

SENATE No. 2499

The Commonwealth of Massachusetts

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

SENATE, November 9, 2023.

The committee on Senate Ways and Means to whom was referred the Senate Bill relative to pharmaceutical access, costs and transparency (Senate, No. 2492), - reports, recommending that the same ought to pass with an amendment substituting a new draft with the same title (Senate, No. 2499).

For the committee,
Michael J. Rodrigues

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An Act relative to pharmaceutical access, costs and transparency.

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

1 SECTION 1. Section 1 of chapter 6D of the General Laws, as appearing in the 2022
2 Official Edition, is hereby amended by inserting after the definition of “Alternative payment
3 methodologies or methods” the following 2 definitions:-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

80 records and shall be exempt from disclosure under clause Twenty-sixth of section 7 of chapter 4
81 or under chapter 66.

82 SECTION 9. Section 4 of said chapter 6D, as so appearing, is hereby amended by
83 striking out, in line 8, the word “manufacturers” and inserting in place thereof the following
84 words:- manufacturing companies, pharmacy benefit managers.

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

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

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

93 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
94 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
95 appropriated by the general court for the expenses of the commission minus amounts collected
96 from: (i) filing fees; (ii) fees and charges generated by the commission's publication or
97 dissemination of reports and information; and (iii) federal matching revenues received for these
98 expenses or received retroactively for expenses of predecessor agencies. A pharmacy benefit
99 manager that is a surcharge payor subject to the preceding paragraph and manages its own
100 prescription drug benefits shall not be subject to additional assessment under this paragraph.

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

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

107 SECTION 15. Said section 8 of said chapter 6D, as so appearing, is hereby further
108 amended by striking out, in line 33, the words “and (xi)” and inserting in place thereof the
109 following words:- (xi) not less than 3 representatives of the pharmaceutical industry; (xii) at least
110 1 representative of the pharmacy benefit management industry; and (xiii).

111 SECTION 16. Said section 8 of said chapter 6D, as so appearing, is hereby further
112 amended by striking out, in line 49, the first time it appears, the word:- and.

113 SECTION 17. Said section 8 of said chapter 6D, as so appearing, is hereby further
114 amended by inserting after the word “commission”, in line 60, the first time it appears, the
115 following words:- ; and (iii) in the case of pharmacy benefit managers and pharmaceutical
116 manufacturing companies, testimony concerning factors underlying prescription drug costs and
117 price increases including, but not limited to, the initial prices of drugs coming to market and
118 subsequent price increases, changes in industry profit levels, marketing expenses, reverse
119 payment patent settlements, the impact of manufacturer rebates, discounts and other price
120 concessions on net pricing, the availability of alternative drugs or treatments, corporate
121 ownership organizational structure and any other matters as determined by the commission.

122 SECTION 18. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is
123 hereby amended by striking out the second sentence and inserting in place thereof the following
124 2 sentences:- The report shall be based on the commission’s analysis of information provided at
125 the hearings by witnesses, providers, provider organizations, payers, pharmaceutical
126 manufacturing companies and pharmacy benefit managers, registration data collected under
127 section 11, data collected or analyzed by the center under sections 8, 9, 10 and 10A of chapter
128 12C and any other available information that the commission considers necessary to fulfill its
129 duties under this section as defined in regulations promulgated by the commission. To the extent
130 practicable, the report shall not contain any data that is likely to compromise the financial,
131 competitive or proprietary nature of the information.

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

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

137 Section 15A. (a) A pharmaceutical manufacturing company shall provide early notice to
138 the commission in a manner described in this section for a: (i) pipeline drug; (ii) generic drug; or
139 (iii) biosimilar drug. The commission shall provide nonconfidential information received under
140 this section to the office of Medicaid, the division of insurance and the group insurance
141 commission.

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

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

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

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

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

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

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

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

176 (d) If a pharmaceutical manufacturing company fails to timely comply with the
177 requirements under subsection (a) or subsection (b), or otherwise knowingly obstructs the
178 commission's ability to receive early notice under this section, including, but not limited to,
179 providing incomplete, false or misleading information, the commission may impose appropriate
180 sanctions against the manufacturer, including reasonable monetary penalties not to exceed
181 \$500,000, in each instance. The commission shall seek to promote compliance with this section
182 and shall only impose a civil penalty on the manufacturer as a last resort. Amounts collected
183 under this section shall be deposited into the Prescription Drug Cost Assistance Trust Fund
184 established in section 2BBBBBB of chapter 29.

185 SECTION 21. Said chapter 6D is hereby further amended by adding the following 3
186 sections:-

187 Section 21. (a) As used in this section, the following words shall have the following
188 meanings unless the context clearly requires otherwise:

189 “Eligible drug”, (i) a brand name drug or biologic, not including a biosimilar, that has a
190 launch wholesale acquisition cost of \$50,000 or more for a 1-year supply or full course of
191 treatment; (ii) a biosimilar drug that has a launch wholesale acquisition cost that is not at least 15
192 per cent lower than the referenced brand biologic at the time the biosimilar is launched; (iii) a
193 public health essential drug, as defined in subsection (f) of section 13 of chapter 17, with a
194 significant price increase over a defined period of time as determined by the commission by
195 regulation or with a wholesale acquisition cost of \$25,000 or more for a 1-year supply or full
196 course of treatment; (iv) all drugs selected pursuant to section 17T of chapter 32A, section 10R
197 of chapter 118E, section 47UU of chapter 175, section 8VV of chapter 176A, section 4VV of
198 chapter 176B and section 4NN of chapter 176G; or (v) other prescription drug products that may
199 have a direct and significant impact and create affordability challenges for the state’s health care
200 system and patients, as determined by the commission; provided, however, that the commission
201 shall promulgate regulations to establish the type of prescription drug products classified under
202 clause (v) prior to classification of any such prescription drug product under said clause (v).

203 “Manufacturer”, a pharmaceutical manufacturer of an eligible drug, or, when applicable,
204 the manufacturer of a delivery device selected pursuant to section 17T of chapter 32A, section
205 10R of chapter 118E, section 47UU of chapter 175, section 8VV of chapter 176A, section 4VV
206 of chapter 176B and section 4NN of chapter 176G.

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

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

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

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

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

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

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

227 (c) Based on the records provided under subsection (b) and available information from
228 the center for health information and analysis or an outside third party, the commission shall
229 identify a proposed value for the eligible drug. The commission may request additional relevant

230 information that it deems necessary from the manufacturer and from other entities, including, but
231 not limited to, pharmacy benefit managers.

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

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

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

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

268 (f) Not later than 60 days after receiving information from the manufacturer under
269 subsection (b) or subsection (e), the commission shall confidentially issue a determination on
270 whether the manufacturer's pricing of an eligible drug substantially exceeds the commission's
271 proposed value of the drug. If the commission determines that the manufacturer's pricing of an
272 eligible drug substantially exceeds the proposed value of the drug, the commission shall
273 confidentially notify the manufacturer, in writing, of its determination and may require the
274 manufacturer to enter into an access and affordability improvement plan under section 22.

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

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

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

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

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

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

302 Section 22. (a) The commission shall establish procedures to assist manufacturers in
303 filing and implementing an access and affordability improvement plan.

304 Upon providing written notice provided under subsection (f) of section 21, the
305 commission may require that a manufacturer whose pricing of an eligible drug substantially
306 exceeds the commission's proposed value of the drug file an access and affordability
307 improvement plan with the commission. Not later than 45 days after receipt of a notice under
308 said subsection (f) of said section 21, a manufacturer shall: (i) file an access and affordability
309 improvement plan; or (ii) provide written notice declining participation in the access and
310 affordability improvement plan.

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

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

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

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

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

340 improvement plan, the manufacturer may file amendments to the access improvement plan,
341 subject to approval of the commission.

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

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

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

356 (j) The commission may assess a civil penalty to a manufacturer of not more than
357 \$500,000, in each instance, if the commission determines that the manufacturer: (i) declined or
358 willfully neglected to file an access and affordability improvement plan with the commission
359 under subsection (a); (ii) failed to file an acceptable access and affordability improvement plan in
360 good faith with the commission; (iii) failed to implement the access and affordability
361 improvement plan in good faith; or (iv) knowingly failed to provide information required by this

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

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

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

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

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

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

394 Section 23. Every 2 years, the commission, in consultation with the center for health
395 information and analysis, the group insurance commission, the office of Medicaid and the
396 division of insurance shall evaluate the impact of section 17T of chapter 32A, section 10R of
397 chapter 118E, section 47UU of chapter 175, section 8VV of chapter 176A, section 4VV of
398 chapter 176B and section 4NN of chapter 176G on the effects of capping co-payments and
399 eliminating deductible and co-insurance requirements for those drugs for individuals with
400 diabetes, asthma and chronic heart conditions on health care access and system cost, including,
401 but not limited to: (i) utilization rates of the drugs selected pursuant to section 10R of chapter
402 118E, section 47UU of chapter 175, section 8VV of chapter 176A, section 4VV of chapter 176B
403 and section 4NN of chapter 176G; (ii) an analysis of the use of those drugs, broken down by
404 patient demographics, geographic region and, where applicable, delivery device; (iii) annual plan
405 costs and member premiums; (iv) the average price of those drugs; (v) the average price of those

406 drugs net of rebates or discounts received by or accrued directly or indirectly by health insurance
407 carriers; (vi) average and total out-of-pocket expenditures on delivery devices used for those
408 drugs and glucose monitoring tests that are not included as part of the underlying drug
409 prescription; (vii) an analysis of the impact of capping co-payments and eliminating deductible
410 and co-insurance requirements for those drugs on patient access to and cost of care by patient
411 demographics and geographic region; and (viii); any barriers to accessing those drugs for
412 individuals with the conditions for which those drugs are prescribed and policy recommendations
413 for resolving such barriers.

414 Biennially, not later than November 30, the commission shall file a report of its findings
415 with the clerks of the house of representatives and senate, the chairs of the joint committee on
416 public health, the chairs of the joint committee on health care financing and the chairs of house
417 and senate committees on ways and means.

418 SECTION 22. Section 1 of chapter 12C of the General Laws, as appearing in the 2022
419 Official Edition, is hereby amended by inserting after the definition of “Ambulatory surgical
420 center services” the following 3 definitions:-

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

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

426 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
427 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an

428 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
429 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
430 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
431 application that was approved by the United States Secretary of Health and Human Services
432 under section 505(c) of the federal Food, Drug and Cosmetic Act, 21 U.S.C. 355(c), before the
433 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
434 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
435 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
436 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the carrier as a brand name drug based on
437 available data resources such as Medi-Span.

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

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

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

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

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

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

472 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
473 1395w-3a(c)(6)(B).

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

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

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

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

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

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

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

499 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
500 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
501 appropriated by the general court for the expenses of the center minus amounts collected from:
502 (i) filing fees; (ii) fees and charges generated by the commission's publication or dissemination
503 of reports and information; and (iii) federal matching revenues received for these expenses or
504 received retroactively for expenses of predecessor agencies. A pharmacy benefit manager that is
505 also a surcharge payor subject to the preceding paragraph and manages its own prescription drug
506 benefits shall not be subject to additional assessment under this paragraph.

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

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

516 health carrier client, health plan sponsor or pharmacy in connection with utilization of the
517 pharmaceutical drug products offered by the pharmaceutical manufacturing company; (v)
518 discounts provided by a pharmaceutical manufacturing company to a consumer in connection
519 with utilization of the pharmaceutical drug products offered by the pharmaceutical
520 manufacturing company, including any discount, rebate, product voucher, coupon or other
521 reduction in a consumer's out-of-pocket expenses including co-payments and deductibles under
522 section 3 of chapter 175H; (vi) research and development costs as a percentage of revenue; (vii)
523 annual marketing and advertising costs, identifying costs for direct-to-consumer advertising;
524 (viii) annual profits over the most recent 5-year period; (ix) disparities between prices charged to
525 purchasers in the commonwealth and purchasers outside of the United States; and (x) any other
526 information deemed necessary by the center.

