

SENATE No. 2520

The Commonwealth of Massachusetts

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

SENATE, November 15, 2023.

The committee on Senate Bills in the Third Reading to whom was referred the Senate Bill relative to pharmaceutical access, costs and transparency (Senate, No. 2499, amended); reports, recommending that the same be amended as follows, and that, when so amended, it will be correctly drawn:-- by substituting a new with the same title (Senate, No. 2520).

For the committee,
Sal N. DiDomenico

SENATE No. 2520

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

An Act relative to pharmaceutical access, costs and transparency.

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

1 SECTION 1. 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 changes including, but not limited to, the initial prices of drugs coming to market and
118 subsequent price changes, changes in industry profit levels, marketing expenses, reverse payment
119 patent settlements, the impact of manufacturer rebates, discounts and other price concessions on
120 net pricing, the availability of alternative drugs or treatments, corporate ownership organizational
121 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 2EEEEEE 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, continuous glucose monitoring system components, all
197 components of the continuous glucose monitoring system of which the component is a part and,
198 when applicable, delivery devices selected pursuant to section 17T of chapter 32A, section 10R
199 of chapter 118E, section 47UU of chapter 175, section 8VV of chapter 176A, section 4VV of
200 chapter 176B and section 4NN of chapter 176G; or (v) other prescription drug products that may
201 have a direct and significant impact and create affordability challenges for the state’s health care
202 system and patients, as determined by the commission; provided, however, that the commission
203 shall promulgate regulations to establish the type of prescription drug products classified under
204 clause (v) prior to classification of any such prescription drug product under said clause (v).

205 “Manufacturer”, a pharmaceutical manufacturer of an eligible drug, or, when applicable,
206 the manufacturer of a delivery device selected pursuant to section 17T of chapter 32A, section
207 10R of chapter 118E, section 47UU of chapter 175, section 8VV of chapter 176A, section 4VV
208 of chapter 176B and section 4NN of chapter 176G.

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

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

214 In conducting a review of eligible drugs, the commission may request information
215 relating to the pricing of an eligible drug from the manufacturer of said eligible drug. Upon
216 receiving a request for information from the commission, a manufacturer shall disclose to the
217 commission, within a reasonable time period, as determined by the commission, applicable
218 information relating to the manufacturer’s pricing of an eligible drug.

219 The disclosed information shall be on a standard reporting form developed by the
220 commission with the input of the manufacturers and shall include, but not be limited to:

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

223 (ii) the total amount of federal and state tax credits, incentives, grants and other subsidies
224 provided to the manufacturer over the previous 10 calendar years that have been used to assist in
225 the research and development of eligible drugs;

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

229 (iv) a narrative description, absent proprietary information and written in plain language,
230 of factors that contributed to reported changes in wholesale acquisition cost during the previous 5
231 calendar years; and

232 (v) any other information that the manufacturer wishes to provide to the commission or
233 that the commission requests.

234 (c) Based on the records provided under subsection (b) and available information from
235 the center for health information and analysis or an outside third party, the commission shall
236 identify a proposed value for the eligible drug. The commission may request additional relevant
237 information that it deems necessary from the manufacturer and from other entities, including, but
238 not limited to, pharmacy benefit managers.

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

251 racial or ethnic groups and on individuals with specific disabilities or health conditions who
252 regularly utilize the eligible drug.

253 (d) If, after review of an eligible drug and after receiving information from the
254 manufacturer under subsection (b) or subsection (e), the commission determines that the
255 manufacturer's pricing of the eligible drug does not substantially exceed the proposed value of
256 the drug, the commission shall notify the manufacturer, in writing, of its determination and shall
257 evaluate other ways to mitigate the eligible drug's cost in order to improve patient access to the
258 eligible drug. The commission may engage with the manufacturer and other relevant
259 stakeholders, including, but not limited to, patients, patient advocacy organizations, consumer
260 advocacy organizations, providers, provider organizations and payers, to explore options for
261 mitigating the cost of the eligible drug. Upon the conclusion of a stakeholder engagement
262 process under this subsection, the commission shall issue recommendations on ways to reduce
263 the cost of the eligible drug for the purpose of improving patient access to the eligible drug.
264 Recommendations may include, but shall not be limited to: (i) an alternative payment plan or
265 methodology; (ii) a bulk purchasing program; (iii) co-payment, deductible, co-insurance or other
266 cost-sharing restrictions; and (iv) a reinsurance program to subsidize the cost of the eligible drug.
267 The recommendations shall be publicly posted on the commission's website and provided to the
268 clerks of the house of representatives and senate, the joint committee on health care financing
269 and the house and senate committees on ways and means; provided, however, that the report
270 shall be published on the website of the commission.

