner
151 and distribution determined by the commission, pay to the commonwealth an amount of the
152 estimated expenses of the commission attributable to the commission’s activities under sections
153 8, 9, 15A, 20 and 21. A pharmacy benefit manager that is a surcharge payor subject to the
154 preceding paragraph and manages its own prescription drug benefits shall not be subject to
155 additional assessment under this paragraph

156 SECTION 14. Section 8 of said chapter 6D, as so appearing, is hereby amended by
157 inserting after the word “organization”, in lines 6 and 7, the following words:- , pharmacy benefit
158 manager, pharmaceutical manufacturing company.

159 SECTION 15. Said section 8 of said chapter 6D, as so appearing, is hereby further
160 amended by inserting after the word “organizations”, in line 14, the following words:- ,
161 pharmacy benefit managers, pharmaceutical manufacturing companies.

162 SECTION 16. Said section 8 of said chapter 6D, as so appearing, is hereby further
163 amended by striking out, in line 32, the words “and (xi)” and inserting in place thereof the
164 following words:- (xi) not less than 3 representatives of the pharmaceutical industry; (xii) at least
165 1 representative of the pharmacy benefit management industry; and (xiii).

166 SECTION 17. Said section 8 of said chapter 6D, as so appearing, is hereby further
167 amended by striking out, in line 48, the first time it appears, the word “and”.

168 SECTION 18. Said section 8 of said chapter 6D, as so appearing, is hereby further
169 amended by inserting after the word “commission”, in line 59, the first time it appears, the
170 following words:- ; and (iii) in the case of pharmacy benefit managers and pharmaceutical
171 manufacturing companies, testimony concerning factors underlying prescription drug costs and
172 price increases including, but not limited to, the initial prices of drugs coming to market and
173 subsequent price increases, changes in industry profit levels, marketing expenses, reverse
174 payment patent settlements, the impact of manufacturer rebates, discounts and other price
175 concessions on net pricing, the availability of alternative drugs or treatments and any other
176 matters as determined by the commission.

177 SECTION 19. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is
178 hereby amended by striking out the second sentence and inserting in place thereof the following
179 2 sentences:-

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

188 SECTION 20. Section 9 of said chapter 6D, as so appearing, is hereby amended by
189 inserting after the word “organization”, in line 72, the following words:- , pharmacy benefit
190 manager, pharmaceutical manufacturing company.

191 SECTION 21. Said chapter 6D is hereby further amended by inserting after section 15
192 the following section:-

193 Section 15A. (a) A pharmaceutical manufacturing company shall provide early notice to
194 the commission in a manner described in this section for a: (i) pipeline drug; (ii) generic drug; or
195 (iii) biosimilar drug. The commission shall provide non-confidential information received under
196 this section to the office of Medicaid, the division of insurance and the group insurance
197 commission.

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

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

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

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

213 (b) A pharmaceutical manufacturing company shall provide early notice to the
214 commission if it plans to increase the wholesale acquisition cost of a: (i) brand-name drug by
215 more than 15 per cent per wholesale acquisition cost unit during any 12-month period; or (ii)
216 generic drug with a significant price increase as determined by the commission during any 12-
217 month period. The commission shall provide non-confidential information received under this
218 section to the office of Medicaid, the division of insurance and the group insurance commission.

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

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

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

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

234 (e) If a pharmaceutical manufacturing company fails to timely comply with the
235 requirements under subsection (a) or subsection (b), or otherwise knowingly obstructs the
236 commission's ability to receive early notice under this section, including, but not limited to,
237 providing incomplete, false or misleading information, the commission may impose appropriate
238 sanctions against the manufacturer, including reasonable monetary penalties not to exceed
239 \$500,000, in each instance. The commission shall seek to promote compliance with this section
240 and shall only impose a civil penalty on the manufacturer as a last resort. Amounts collected

241 under this section shall be deposited into the Prescription Drug Cost Assistance Trust Fund
242 established in section 2RRRRR of chapter 29.

243 SECTION 22. Said chapter 6D is hereby further amended by adding the following 2
244 sections:-

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

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

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

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

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

265 In order to conduct a review of eligible drugs, the commission may require a
266 manufacturer to disclose to the commission within a reasonable time period information relating
267 to the manufacturer's pricing of an eligible drug. The disclosed information shall be on a
268 standard reporting form developed by the commission with the input of the manufacturers and
269 shall include, but not be limited to:

270 (i) a schedule of the drug's wholesale acquisition cost increases over the previous 5
271 calendar years;

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

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

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

280 (c) Based on the records furnished under subsection (b) and available information from
281 the center for health information and analysis or an outside third party, the commission shall

282 identify a proposed value for the eligible drug. The commission may request additional relevant
283 information that it deems necessary.

284 Any information, analyses or reports regarding an eligible drug review shall be provided
285 to the manufacturer. The commission shall consider any clarifications or data provided by the
286 manufacturer with respect to the eligible drug. The commission shall not base its determination
287 on the proposed value of the eligible drug solely on the analysis or research of an outside third
288 party and shall not employ a measure or metric that assigns a reduced value to the life extension
289 provided by a treatment based on a pre-existing disability or chronic health condition of the
290 individuals whom the treatment would benefit. If the commission relies upon a third party to
291 provide cost-effectiveness analysis or research related to the proposed value of the eligible drug,
292 such analysis or research shall also include, but not be limited to: (i) a description of the
293 methodologies and models used in its analysis; (ii) any assumptions and potential limitations of
294 research findings in the context of the results; and (iii) outcomes for affected subpopulations that
295 utilize the drug, including, but not limited to, potential impacts on individuals of marginalized
296 racial or ethnic groups, and on individuals with specific disabilities or health conditions who
297 regularly utilize the eligible drug.

298 (d) If, after review of an eligible drug and after receiving information from the
299 manufacturer under subsection (b) or subsection (e), the commission determines that the
300 manufacturer's pricing of the eligible drug does not substantially exceed the proposed value of
301 the drug, the commission shall notify the manufacturer, in writing, of its determination and shall
302 evaluate other ways to mitigate the eligible drug's cost in order to improve patient access to the
303 eligible drug. The commission may engage with the manufacturer and other relevant
304 stakeholders, including, but not limited to, patients, patient advocacy organizations, consumer

305 advocacy organizations, providers, provider organizations and payers, to explore options for
306 mitigating the cost of the eligible drug. Upon the conclusion of a stakeholder engagement
307 process under this subsection, the commission shall issue recommendations on ways to reduce
308 the cost of the eligible drug for the purpose of improving patient access to the eligible drug.
309 Recommendations may include, but shall not be limited to: (i) an alternative payment plan or
310 methodology; (ii) a bulk purchasing program; (iii) co-pay, deductible, coinsurance or other cost-
311 sharing restrictions; and (iv) a reinsurance program to subsidize the cost of the eligible drug. The
312 recommendations shall be publicly posted on the commission's website and provided to the
313 clerks of the house of representatives and senate, the joint committee on health care financing
314 and the house and senate committees on ways and means.

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

320 (f) Not later than 60 days after receiving information from the manufacturer under
321 subsection (b) or subsection (e), the commission shall confidentially issue a determination on
322 whether the manufacturer's pricing of an eligible drug substantially exceeds the commission's
323 proposed value of the drug. If the commission determines that the manufacturer's pricing of an
324 eligible drug substantially exceeds the proposed value of the drug, the commission shall
325 confidentially notify the manufacturer, in writing, of its determination and request the
326 manufacturer to enter into an access and affordability improvement plan under section 21.

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

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

338 (h) The commission's proposed value of an eligible and the commission's underlying
339 analysis of the eligible drug is not intended to be used to determine whether any individual
340 patient meets prior authorization or utilization management criteria for the eligible drug. The
341 proposed value and underlying analysis shall not be the sole factor in determining whether a drug
342 is included in a formulary or whether the drug is subject to step therapy.