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

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

540 (b) The center shall promulgate regulations necessary to ensure the uniform reporting of
541 information from pharmacy benefit managers to enable the center to analyze: (i) trends in
542 estimated aggregate drug rebates and other drug price reductions, if any, provided by a pharmacy
543 benefit manager to a health carrier client or health plan sponsor or passed through from a
544 pharmacy benefit manager to a health carrier client or health plan sponsor in connection with
545 utilization of drugs in the commonwealth offered through the pharmacy benefit manager and a
546 measure of lives covered by each health carrier client or health plan sponsor in the
547 commonwealth; (ii) pharmacy benefit manager practices with regard to drug rebates and other
548 drug price reductions, if any, provided by a pharmacy benefit manager to a health carrier client
549 or health plan sponsor or to consumers in the commonwealth or passed through from a pharmacy
550 benefit manager to a health carrier client or health plan sponsor or to consumers in the
551 commonwealth; and (iii) any other information deemed necessary by the center.

552 The center shall require the submission of available data and other information from
553 pharmacy benefit managers including, but not limited to: (i) true net typical prices paid by
554 pharmacy benefits managers for prescription drug products identified by the center, net of any
555 rebate or other payments from the manufacturer to the pharmacy benefit manager and from the
556 pharmacy benefit manager to the manufacturer; (ii) the amount of all rebates that the pharmacy
557 benefit manager received from all pharmaceutical manufacturing companies for all health carrier
558 clients in the aggregate and for each health carrier client or health plan sponsor individually,
559 attributable to patient utilization in the commonwealth; (iii) the administrative fees that the
560 pharmacy benefit manager received from all health carrier clients or health plan sponsors in the

561 aggregate and for each health carrier client or health plans sponsors individually; (iv) the
562 aggregate amount of rebates a pharmacy benefit manager: (A) retains based on its contractual
563 arrangement with each health plan client or health plan sponsor individually; and (B) passes
564 through to each health care client individually; (v) the aggregate amount of all retained rebates
565 that the pharmacy benefit manager received from all pharmaceutical manufacturing companies
566 and did not pass through to each pharmacy benefit manager's health carrier client or health plan
567 sponsor individually; (vi) the percentage of contracts that a pharmacy benefit manager holds
568 where the pharmacy benefit manager: (A) retains all rebates; (B) passes all rebates through to the
569 client; and (C) shares rebates with the client; and (vii) other information as determined by the
570 center, including, but not limited to, pharmacy benefit manager practices related to spread
571 pricing, administrative fees, claw backs and formulary placement.

572 (c) Except as specifically provided otherwise by the center or under this chapter, data
573 collected by the center pursuant to this section from pharmaceutical manufacturing companies
574 and pharmacy benefit managers shall not be a public record under clause Twenty-sixth of section
575 7 of chapter 4 or under chapter 66.

576 SECTION 34. Said chapter 12C is hereby further amended by striking out section 11, as
577 appearing in the 2022 Official Edition, and inserting in place thereof the following section:-

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

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

593 SECTION 35. Section 12 of said chapter 12C, as so appearing, is hereby amended by
594 striking out, in line 2, the words “and 10” and inserting in place thereof the following words:- ,
595 10 and 10A.

596 SECTION 36. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby
597 amended by striking out the first sentence and inserting in place thereof the following sentence:-
598 The center shall publish an annual report based on the information submitted under: (i) sections
599 8, 9, 10 and 10A concerning health care provider, provider organization, private and public
600 health care payer, pharmaceutical manufacturing company and pharmacy benefit manager costs
601 and cost and price trends; (ii) section 13 of chapter 6D relative to market power reviews; and (iii)
602 section 15 of said chapter 6D relative to quality data.

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

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

607 As part of its annual report, the center shall report on prescription drug utilization and
608 spending for pharmaceutical drugs provided in an outpatient setting or sold in a retail setting for
609 private and public health care payers, including, but not limited to, information sufficient to
610 show the: (i) highest utilization drugs; (ii) drugs with the greatest increases in utilization; (iii)
611 drugs that are most impactful on plan spending, net of rebates; and (iv) drugs with the highest
612 year-over-year price increases, net of rebates. The report shall not contain any data that is likely
613 to compromise the financial, competitive or proprietary nature of the information
614 contained in the report.

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

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

619 “Public health essential drug”, a prescription drug, biologic or biosimilar approved by the
620 United States Food and Drug Administration that: (i) appears on the Model List of Essential
621 Medicines most recently adopted by the World Health Organization; (ii) is selected pursuant to
622 section 17T of chapter 32A, section 10R of chapter 118E, section 47UU of chapter 175, section
623 8VV of chapter 176A, section 4VV of chapter 176B and section 4NN of chapter 176G; or (iii) is
624 deemed an essential medicine by the commission due to its efficacy in treating a life-threatening
625 health condition or a chronic health condition that substantially impairs an individual’s ability to
626 engage in activities of daily living or because limited access to a certain population would pose a

627 public health challenge. “Public health essential drug” shall also include all delivery devices
628 selected pursuant to section 17T of chapter 32A, section 10R of chapter 118E, section 47UU of
629 chapter 175, section 8VV of chapter 176A, section 4VV of chapter 176B and section 4NN of
630 chapter 176G.

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

636 SECTION 40. Chapter 29 of the General Laws is hereby amending by inserting after
637 section 2AAAAAA the following section:-

638 2BBBBBB. (a) There shall be a Prescription Drug Cost Assistance Trust Fund. The
639 secretary of health and human services shall administer the fund and shall make expenditures
640 from the fund, without further appropriation, to provide financial assistance to residents of the
641 commonwealth for the cost of prescription drugs through the prescription drug costs assistance
642 program established under section 245 of chapter 111. For the purpose of this section,
643 “prescription drug” shall include the prescription drug and any drug delivery device needed to
644 administer the drug that is not included as part of the underlying drug prescription.

645 The fund shall consist of: (i) revenue from appropriations or other money authorized by
646 the general court and specifically designated to be credited to the fund; and (ii) funds from public
647 or private sources, including, but not limited to, gifts, grants, donations, rebates and settlements
648 received by the commonwealth that are specifically designated to be credited to the fund. Money

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

651 (b) Annually, not later than March 1, the secretary shall report on the fund's activities
652 detailing expenditures from the previous calendar year. The report shall include: (i) the number
653 of individuals who received financial assistance from the fund; (ii) the breakdown of fund
654 recipients by race, gender, age range, geographic region and income level; (iii) a list of all
655 prescription drugs that were covered by money from the fund; and (iv) the total cost savings
656 received by all fund recipients and the cost savings broken down by race, gender, age range and
657 income level. The report shall be submitted to the clerks of the senate and house of
658 representatives, senate and house committees on ways and means and the joint committee on
659 health care financing.

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

662 SECTION 41. Chapter 32A of the General Laws is hereby amended by inserting after
663 section 17S the following section:-

664 Section 17T. (a) As used in this section, the following terms shall have the following
665 meanings, unless the context clearly requires otherwise:

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

671 application that was approved by the United States Secretary of Health and Human Services
672 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
673 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
674 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
675 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
676 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
677 based on available data resources such as Medi-Span.

678 “Delivery device”, a device that is used to deliver a brand name drug or generic drug and
679 that an individual can obtain with a prescription.

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

685 “Separate delivery device”, a device that is used to deliver a brand name drug or a
686 generic drug and that can be obtained with a prescription separate from, or in addition to, the
687 brand name drug or generic drug that the device delivers.

688 (b) The commission shall select 1 generic drug and 1 brand name drug used to treat each
689 of the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) heart conditions, including,
690 but not limited to, those heart conditions that disproportionately impact a particular demographic
691 group, including people of color.

692 The commission shall select insulin as the drug used to treat diabetes. In selecting 1
693 insulin brand name drug and 1 insulin generic drug as the drug used to treat diabetes, the
694 commission shall select 1 insulin brand name drug per dosage and type, including rapid-acting,
695 short-acting, intermediate-acting, long-acting, ultra long-acting and premixed. To the extent
696 possible, the commission shall select 1 generic insulin per dosage and type, including rapid-
697 acting, short-acting, intermediate-acting, long-acting, ultra long-acting and premixed, subject to
698 such generic drug's availability.

699 (c) In selecting the 1 generic drug, the 1 brand name drug and the delivery device, when
700 applicable, used to treat each chronic condition pursuant to subsection (b), the commission shall
701 select a drug that is among the top three of the commission's most prescribed or of the highest
702 volume for the chronic condition, and shall consider whether the drug is:

703 (i) of clear benefit and strongly supported by clinical evidence;

704 (ii) likely to reduce hospitalizations or emergency department visits, reduce future
705 exacerbations of illness progression or improve quality of life;

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

708 (iv) at low risk for overutilization, abuse, addiction, diversion or fraud;

709 (v) likely to have a considerable financial impact on individual patients by reducing or
710 eliminating patient cost-sharing pursuant to this section; and

711 (vi) likely to enhance equity in disproportionately impacted demographic groups,
712 including people of color.

713 (d) The commission shall provide coverage for the brand name drugs, generic drugs and
714 delivery devices selected pursuant to subsection (b). Coverage for the selected generic drugs
715 shall not be subject to any cost-sharing, including copayments and coinsurance, and shall not be
716 subject to any deductible. Coverage for selected brand name drugs shall not be subject to any
717 deductible or coinsurance and a copayment shall not exceed \$25 per 30-day supply; provided,
718 however, that nothing in this section shall prevent co-payments for a 30-day supply of the
719 selected brand name drugs from being reduced below the amount specified in this section.

720 (e) If use of a brand name drug or generic drug that the commission selects requires a
721 separate delivery device, the commission shall select a delivery device for that drug in
722 accordance with the factors established in subsection (c) for selecting brand name drugs and
723 generic drugs, to the extent possible. The commission shall provide coverage for the delivery
724 device and the delivery device shall not be subject to any cost-sharing, including co-payments
725 and co-insurance, and shall not be subject to any deductible.

726 (f) A member and their prescribing health care provider shall have access to a clear,
727 readily accessible and convenient process to request to use a different brand name drug or
728 generic drug of the same pharmacological class in place of a brand name drug or generic drug
729 selected under subsection (b). Such request for an exception shall be granted if: (i) the brand
730 name drugs and generic drugs selected under subsection (b) are contraindicated or will likely
731 cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name drugs
732 and generic drugs selected under subsection (b) are expected to be ineffective based on the
733 known clinical characteristics of the member and the known characteristics of the prescription
734 drug regimen; (iii) the member or prescribing health care provider: (A) has provided
735 documentation to the commission establishing that the member has previously tried the brand

736 name drugs and generic drugs selected under subsection (b), or another prescription drug in the
737 same pharmacologic class or with the same mechanism of action, while covered by the
738 commission or by a previous health insurance carrier or a health benefit plan; and (B) such
739 prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or
740 an adverse event; or (iv) the member or prescribing health care provider has provided
741 documentation to the commission establishing that the member: (A) is stable on a prescription
742 drug prescribed by the health care provider; and (B) switching drugs will likely cause an adverse
743 reaction in or physical or mental harm to the member. When applicable this subsection shall
744 apply to delivery devices.