271 (e) If, after review of an eligible drug, the commission determines that the manufacturer's
272 pricing of the eligible drug substantially exceeds the proposed value of the drug, the commission
273 shall request that the manufacturer provide further information related to the pricing of the

274 eligible drug and the manufacturer's reasons for the pricing not later than 30 days after receiving
275 the request.

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

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

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

294 (h) The commission's proposed value of an eligible drug and the commission's
295 underlying analysis of the eligible drug is not intended to be used to determine whether any

296 individual patient meets prior authorization or utilization management criteria for the eligible
297 drug. The proposed value and underlying analysis shall not be the sole factor in determining
298 whether a drug is included in a formulary or whether the drug is subject to step therapy.

299 (i) If the manufacturer fails to timely comply with the commission's request for records
300 under subsection (b) or subsection (e), or otherwise knowingly obstructs the commission's
301 ability to issue its determination under subsection (f), including, but not limited to, by providing
302 incomplete, false or misleading information, the commission may impose appropriate sanctions
303 against the manufacturer, including reasonable monetary penalties not to exceed \$500,000, in
304 each instance. The commission shall seek to promote compliance with this section and shall only
305 impose a civil penalty on the manufacturer as a last resort. Penalties collected under this
306 subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established
307 in section 2EEEEEE of chapter 29.

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

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

312 Upon providing written notice provided under subsection (f) of section 21, the
313 commission may require that a manufacturer whose pricing of an eligible drug substantially
314 exceeds the commission's proposed value of the drug file an access and affordability
315 improvement plan with the commission. Not later than 45 days after receipt of a notice under
316 said subsection (f) of said section 21, a manufacturer shall: (i) file an access and affordability

317 improvement plan; or (ii) provide written notice declining participation in the access and
318 affordability improvement plan.

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

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

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

336 (e) Upon approval of the proposed access and affordability improvement plan, the
337 commission shall notify the manufacturer to begin immediate implementation of the access and
338 affordability improvement plan. Public notice shall be provided by the commission on its

339 website, identifying that the manufacturer is implementing an access and affordability
340 improvement plan; provided, however, that upon the successful completion of the access and
341 affordability improvement plan, the identity of the manufacturer shall be removed from the
342 commission's website. All manufacturers implementing an approved access improvement plan
343 shall be subject to additional reporting requirements and compliance monitoring as determined
344 by the commission. The commission shall provide assistance to the manufacturer in the
345 successful implementation of the access and affordability improvement plan.

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

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

358 (h) The commission shall submit a recommendation for proposed legislation to the joint
359 committee on health care financing if the commission determines that further legislative

360 authority is needed to assist manufacturers with the implementation of access and affordability
361 improvement plans or to otherwise ensure compliance with this section.

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

364 (j) The commission may assess a civil penalty to a manufacturer of not more than
365 \$500,000, in each instance, if the commission determines that the manufacturer: (i) declined or
366 willfully neglected to file an access and affordability improvement plan with the commission
367 under subsection (a); (ii) failed to file an acceptable access and affordability improvement plan in
368 good faith with the commission; (iii) failed to implement the access and affordability
369 improvement plan in good faith; or (iv) knowingly failed to provide information required by this
370 section to the commission or knowingly falsified the information. The commission shall seek to
371 promote compliance with this section and shall only impose a civil penalty as a last resort.
372 Penalties collected under this subsection shall be deposited into the Prescription Drug Cost
373 Assistance Trust Fund established in section 2EEEEEE of chapter 29.

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

382 joint committee on health care financing and the house and senate committees on ways and
383 means.