343 (i) If the manufacturer fails to timely comply with the commission's request for records
344 under subsection (b) or subsection (e), or otherwise knowingly obstructs the commission's
345 ability to issue its determination under subsection (f), including, but not limited to, by providing
346 incomplete, false or misleading information, the commission may impose appropriate sanctions
347 against the manufacturer, including reasonable monetary penalties not to exceed \$500,000, in
348 each instance. The commission shall seek to promote compliance with this section and shall only

349 impose a civil penalty on the manufacturer as a last resort. Penalties collected under this
350 subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established
351 in section 2RRRRR of chapter 29.

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

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

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

362 (b) An access and affordability improvement plan shall: (i) be generated by the
363 manufacturer; (ii) identify the reasons for the manufacturer's drug price; and (iii) include, but not
364 be limited to, specific strategies, adjustments and action steps the manufacturer proposes to
365 implement to address the cost of the eligible drug in order to improve the accessibility and
366 affordability of the eligible drug for patients and the state's health system. The proposed access
367 and affordability improvement plan shall include specific identifiable and measurable expected
368 outcomes and a timetable for implementation. The timetable for an access and affordability
369 improvement plan shall not exceed 18 months.

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

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

379 (e) Upon approval of the proposed access and affordability improvement plan, the
380 commission shall notify the manufacturer to begin immediate implementation of the access and
381 affordability improvement plan. Public notice shall be provided by the commission on its
382 website, identifying that the manufacturer is implementing an access and affordability
383 improvement plan; provided, however, that upon the successful completion of the access and
384 affordability improvement plan, the identity of the manufacturer shall be removed from the
385 commission's website. All manufacturers implementing an approved access improvement plan
386 shall be subject to additional reporting requirements and compliance monitoring as determined
387 by the commission. The commission shall provide assistance to the manufacturer in the
388 successful implementation of the access and affordability improvement plan.

389 (f) All manufacturers shall work in good faith to implement the access and affordability
390 improvement plan. At any point during the implementation of the access and affordability

391 improvement plan, the manufacturer may file amendments to the access improvement plan,
392 subject to approval of the commission.

393 (g) At the conclusion of the timetable established in the access and affordability
394 improvement plan, the manufacturer shall report to the commission regarding the outcome of the
395 access and affordability improvement plan. If the commission determines that the access and
396 affordability improvement plan was unsuccessful, the commission shall: (i) extend the
397 implementation timetable of the existing access and affordability improvement plan; (ii) approve
398 amendments to the access and affordability improvement plan as proposed by the manufacturer;
399 (iii) require the manufacturer to submit a new access and affordability improvement plan; or (iv)
400 waive or delay the requirement to file any additional access and affordability improvement plans.

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

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

407 (j) The commission may assess a civil penalty to a manufacturer of not more than
408 \$500,000, in each instance, if the commission determines that the manufacturer: (i) willfully
409 neglected to file an access and affordability improvement plan with the commission under
410 subsection (a); (ii) failed to file an acceptable access and affordability improvement plan in good
411 faith with the commission; (iii) failed to implement the access and affordability improvement
412 plan in good faith; or (iv) knowingly failed to provide information required by this section to the

413 commission or knowingly falsified the information. The commission shall seek to promote
414 compliance with this section and shall only impose a civil penalty as a last resort. Penalties
415 collected under this subsection shall be deposited into the Prescription Drug Cost Assistance
416 Trust Fund established in section 2RRRRR of chapter 29.

417 (k) If a manufacturer declines to enter into an access and affordability improvement plan
418 under this section, the commission may publicly post the proposed value of the eligible drug,
419 hold a public hearing on the proposed value of the eligible drug and solicit public comment. The
420 manufacturer shall appear and testify at the public hearing held on the eligible drug's proposed
421 value. Upon the conclusion of a public hearing under this subsection, the commission shall issue
422 recommendations on ways to reduce the cost of an eligible drug for the purpose of improving
423 patient access to the eligible drug. The recommendations shall be publicly posted on the
424 commission's website and provided to the clerks of the house of representatives and senate, the
425 joint committee on health care financing and the house and senate committees on ways and
426 means.

427 If a manufacturer is deemed to not be acting in good faith to develop an acceptable or
428 complete access and affordability improvement plan, the commission may publicly post the
429 proposed value of the eligible drug, hold a public hearing on the proposed value of the eligible
430 drug and solicit public comment. The manufacturer shall appear and testify at any hearing held
431 on the eligible drug's proposed value. Upon the conclusion of a public hearing under this
432 subsection, the commission shall issue recommendations on ways to reduce the cost of an
433 eligible drug for the purpose of improving patient access to the eligible drug. The
434 recommendations shall be publicly posted on the commission's website and provided to the

435 clerks of the house of representatives and senate, the joint committee on health care financing
436 and the house and senate committees on ways and means.

437 Before making a determination that the manufacturer is not acting in good faith, the
438 commission shall send a written notice to the manufacturer that the commission shall deem the
439 manufacturer to not be acting in good faith if the manufacturer does not submit an acceptable
440 access and affordability improvement plan within 30 days of receipt of notice; provided,
441 however, that the commission shall not send a notice under this paragraph within 120 calendar
442 days from the date that the commission issued its request that the manufacturer enter into the
443 access and affordability improvement plan.

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

445 SECTION 23. Section 1 of chapter 12C of the General Laws, as appearing in the 2020
446 Official Edition, is hereby amended by inserting after the definition of “Ambulatory surgical
447 center services” the following 3 definitions:-

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

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

453 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
454 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
455 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that

456 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
457 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
458 application that was approved by the United States Secretary of Health and Human Services
459 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
460 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
461 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic as defined by 42 C.F.R.
462 447.502; (ii) produced or distributed pursuant to a biologics license application approved under
463 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug based
464 on available data resources such as Medi-Span.

465 SECTION 24. Said section 1 of said chapter 12C, as so appearing, is hereby further
466 amended by inserting after the definition of “General health supplies, care or rehabilitative
467 services and accommodations” the following definition:-

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

473 SECTION 25. Said section 1 of said chapter 12C, as so appearing, is hereby further
474 amended by inserting after the definition of “Patient-centered medical home” the following 2
475 definitions:-

476 “Pharmaceutical manufacturing company”, an entity engaged in the: (i) production,
477 preparation, propagation, compounding, conversion or processing of prescription drugs, directly

478 or indirectly, by extraction from substances of natural origin, independently by means of
479 chemical synthesis or by a combination of extraction and chemical synthesis; or (ii) packaging,
480 repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that
481 “pharmaceutical manufacturing company” shall not include a wholesale drug distributor licensed
482 under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said
483 chapter 112.

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

497 SECTION 26. Said section 1 of said chapter 12C, as so appearing, is hereby further
498 amended by adding the following definition:-

499 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
500 1395w-3a(c)(6)(B).

501 SECTION 27. Section 3 of said chapter 12C, as so appearing, is hereby amended by
502 inserting after the word “organizations”, in lines 13 and 14, the following words:- ,
503 pharmaceutical manufacturing companies, pharmacy benefit managers.

504 SECTION 28. Said section 3 of said chapter 12C, as so appearing, is hereby further
505 amended by striking out, in line 24, the words “and payer” and inserting in place thereof the
506 following words:- , payer, pharmaceutical manufacturing company and pharmacy benefit
507 manager.

508 SECTION 29. Section 5 of said chapter 12C, as so appearing, is hereby amended by
509 striking out, in lines 11 and 12, the words “and public health care payers” and inserting in place
510 thereof the following words:- , public health care payers, pharmaceutical manufacturing
511 companies and pharmacy benefit managers.

512 SECTION 30. Said section 5 of said chapter 12C, as so appearing, is hereby further
513 amended by striking out, in line 15, the words “and affected payers” and inserting in place
514 thereof the following words:- affected payers, affected pharmaceutical manufacturing companies
515 and affected pharmacy benefit managers.

516 SECTION 31. The first paragraph of section 7 of said chapter 12C, as so appearing, is
517 hereby amended by adding the following sentence:- Each pharmaceutical and biopharmaceutical
518 manufacturing company and pharmacy benefit manager shall pay to the commonwealth an
519 amount for the estimated expenses of the center and for the other purposes described in this
520 chapter.