745 (g) The commission shall implement a continuity of coverage to apply to members that
746 are new to the commission and that provides coverage for a 90-day fill of a United States Food
747 and Drug Administration-approved drug reimbursed through a pharmacy benefit that the member
748 has already been prescribed and on which the member is stable, upon documentation by the
749 member's prescriber; provided, however, that the commission shall not apply any greater
750 deductible, co-insurance, co-payments or out-of-pocket limits than would otherwise apply to
751 other drugs covered by the plan; and provided further, that the commission shall provide a
752 member or their prescribing health care provider with information regarding the request pursuant
753 to subsection (f) within 30 days of a member or their health care provider contacting the
754 commission to use a different brand name drug or generic drug of the same pharmacological
755 class as the drugs selected pursuant to subsection (b).

756 (h) Upon granting a request pursuant to subsection (f) or implementing a continuity of
757 coverage pursuant to subsection (g), the commission shall provide coverage for the prescription

758 drug or delivery device prescribed by the member's health care provider at the same cost as
759 required under subsection (d). A denial of an exception shall be eligible for appeal by a member.

760 (i) The commission shall grant or deny a request pursuant to subsection (f) and (g) not
761 more than 3 business days following the receipt of all necessary information to establish the
762 medical necessity of the prescribed treatment; provided, however, that if additional delay would
763 result in significant risk to the member's health or well-being, the commission shall respond not
764 more than 24 hours following the receipt of all necessary information to establish the medical
765 necessity of the prescribed treatment. If a response by the commission is not received within the
766 time required under this subsection, an exception shall be deemed granted.

767 (j) The commission shall make changes in selected drugs and delivery devices not more
768 than annually and shall provide notice to the health policy commission not less than 90 days
769 before making changes to the selected drugs and delivery devices and an explanation of such
770 changes. Upon verification by the health policy commission that the selected drugs meet the
771 criteria identified in subsection (c), the commission shall provide notice to its members not less
772 than 30 days before any changes to the selected drugs are made.

773 (k) The commission shall make public the drugs and delivery devices selected pursuant to
774 this section.

775 (l) If a high deductible health plan subject to this section is used to establish a savings
776 account that is tax-exempt under the federal Internal Revenue Code, the provisions in this section
777 shall apply to the plan to the maximum extent possible without causing the account to lose its
778 tax-exempt status.

779 SECTION 42. Chapter 111 of the General Laws is hereby amended by adding the
780 following section:-

781 Section 245. (a) The department shall establish and administer a prescription drug cost
782 assistance program, which shall be funded by the Prescription Drug Cost Assistance Trust Fund
783 established in section 2BBBBBB of chapter 29. The program shall provide financial assistance
784 for prescription drugs used to treat: (i) chronic respiratory conditions, including, but not limited
785 to, chronic obstructive pulmonary disease and asthma; (ii) chronic heart conditions, including,
786 but not limited to, those heart conditions that disproportionately impact a particular demographic
787 group, including people of color; (iii) diabetes; and (iv) any other chronic condition identified by
788 the department that disproportionately impacts a particular demographic group, including people
789 of color; provided, however, that “prescription drug” shall include the prescription drug and any
790 drug delivery device needed to administer the drug that is not included as part of the underlying
791 drug prescription. Financial assistance shall cover the cost of any copayment, coinsurance and
792 deductible for the prescription drug for an individual who is eligible for the program.

793 (b) An individual shall be eligible for the program if the individual: (i) is a resident of the
794 commonwealth; (ii) has a current prescription from a health care provider for a drug that is used
795 to treat a chronic condition listed in subsection (a); (iii) has a family income of not more than
796 500 per cent of the federal poverty level; and (iv) is not enrolled in MassHealth.

797 (c) The department shall create an application process, which shall be available
798 electronically and in hard copy form, to determine whether an individual meets the program
799 eligibility requirements under subsection (b). The department shall determine an applicant’s
800 eligibility and notify the applicant of the department’s determination within 10 business days of

801 receiving the application. If necessary for its determination, the department may request
802 additional information from the applicant; provided, however, that the department shall notify
803 the applicant within 5 business days of receipt of the original application as to what specific
804 additional information is being requested. If additional information is requested, the department
805 shall, within 3 business days of receipt of the additional information, determine the applicant's
806 eligibility and notify said applicant of the department's determination.

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

811 If the department determines that an applicant is eligible for the program, the department
812 shall provide the applicant with a prescription drug cost assistance program identification card,
813 which shall indicate the applicant's eligibility; provided, however, that the program identification
814 card shall include, but not be limited to, the applicant's full name and the full name of the
815 prescription drug that the applicant is eligible to receive under the program without having to pay
816 a co-payment, co-insurance or deductible. An applicant's program identification card shall be
817 valid for 12 months and shall be renewable upon a redetermination of program eligibility.

818 (d) An individual with a valid program identification card may present such card at any
819 pharmacy in the commonwealth and, upon presentation of such card, the pharmacy shall fill the
820 individual's prescription and provide the prescribed drug to the individual without requiring the
821 individual to pay a co-payment, co-insurance or deductible; provided, however, that the
822 pharmacy shall be reimbursed by the Prescription Drug Cost Assistance Trust Fund established

823 in section 2BBBBBB of chapter 29 in a manner determined by the department, in an amount
824 equal to what the pharmacy would have received had the individual been required to pay a co-
825 payment, co-insurance or deductible.

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

833 (f) The department shall compile a report detailing information about the program from
834 the previous calendar year. The report shall include: (i) the number of applications received,
835 approved, denied and appealed; (ii) the total number of applicants approved, and the number of
836 applicants approved broken down by race, gender, age range and income level; (iii) a list of all
837 prescription drugs that qualify for the program under subsection (b) and a list of prescription
838 drugs for which applicants actually received financial assistance; and (iv) the total cost savings
839 received by all approved applicants and the cost savings broken down by race, gender, age range
840 and income level. The report shall be submitted annually, not later than March 1, to the clerks of
841 the senate and house of representatives, the house and senate committees on ways and means and
842 the joint committee on health care financing.

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

845 SECTION 43. Chapter 112 of the General Laws is hereby amended by inserting after
846 section 39J the following section:-

847 Section 39K. (a) For the purposes of this section, “specialty pharmacy” may include any
848 pharmacy engaged in the dispensing of specialty drugs as defined by the board.

849 The board shall establish a specialty pharmacy licensure category for pharmacies that
850 ship, mail, sell or dispense specialty drugs into, within or from the commonwealth. The board
851 shall ensure that all shipments of specialty pharmaceutical drugs from in-state pharmacies to out-
852 of-state destinations comply with the licensing procedures applicable to pharmacies in the
853 commonwealth.

854 (b) A specialty pharmacy shall designate a manager of record who shall disclose to the
855 board the location, name and title of all principal managers and the name and Massachusetts
856 license number of the designated manager of record annually and within 30 days after any
857 change of office, corporate office or manager of record.

858 (c) The board shall: (i) adopt written policies or procedures or promulgate regulations
859 that the board determines are necessary to implement this section; and (ii) establish standards for
860 special handling, administration, quality, safety, and monitoring of specialty drugs; provided,
861 however, that the board shall define the term “specialty drug” for the purposes of this section.

862 SECTION 44. Chapter 118E of the General Laws is hereby amended by inserting after
863 section 10Q the following section:-

864 Section 10R. (a) As used in this section, the following terms shall have the following
865 meanings unless the context clearly requires otherwise:

866 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
867 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
868 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
869 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
870 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
871 application that was approved by the United States Secretary of Health and Human Services
872 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
873 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
874 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
875 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
876 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
877 based on available data resources such as Medi-Span.

878 “Delivery device”, a device that: (i) is used to deliver a brand name drug or a generic
879 drug; and (ii) an individual can obtain with a prescription.

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

885 “Separate delivery device”, a device that is used to deliver a brand name drug or a
886 generic drug and that can be obtained with a prescription separate from, or in addition to, the
887 brand name drug or generic drug that the device delivers.

888 (b) The division shall select 1 generic drug and 1 brand name drug used to treat each of
889 the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) heart conditions, including,
890 but not limited to those heart conditions that disproportionately impact a particular demographic
891 group, including people of color.

892 The division shall select insulin as the drug used to treat diabetes. In selecting 1 insulin
893 brand name drug and 1 insulin generic drug, the division shall select 1 insulin brand name drug
894 per dosage and type including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
895 long-acting and premixed. To the extent possible, the division shall select 1 generic insulin per
896 dosage and type including rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-
897 acting and premixed, subject to such generic drug's availability.

898 (c) In selecting the 1 generic drug and 1 brand name drug used to treat each chronic
899 condition, the division shall select a drug that is among the top three of the division's most
900 prescribed or of the highest volume for the chronic condition, and shall consider whether the
901 drug is:

902 (i) of clear benefit and strongly supported by clinical evidence;

903 (ii) likely to reduce hospitalizations or emergency department visits, reduce future
904 exacerbations of illness progression or improve quality of life;

905 (iii) relatively low-cost when compared to the cost of an acute illness of incident
906 prevented or delayed by the use of the service, treatment or drug;

907 (iv) at low risk for overutilization, abuse, addiction, diversion or fraud; and

908 (v) likely to have a considerable financial impact on individual patients by reducing or
909 eliminating patient cost-sharing pursuant to this section; and

910 (vi) likely to enhance equity in disproportionately impacted demographic groups,
911 including people of color.

912 (d) The division and its contracted Medicaid managed care organizations, accountable
913 care organizations, behavioral health management firms and third-party administrators shall
914 provide coverage for the brand name drugs, generic drugs and delivery devices selected pursuant
915 to subsection (b). Coverage for the selected generic drugs shall not be subject to any cost-
916 sharing, including co-payments and co-insurance, and shall not be subject to any deductible.
917 Coverage for selected brand name drugs and delivery devices shall not be subject to any
918 deductible or co-insurance and any co-payment shall not exceed \$25 per 30-day supply;
919 provided, however, that nothing in this section shall prevent co-payments for a 30-day supply of
920 the selected brand name drugs from being reduced below the amount specified in this section.

921 (e) If use of a brand name drug or generic drug that the division selects requires a
922 separate delivery device, the division shall select a delivery device for that drug in accordance
923 with the provisions this section establishes for selecting brand name drugs and generic drugs, to
924 the extent possible. The division shall provide coverage for the delivery device and the delivery
925 device shall not be subject to any cost-sharing, including co-payments and co-insurance, and
926 shall not be subject to any deductible.

927 (f) An enrollee and their prescribing health care provider shall have access to a clear,
928 readily accessible and convenient process to request to use a different brand name drug or
929 generic drug of the same pharmacological class in place of a brand name drug or generic drug.

930 Such request for an exception shall be granted if any of the following conditions are satisfied: (i)
931 the brand name drugs and generic drugs selected pursuant to subsection (b) are contraindicated
932 or will likely cause an adverse reaction in or physical or mental harm to the enrollee; (ii) the
933 brand name drugs and generic drugs selected pursuant to subsection (b) are expected to be
934 ineffective based on the known clinical characteristics of the enrollee and the known
935 characteristics of the prescription drug regimen; (iii) the member or prescribing health care
936 provider: (A) has provided documentation to the division establishing that the enrollee has
937 previously tried the brand name drugs and generic drugs selected pursuant to subsection (b), or
938 another prescription drug in the same pharmacologic class or with the same mechanism of
939 action, while covered by the division or by a previous health insurance carrier or a health benefit
940 plan; and (B) such prescription drug was discontinued due to lack of efficacy or effectiveness,
941 diminished effect or an adverse event; (iv) the enrollee or prescribing health care provider has
942 provided documentation to the division establishing that the enrollee: (A) is stable on a
943 prescription drug prescribed by the health care provider; and (B) switching drugs will likely
944 cause an adverse reaction in or physical or mental harm to the enrollee. When applicable this
945 subsection shall apply to delivery devices.

946 (g) This section shall not apply to health plans providing coverage in the Senior Care
947 Options program to MassHealth-only members who are ages 65 and older.