384 If a manufacturer is deemed to not be acting in good faith to develop an acceptable or
385 complete access and affordability improvement plan, the commission may publicly post the
386 proposed value of the eligible drug, hold a public hearing on the proposed value of the eligible
387 drug and solicit public comment. The manufacturer shall appear and testify at any hearing held
388 on the eligible drug's proposed value. Upon the conclusion of a public hearing under this
389 subsection, the commission shall issue recommendations on ways to reduce the cost of an
390 eligible drug for the purpose of improving patient access to the eligible drug. The
391 recommendations shall be publicly posted on the commission's website and provided to the
392 clerks of the house of representatives and senate, the joint committee on health care financing
393 and the house and senate committees on ways and means.

394 Before making a determination that the manufacturer is not acting in good faith, the
395 commission shall send a written notice to the manufacturer that the commission shall deem the
396 manufacturer to not be acting in good faith if the manufacturer does not submit an acceptable
397 access and affordability improvement plan within 30 days of receipt of notice; provided,
398 however, that the commission shall not send a notice under this paragraph within 120 calendar
399 days from the date that the commission notified the manufacturer of its requirement to enter into
400 the access and affordability improvement plan.

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

402 Section 23. Every 2 years, the commission, in consultation with the center for health
403 information and analysis, the group insurance commission, the office of Medicaid and the

404 division of insurance shall evaluate the impact of section 17T of chapter 32A, section 10R of
405 chapter 118E, section 47UU of chapter 175, section 8VV of chapter 176A, section 4VV of
406 chapter 176B and section 4NN of chapter 176G on the effects of capping co-payments and
407 eliminating deductible and co-insurance requirements for those drugs for individuals with
408 diabetes, asthma and chronic heart conditions on health care access and system cost, including,
409 but not limited to: (i) utilization rates of the drugs selected pursuant to section 10R of chapter
410 118E, section 47UU of chapter 175, section 8VV of chapter 176A, section 4VV of chapter 176B
411 and section 4NN of chapter 176G; (ii) an analysis of the use of those drugs, broken down by
412 patient demographics, geographic region and, where applicable, delivery device; (iii) annual plan
413 costs and member premiums; (iv) the average price of those drugs; (v) the average price of those
414 drugs net of rebates or discounts received by or accrued directly or indirectly by health insurance
415 carriers; (vi) average and total out-of-pocket expenditures on delivery devices used for those
416 drugs and glucose monitoring tests that are not included as part of the underlying drug
417 prescription; (vii) an analysis of the impact of capping co-payments and eliminating deductible
418 and co-insurance requirements for those drugs on patient access to and cost of care by patient
419 demographics and geographic region; and (viii) any barriers to accessing those drugs for
420 individuals with the conditions for which those drugs are prescribed and policy recommendations
421 for resolving such barriers. This section shall also apply to selected continuous glucose
422 monitoring system components, all components of the continuous glucose monitoring system of
423 which the component is a part and delivery devices, when applicable.

424 Biennially, not later than November 30, the commission shall file a report of its findings
425 with the clerks of the house of representatives and senate, the chairs of the joint committee on

426 public health, the chairs of the joint committee on health care financing and the chairs of house
427 and senate committees on ways and means.

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

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

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

436 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
437 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
438 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
439 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
440 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
441 application that was approved by the United States Secretary of Health and Human Services
442 under section 505(c) of the federal Food, Drug and Cosmetic Act, 21 U.S.C. 355(c), before the
443 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
444 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
445 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
446 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the carrier as a brand name drug based on
447 available data resources such as Medi-Span.

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

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

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

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

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

470 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
471 management services shall include, but not be limited to: (i) the processing and payment of
472 claims for prescription drugs; (ii) the performance of drug utilization review; (iii) the processing
473 of drug prior authorization requests; (iv) pharmacy contracting; (v) the adjudication of appeals or
474 grievances related to prescription drug coverage contracts; (vi) formulary administration; (vii)
475 drug benefit design; (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x)
476 clinical, safety and adherence programs for pharmacy services; and (xi) managing the cost of
477 covered prescription drugs; provided further, that “pharmacy benefit manager” shall include a
478 health benefit plan sponsor that does not contract with a pharmacy benefit manager and manages
479 its own prescription drug benefits unless specifically exempted by the commission.