521 SECTION 32. Said section 7 of said chapter 12C, as so appearing, is hereby further
522 amended by striking out, in lines 8 and 42, the figure “33” and inserting in place thereof, in each
523 instance, the following figure:- 25.

524 SECTION 33. Said section 7 of said chapter 12C, as so appearing, is hereby further
525 amended by adding the following paragraph:-

526 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
527 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
528 appropriated by the general court for the expenses of the center minus amounts collected from:
529 (i) filing fees; (ii) fees and charges generated by the commission's publication or dissemination
530 of reports and information; and (iii) federal matching revenues received for these expenses or
531 received retroactively for expenses of predecessor agencies. Pharmaceutical and
532 biopharmaceutical manufacturing companies and pharmacy benefit managers shall, in a manner
533 and distribution determined by the center, pay to the commonwealth an amount of the estimated
534 expenses of the center attributable to the center’s activities under sections 3, 10A, 12 and 16. The
535 assessed amount shall be based on business conducted in the commonwealth by the
536 pharmaceutical and biopharmaceutical manufacturing company and pharmacy benefit manager.
537 A pharmacy benefit manager that is also a surcharge payor subject to the preceding paragraph
538 and manages its own prescription drug benefits shall not be subject to additional assessment
539 under this paragraph.

540 SECTION 34. Said chapter 12C is hereby further amended by inserting after section 10
541 the following section:-

542 Section 10A. (a) The center shall promulgate the regulations necessary to ensure the
543 uniform reporting of information from pharmaceutical manufacturing companies to enable the
544 center to analyze: (i) year-over-year changes in wholesale acquisition cost and average
545 manufacturer price for prescription drug products; (ii) year-over-year trends in net expenditures;
546 (iii) net expenditures on subsets of biosimilar, brand name and generic drugs identified by the
547 center; (iv) trends in estimated aggregate drug rebates, discounts or other remuneration paid or
548 provided by a pharmaceutical manufacturing company to a pharmacy benefit manager,
549 wholesaler, distributor, health carrier client, health plan sponsor or pharmacy in connection with
550 utilization of the pharmaceutical drug products offered by the pharmaceutical manufacturing
551 company; (v) discounts provided by a pharmaceutical manufacturing company to a consumer in
552 connection with utilization of the pharmaceutical drug products offered by the pharmaceutical
553 manufacturing company, including any discount, rebate, product voucher, coupon or other
554 reduction in a consumer's out-of-pocket expenses including co-payments and deductibles under
555 section 3 of chapter 175H; (vi) research and development costs as a percentage of revenue; (vii)
556 annual marketing and advertising costs, identifying costs for direct-to-consumer advertising;
557 (viii) annual profits over the most recent 5-year period; (ix) disparities between prices charged to
558 purchasers in the commonwealth and purchasers outside of the United States; and (x) any other
559 information deemed necessary by the center.

560 The center shall require the submission of available data and other information from
561 pharmaceutical manufacturing companies including, but not limited to: (i) wholesale acquisition
562 costs and average manufacturer prices for prescription drug products as identified by the center;
563 (ii) true net typical prices charged to pharmacy benefits managers by payor type for prescription
564 drug products identified by the center, net of any rebate or other payments from the manufacturer

565 to the pharmacy benefits manager and from the pharmacy benefits manager to the manufacturer;
566 (iii) aggregate, company-level research and development costs to the extent attributable to a
567 specific product and other relevant capital expenditures for the most recent year for which final
568 audited data is available for prescription drug products as identified by the center; (iv) annual
569 marketing and advertising expenditures; and (v) a description, absent proprietary information and
570 written in plain language, of factors that contributed to reported changes in wholesale acquisition
571 costs, net prices and average manufacturer prices for prescription drug products as identified by
572 the center.

573 (b) The center shall promulgate the regulations necessary to ensure the uniform reporting
574 of information from pharmacy benefit managers to enable the center to analyze: (i) trends in
575 estimated aggregate drug rebates and other drug price reductions, if any, provided by a pharmacy
576 benefit manager to a health carrier client or health plan sponsor or passed through from a
577 pharmacy benefit manager to a health carrier client or health plan sponsor in connection with
578 utilization of drugs in the commonwealth offered through the pharmacy benefit manager and a
579 measure of lives covered by each health carrier client or health plan sponsor in the
580 commonwealth; (ii) pharmacy benefit manager practices with regard to drug rebates and other
581 drug price reductions, if any, provided by a pharmacy benefit manager to a health carrier client
582 or health plan sponsor or to consumers in the commonwealth or passed through from a pharmacy
583 benefit manager to a health carrier client or health plan sponsor or to consumers in the
584 commonwealth; and (iii) any other information deemed necessary by the center.

585 The center shall require the submission of available data and other information from
586 pharmacy benefit managers including, but not limited to: (i) true net typical prices charged by
587 pharmacy benefits managers for prescription drug products identified by the center, net of any

588 rebate or other payments from the manufacturer to the pharmacy benefits manager and from the
589 pharmacy benefits manager to the manufacturer; (ii) the amount of all rebates that the pharmacy
590 benefit manager received from all pharmaceutical manufacturing companies for all health carrier
591 clients in the aggregate and for each health carrier client or health plan sponsor individually,
592 attributable to patient utilization in the commonwealth; (iii) the administrative fees that the
593 pharmacy benefit manager received from all health carrier clients or health plan sponsors in the
594 aggregate and for each health carrier client or health plans sponsors individually; (iv) the
595 aggregate amount of all retained rebates that the pharmacy benefit manager received from all
596 pharmaceutical manufacturing companies and did not pass through to each pharmacy benefit
597 manager's health carrier client or health plan sponsor individually; (v) the aggregate amount of
598 rebates a pharmacy benefit manager: (A) retains based on its contractual arrangement with each
599 health plan client or health plan sponsor individually; and (B) passes through to each health care
600 client individually; (vi) the percentage of contracts that a pharmacy benefit manager holds where
601 the pharmacy benefit manager: (A) retains all rebates; (B) passes all rebates through to the client;
602 and (C) shares rebates with the client; and (vii) other information as determined by the center,
603 including, but not limited to, pharmacy benefit manager practices related to spread pricing,
604 administrative fees, claw backs and formulary placement.

605 (c) Except as specifically provided otherwise by the center or under this chapter, data
606 collected by the center pursuant to this section from pharmaceutical manufacturing companies
607 and pharmacy benefit managers shall not be a public record under clause Twenty-sixth of section
608 7 of chapter 4 or under chapter 66.

609 SECTION 35. Said chapter 12C is hereby further amended by striking out section 11, as
610 so appearing, and inserting in place thereof the following section:-

611 Section 11. The center shall ensure the timely reporting of information required under
612 sections 8, 9, 10 and 10A. The center shall notify private health care payers, providers, provider
613 organizations, pharmacy benefit managers, pharmaceutical manufacturing companies and their
614 parent organization and other affiliates of any applicable reporting deadlines. The center shall
615 notify, in writing, a private health care payer, provider, provider organization, pharmacy benefit
616 manager or pharmaceutical manufacturing company, and their parent organization and other
617 affiliates, that has failed to meet a reporting deadline of such failure and that failure to respond
618 within 2 weeks of the receipt of the notice may result in penalties. The center may assess a
619 penalty against a private health care payer, provider, provider organization, pharmacy benefit
620 manager or pharmaceutical manufacturing company, and their parent organization and other
621 affiliates, that fails, without just cause, to provide the requested information, including subsets of
622 the requested information, within 2 weeks following receipt of the written notice required under
623 this section, of not more than \$2,000 per week for each week of delay after the 2-week period
624 following receipt of the notice. Amounts collected under this section shall be deposited in the
625 Healthcare Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

626 SECTION 36. Section 12 of said chapter 12C, as so appearing, is hereby amended by
627 striking out, in line 2, the words “and 10” and inserting in place thereof the following words:- ,
628 10 and 10A.