948 (h) The division shall implement a continuity of coverage policy for enrollees that are
949 new to the Medicaid program and that provides coverage for a 90-day fill of a United States
950 Food and Drug Administration-approved drug reimbursed through a pharmacy benefit that the
951 member has already been prescribed and on which the member is stable, upon documentation by
952 the member's prescriber; provided, however, that the division shall not apply any greater

953 deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to other
954 drugs covered by the plan; and provided further, that the commission shall provide a member or
955 their prescribing health care provider with information regarding the request pursuant to
956 subsection (f) within 30 days of a member or their health care provider contacting the
957 commission to use a different brand name drug or generic drug of the same pharmacological
958 class as the drugs selected pursuant to subsection (b).

959 (i) Upon granting a request pursuant to subsection (f) or (h), the division shall provide
960 coverage for the prescription drug or delivery device prescribed by the member's health care
961 provider at the same cost as required under subsection (d). A denial of an exception shall be
962 eligible for appeal by a member.

963 (j) The division shall grant or deny a request pursuant to subsection (f) or (h) not more
964 than 3 business days following the receipt of all necessary information to establish the medical
965 necessity of the prescribed treatment. If additional delay would result in significant risk to the
966 member's health or well-being, the division shall respond not more than 24 hours following the
967 receipt of all necessary information to establish the medical necessity of the prescribed treatment.
968 If a response by the division is not received within the time required under this subsection, an
969 exception shall be deemed granted.

970 (k) The division shall make changes in selected drugs not more than once annually and
971 shall provide notice to the health policy commission not less than 90 days before making
972 changes to the selected drugs and delivery devices and an explanation of such changes. Upon
973 verification by the health policy commission that the selected drugs meet the criteria identified in

974 subsection (c), the division shall provide notice to its enrollees not less than 30 days before any
975 changes to the selected drugs are made.

976 (l) The division shall make public the drugs and delivery devices selected pursuant to this
977 section.

978 (m) If a high deductible health plan subject to this section is used to establish a savings
979 account that is tax-exempt under the federal Internal Revenue Code, the provisions of this
980 section shall apply to the plan to the maximum extent possible without causing the account to
981 lose its tax-exempt status.

982 SECTION 45. Chapter 175 of the General Laws is hereby amended by inserting after
983 section 47TT the following section:-

984 Section 47UU. (a) The following terms shall have the following meanings, unless the
985 context clearly requires otherwise:

986 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
987 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
988 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
989 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
990 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
991 application that was approved by the United States Secretary of Health and Human Services
992 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
993 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
994 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
995 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved

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

998 “Delivery device”, a device that: (i) is used to deliver a brand name drug or a generic
999 drug; and (ii) an individual can obtain with a prescription.

1000 “Generic drug”, a retail drug that is: (i) marketed or distributed pursuant to an
1001 abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic
1002 drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962
1003 and was not originally marketed under a new drug application; or (iv) identified by the health
1004 benefit plan as a generic drug based on available data resources such as Medi-Span.

1005 “Separate delivery device”, a device that is used to deliver a brand name drug or a
1006 generic drug and that can be obtained with a prescription separate from, or in addition to, the
1007 brand name drug or generic drug that the device delivers.

1008 (b) Any carrier offering a policy, contract or certificate of health insurance under this
1009 chapter shall provide coverage for the brand name drugs, generic drugs and delivery devices
1010 used to treat: (i) diabetes; (ii) asthma; and (iii) heart conditions, including, but not limited to,
1011 those heart conditions that disproportionately impact a particular demographic group, including
1012 people of color.

1013 The carrier shall select insulin as the drug used to treat diabetes. In selecting 1 insulin
1014 brand name drug and 1 insulin generic drug, the carrier shall select 1 insulin brand name drug per
1015 dosage and type including rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-
1016 acting and premixed. To the extent possible, the carrier shall select 1 generic insulin per dosage

1017 and type including rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting
1018 and premixed, subject to such generic drug's availability.

1019 (c) In selecting the 1 generic drug and 1 brand name drug used to treat each chronic
1020 condition, the carrier shall select a drug that is among the top three of the carrier's most
1021 prescribed or of the highest volume for the chronic condition, and shall consider whether the
1022 drug is:

1023 (i) of clear benefit and strongly supported by clinical evidence;

1024 (ii) likely to reduce hospitalizations or emergency department visits, reduce future
1025 exacerbations of illness progression or improve quality of life;

1026 (iii) relatively low cost when compared to the cost of an acute illness of incident
1027 prevented or delayed by the use of the service, treatment or drug;

1028 (iv) at low risk for overutilization, abuse, addiction, diversion or fraud;

1029 (v) likely to have a considerable financial impact on individual patients by reducing or
1030 eliminating patient cost-sharing pursuant to this section; and

1031 (vi) likely to enhance equity in disproportionately impacted demographic groups,
1032 including people of color.

1033 (d) Any carrier offering a policy, contract or certificate of health insurance under this
1034 chapter shall provide coverage for the brand name drugs and generic drugs selected pursuant to
1035 subsection (b). Coverage for the selected generic drugs shall not be subject to any cost-sharing,
1036 including co-payments and co-insurance, and shall not be subject to any deductible. Coverage for
1037 selected brand name drugs shall not be subject to any deductible or co-insurance and any co-

1038 payment shall not exceed \$25 per 30-day supply; provided, however, that nothing in this section
1039 shall prevent co-payments for a 30-day supply of the selected brand name drugs from being
1040 reduced below the amount specified in this section.

1041 (e) If use of a brand name drug or generic drug that the carrier selects requires a separate
1042 delivery device, the carrier shall select a delivery device for that drug in accordance with the
1043 criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the
1044 extent possible. The carrier shall provide coverage for the delivery device and the delivery
1045 device shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1046 shall not be subject to any deductible.

1047 (f) A member and their prescribing health care provider shall have access to a clear,
1048 readily accessible and convenient process to request to use a different brand name drug or
1049 generic drug of the same pharmacological class in place of a brand name drug or generic drug.
1050 Such request for an exception shall be granted if: (i) the brand name drugs and generic drugs
1051 selected pursuant to subsection (b) are contraindicated or will likely cause an adverse reaction in
1052 or physical or mental harm to the member; (ii) the brand name drugs and generic drugs selected
1053 pursuant to subsection (b) are expected to be ineffective based on the known clinical
1054 characteristics of the member and the known characteristics of the prescription drug regimen;
1055 (iii) the member or prescribing health care provider: (A) has provided documentation to the
1056 carrier establishing that the member has previously tried the brand name drugs and generic drugs
1057 selected pursuant to subsection (b), or another prescription drug in the same pharmacologic class
1058 or with the same mechanism of action, while covered by the carrier or by a previous health
1059 insurance carrier or a health benefit plan; and (B) such prescription drug was discontinued due to
1060 lack of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the member or

1061 prescribing health care provider has provided documentation to the carrier establishing that the
1062 member: (A) is stable on a prescription drug prescribed by the health care provider; and (B)
1063 switching drugs will likely cause an adverse reaction in or physical or mental harm to the
1064 member. When applicable this subsection shall apply to delivery devices.

1065 (g) The carrier shall implement a continuity of coverage policy to apply to members that
1066 are new to the carrier and that provides coverage for a 90-day fill of a United States Food and
1067 Drug Administration-approved drug reimbursed through a pharmacy benefit that the member has
1068 already been prescribed and on which the member is stable, upon documentation by the
1069 member's prescriber; provided, however, that a carrier shall not apply any greater deductible,
1070 coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs
1071 covered by the plan; and provided further, that the commission shall provide a member or their
1072 prescribing health care provider with information regarding the request pursuant to subsection (f)
1073 within 30 days of a member or their health care provider contacting the commission to use a
1074 different brand name drug or generic drug of the same pharmacological class as the drugs
1075 selected pursuant to subsection (b).

1076 (h) Upon granting a request pursuant to subsection (f) or implementing a continuity of
1077 coverage pursuant to subsection (g), the carrier shall provide coverage for the prescription drug
1078 or delivery device prescribed by the member's health care provider at the same cost as required
1079 under subsection (d). A denial of an exception shall be eligible for appeal by a member.

1080 (i) The carrier shall grant or deny a request pursuant to subsection (f) or (g) not more than
1081 3 business days following the receipt of all necessary information to establish the medical
1082 necessity of the prescribed treatment. If additional delay would result in significant risk to the

1083 member's health or well-being, the carrier shall respond not more than 24 hours following the
1084 receipt of all necessary information to establish the medical necessity of the prescribed treatment.
1085 If a response by the carrier is not received within the time required under this subsection, an
1086 exception shall be deemed granted.

1087 (j) The carrier shall make changes in selected drugs and delivery devices not more than
1088 once annually and shall provide notice to the health policy commission not less than 90 days
1089 before making changes to the selected drugs and delivery devices and an explanation of such
1090 changes. Upon verification by the health policy commission that the selected drugs meet the
1091 criteria identified in subsection (c), the carrier shall provide notice to its members not less than
1092 30 days before any changes to the selected drugs are made.

1093 (k) The carrier shall make public the drugs and delivery devices selected pursuant to this
1094 section.

1095 (j) If a high deductible health plan subject to this section is used to establish a savings
1096 account that is tax-exempt under the federal Internal Revenue Code, the provisions of this
1097 section shall apply to the plan to the maximum extent possible without causing the account to
1098 lose its tax-exempt status.

1099 SECTION 46. Section 226 of said chapter 175, as appearing in the 2022 Official Edition,
1100 is hereby amended by striking out subsection (a) and inserting in place thereof the following
1101 subsection:-

1102 (a) For the purposes of this section, the term "pharmacy benefit manager" shall mean a
1103 person, business or other entity, however organized, that directly or through a subsidiary
1104 provides pharmacy benefit management services for prescription drugs and devices on behalf of

1105 a health benefit plan sponsor, including, but not limited to, a self-insurance plan, labor union or
1106 other third-party payer; provided, however, that pharmacy benefit management services shall
1107 include, but not be limited to: (i) the processing and payment of claims for prescription drugs;
1108 (ii) the performance of drug utilization review; (iii) the processing of drug prior authorization
1109 requests; (iv) pharmacy contracting; (v) the adjudication of appeals or grievances related to
1110 prescription drug coverage contracts; (vi) formulary administration; (vii) drug benefit design;
1111 (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x) clinical, safety and
1112 adherence programs for pharmacy services; and (xi) managing the cost of covered prescription
1113 drugs; provided further, that “pharmacy benefit manager” shall include a health benefit plan
1114 sponsor that does not contract with a pharmacy benefit manager and manages its own
1115 prescription drug benefits unless specifically exempted.

1116 SECTION 47. Chapter 176A of the General Laws is hereby amended by inserting after
1117 section 8UU the following section:-

1118 Section 8VV. (a) As used in this section, the following terms shall have the following
1119 meanings unless the context clearly requires otherwise:

1120 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
1121 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
1122 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
1123 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
1124 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
1125 application that was approved by the United States Secretary of Health and Human Services
1126 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the

1127 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
1128 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
1129 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
1130 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
1131 based on available data resources such as Medi-Span.

1132 “Delivery device”, a device that: (i) is used to deliver a brand name drug or a generic
1133 drug; and (ii) an individual can obtain with a prescription.

1134 “Generic drug”, a retail drug that is: (i) marketed or distributed pursuant to an
1135 abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic
1136 drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962
1137 and was not originally marketed under a new drug application; or (iv) identified by the health
1138 benefit plan as a generic drug based on available data resources such as Medi-Span.

1139 “Separate delivery device”, a device that is used to deliver a brand name drug or a
1140 generic drug and that can be obtained with a prescription separate from, or in addition to, the
1141 brand name drug or generic drug that the device delivers.