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

482 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
483 1395w-3a(c)(6)(B).

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

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

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

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

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

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

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

509 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
510 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
511 appropriated by the general court for the expenses of the center minus amounts collected from:
512 (i) filing fees; (ii) fees and charges generated by the commission's publication or dissemination

513 of reports and information; and (iii) federal matching revenues received for these expenses or
514 received retroactively for expenses of predecessor agencies. A pharmacy benefit manager that is
515 also a surcharge payor subject to the preceding paragraph and manages its own prescription drug
516 benefits shall not be subject to additional assessment under this paragraph.

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

519 Section 10A. (a) The center shall promulgate regulations necessary to ensure the uniform
520 reporting of information from pharmaceutical manufacturing companies to enable the center to
521 analyze: (i) year-over-year changes in wholesale acquisition cost and average manufacturer price
522 for prescription drug products; (ii) year-over-year trends in net expenditures; (iii) net
523 expenditures on subsets of biosimilar, brand name and generic drugs identified by the center; (iv)
524 trends in estimated aggregate drug rebates, discounts or other remuneration paid or provided by a
525 pharmaceutical manufacturing company to a pharmacy benefit manager, wholesaler, distributor,
526 health carrier client, health plan sponsor or pharmacy in connection with utilization of the
527 pharmaceutical drug products offered by the pharmaceutical manufacturing company; (v)
528 discounts provided by a pharmaceutical manufacturing company to a consumer in connection
529 with utilization of the pharmaceutical drug products offered by the pharmaceutical
530 manufacturing company, including any discount, rebate, product voucher, coupon or other
531 reduction in a consumer's out-of-pocket expenses including co-payments and deductibles under
532 section 3 of chapter 175H; (vi) research and development costs as a percentage of revenue; (vii)
533 annual marketing and advertising costs, identifying costs for direct-to-consumer advertising;
534 (viii) annual profits over the most recent 5-year period; (ix) disparities between prices charged to

535 purchasers in the commonwealth and purchasers outside of the United States; and (x) any other
536 information deemed necessary by the center.

537 The center shall require the submission of available data and other information from
538 pharmaceutical manufacturing companies including, but not limited to: (i) wholesale acquisition
539 costs and average manufacturer prices for prescription drug products as identified by the center;
540 (ii) true net typical prices charged to pharmacy benefits managers by payor type for prescription
541 drug products identified by the center, net of any rebate or other payments from the manufacturer
542 to the pharmacy benefits manager and from the pharmacy benefits manager to the manufacturer;
543 (iii) aggregate, company-level research and development costs to the extent attributable to a
544 specific product and other relevant capital expenditures for the most recent year for which final
545 audited data is available for prescription drug products as identified by the center; (iv) annual
546 marketing and advertising expenditure; (v) the total amount of federal and state tax credits,
547 incentives, grants and other subsidies provided to the manufacturer over the previous 10 calendar
548 years that have been used to assist in the research and development of eligible drugs; and (vi) a
549 description, absent proprietary information and written in plain language, of factors that
550 contributed to reported changes in wholesale acquisition costs, net prices and average
551 manufacturer prices for prescription drug products as identified by the center.

552 (b) The center shall promulgate regulations necessary to ensure the uniform reporting of
553 information from pharmacy benefit managers to enable the center to analyze: (i) trends in
554 estimated aggregate drug rebates and other drug price reductions, if any, provided by a pharmacy
555 benefit manager to a health carrier client or health plan sponsor or passed through from a
556 pharmacy benefit manager to a health carrier client or health plan sponsor in connection with
557 utilization of drugs in the commonwealth offered through the pharmacy benefit manager and a

558 measure of lives covered by each health carrier client or health plan sponsor in the
559 commonwealth; (ii) pharmacy benefit manager practices with regard to drug rebates and other
560 drug price reductions, if any, provided by a pharmacy benefit manager to a health carrier client
561 or health plan sponsor or to consumers in the commonwealth or passed through from a pharmacy
562 benefit manager to a health carrier client or health plan sponsor or to consumers in the
563 commonwealth; and (iii) any other information deemed necessary by the center.