629 SECTION 37. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby
630 amended by striking out the first sentence and inserting in place thereof the following sentence:-
631 The center shall publish an annual report based on the information submitted under: (i) sections
632 8, 9, 10 and 10A concerning health care provider, provider organization, private and public
633 health care payer, pharmaceutical manufacturing company and pharmacy benefit manager costs

634 and cost and price trends; (ii) section 13 of chapter 6D relative to market power reviews; and (iii)
635 section 15 of said chapter 6D relative to quality data.

636 SECTION 38. Said section 16 of said chapter 12C, as so appearing, is hereby further
637 amended by striking out, in line 18, the words “in the aggregate”.

638 SECTION 39. Said section 16 of said chapter 12C, as so appearing, is hereby further
639 amended by inserting after the second paragraph the following paragraph:-

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

646 SECTION 40. Section 13 of chapter 17 of the General Laws, as so appearing, is hereby
647 amended by adding the following subsection:-

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

650 “Public health essential drug”, a prescription drug, biologic or biosimilar approved by the
651 United States Food and Drug Administration that: (i) appears on the Model List of Essential
652 Medicines most recently adopted by the World Health Organization; or (ii) is deemed an
653 essential medicine by the commission due to its efficacy in treating a life-threatening health
654 condition or a chronic health condition that substantially impairs an individual’s ability to engage

655 in activities of daily living or because limited access to a certain population would pose a public
656 health challenge.

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

662 SECTION 41. Chapter 29 of the General Laws is hereby amending by inserting after
663 section 2QQQQQ the following section:-

664 2RRRRR. (a) There shall be a Prescription Drug Cost Assistance Trust Fund. The
665 secretary of health and human services shall administer the fund and shall make expenditures
666 from the fund, without further appropriation, to provide financial assistance to state residents for
667 the cost of prescription drugs through the prescription drug costs assistance program established
668 under section 244 of chapter 111. For the purpose of this section “prescription drug” shall
669 include the prescription drug and any drug delivery device needed to administer the drug that is
670 not included as part of the underlying drug prescription.

671 The fund shall consist of: (i) revenue generated from the penalty established under
672 chapter 63E; (ii) revenue from appropriations or other money authorized by the general court and
673 specifically designated to be credited to the fund; and (iii) funds from public or private sources,
674 including, but not limited to, gifts, grants, donations, rebates and settlements received by the
675 commonwealth that are specifically designated to be credited to the fund. An amount equal to the
676 total receipts deposited each quarter from the penalty on drug manufacturers for excessive price

677 increases established under chapter 63E shall be transferred from the General Fund to the
678 Prescription Drug Costs Assistance Trust Fund before the end of each fiscal year. Money
679 remaining in the fund at the close of a fiscal year shall not revert to the General Fund and shall
680 be available for expenditure in the following fiscal year.

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

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

692 SECTION 42. Section 17G of chapter 32A of the General Laws, as appearing in the 2020
693 Official Edition, is hereby amended by adding the following sentence:-

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

699 SECTION 43. Said chapter 32A, as so appearing, is hereby further amended by inserting
700 after section 17R the following section:-

701 Section 17S. Any carrier offering a policy, contract or certificate of health insurance
702 under this chapter shall provide coverage for the brand name drugs and generic drugs identified
703 by the drug access program established in section 16DD in chapter 6A. Coverage for identified
704 generic drugs shall not be subject to any cost-sharing, including co-payments and co-insurance,
705 and shall not be subject to any deductible. Coverage for identified brand name drugs shall not be
706 subject to any deductible or co-insurance and any co-payment shall not exceed \$25 per 30-day
707 supply.

708 Notwithstanding this section or any other general or special law to the contrary, coverage
709 for insulin shall be provided under section 17G of this chapter.

710 SECTION 44. The General Laws are hereby amended by inserting after chapter 63D the
711 following chapter:-

712 Chapter 63E. PENALTY ON DRUG MANUFACTURERS FOR EXCESSIVE PRICE
713 INCREASES

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

716 “Commissioner”, the commissioner of revenue.

717 “Core consumer price index”, the consumer price index for all urban consumers (CPI-U):
718 U.S. city average, for all Items less food and energy, as reported by the U.S. Bureau of Labor
719 Statistics.

720 “Drug”, any medication, as identified by a National Drug Code, approved for sale by the
721 U.S. Food and Drug Administration.

722 “Excessive price,” the price of a drug that exceeds the sum of the reference price of that
723 drug plus the three -year average of the core consumer price index, as measured on January 1 of
724 the current calendar year.

725 “Excessive price increase”, the amount by which the price of a drug exceeds the sum of
726 the reference price of that drug plus the three-year average of the core consumer price index, as
727 measured on January 1 of the current calendar year.

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

729 “Price”, the wholesale acquisition cost of a drug, per unit, as reported to the First Data
730 Bank or other appropriate price compendium designated by the commissioner.

731 “Reference date”, January 1 of the calendar year prior to the current calendar year.

732 “Reference price”, the price of a drug on the reference date, or in the case of any drug
733 first commercially marketed in the United States after the reference date, the price of the drug on
734 the date when first marketed in the United States.

735 “Related party”, an entity is a related party with respect to a person if that entity (i)
736 belongs to the same affiliated group as that person under section 1504 of the Internal Revenue
737 Code provided that the term 50 per cent shall be substituted for the term 80 per cent each time it
738 appears in said section 1504, (ii) has a relationship with that person that is specified in
739 subsections (b) and (c) of section 267 of the Internal Revenue Code, or (iii) is otherwise under
740 common ownership and control with regard to that person; provided, that all references to the

741 Internal Revenue Code in this definition refer to the Internal Revenue Code as amended and in
742 effect for the taxable year.

743 “Unit”, the lowest dispensable amount of a drug.

744 Section 2. (a) Any person who manufactures and sells drugs, directly or through another
745 person, for distribution in the commonwealth and who establishes an excessive price for any
746 such drug directly or in cooperation with a related party, shall pay a per unit penalty on all units
747 of the drug ultimately dispensed or administered in the commonwealth. The penalty for each unit
748 shall be 80 per cent of the excessive price increase for each unit.

749 (b) A person who establishes an excessive price for a drug as described in subsection (a)
750 shall file a return as provided in section 4 declaring all units of excessively priced drug sold for
751 distribution in the commonwealth during each calendar quarter. In the event that a person filing
752 such a return pays a penalty with regard to one or more units of drug that are ultimately
753 dispensed or administered outside of the commonwealth, the person may claim a credit for such
754 penalty amounts on the return for the tax period during which such units are ultimately dispensed
755 or administered.

756 Section 3. The penalty under section 2 shall apply for any calendar quarter only to a
757 person who maintains a place of business in the commonwealth or whose total sales of all
758 products, directly or through another person, for distribution in the commonwealth were more
759 than \$100,000 in the calendar year beginning with the reference date. The penalty shall not apply
760 more than once to any unit of drug sold.

761 Section 4. Any person subject to the penalty under section 2 shall file a return with the
762 commissioner and shall pay the penalty by the fifteenth day of the third month following the end

763 of each calendar quarter, subject to such reasonable extensions of time for filing as the
764 commissioner may allow. The return shall set out the person's total sales subject to penalty in the
765 immediately preceding calendar quarter and shall provide such other information as the
766 commissioner may require.

767 Section 5. The penalty imposed under this chapter shall be in addition to, and not a
768 substitute for or credit against, any other penalty, tax or excise imposed under the General Laws.

769 Section 6. The commissioner may disclose information contained in returns filed under
770 this chapter to the department of public health, the executive office of health and human services,
771 or other appropriate agency for purposes of verifying that a filer's sales subject to penalty are
772 properly declared and that all reporting is otherwise correct. Return information so disclosed
773 shall remain confidential and shall not be public record.

774 Section 7. To the extent that a person subject to penalty under section 2 fails to pay
775 amounts due under this chapter, a related party of such person that directly or indirectly
776 distributes in the commonwealth any drug whose sales are subject to this chapter shall be jointly
777 and severally liable for the penalty due.