1142 (b) Any carrier offering a policy, contract, or certificate of health insurance under this
1143 chapter shall select 1 generic drug and 1 brand name drug used to treat each of the following
1144 chronic conditions.

1145 The carrier shall select insulin as the drug used to treat diabetes. In selecting 1 insulin
1146 brand name drug and 1 insulin generic drug, the commission shall select 1 insulin brand name
1147 drug per dosage and type including rapid-acting, short-acting, intermediate-acting, long-acting,
1148 ultra long-acting and premixed. To the extent possible, the commission shall select 1 generic

1149 insulin per dosage and type including rapid-acting, short-acting, intermediate-acting, long-acting,
1150 ultra long-acting and premixed, subject to such generic drug's availability.

1151 (c) In selecting the 1 generic drug and 1 brand name drug used to treat each chronic
1152 condition, the carrier shall select a drug that is among the top three of the carrier's most
1153 prescribed or of the highest volume for the chronic condition, and shall consider whether the
1154 drug is:

1155 (i) of clear benefit and strongly supported by clinical evidence;

1156 (ii) likely to reduce hospitalizations or emergency department visits, reduce future
1157 exacerbations of illness progression or improve quality of life;

1158 (iii) relatively low-cost when compared to the cost of an acute illness of incident
1159 prevented or delayed by the use of the service, treatment or drug;

1160 (iv) at low risk for overutilization, abuse, addiction, diversion or fraud;

1161 (v) likely to have a considerable financial impact on individual patients by reducing or
1162 eliminating patient cost-sharing pursuant to this section; and

1163 (vi) likely to enhance equity in disproportionately impacted demographic groups,
1164 including people of color.

1165 (d) Any carrier offering a policy, contract or certificate of health insurance under this
1166 chapter shall provide coverage for the brand name drugs and generic drugs selected pursuant to
1167 subsection (b). Coverage for the selected generic drugs shall not be subject to any cost-sharing,
1168 including co-payments and co-insurance, and shall not be subject to any deductible. Coverage for
1169 selected brand name drugs shall not be subject to any deductible or coinsurance and any

1170 copayment shall not exceed \$25 per 30-day supply; provided, however, that nothing in this
1171 section shall prevent co-payments for a 30-day supply of the selected brand name drugs from
1172 being reduced below the amount specified in this section.

1173 (e) If use of a brand name drug or generic drug that the carrier selects requires a separate
1174 delivery device, the carrier shall select a delivery device for that drug in accordance with the
1175 criteria established under subsection (c) for selecting brand name drugs and generic drugs, to the
1176 extent possible. The carrier shall provide coverage for the delivery device, and the delivery
1177 device shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1178 shall not be subject to any deductible.

1179 (f) A member and their prescribing health care provider shall have access to a clear,
1180 readily accessible and convenient process to request to use a different brand name drug or
1181 generic drug of the same pharmacological class in place of a brand name drug or generic drug.
1182 Such request for an exception shall be granted if: (i) the brand name drugs and generic drugs
1183 selected pursuant to subsection (b) are contraindicated or will likely cause an adverse reaction in
1184 or physical or mental harm to the member; (ii) the brand name drugs and generic drugs selected
1185 pursuant to subsection (b) are expected to be ineffective based on the known clinical
1186 characteristics of the member and the known characteristics of the prescription drug regimen;
1187 (iii) the member or prescribing health care provider: (A) has provided documentation to the
1188 carrier establishing that the member has previously tried the brand name drugs and generic drugs
1189 selected pursuant to subsection (b), or another prescription drug in the same pharmacologic class
1190 or with the same mechanism of action, while covered by the carrier or by a previous health
1191 insurance carrier or a health benefit plan; and (B) such prescription drug was discontinued due to
1192 lack of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the member or

1193 prescribing health care provider has provided documentation to the carrier establishing that the
1194 member: (A) is stable on a prescription drug prescribed by the health care provider; and (B)
1195 switching drugs will likely cause an adverse reaction in or physical or mental harm to the
1196 member. When applicable this subsection shall apply to delivery devices.

1197 (g) The carrier shall implement a continuity of coverage policy to apply to members that
1198 are new to the plan and that provides coverage for a 90-day fill of a United States Food and Drug
1199 Administration-approved drug reimbursed through a pharmacy benefit that the member has
1200 already been prescribed and on which the member is stable, upon documentation by the
1201 member's prescriber; provided, however, that a carrier shall not apply any greater deductible,
1202 coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs
1203 covered by the plan; and provided further, that the commission shall provide a member or their
1204 prescribing health care provider with information regarding the request pursuant to subsection (f)
1205 within 30 days of a member or their health care provider contacting the commission to use a
1206 different brand name drug or generic drug of the same pharmacological class as the drugs
1207 selected pursuant to subsection (b).

1208 (h) Upon granting a request pursuant to subsection (f) or implementing a continuity of
1209 coverage pursuant to subsection (g), the carrier shall provide coverage for the prescription drug
1210 or delivery device prescribed by the member's health care provider at the same cost as required
1211 under subsection (d). A denial of an exception shall be eligible for appeal by a member.

1212 (i) The carrier shall grant or deny a request pursuant to subsection (f) or (g) not more than
1213 3 business days following the receipt of all necessary information to establish the medical
1214 necessity of the prescribed treatment. If additional delay would result in significant risk to the

1215 member's health or well-being, the carrier shall respond not more than 24 hours following the
1216 receipt of all necessary information to establish the medical necessity of the prescribed treatment.
1217 If a response by the carrier is not received within the time required under this subsection, an
1218 exception shall be deemed granted.

1219 (j) The carrier shall make changes in selected drugs and delivery devices not more than
1220 once annually and shall provide notice to the health policy commission not less than 90 days
1221 before making changes to the selected drugs and delivery devices and an explanation of such
1222 changes. Upon verification by the health policy commission that the selected drugs meet the
1223 criteria identified in subsection (c), the carrier shall provide notice to its members not less than
1224 30 days before any changes to the selected drugs are made.

1225 (k) The carrier shall make public the drugs and delivery devices selected pursuant to this
1226 section.

1227 (l) If a high deductible health plan subject to this section is used to establish a savings
1228 account that is tax-exempt under the federal Internal Revenue Code, the provisions of this
1229 section shall apply to the plan to the maximum extent possible without causing the account to
1230 lose its tax-exempt status.

1231 SECTION 48. Chapter 176B of the General Laws is hereby amended by inserting after
1232 section 4UU the following section:-

1233 Section 4VV. (a) As used in this section, the following words shall have the following
1234 meanings unless the context clearly requires otherwise:

1235 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
1236 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
1237 application submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that
1238 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
1239 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
1240 application that was approved by the United States Secretary of Health and Human Services
1241 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
1242 date of the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984,
1243 Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42 C.F.R.
1244 447.502; (ii) produced or distributed pursuant to a biologics license application approved under
1245 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug based
1246 on available data resources, including Medi-Span.

1247 “Delivery device”, a device that: (i) is used to deliver a brand name drug or a generic
1248 drug; and (ii) an individual can obtain with a prescription.

1249 “Generic drug”, a retail drug that is: (i) marketed or distributed pursuant to an
1250 abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic
1251 drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962
1252 and was not originally marketed under a new drug application; or (iv) identified by the health
1253 benefit plan as a generic drug based on available data resources such as Medi-Span.

1254 “Separate delivery device”, a device that: (i) is used to deliver a brand name drug or a
1255 generic drug; and (ii) can be obtained with a prescription separate from or in addition to the brand
1256 name drug or generic drug that the device delivers.

1257 (b) Any carrier offering a policy, contract or certificate of health insurance under this
1258 chapter shall select 1 generic drug and 1 brand name drug used to treat each of the following
1259 chronic conditions: (i) diabetes; (ii) asthma; and (iii) heart conditions, including, but not limited
1260 to, those heart conditions that disproportionately impact a particular demographic group,
1261 including people of color.

1262 The carrier shall select insulin as the drug used to treat diabetes. In selecting 1 insulin
1263 brand name drug and 1 insulin generic drug, the commission shall select 1 insulin brand name
1264 drug per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting,
1265 ultra long-acting and premixed. To the extent possible, the commission shall select 1 generic
1266 insulin per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-
1267 acting, ultra long-acting and premixed, subject to such generic drug's availability.

1268 (c) In selecting the 1 generic drug and 1 brand name drug used to treat each chronic
1269 condition, the carrier shall select a drug that is among the top three of the carrier's most
1270 prescribed or of the highest volume for the chronic condition, and shall consider whether the
1271 drug is:

1272 (i) of clear benefit and strongly supported by clinical evidence;

1273 (ii) likely to reduce hospitalizations or emergency department visits, reduce future
1274 exacerbations of illness progression or improve quality of life;

1275 (iii) relatively low cost when compared to the cost of an acute illness or incident
1276 prevented or delayed by the use of the service, treatment or drug;

1277 (iv) at low risk for overutilization, abuse, addiction, diversion or fraud;

1278 (v) likely to have a considerable financial impact on individual patients by reducing or
1279 eliminating patient cost-sharing pursuant to this section; and

1280 (vi) likely to enhance equity in disproportionately impacted demographic groups,
1281 including people of color.

1282 (d) Any carrier offering a policy, contract or certificate of health insurance under this
1283 chapter shall provide coverage for the brand name drugs and generic drugs selected pursuant to
1284 subsection (b). Coverage for the selected generic drugs shall not be subject to any cost-sharing,
1285 including co-payments and co-insurance, and shall not be subject to any deductible. Coverage for
1286 selected brand name drugs shall not be subject to any deductible or coinsurance and no
1287 copayment shall exceed \$25 per 30-day supply; provided, however, that nothing in this section
1288 shall prevent co-payments for a 30-day supply of the selected brand name drugs from being
1289 reduced below the amount specified in this section.

1290 (e) If use of a brand name drug or generic drug that the carrier selects requires a separate
1291 delivery device, the carrier shall select a delivery device for that drug in accordance with the
1292 criteria established under subsection (c) for selecting brand name drugs and generic drugs, to the
1293 extent possible. The carrier shall provide coverage for the delivery device and the delivery
1294 device shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1295 shall not be subject to any deductible.

1296 (f) A member and their prescribing health care provider shall have access to a clear,
1297 readily accessible and convenient process to request to use a different brand name drug or
1298 generic drug of the same pharmacological class in place of a brand name drug or generic drug.
1299 Such request for an exception shall be granted if: (i) the brand name drugs and generic drugs

1300 selected pursuant to said subsection (b) are contraindicated or will likely cause an adverse
1301 reaction in or physical or mental harm to the member; (ii) the brand name drugs and generic
1302 drugs selected pursuant to said subsection (b) are expected to be ineffective based on the known
1303 clinical characteristics of the member and the known characteristics of the prescription drug
1304 regimen; (iii) the member or prescribing health care provider: (A) has provided documentation to
1305 the carrier establishing that the member has previously tried the brand name drugs and generic
1306 drugs selected pursuant to said subsection (b) or another prescription drug in the same
1307 pharmacologic class or with the same mechanism of action while covered by the carrier or by a
1308 previous health insurance carrier or a health benefit plan; and (B) such prescription drug was
1309 discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or
1310 (iv) the member or prescribing health care provider has provided documentation to the carrier
1311 establishing that the member: (A) is stable on a prescription drug prescribed by the health care
1312 provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental
1313 harm to the member. When applicable this subsection shall apply to delivery devices.

1314 (g) The carrier shall implement a continuity of coverage policy to apply to members who
1315 are new to the plan and that provides coverage for a 90-day fill of a United States Food and Drug
1316 Administration-approved drug reimbursed through a pharmacy benefit that the member has
1317 already been prescribed and on which the member is stable, upon documentation by the
1318 member's prescriber; provided, however, that a carrier shall not apply any greater deductible,
1319 coinsurance, copayment or out-of-pocket limit than would otherwise apply to other drugs
1320 covered by the plan; and provided further, that the commission shall provide a member or their
1321 prescribing health care provider with information regarding the request pursuant to subsection (f)
1322 within 30 days of a member or their health care provider contacting the commission to use a

1323 different brand name drug or generic drug of the same pharmacological class as the drugs
1324 selected pursuant to subsection (b).

1325 (h) Upon granting a request pursuant to subsection (f) or implementing a continuity of
1326 coverage pursuant to subsection (g), the carrier shall provide coverage for the prescription drug
1327 or delivery device prescribed by the member's health care provider at the same cost as required
1328 under subsection (d). A denial of an exception shall be eligible for appeal by a member.

1329 (i) The carrier shall grant or deny a request pursuant to subsection (f) or (g) not more than
1330 3 business days following the receipt of all necessary information to establish the medical
1331 necessity of the prescribed treatment. If additional delay would result in significant risk to the
1332 member's health or well-being, the carrier shall respond not more than 24 hours following the
1333 receipt of all necessary information to establish the medical necessity of the prescribed treatment.
1334 If a response by the carrier is not received within the time required under this subsection, an
1335 exception shall be deemed granted.

1336 (j) The carrier shall make changes in selected drugs and delivery devices not more than
1337 once annually and shall provide notice to the health policy commission not less than 90 days
1338 before making any such changes to the selected drugs and delivery devices and an explanation of
1339 those changes. Upon verification by the health policy commission that the selected drugs meet
1340 the criteria identified in subsection (c), the carrier shall provide notice to its members not less
1341 than 30 days before any changes to the selected drugs are made.

1342 (k) The carrier shall make public the drugs and delivery devices selected pursuant to this
1343 section.

1344 (l) If a high deductible health plan subject to this section is used to establish a savings
1345 account that is tax-exempt under the federal Internal Revenue Code, the provisions of this
1346 section shall apply to the plan to the maximum extent possible without causing the account to
1347 lose its tax-exempt status.

1348 SECTION 49. The fourth paragraph of section 3B of chapter 176D of the General Laws,
1349 as appearing in the 2022 Official Edition, is hereby amended by inserting after the second
1350 sentence the following sentence:- A carrier shall not prohibit the dispensing of specialty drugs
1351 that are included in its pharmaceutical drug benefits to insureds by any network specialty
1352 pharmacy licensed under section 39K of chapter 112; provided, however, that the pharmacy
1353 agrees to the in-network reimbursement rate for the specialty drug.

1354 SECTION 50. Said section 3B of said chapter 176D, as so appearing, is hereby further
1355 amended by striking out the fifth paragraph and inserting in place thereof the following
1356 paragraph:-

1357 A carrier shall not prohibit a network pharmacy from offering and providing mail
1358 delivery services to an insured; provided, however, that the network pharmacy agrees to the
1359 reimbursement terms and conditions and discloses to the insured any delivery service fee
1360 associated with the delivery service.

1361 SECTION 51. The eighth paragraph of said section 3B of said chapter 176D, as so
1362 appearing, is hereby amended by adding the following sentence:- The term “specialty drugs”
1363 shall mean a specialty drug as defined under section 39K of chapter 112.

1364 SECTION 52. Chapter 176G of the General Laws is hereby amended by inserting after
1365 section 4MM the following section:-

1366 Section 4NN. (a) As used in this section. the following words shall have the following
1367 meanings unless the context clearly requires otherwise:

1368 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
1369 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
1370 application submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that
1371 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
1372 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
1373 application that was approved by the United States Secretary of Health and Human Services
1374 under section 505(c) of said federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
1375 date of the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984,
1376 Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42 C.F.R.
1377 447.502; (ii) produced or distributed pursuant to a biologics license application approved under
1378 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug based
1379 on available data resources, such as Medi-Span.

1380 “Delivery device”, a device that: (i) is used to deliver a brand name drug or a generic
1381 drug; and (ii) an individual can obtain with a prescription.

1382 “Generic drug”, a retail drug that is: (i) marketed or distributed pursuant to an
1383 abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic
1384 drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962
1385 and was not originally marketed under a new drug application; or (iv) identified by the health
1386 benefit plan as a generic drug based on available data resources, such as Medi-Span.

1387 “Separate delivery device”, a device that: (i) is used to deliver a brand name drug or a
1388 generic drug; and (ii) can be obtained with a prescription separate from or in addition to the
1389 brand name drug or generic drug that the device delivers.

1390 (b) Any carrier offering a policy, contract or certificate of health insurance under this
1391 chapter shall select 1 generic drug and 1 brand name drug used to treat each of the following
1392 chronic conditions: (i) diabetes; (ii) asthma; and (iii) heart conditions, including, but not limited
1393 to, those heart conditions that disproportionately impact a particular demographic group,
1394 including people of color.

1395 The carrier shall select insulin as the drug used to treat diabetes. In selecting 1 insulin
1396 brand name drug and 1 insulin generic drug, the commission shall select 1 insulin brand name
1397 drug per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting,
1398 ultra long-acting and premixed. To the extent possible, the commission shall select 1 generic
1399 insulin per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-
1400 acting, ultra long-acting and premixed, subject to such generic drug’s availability.

1401 (c) In selecting the 1 generic drug and 1 brand name drug used to treat each chronic
1402 condition, the carrier shall select a drug that is among the top three of the commission’s most
1403 prescribed or of the highest volume for the chronic condition, and shall consider whether the
1404 drug is:

1405 (i) of clear benefit and strongly supported by clinical evidence;

1406 (ii) likely to reduce hospitalizations or emergency department visits, reduce future
1407 exacerbations of illness progression or improve quality of life;

1408 (iii) relatively low cost when compared to the cost of an acute illness or incident
1409 prevented or delayed by the use of the service, treatment or drug;

1410 (iv) at low risk for overutilization, abuse, addiction, diversion or fraud;

1411 (v) likely to have a considerable financial impact on individual patients by reducing or
1412 eliminating patient cost-sharing pursuant to this section; and

1413 (vi) likely to enhance equity in disproportionately impacted demographic groups,
1414 including people of color.

1415 (d) Any carrier offering a policy, contract, or certificate of health insurance under this
1416 chapter shall provide coverage for the brand name drugs and generic drugs selected pursuant to
1417 subsection (b). Coverage for the selected generic drugs shall not be subject to any cost-sharing,
1418 including co-payments and co-insurance, and shall not be subject to any deductible. Coverage for
1419 selected brand name drugs shall not be subject to any deductible or co-insurance and any co-
1420 payment shall not exceed \$25 per 30-day supply; provided, however, that nothing in this section
1421 shall prevent co-payments for a 30-day supply of the selected brand name drugs from being
1422 reduced below the amount specified in this section.

1423 (e) If use of a brand name drug or generic drug that the carrier selects requires a separate
1424 delivery device, the carrier shall select a delivery device for that drug in accordance with the
1425 criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the
1426 extent possible. The carrier shall provide coverage for the delivery device and the delivery
1427 device shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1428 shall not be subject to any deductible.

1429 (f) A member and their prescribing health care provider shall have access to a clear,
1430 readily accessible and convenient process to request to use a different brand name drug or
1431 generic drug of the same pharmacological class in place of a brand name drug or generic drug.
1432 Such request for an exception shall be granted if: (i) the brand name drugs and generic drugs
1433 selected pursuant to said subsection (b) are contraindicated or will likely cause an adverse
1434 reaction in or physical or mental harm to the member; (ii) the brand name drugs and generic
1435 drugs selected pursuant to said subsection (b) are expected to be ineffective based on the known
1436 clinical characteristics of the member and the known characteristics of the prescription drug
1437 regimen; (iii) the member or prescribing health care provider: (A) has provided documentation to
1438 the carrier establishing that the member has previously tried the brand name drugs and generic
1439 drugs selected pursuant to subsection (b), or another prescription drug in the same pharmacologic
1440 class or with the same mechanism of action, while covered by the carrier or by a previous health
1441 insurance carrier or a health benefit plan; and (B) such prescription drug was discontinued due to
1442 lack of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the member or
1443 prescribing health care provider has provided documentation to the carrier establishing that the
1444 member: (A) is stable on a prescription drug prescribed by the health care provider; and (B)
1445 switching drugs will likely cause an adverse reaction in or physical or mental harm to the
1446 member. When applicable this subsection shall apply to delivery devices.

1447 (g) The carrier shall implement a continuity of coverage policy to apply to members who
1448 are new to the plan and that provides coverage for a 90-day fill of a United States Food and Drug
1449 Administration-approved drug reimbursed through a pharmacy benefit that the member has
1450 already been prescribed and on which the member is stable, upon documentation by the
1451 member's prescriber; provided, however, that a carrier shall not apply any greater deductible,

1452 coinsurance, copayment or out-of-pocket limit than would otherwise apply to other drugs
1453 covered by the plan; and provided further, that the commission shall provide a member or their
1454 prescribing health care provider with information regarding the request pursuant to subsection (f)
1455 within 30 days of a member or their health care provider contacting the commission to use a
1456 different brand name drug or generic drug of the same pharmacological class as the drugs
1457 selected pursuant to subsection (b).

1458 (h) Upon granting a request pursuant to subsection (f) or implementing a continuity of
1459 coverage pursuant to subsection (g), the carrier shall provide coverage for the prescription drug
1460 or delivery device prescribed by the member's health care provider at the same cost as required
1461 under subsection (d). A denial of an exception shall be eligible for appeal by a member.

1462 (i) The carrier shall grant or deny a request pursuant to subsection (f) or (g) not more than
1463 3 business days following the receipt of all necessary information to establish the medical
1464 necessity of the prescribed treatment. If additional delay would result in significant risk to the
1465 member's health or well-being, the carrier shall respond not more than 24 hours following the
1466 receipt of all necessary information to establish the medical necessity of the prescribed treatment.
1467 If a response by the carrier is not received within the time required under this subsection, an
1468 exception shall be deemed granted.

1469 (j) The carrier shall make changes in selected drugs and delivery devices not more than
1470 once annually and shall provide notice to the health policy commission not less than 90 days
1471 before making any such changes to the selected drugs and delivery devices and an explanation of
1472 those changes. Upon verification by the health policy commission that the selected drugs meet

1473 the criteria identified in subsection (c), the carrier shall provide notice to its members not less
1474 than 30 days before any changes to the selected drugs are made.

1475 (k) The carrier shall make public the drugs and delivery devices selected pursuant to this
1476 section.

1477 (l) If a high deductible health plan subject to this section is used to establish a savings
1478 account that is tax-exempt under the federal Internal Revenue Code, the provisions of this
1479 section shall apply to the plan to the maximum extent possible without causing the account to
1480 lose its tax-exempt status.

1481 SECTION 53. Section 2 of chapter 176O of the General Laws, as appearing in the 2022
1482 Official Edition, is hereby amended by adding the following subsection:-

1483 (i) Every 3 years, a carrier that contracts with a pharmacy benefit manager shall
1484 coordinate an audit of the operations of the pharmacy benefit manager to ensure compliance with
1485 this chapter and to examine the pricing and rebates applicable to prescription drugs that are
1486 provided to the carrier's covered persons.

1487 SECTION 54. Said chapter 176O is hereby further amended by inserting after section 22
1488 the following section:-

1489 Section 22A. Notwithstanding any other general or special law to the contrary, each
1490 carrier shall require that a pharmacy benefit manager receive a license from the division under
1491 chapter 176Y as a condition of contracting with that carrier.