778 Section 8. The commissioner may promulgate regulations for the implementation of this
779 chapter.

780 SECTION 45. Chapter 111 of the General Laws is hereby amended by adding the
781 following section:-

782 Section 244. (a) The department shall establish and administer a prescription drug cost
783 assistance program, which shall be funded by the Prescription Drug Cost Assistance Trust Fund

784 established in section 2RRRRR of chapter 29. The program shall provide financial assistance for
785 prescription drugs used to treat: (1) chronic respiratory conditions, including, but not limited to,
786 chronic obstructive pulmonary disease and asthma; (2) chronic heart conditions, including, but
787 not limited to, heart failure, coronary artery disease, hypertension and high blood pressure; (3)
788 diabetes; and (4) any other chronic condition identified by the department that disproportionately
789 impacts people of color or is a risk factor for increased COVID-19 complications; provided, that
790 for paragraphs (1) and (3), “prescription drug” shall include the prescription drug and any drug
791 delivery device needed to administer the drug that is not included as part of the underlying drug
792 prescription. Such financial assistance shall cover the full cost of any co-payment, co-insurance
793 or deductible for the prescription drug for an individual who is eligible for the program.

794 (b) An individual shall be eligible for the program if the individual: (1) is a resident of
795 Massachusetts; (2) has a current prescription from a health care provider for a drug that is used to
796 treat a chronic condition listed in subsection (a); (3) has a family income equal to or less than
797 500 per cent of the federal poverty level; and (4) is not enrolled in MassHealth.

798 (c) The department shall create an application process, which shall be available
799 electronically and in hard copy form, to determine whether an individual meets the program
800 eligibility requirements under subsection (b). Upon receipt of such application, the department
801 shall determine an applicant’s eligibility and notify the applicant of the department’s
802 determination within 10 business days. If necessary for its determination, the department may
803 request additional information from the applicant; provided, that the department shall notify the
804 applicant within 5 business days of receipt of the original application as to what specific
805 additional information is being requested. If additional information is being requested, the
806 department shall, within 3 business days of receipt of the additional information, determine

807 whether the applicant is eligible for the program and notify the applicant of the department's
808 determination.

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

813 If the department determines that an applicant is eligible for the program, the department
814 shall provide the applicant with a prescription drug cost assistance program identification card,
815 which shall clearly indicate that the department has determined that the applicant is eligible for
816 the program; provided, that the program identification card shall include, at a minimum: (1) the
817 applicant's full name, and (2) the full name of the prescription drug that the applicant is eligible
818 to receive under the program without having to pay a co-payment, co-insurance or deductible.
819 An applicant's program identification card shall be valid for 12 months and shall be renewable
820 upon a redetermination of program eligibility.

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

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

836 (f) The department shall compile a report detailing information about the program from
837 the previous calendar year. The report shall include: (1) the number of applications received,
838 approved, denied and appealed; (2) the total number of applicants approved, and the number of
839 applicants approved broken down by race, gender, age range and income level; (3) a list of all
840 prescription drugs that qualify for the program under subsection (b) and a list of prescription
841 drugs that applicants actually received financial assistance for; and (4) the total cost savings
842 received by all approved applicants, and the cost savings broken down by race, gender, age range
843 and income level. The report shall be submitted annually, by March 1, to the clerks of the senate
844 and house of representatives, the chairs of the joint committee on ways and means and the chairs
845 of the joint committee on health care financing.

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

848 SECTION 46. Section 10C of chapter 118E of the General Laws, as appearing in the
849 2020 Official Edition, is hereby amended by adding the following sentence:-

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

858 SECTION 47. Said chapter 118E, as so appearing, is hereby amended by inserting after
859 section 10N the following section:-

860 Section 10O. Any carrier offering a policy, contract or certificate of health insurance
861 under this chapter shall provide coverage for the brand name drugs and generic drugs identified
862 by the drug access program established in section 16DD in chapter 6A. Coverage for identified
863 generic drugs shall not be subject to any cost-sharing, including co-payments and co-insurance,
864 and shall not be subject to any deductible. Coverage for identified brand name drugs shall not be
865 subject to any deductible or co-insurance and any co-payment shall not exceed \$25 per 30-day
866 supply.

867 Notwithstanding this section or any other general or special law to the contrary, coverage
868 for insulin shall be provided under section 10C of this chapter.

869 SECTION 48. Section 47N of chapter 175 of the General Laws, as so appearing, is
870 hereby amended by adding the following paragraph:-

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

880 SECTION 49. Said chapter 175, as so appearing, is hereby further amended by inserting
881 after section 47PP the following new section:-

882 Section 47QQ. Any carrier offering a policy, contract or certificate of health insurance
883 under this chapter shall provide coverage for the brand name drugs and generic drugs identified
884 by the drug access program established in section 16DD in chapter 6A. Coverage for identified
885 generic drugs shall not be subject to any cost-sharing, including co-payments and co-insurance,
886 and shall not be subject to any deductible. Coverage for identified brand name drugs shall not be
887 subject to any deductible or co-insurance and any co-payment shall not exceed \$25 per 30-day
888 supply.

889 Notwithstanding this section or any other general or special law to the contrary, coverage
890 for insulin shall be provided under section 47N of this chapter.

891 SECTION 50. Section 226 of said chapter 175, as so appearing, is hereby amended by
892 striking out subsection (a) and inserting in place thereof the following subsection:-

893 (a) For the purposes of this section, the term “pharmacy benefit manager” shall mean a
894 person, business or other entity, however organized, that directly or through a subsidiary
895 provides pharmacy benefit management services for prescription drugs and devices on behalf of
896 a health benefit plan sponsor, including, but not limited to, a self-insurance plan, labor union or
897 other third-party payer; provided, however, that pharmacy benefit management services shall
898 include, but not be limited to: (i) the processing and payment of claims for prescription drugs;
899 (ii) the performance of drug utilization review; (iii) the processing of drug prior authorization
900 requests; (iv) pharmacy contracting; (v) the adjudication of appeals or grievances related to
901 prescription drug coverage contracts; (vi) formulary administration; (vii) drug benefit design;
902 (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x) clinical, safety and
903 adherence programs for pharmacy services; and (xi) managing the cost of covered prescription
904 drugs; provided further, that “pharmacy benefit manager” shall include a health benefit plan that
905 does not contract with a pharmacy benefit manager and manages its own prescription drug
906 benefits unless specifically exempted.

907 SECTION 51. Section 8P of chapter 176A of the General Laws, as so appearing, is
908 hereby amended by adding the following paragraph:-

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

916 SECTION 52. Said chapter 176A, as so appearing, is hereby further amended by
917 inserting after section 8QQ the following new section:-

918 Section 8RR. Any carrier offering a policy, contract or certificate of health insurance
919 under this chapter shall provide coverage for the brand name drugs and generic drugs identified
920 by the drug access program established in section 16DD in chapter 6A. Coverage for identified
921 generic drugs shall not be subject to any cost-sharing, including co-payments and co-insurance,
922 and shall not be subject to any deductible. Coverage for identified brand name drugs shall not be
923 subject to any deductible or co-insurance and any co-payment shall not exceed \$25 per 30-day
924 supply.

925 Notwithstanding this section or any other general or special law to the contrary, coverage
926 for insulin shall be provided under section 8P of this chapter.

927 SECTION 53. Section 4S of chapter 176B of the General Laws, as so appearing, is
928 hereby amended by adding the following sentence:-

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

935 SECTION 54. Said chapter 176B, as so appearing, is hereby further amended by inserting
936 after section 4QQ the following new section:-

937 Section 4RR. Any carrier offering a policy, contract or certificate of health insurance
938 under this chapter shall provide coverage for the brand name drugs and generic drugs identified
939 by the drug access program established in section 16DD in chapter 6A. Coverage for identified
940 generic drugs shall not be subject to any cost-sharing, including co-payments and co-insurance,
941 and shall not be subject to any deductible. Coverage for identified brand name drugs shall not be
942 subject to any deductible or co-insurance and any co-payment shall not exceed \$25 per 30-day
943 supply.

944 Notwithstanding this section or any other general or special law to the contrary, coverage
945 for insulin shall be provided under section 4S of this chapter.

946 SECTION 55. Section 4H of chapter 176G of the General Laws, as so appearing, is
947 hereby amended by adding the following paragraph:-

948 Coverage for insulin under this section shall not be subject to any deductible or co-
949 insurance and any co-payment shall not exceed \$25 per 30-day supply, regardless of the amount
950 or type of insulin needed to fill an insured's insulin prescription; provided, however, that nothing
951 in this section shall prevent any individual or group health maintenance contract that is issued or
952 renewed within or without the commonwealth, from reducing the co-payment for insulin for a
953 30-day supply below the amount specified in this section.

954 SECTION 56. Said chapter 176G, as so appearing, is hereby further amended by
955 inserting after section 4GG the following new section:-

956 Section 4HH. Any carrier offering a policy, contract or certificate of health insurance
957 under this chapter shall provide coverage for the brand name drugs and generic drugs identified
958 by the drug access program established in section 16DD in chapter 6A. Coverage for identified

959 generic drugs shall not be subject to any cost-sharing, including co-payments and co-insurance,
960 and shall not be subject to any deductible. Coverage for identified brand name drugs shall not be
961 subject to any deductible or co-insurance and any co-payment shall not exceed \$25 per 30-day
962 supply.

963 Notwithstanding this section or any other general or special law to the contrary, coverage
964 for insulin shall be provided under section 4H of this chapter.

965 SECTION 57. Section 2 of chapter 176O of the General Laws, as so appearing, is hereby
966 amended by adding the following subsection:-

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

971 SECTION 58. Said chapter 176O, as so appearing, is hereby further amended by
972 inserting after section 22 the following section:-

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

976 SECTION 59. Said chapter 176O as so appearing, is hereby further amended by adding
977 the following section:-

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

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

982 “Pharmacy retail price”, the amount an individual would pay for a prescription
983 medication at a pharmacy if the individual purchased that prescription medication at that
984 pharmacy without using a health benefit plan or any other prescription medication benefit or
985 discount.

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

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

993 SECTION 60. The General Laws are hereby amended by inserting after chapter 176W
994 the following chapter:-

995 Chapter 176X. LICENSING AND REGULATION OF PHARMACY BENEFIT
996 MANAGERS.

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

999 “Carrier”, an insurer licensed or otherwise authorized to transact accident or health
1000 insurance under chapter 175, a nonprofit hospital service corporation organized under chapter

1001 176A, a non-profit medical service corporation organized under chapter 176B, a health
1002 maintenance organization organized under chapter 176G and an organization entering into a
1003 preferred provider arrangement under chapter 176I; provided, however, that the term “carrier”
1004 shall not include an employer purchasing coverage or acting on behalf of its employees or the
1005 employees of any subsidiary or affiliated corporation of the employer; provided further, that
1006 unless otherwise provided, the term “carrier” shall not include any entity to the extent it offers a
1007 policy, certificate or contract that provides coverage solely for dental care services or vision care
1008 services.

1009 “Center”, the center for health information and analysis established in chapter 12C.

1010 “Commissioner”, the commissioner of insurance.

1011 “Division”, the division of insurance.

1012 “Health benefit plan”, a contract, certificate or agreement entered into, offered or issued
1013 by a carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care
1014 services; provided, however, that the commissioner may by regulation define other health
1015 coverage as a “health benefit plan” for the purposes of this chapter.

1016 “Pharmacy”, a physical or electronic facility under the direction or supervision of a
1017 registered pharmacist that is authorized to dispense prescription drugs and has entered into a
1018 network contract with a pharmacy benefit manager or a carrier.

1019 “Pharmacy benefit manager”, a person, business or other entity, however organized, that
1020 directly or through a subsidiary provides pharmacy benefit management services for prescription
1021 drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-

1022 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
1023 management services shall include, but not be limited to: (i) the processing and payment of
1024 claims for prescription drugs; (ii) the performance of drug utilization review; (iii) the processing
1025 of drug prior authorization requests; (iv) pharmacy contracting; (v) the adjudication of appeals or
1026 grievances related to prescription drug coverage contracts; (vi) formulary administration; (vii)
1027 drug benefit design; (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x)
1028 clinical, safety and adherence programs for pharmacy services; and (xi) managing the cost of
1029 covered prescription drugs; provided further, that “pharmacy benefit manager” shall not include
1030 a health benefit plan unless otherwise specified by the division.

1031 Section 2. (a) A person, business or other entity shall not establish or operate as a
1032 pharmacy benefit manager without obtaining a license from the division pursuant to this section.
1033 The division shall issue a pharmacy benefit manager license to a person, business or other entity
1034 that demonstrates to the division that it has the necessary organization, background expertise and
1035 financial integrity to maintain such a license. A pharmacy benefit manager license shall be valid
1036 for a period of 3 years and shall be renewable for additional 3-year periods. Initial application
1037 and renewal fees for the license shall be established pursuant to section 3B of chapter 7.

1038 (b) A license granted pursuant to this section and any rights or interests therein shall not
1039 be transferable.

1040 (c) A person, business or other entity licensed as a pharmacy benefit manager shall
1041 submit data and reporting information to the center according to the standards and methods
1042 specified by the center pursuant to section 10A of chapter 12C.

1043 (d) The division may issue or renew a license pursuant to this section, subject to
1044 restrictions in order to protect the interests of consumers. Such restrictions may include: (i)
1045 limiting the type of services that a license holder may provide; (ii) limiting the activities in which
1046 the license holder may be engaged; or (iii) addressing conflicts of interest between pharmacy
1047 benefit managers and health plan sponsors.

1048 (e) The division shall develop an application for licensure of pharmacy benefit managers
1049 that shall include, but not be limited to: (i) the name of the applicant or pharmacy benefit
1050 manager; (ii) the address and contact telephone number for the applicant or pharmacy benefit
1051 manager; (iii) the name and address of the agent of the applicant or pharmacy benefit manager
1052 for service of process in the commonwealth; (iv) the name and address of any person with
1053 management or control over the applicant or pharmacy benefit manager; and (v) any audited
1054 financial statements specific to the applicant or pharmacy benefit manager. An applicant or
1055 pharmacy benefit manager shall report to the division any material change to the information
1056 contained in its application, certified by an officer of the pharmacy benefit manager, within 30
1057 days of such a change.

1058 (f) The division may suspend, revoke, refuse to issue or renew or place on probation a
1059 pharmacy benefit manager license for cause, which shall include, but not be limited to: (i) the
1060 applicant or pharmacy benefit manager engaging in fraudulent activity that is found by a court of
1061 law to be a violation of state or federal law; (ii) the division receiving consumer complaints that
1062 justify an action under this chapter to protect the health, safety and interests of consumers; (iii)
1063 the applicant or pharmacy benefit manager failing to pay an application or renewal fee for a
1064 license; (iv) the applicant or pharmacy benefit manager failing to comply with reporting

1065 requirements of the center under section 10A of chapter 12C; or (v) the applicant pharmacy
1066 benefit manager's failing to comply with a requirement of this chapter.

1067 The division shall provide written notice to the applicant or pharmacy benefit manager
1068 and advise in writing of the reason for any suspension, revocation, refusal to issue or renew or
1069 placement on probation of a pharmacy benefit manager license under this chapter. A copy of the
1070 notice shall be forwarded to the center. The applicant or pharmacy benefit manager may make
1071 written demand upon the division within 30 days of receipt of such notification for a hearing
1072 before the division to determine the reasonableness of the division's action. The hearing shall be
1073 held pursuant to chapter 30A.

1074 The division shall not suspend or cancel a license unless the division has first afforded
1075 the pharmacy benefit manager an opportunity for a hearing pursuant to said chapter 30A.

1076 (g) If a person, business or other entity performs the functions of a pharmacy benefit
1077 manager in violation of this chapter, the person, business or other entity shall be subject to a fine
1078 of \$5,000 per day for each day that the person, business or other entity is found to be in violation.
1079 Penalties collected under this subsection shall be deposited into the Prescription Drug Cost
1080 Assistance Trust Fund established in section 2RRRRR of chapter 29.

1081 (h) A pharmacy benefit manager licensed under this section shall notify a health carrier
1082 client in writing of any activity, policy, practice contract or arrangement of the pharmacy benefit
1083 manager that directly or indirectly presents any conflict of interest with the pharmacy benefit
1084 manager's relationship with or obligation to the health carrier client.