1492 SECTION 55. Said chapter 176O is hereby further amended by adding the following
1493 section:-

1494 Section 30. (a) For the purposes of this section, the following words shall have the
1495 following meanings unless the context clearly requires otherwise:

1496 “Cost-sharing”, an amount owed by an individual under the terms of the individual’s
1497 health benefit plan.

1498 “Pharmacy retail price”, the amount an individual would pay for a prescription drug at a
1499 pharmacy if the individual purchased that prescription drug at that pharmacy without using a
1500 health benefit plan or any other prescription drug benefit or discount.

1501 (b) At the point of sale, a pharmacy shall charge an individual the lesser of: (i)
1502 appropriate cost-sharing amount; or (ii) pharmacy retail price; provided, however, that a carrier,
1503 or an entity that manages or administers benefits for a carrier, shall not require an individual to
1504 make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser
1505 of the: (A) individual’s cost share; or (B) pharmacy retail price.

1506 (c) A contract shall not: (i) prohibit a pharmacist from complying with this section; or (ii)
1507 impose a penalty on the pharmacist or pharmacy for complying with this section.

1508 SECTION 56. The General Laws are hereby amended by inserting after chapter 176X the
1509 following chapter:-

1510 Chapter 176Y. LICENSING AND REGULATION OF PHARMACY BENEFIT
1511 MANAGERS.

1512 Section 1. As used in this chapter, the following words shall have the following meanings
1513 unless the context clearly requires otherwise:

1514 “Carrier”, an insurer licensed or otherwise authorized to transact accident or health
1515 insurance under chapter 175, a nonprofit hospital service corporation organized under chapter
1516 176A, a non-profit medical service corporation organized under chapter 176B, a health
1517 maintenance organization organized under chapter 176G and an organization entering into a
1518 preferred provider arrangement under chapter 176I; provided, however, that “carrier” shall not
1519 include an employer purchasing coverage or acting on behalf of its employees or the employees
1520 of any subsidiary or affiliated corporation of the employer; and provided further, that unless
1521 otherwise provided, “carrier” shall not include any entity to the extent it offers a policy,
1522 certificate or contract that provides coverage solely for dental care services or vision care
1523 services.

1524 “Center”, the center for health information and analysis established in chapter 12C.

1525 “Commissioner”, the commissioner of insurance.

1526 “Division”, the division of insurance.

1527 “Health benefit plan”, a contract, certificate or agreement entered into, offered or issued
1528 by a carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care
1529 services; provided, however, that the commissioner may by regulation define other health
1530 coverage as a “health benefit plan” for the purposes of this chapter.

1531 “Pharmacy”, a physical or electronic facility under the direction or supervision of a
1532 registered pharmacist that is authorized to dispense prescription drugs and has entered into a
1533 network contract with a pharmacy benefit manager or a carrier.

1534 “Pharmacy benefit manager”, a person, business or other entity, however organized, that
1535 directly or through a subsidiary provides pharmacy benefit management services for prescription
1536 drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-
1537 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
1538 management services shall include, but not be limited to: (i) the processing and payment of
1539 claims for prescription drugs; (ii) the performance of drug utilization review; (iii) the processing
1540 of drug prior authorization requests; (iv) pharmacy contracting; (v) the adjudication of appeals or
1541 grievances related to prescription drug coverage contracts; (vi) formulary administration; (vii)
1542 drug benefit design; (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x)
1543 clinical, safety and adherence programs for pharmacy services; and (xi) managing the cost of
1544 covered prescription drugs; provided further, that “pharmacy benefit manager” shall not include
1545 a health benefit plan sponsor unless otherwise specified by the division.

1546 Section 2. (a) No person, business or other entity shall establish or operate as a pharmacy
1547 benefit manager without obtaining a license from the division pursuant to this section. A license
1548 may be granted only when the division is satisfied that the entity possesses the necessary
1549 organization, background expertise, and financial integrity to supply the services sought to be
1550 offered. A pharmacy benefit manager license shall be valid for a period of 3 years and shall be
1551 renewable for additional 3-year periods. Initial application and renewal fees for the license shall
1552 be established pursuant to section 3B of chapter 7.

1553 (b) A license granted pursuant to this section and any rights or interests therein shall not
1554 be transferable.

1555 (c) A person, business or other entity licensed as a pharmacy benefit manager shall
1556 submit data and reporting information to the center according to the standards and methods
1557 specified by the center pursuant to section 10A of chapter 12C.

1558 (d) The division may issue or renew a license pursuant to this section, subject to
1559 restrictions in order to protect the interests of consumers. Such restrictions may include: (i)
1560 limiting the type of services that a license holder may provide; (ii) limiting the activities in which
1561 the license holder may be engaged; or (iii) addressing conflicts of interest between pharmacy
1562 benefit managers and health plan sponsors.

1563 (e) The division shall develop an application for licensure of pharmacy benefit managers
1564 that shall include, but not be limited to: (i) the name of the applicant or pharmacy benefit
1565 manager; (ii) the address and contact telephone number for the applicant or pharmacy benefit
1566 manager; (iii) the name and address of the agent of the applicant or pharmacy benefit manager
1567 for service of process in the commonwealth; (iv) the name and address of any person with
1568 management or control over the applicant or pharmacy benefit manager; and (v) any audited
1569 financial statements specific to the applicant or pharmacy benefit manager. An applicant or
1570 pharmacy benefit manager shall report to the division any material change to the information
1571 contained in its application, certified by an officer of the pharmacy benefit manager, within 30
1572 days of such a change.

1573 (f) The division may suspend, revoke, refuse to issue or renew or place on probation a
1574 pharmacy benefit manager license for cause, which shall include, but not be limited to: (i) the
1575 applicant or pharmacy benefit manager engaging in fraudulent activity that is found by a court of
1576 law to be a violation of state or federal law; (ii) the division receiving consumer complaints that

1577 justify an action under this chapter to protect the health, safety and interests of consumers; (iii)
1578 the applicant or pharmacy benefit manager failing to pay an application or renewal fee for a
1579 license; (iv) the applicant or pharmacy benefit manager failing to comply with reporting
1580 requirements of the center under section 10A of chapter 12C; or (v) the applicant pharmacy
1581 benefit manager's failing to comply with a requirement of this chapter.

1582 The division shall provide written notice to the applicant or pharmacy benefit manager
1583 and advise in writing of the reason for any suspension, revocation, refusal to issue or renew or
1584 placement on probation of a pharmacy benefit manager license under this chapter. A copy of the
1585 notice shall be forwarded to the center. The applicant or pharmacy benefit manager may make
1586 written demand upon the division within 30 days of receipt of such notification for a hearing
1587 before the division to determine the reasonableness of the division's action. The hearing shall be
1588 held pursuant to chapter 30A.

1589 The division shall not suspend or cancel a license unless the division has first afforded
1590 the pharmacy benefit manager an opportunity for a hearing pursuant to said chapter 30A.

1591 (g) If a person, business or other entity performs the functions of a pharmacy benefit
1592 manager in violation of this chapter, the person, business or other entity shall be subject to a fine
1593 of \$5,000 per day for each day that the person, business or other entity is found to be in violation.
1594 Penalties collected under this subsection shall be deposited into the Prescription Drug Cost
1595 Assistance Trust Fund established in section 2BBBBBB of chapter 29.

1596 (h) A pharmacy benefit manager licensed under this section shall notify a health carrier
1597 client in writing of any activity, policy, practice contract or arrangement of the pharmacy benefit

1598 manager that directly or indirectly presents any conflict of interest with the pharmacy benefit
1599 manager's relationship with or obligation to the health carrier client.

1600 (i) The division shall adopt any written policies, procedures or regulations that the
1601 division determines are necessary to implement this section.

1602 Section 3. (a) The commissioner may make an examination of the affairs of a pharmacy
1603 benefit manager when the commissioner deems prudent but not less frequently than once every 3
1604 years. The focus of the examination shall be to ensure that a pharmacy benefit manager is able to
1605 meet its responsibilities under contracts with carriers licensed under chapters 175, 176A, 176B,
1606 or 176G. The examination shall be conducted according to the procedures set forth in paragraph
1607 (6) of section 4 of chapter 175.

1608 (b) The commissioner, a deputy or an examiner may conduct an on-site examination of
1609 each pharmacy benefit manager in the commonwealth to thoroughly inspect and examine its
1610 affairs.

1611 (c) The charge for each such examination shall be determined annually according to the
1612 procedures set forth in paragraph (6) of section 4 of chapter 175.

1613 (d) Not later than 60 days following completion of the examination, the examiner in
1614 charge shall file with the commissioner a verified written report of examination under oath.
1615 Upon receipt of the verified report, the commissioner shall transmit the report to the pharmacy
1616 benefit manager examined with a notice that shall afford the pharmacy benefit manager
1617 examined a reasonable opportunity of not more than 30 days to make a written submission or
1618 rebuttal with respect to any matters contained in the examination report. Within 30 days of the
1619 end of the period allowed for the receipt of written submissions or rebuttals, the commissioner

1620 shall consider and review the reports together with any written submissions or rebuttals and any
1621 relevant portions of the examiner's work papers and enter an order:

1622 (i) adopting the examination report as filed with modifications or corrections and, if the
1623 examination report reveals that the pharmacy benefit manager is operating in violation of this
1624 section or any regulation or prior order of the commissioner, the commissioner may order the
1625 pharmacy benefit manager to take any action the commissioner considers necessary and
1626 appropriate to cure such violation;

1627 (ii) rejecting the examination report with directions to examiners to reopen the
1628 examination for the purposes of obtaining additional data, documentation or information and re-
1629 filing pursuant to the above provisions; or

1630 (iii) calling for an investigatory hearing with not less than 20 days' notice to the
1631 pharmacy benefit manager for purposes of obtaining additional documentation, data, information
1632 and testimony.

1633 (e) Notwithstanding any general or special law to the contrary, including clause Twenty-
1634 sixth of section 7 of chapter 4 and chapter 66, the records of any such audit, examination or other
1635 inspection and the information contained in the records, reports or books of any pharmacy
1636 benefit manager examined pursuant to this section shall be confidential and open only to the
1637 inspection of the commissioner, or the examiners and assistants. Access to such confidential
1638 material may be granted by the commissioner to law enforcement officials of the commonwealth
1639 or any other state or agency of the federal government at any time if the agency or office
1640 receiving the information agrees in writing to keep such material confidential. Nothing in this
1641 subsection shall be construed to prohibit the required production of such records, and

1642 information contained in the reports of such company or organization before any court of the
1643 commonwealth or any master or auditor appointed by any such court, in any criminal or civil
1644 proceeding, affecting such pharmacy benefit manager, its officers, partners, directors or
1645 employees. The final report of any such audit, examination or any other inspection by or on
1646 behalf of the division of insurance shall be a public record.

1647 SECTION 57. (a) Notwithstanding any general or special law to the contrary, the
1648 commonwealth health insurance connector authority, in consultation with the division of
1649 insurance, shall report on the impact of pharmaceutical pricing on health care costs and outcomes
1650 for ConnectorCare and non-group and small group plans offered through the connector and its
1651 members.

1652 The report shall include, but not be limited to: (i) information on the differential between
1653 drug list price and price net of rebates for plans offered and the impact of those differentials on
1654 member premiums; (ii) the relationship between drug list price and member cost-sharing
1655 requirements; (iii) the impact of drug price changes over time on premium and out-of-pocket
1656 costs in plans authorized under section 3 of chapter 176J of the General Laws offered through the
1657 commonwealth health insurance connector authority; (iv) trends in changes in drug list price and
1658 price net of rebates by health plan; (v) an analysis of the impact of member out-of-pocket costs
1659 on drug utilization and member experience; and (vi) an analysis of the impact of drug list price
1660 and price net of rebates on member formulary access to drug. Data collected under this
1661 subsection shall be protected as confidential and shall not be a public record under clause
1662 Twenty-sixth of section 7 of chapter 4 of the General Laws or under chapter 66 of the General
1663 Laws.