1085 (i) The division shall adopt any written policies, procedures or regulations that the
1086 division determines are necessary to implement this section.

1087 Section 3. (a) The commissioner may make an examination of the affairs of a pharmacy
1088 benefit manager when the commissioner deems prudent but not less frequently than once every 3
1089 years. The focus of the examination shall be to ensure that a pharmacy benefit manager is able to
1090 meet its responsibilities under contracts with carriers licensed under chapters 175, 176A, 176B,
1091 or 176G. The examination shall be conducted according to the procedures set forth in paragraph
1092 (6) of section 4 of chapter 175.

1093 (b) The commissioner, a deputy or an examiner may conduct an on-site examination of
1094 each pharmacy benefit manager in the commonwealth to thoroughly inspect and examine its
1095 affairs.

1096 (c) The charge for each such examination shall be determined annually according to the
1097 procedures set forth in paragraph (6) of section 4 of chapter 175.

1098 (d) Not later than 60 days following completion of the examination, the examiner in
1099 charge shall file with the commissioner a verified written report of examination under oath.
1100 Upon receipt of the verified report, the commissioner shall transmit the report to the pharmacy
1101 benefit manager examined with a notice that shall afford the pharmacy benefit manager
1102 examined a reasonable opportunity of not more than 30 days to make a written submission or
1103 rebuttal with respect to any matters contained in the examination report. Within 30 days of the
1104 end of the period allowed for the receipt of written submissions or rebuttals, the commissioner
1105 shall consider and review the reports together with any written submissions or rebuttals and any
1106 relevant portions of the examiner's work papers and enter an order:

1107 (i) adopting the examination report as filed with modifications or corrections and, if the
1108 examination report reveals that the pharmacy benefit manager is operating in violation of this

1109 section or any regulation or prior order of the commissioner, the commissioner may order the
1110 pharmacy benefit manager to take any action the commissioner considered necessary and
1111 appropriate to cure such violation;

1112 (ii) rejecting the examination report with directions to examiners to reopen the
1113 examination for the purposes of obtaining additional data, documentation or information and re-
1114 filing pursuant to the above provisions; or

1115 (iii) calling for an investigatory hearing with not less than 20 days' notice to the
1116 pharmacy benefit manager for purposes of obtaining additional documentation, data, information
1117 and testimony.

1118 (e) Notwithstanding any general or special law to the contrary, including clause Twenty-
1119 sixth of section 7 of chapter 4 and chapter 66, the records of any such audit, examination or other
1120 inspection and the information contained in the records, reports or books of any pharmacy
1121 benefit manager examined pursuant to this section shall be confidential and open only to the
1122 inspection of the commissioner, or the examiners and assistants. Access to such confidential
1123 material may be granted by the commissioner to law enforcement officials of the commonwealth
1124 or any other state or agency of the federal government at any time if the agency or office
1125 receiving the information agrees in writing to keep such material confidential. Nothing in this
1126 subsection shall be construed to prohibit the required production of such records, and
1127 information contained in the reports of such company or organization before any court of the
1128 commonwealth or any master or auditor appointed by any such court, in any criminal or civil
1129 proceeding, affecting such pharmacy benefit manager, its officers, partners, directors or

1130 employees. The final report of any such audit, examination or any other inspection by or on
1131 behalf of the division of insurance shall be a public record.

1132 SECTION 61. Notwithstanding any general or special law to the contrary, the health
1133 policy commission, in consultation with the center for health information and analysis, the
1134 executive office of health and human services and the division of insurance, shall produce
1135 interim and final reports on the use of insulin in the commonwealth and the effects of capping
1136 copayments and eliminating deductible and co-insurance requirements for insulin for individuals
1137 with diabetes on health care access and system cost.

1138 The interim and final report shall include, but not be limited to: (i) rates of insulin
1139 utilization; (ii) an analysis of the use of insulin, broken down by patient demographics,
1140 geographic region and insulin delivery device; (iii) annual plan costs and member premiums; (iv)
1141 the average price of insulin; (v) the average insulin price net of rebates or discounts received by
1142 or accrued directly or indirectly by health insurance carriers; (vi) average and total out-of-pocket
1143 expenditures on insulin delivery devices and glucose monitoring tests that are not included as
1144 part of an insulin prescription; (vii) an analysis of the impact of capping co-payments and
1145 eliminating deductible and co-insurance requirements for insulin on patient access to and cost of
1146 care by patient demographics and geographic region; (viii) additional funding sources for the
1147 Prescription Drug Cost Assistance Trust Fund established in section 2RRRRR of chapter 29 of
1148 the General Laws; and (ix) any barriers to accessing insulin for individuals with diabetes and
1149 policy recommendations for resolving such barriers. The interim report, including any
1150 recommendations for expanding access to insulin for individuals with diabetes, shall be filed
1151 with the clerks of the house of representatives and senate, the joint committee on public health,
1152 the joint committee on health care financing and the house and senate committees on ways and

1153 means not later than 18 months after the effective date of this act. The final report, including any
1154 recommendations for expanding access to insulin for individuals with diabetes, shall be filed
1155 with the clerks of the house of representatives and senate, the joint committee on public health,
1156 the joint committee on health care financing and the house and senate committees on ways and
1157 means not later than 3 years after the effective date of this act.

1158 SECTION 62. (a) Notwithstanding any general or special law to the contrary, the
1159 commonwealth health insurance connector authority, in consultation with the division of
1160 insurance, shall report on the impact of pharmaceutical pricing on health care costs and outcomes
1161 for ConnectorCare and non-group and small group plans offered through the connector and its
1162 members.

1163 The report shall include, but not be limited to: (i) information on the differential between
1164 medication list price and price net of rebates for plans offered and the impact of those
1165 differentials on member premiums; (ii) the relationship between medication list price and
1166 member cost-sharing requirements; (iii) the impact of medication price changes over time on
1167 premium and out-of-pocket costs in plans authorized under section 3 of chapter 176J of the
1168 General Laws offered through the commonwealth health insurance connector authority; (iv)
1169 trends in changes in medication list price and price net of rebates by health plan; (v) an analysis
1170 of the impact of member out-of-pocket costs on medication utilization and member experience;
1171 and (vi) an analysis of the impact of medication list price and price net of rebates on member
1172 formulary access to medications. Data collected under this subsection shall be protected as
1173 confidential and shall not be a public record under clause Twenty-sixth of section 7 of chapter 4
1174 or under chapter 66 of the General Laws.

1175 The report shall be submitted to the joint committee on health care financing and the
1176 house and senate committees on ways and means not later than July 1, 2025.

1177 (b) In fiscal year 2024, the amount required to be paid pursuant to the last paragraph of
1178 section 6 of chapter 6D of the General Laws shall be increased by \$500,000; provided, however,
1179 that said \$500,000 shall be provided to the commonwealth health insurance connector authority
1180 not later than October 14, 2023 for data collection and analysis costs associated with the report
1181 required by this section.

1182 SECTION 63. Notwithstanding any general or special law to the contrary, there shall be a
1183 special commission to examine the feasibility of: (i) establishing a system for the bulk
1184 purchasing and distribution of pharmaceutical products with a significant public health benefit
1185 and the potential for significant health care cost savings for consumers through overall increased
1186 purchase capacity; and (ii) making bulk purchase pricing information available to purchasers in
1187 other states.

1188 The commission shall consist of: the commissioner of public health or a designee, who
1189 shall serve as chair; the executive director of the group insurance commission or a designee; the
1190 chief of pharmacy of the state office for pharmacy services; the MassHealth director of
1191 pharmacy; the secretary of technology services and security; and 9 members to be appointed by
1192 the commissioner of public health, 2 of whom shall be health care economists, 1 of whom shall
1193 be an expert in health law and policy innovation, 1 of whom shall be an academic with relevant
1194 expertise in the field, 1 of whom shall be a representative from a community health center, 1 of
1195 whom shall be the chief executive officer of a hospital licensed in the commonwealth, 1 of
1196 whom shall be a representative of the Massachusetts Association of Health Plans, Inc., 1 of

1197 whom shall be a representative of Blue Cross Blue Shield of Massachusetts, Inc. and 1 of whom
1198 shall be a member of the public with experience with health care and consumer protection.