1664 The report shall be submitted to the joint committee on health care financing and the
1665 house and senate committees on ways and means not later than July 1, 2025.

1666 (b) In fiscal year 2024, the amount required to be paid pursuant to the last paragraph of
1667 section 6 of chapter 6D of the General Laws shall be increased by \$500,000; provided, however,
1668 that said \$500,000 shall be provided to the commonwealth health insurance connector authority
1669 not later than March 14, 2024 for data collection and analysis costs associated with the report
1670 required by this section.

1671 SECTION 58. Notwithstanding any general or special law to the contrary, there shall be a
1672 special commission to examine the feasibility of: (i) establishing a system for the bulk
1673 purchasing and distribution of pharmaceutical products with a significant public health benefit
1674 and the potential for significant health care cost savings for consumers through overall increased
1675 purchase capacity; and (ii) making bulk purchase pricing information available to purchasers in
1676 other states.

1677 The commission shall consist of: the commissioner of public health or a designee, who
1678 shall serve as chair; the executive director of the group insurance commission or a designee; the
1679 chief of pharmacy of the state office for pharmacy services; the MassHealth director of
1680 pharmacy; the secretary of technology services and security; and 9 members to be appointed by
1681 the commissioner of public health, 2 of whom shall be health care economists, 1 of whom shall
1682 be an expert in health law and policy innovation, 1 of whom shall be an academic with relevant
1683 expertise in the field, 1 of whom shall be a representative from a community health center, 1 of
1684 whom shall be the chief executive officer of a hospital licensed in the commonwealth, 1 of
1685 whom shall be a representative of the Massachusetts Association of Health Plans, Inc., 1 of

1686 whom shall be a representative of Blue Cross Blue Shield of Massachusetts, Inc. and 1 of whom
1687 shall be a member of the public with experience with health care and consumer protection.

1688 The commission shall hold not less than 3 public hearings in different geographic areas of
1689 the commonwealth, accept input from the public and solicit expert testimony from individuals
1690 representing health insurance carriers, pharmaceutical companies, independent and chain
1691 pharmacies, hospitals, municipalities, health care practitioners, health care technology
1692 professionals, community health centers, substance abuse disorder providers, public health
1693 educational institutions and other experts identified by the commission.

1694 The commission shall consider: (i) the process by which the commonwealth could make
1695 bulk purchases of pharmaceutical products with a significant public health benefit and the
1696 potential for significant health care cost savings to consumers; (ii) the process by which both
1697 governmental and nongovernmental entities may participate in a collaborative to purchase
1698 pharmaceutical products with a significant public health benefit and the potential for significant
1699 health care cost savings; (iii) the feasibility of developing an electronic information interchange
1700 system to exchange bulk purchase price information with partnering states; (iv) potential sources
1701 of funding available to implement bulk purchases; (v) potential cost savings of bulk purchases to
1702 the commonwealth or other participating nongovernmental entities; (vi) the feasibility of
1703 partnering with the federal government or other states in the New England region; and (vii) any
1704 other factors that the commission deems relevant.

1705 The commission shall file a report of its analysis, along with any recommended
1706 legislation, if any, to the clerks of the senate and house of representatives, the house and senate
1707 committees on ways and means, the joint committee on health care financing, the joint

1708 committee on public health, the joint committee on elder affairs and the joint committee on
1709 mental health, substance abuse and recovery not later than September 1, 2024.

1710 SECTION 59. (a) As used in this section, the following words shall have the following
1711 meanings unless the context clearly requires otherwise:

1712 “Chain pharmacist”, a pharmacist employed by a retail drug organization operating not
1713 less than 10 retail drug stores within the commonwealth under section 39 of chapter 112 of the
1714 General Laws.

1715 “Independent pharmacist”, a pharmacist actively engaged in the business of retail
1716 pharmacy and employed in an organization of not more than 9 registered retail drugstores in the
1717 commonwealth under said section 39 of said chapter 112 that employs not more than a total of
1718 20 full-time pharmacists.

1719 (b) There shall be a task force to: (i) review the drug supply chain and reimbursement
1720 structures including, but not limited to: (A) plan and pharmacy benefit manager reimbursements
1721 to pharmacies; (B) wholesaler prices to pharmacies; (C) pharmacy services administrative
1722 organization fees and contractual relationships with pharmacies; and (D) drug manufacturer
1723 prices to wholesalers; (ii) review ways to recognize the unique challenges of small and
1724 independent pharmacies; (iii) identify methods to increase pricing transparency throughout the
1725 supply chain; (iv) make recommendations on the use of multiple maximum allowable costs lists
1726 and their frequency of use for mail order products; (v) review the utilization of maximum
1727 allowable costs lists or similar reimbursement structures established by a pharmacy benefit
1728 manager or payer; (vi) review the availability of drugs to independent and chain pharmacies on
1729 the maximum allowable cost list or any similar reimbursement structures established by a

1730 pharmacy benefit manager or payer; (vii) review the pharmacy acquisition cost from national or
1731 regional wholesalers that serve pharmacies compared to the reimbursement amount provided
1732 through a maximum allowable cost list or any similar reimbursement structures established by a
1733 pharmacy benefit manager or payer and the conditions under which an adjustment to a
1734 reimbursement is appropriate; (viii) review the timing of pharmacy purchases of products and the
1735 relative risk of list price changes related to the timing of dispensing the products; (ix) assess
1736 ways to increase transparency for chain and independent pharmacists to understand the
1737 methodology used by a pharmacy benefit manager or payer to develop a maximum allowable
1738 cost list or any similar reimbursement structure established by the pharmacy benefit manager or
1739 payer; (x) assess the prevalence and appropriateness of pharmacy benefit managers requiring, or
1740 using financial incentives or penalties to incentivize, customer use of pharmacies with whom the
1741 pharmacy benefit manager has an ownership or financial interest; (xi) examine the impact of the
1742 merger or consolidation of pharmacy benefit managers and health carrier clients on drug costs;
1743 (xii) review current appeals processes for a chain or independent pharmacist to request an
1744 adjustment on a reimbursement subject to a maximum allowable cost list or any similar
1745 reimbursement structure established by a pharmacy benefit manager or payer; and (xiii) evaluate
1746 the effect of differences between pharmacy benefit manager payments to pharmacies and charges
1747 made to health carrier clients on drug price.

1748 (c) The task force shall consist of: the commissioner of insurance or a designee, who shall
1749 serve as chair; and 9 members to be appointed by the commissioner, 2 of whom shall be
1750 independent pharmacists employed in the independent pharmacy setting or representatives of
1751 independent pharmacies, 2 of whom shall be chain pharmacists employed in the chain pharmacy
1752 setting or representatives of chain pharmacies, 2 of whom shall be representatives of a pharmacy

1753 benefit managers or payers who manage their own pharmacy benefit services, 1 of whom shall
1754 represent the Massachusetts Association of Health Plans, Inc., 1 of whom shall represent Blue
1755 Cross Blue Shield of Massachusetts, Inc. and 1 of whom shall be a representative of wholesalers
1756 or pharmacy services administrative organizations. If more than 1 independent pharmacist is
1757 appointed, each appointee shall represent a distinct practice setting. If more than 1 chain
1758 pharmacist is appointed, each appointee shall represent a distinct practice setting. A pharmacy
1759 benefit manager or payer appointed to the task force shall not be co-owned or have any
1760 ownership relationship with any other payer, pharmacy benefit manager or chain pharmacist also
1761 appointed to the task force.

1762 (d) The commissioner shall file the task force's findings with the clerks of the house of
1763 representatives and the senate, the joint committee on health care financing and the house and
1764 senate committees on ways and means not later than December 1, 2024.

1765 SECTION 60. The health policy commission shall consult with relevant stakeholders,
1766 including, but not limited to, consumers, consumer advocacy organizations, organizations
1767 representing people with disabilities and chronic health conditions, providers, provider
1768 organizations, payers, pharmaceutical manufacturers, pharmacy benefit managers and health care
1769 economists and other academics, to assist in the development and periodic review of regulations
1770 to implement section 21 of chapter 6D of the General Laws, including, but not limited to: (i)
1771 establishing the criteria and processes for identifying the proposed value of an eligible drug as
1772 defined in said section 21 of said chapter 6D; and (ii) determining the appropriate price increase
1773 for a public health essential drug as described within the definition of eligible drug in said
1774 section 21 of said chapter 6D.

1775 The commission shall hold its first public outreach not more than 45 days after the
1776 effective date of this act and shall, to the extent possible, ensure fair representation and input
1777 from a diverse array of stakeholders.

1778 SECTION 61. Annually, each carrier shall report to the division of insurance the drugs
1779 selected to be provided with no or limited cost-sharing under section 17T of chapter 32A of the
1780 General Laws, section 10R of chapter 118E of the General Laws, section 47UU of chapter 175 of
1781 the General Laws, section 8VV of chapter 176A of the General Laws, section 4VV of chapter
1782 176B of the General Laws and section 4NN of chapter 176G of the General Laws. The division
1783 of insurance shall consult with the health policy commission and the center for health and
1784 information analysis to review the drugs to verify that the selected drugs meet the criteria
1785 identified in said section 17T of said chapter 32A, said section 10R of said chapter 118E, said
1786 section 47UU of said chapter 175, said section 8VV of said chapter 176A, said section 4VV of
1787 said chapter 176B and said section 4NN of said chapter 176G. If a selected drug shall be deemed
1788 by the division to not meet the criteria, the division may require a different drug to be selected.
1789 The division shall disclose the list of drugs selected by each entity annually on the division's
1790 website.

1791 SECTION 62. Notwithstanding subsection (b) of section 15A of chapter 6D of the
1792 General Laws, for the purposes of providing early notice under said section 15A of said chapter
1793 6D, the health policy commission shall determine a significant price increase for a generic drug
1794 to be defined as a generic drug priced at \$100 or more per wholesale acquisition cost unit that
1795 increases in cost by 100 per cent or more during any 12-month period.

1796 SECTION 63. Section 62 is hereby repealed.

1797 SECTION 64. The health policy commission, in consultation with the department of
1798 public health, the office of Medicaid, the group insurance commission and the division of
1799 insurance, shall study and analyze health insurance payer, including public and private payer,
1800 specialty pharmacy networks in the commonwealth. The study shall include: (i) a description of
1801 the type of specialty drugs most often provided by specialty pharmacies; (ii) the impact of
1802 existing health insurance payers' specialty pharmacy networks on patient access, availability of
1803 clinical support, continuity of care, safety, quality, cost sharing and health care costs; and (iii)
1804 any recommendations for increasing patient access to and choice of specialty drugs, maintaining
1805 high-quality specialty pharmacy standards and meeting the commonwealth's health care cost
1806 containment goals.

1807 The commission shall submit a report of its findings and recommendations to the clerks
1808 of the senate and house of representatives, the senate and house committees on ways and means,
1809 the joint committee on health care financing and the joint committee on public health not later
1810 than July 1, 2024.

1811 SECTION 65. The regulations required by subsection (d) of section 39K of chapter 112
1812 of the General Laws shall be promulgated not later than December 31, 2023.

1813 SECTION 66. Sections 21 and 39 shall take effect on July 1, 2024.

1814 SECTION 67. Sections 41, 44, 45, 47, 48, 52 and 61 shall take effect as of July 1, 2025.

1815 SECTION 68. Section 43 shall take effect on April 1, 2024.

1816 SECTION 69. Section 54 shall take effect on July 1, 2024.

1817 SECTION 70. Section 56 shall take effect on March 30, 2024.

1818

SECTION 71. Section 63 shall take effect on January 1, 2025.