1199 The commission shall hold not less than 3 public hearings in different geographic areas of
1200 the commonwealth, accept input from the public and solicit expert testimony from individuals
1201 representing health insurance carriers, pharmaceutical companies, independent and chain
1202 pharmacies, hospitals, municipalities, health care practitioners, health care technology
1203 professionals, community health centers, substance abuse disorder providers, public health
1204 educational institutions and other experts identified by the commission.

1205 The commission shall consider: (i) the process by which the commonwealth could make
1206 bulk purchases of pharmaceutical products with a significant public health benefit and the
1207 potential for significant health care cost savings to consumers; (ii) the process by which both
1208 governmental and nongovernmental entities may participate in a collaborative to purchase
1209 pharmaceutical products with a significant public health benefit and the potential for significant
1210 health care cost savings; (iii) the feasibility of developing an electronic information interchange
1211 system to exchange bulk purchase price information with partnering states; (iv) potential sources
1212 of funding available to implement bulk purchases; (v) potential cost savings of bulk purchases to
1213 the commonwealth or other participating nongovernmental entities; (vi) the feasibility of
1214 partnering with the federal government and or other states in the New England region; and (vii)
1215 any other factors that the commission deems relevant.

1216 The commission shall file a report of its analysis, along with any recommended
1217 legislation, if any, to the clerks of the senate and house of representatives, the house and senate
1218 committees on ways and means, the joint committee on health care financing, the joint

1219 committee on public health, the joint committee on elder affairs and the joint committee on
1220 mental health, substance abuse and recovery not later than September 1, 2024.

1221 SECTION 64. (a) As used in this section, the following words shall have the following
1222 meanings, unless the context clearly requires otherwise:

1223 “Chain pharmacist”, a pharmacist employed by a retail drug organization operating not
1224 less than 10 retail drug stores within the commonwealth under section 39 of chapter 112 of the
1225 General Laws.

1226 “Independent pharmacist”, a pharmacist actively engaged in the business of retail
1227 pharmacy and employed in an organization of not more than 9 registered retail drugstores in the
1228 commonwealth under said section 39 of said chapter 112 that employs not more than a total of
1229 20 full-time pharmacists.

1230 (b) There shall be a task force to: (i) review the drug supply chain including, but not
1231 limited to: (A) plan and pharmacy benefit manager reimbursements to pharmacies; (B)
1232 wholesaler or pharmacy service administrative organization prices to pharmacies; and (C) drug
1233 manufacturer prices to pharmacies; (ii) review ways to recognize the unique challenges of small
1234 and independent pharmacies; (iii) identify methods to increase pricing transparency throughout
1235 the supply chain; (iv) make recommendations on the use of multiple maximum allowable costs
1236 lists and their frequency of use for mail order products; (v) review the utilization of maximum
1237 allowable costs lists or similar reimbursement structures established by a pharmacy benefit
1238 manager or payer; (vi) review the availability of drugs to independent and chain pharmacies on
1239 the maximum allowable cost list or any similar reimbursement structures established by a
1240 pharmacy benefit manager or payer; (vii) review the pharmacy acquisition cost from national or

1241 regional wholesalers that serve pharmacies compared to the reimbursement amount provided
1242 through a maximum allowable cost list or any similar reimbursement structures established by a
1243 pharmacy benefit manager or payer and the conditions under which an adjustment to a
1244 reimbursement is appropriate; (viii) review the timing of pharmacy purchases of products and the
1245 relative risk of list price changes related to the timing of dispensing the products; (ix) assess
1246 ways to increase transparency for chain and independent pharmacists to understand the
1247 methodology used by a pharmacy benefit manager or payer to develop a maximum allowable
1248 cost list or any similar reimbursement structure established by the pharmacy benefit manager or
1249 payer; (x) assess the prevalence and appropriateness of pharmacy benefit managers requiring, or
1250 using financial incentives or penalties to incentivize, customer use of pharmacies with whom the
1251 pharmacy benefit manager has an ownership or financial interest; (xi) examine the impact of the
1252 merger or consolidation of pharmacy benefit managers and health carrier clients on drug costs;
1253 (xii) review current appeals processes for a chain or independent pharmacist to request an
1254 adjustment on a reimbursement subject to a maximum allowable cost list or any similar
1255 reimbursement structure established by a pharmacy benefit manager or payer; and (xiii) evaluate
1256 the effect of differences between pharmacy benefit manager payments to pharmacies and charges
1257 made to health carrier clients on drug price.

1258 (c) The task force shall consist of: the commissioner of insurance or a designee, who shall
1259 serve as chair; and 6 members to be appointed by the commissioner, 2 of whom shall be
1260 independent pharmacists employed in the independent pharmacy setting or representatives of
1261 independent pharmacies, 2 of whom shall be chain pharmacists employed in the chain pharmacy
1262 setting or representatives of chain pharmacies and 2 of whom shall be representatives of a
1263 pharmacy benefit managers or payers who manage their own pharmacy benefit services. If more

1264 than 1 independent pharmacist is appointed, each appointee shall represent a distinct practice
1265 setting. If more than 1 chain pharmacist is appointed, each appointee shall represent a distinct
1266 practice setting. A pharmacy benefit manager or payer appointed to the task force shall not be
1267 co-owned or have any ownership relationship with any other payer, pharmacy benefit manager or
1268 chain pharmacist also appointed to the task force.

1269 (d) The commissioner shall file the task force's findings with the clerks of the house of
1270 representatives and the senate, the joint committee on health care financing and the house and
1271 senate committees on ways and means not later than December 1, 2024.

1272 SECTION 65. The health policy commission shall consult with relevant stakeholders,
1273 including, but not limited to, consumers, consumer advocacy organizations, organizations
1274 representing people with disabilities and chronic health conditions, providers, provider
1275 organizations, payers, pharmaceutical manufacturers, pharmacy benefit managers and health care
1276 economists and other academics, to assist in the development and periodic review of regulations
1277 to implement section 20 of chapter 6D of the General Laws, including, but not limited to: (i)
1278 establishing the criteria and processes for identifying the proposed value of an eligible drug as
1279 defined in said section 20 of said chapter 6D; and (ii) determining the appropriate price increase
1280 for a public health essential drug as described within the definition of eligible drug in said
1281 section 20 of said chapter 6D.

1282 The commission shall hold its first public outreach not more than 45 days after the
1283 effective date of this act and shall, to the extent possible, ensure fair representation and input
1284 from a diverse array of stakeholders.

1285 SECTION 66. Notwithstanding subsection (b) of section 15A of chapter 6D of the
1286 General Laws, for the purposes of providing early notice under said section 15A of said chapter
1287 6D, the health policy commission shall determine a significant price increase for a generic drug
1288 to be defined as a generic drug priced at \$100 or more per wholesale acquisition cost unit that
1289 increases in cost by 100 per cent or more during any 12-month period.

1290 SECTION 67. Section 66 is hereby repealed.

1291 SECTION 68. The drug access program, established in section 16DD of chapter 6A of
1292 the General Laws, shall take effect not later than 1 year after the effective date of this act.

1293 SECTION 69. To implement chapter 63E of the General Laws, as inserted by section 44,
1294 the commissioner of revenue shall promulgate regulations or other guidance regarding the
1295 reporting and payment of the penalty as soon as practicable after the effective date of this act.

1296 SECTION 70. Chapter 63E of the General Laws, as inserted by section 44, shall apply to
1297 sales commencing on or after the effective date of this act.

1298 SECTION 71. Sections 22 and 40 shall take effect on July 1, 2024.

1299 SECTION 72. Sections 42, 46, 48, 51, 53 and 55 shall take effect January 1, 2024.

1300 SECTION 73. Section 58 shall take effect on July 1, 2024.

1301 SECTION 74. Section 60 shall take effect on March 30, 2024.

1302 SECTION 75. Section 67 shall take effect on January 1, 2025.