564 The center shall require the submission of available data and other information from
565 pharmacy benefit managers including, but not limited to: (i) true net typical prices paid by
566 pharmacy benefits managers for prescription drug products identified by the center, net of any
567 rebate or other payments from the manufacturer to the pharmacy benefit manager and from the
568 pharmacy benefit manager to the manufacturer; (ii) the amount of all rebates that the pharmacy
569 benefit manager received from all pharmaceutical manufacturing companies: (A) for all health
570 carrier clients in the aggregate; (B) for each health carrier client or health plan sponsor
571 individually; and (C) by drug, for 30 of the most utilized drugs in the commonwealth as
572 determined by the center; (iii) the administrative fees that the pharmacy benefit manager
573 received from all health carrier clients or health plan sponsors in the aggregate and for each
574 health carrier client or health plans sponsors individually; (iv) the aggregate amount of rebates a
575 pharmacy benefit manager: (A) retains based on its contractual arrangement with each health
576 plan client or health plan sponsor individually; and (B) passes through to each health care client
577 individually; (v) the aggregate amount of all retained rebates that the pharmacy benefit manager
578 received from all pharmaceutical manufacturing companies and did not pass through to each
579 pharmacy benefit manager's health carrier client or health plan sponsor individually; (vi) the
580 percentage of contracts that a pharmacy benefit manager holds where the pharmacy benefit

581 manager: (A) retains all rebates; (B) passes all rebates through to the client; and (C) shares
582 rebates with the client; and (vii) other information as determined by the center, including, but not
583 limited to, pharmacy benefit manager practices related to spread pricing, administrative fees,
584 claw backs and formulary placement.

585 (c) Except as specifically provided otherwise by the center or under this chapter, data
586 collected by the center pursuant to this section from pharmaceutical manufacturing companies
587 and pharmacy benefit managers shall not be a public record under clause Twenty-sixth of section
588 7 of chapter 4 or under chapter 66.

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

591 Section 11. The center shall ensure the timely reporting of information required under
592 sections 8, 9, 10 and 10A. The center shall notify private health care payers, providers, provider
593 organizations, pharmacy benefit managers, pharmaceutical manufacturing companies and their
594 parent organization and other affiliates of any applicable reporting deadlines. The center shall
595 notify, in writing, a private health care payer, provider, provider organization, pharmacy benefit
596 manager or pharmaceutical manufacturing company and their parent organization and other
597 affiliates, that has failed to meet a reporting deadline of such failure and that failure to respond
598 within 2 weeks of the receipt of the notice shall result in penalties. The center shall assess a
599 penalty against a private health care payer, provider, provider organization, pharmacy benefit
600 manager or pharmaceutical manufacturing company and their parent organization and other
601 affiliates, that fails, without just cause, to provide the requested information, including subsets of
602 the requested information, within 2 weeks following receipt of the written notice required under

603 this section, of not more than \$2,000 per week for each week of delay after the 2-week period
604 following receipt of the notice. Amounts collected under this section shall be deposited in the
605 Healthcare Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.
606 The center may promulgate regulations to define “just cause” for the purpose of this section.

607 SECTION 35. Section 12 of said chapter 12C, as so appearing, is hereby amended by
608 striking out, in line 2, the words “and 10” and inserting in place thereof the following words:- ,
609 10 and 10A.

610 SECTION 36. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby
611 amended by striking out the first sentence and inserting in place thereof the following sentence:-
612 The center shall publish an annual report based on the information submitted under: (i) sections
613 8, 9, 10 and 10A concerning health care provider, provider organization, private and public
614 health care payer, pharmaceutical manufacturing company and pharmacy benefit manager costs
615 and cost and price trends; (ii) section 13 of chapter 6D relative to market power reviews; and (iii)
616 section 15 of said chapter 6D relative to quality data.

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

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

621 As part of its annual report, the center shall report on prescription drug utilization and
622 spending for pharmaceutical drugs provided in an outpatient setting or sold in a retail setting for
623 private and public health care payers, including, but not limited to, information sufficient to
624 show the: (i) highest utilization drugs; (ii) drugs with the greatest increases in utilization; (iii)

625 drugs that are most impactful on plan spending, net of rebates; and (iv) drugs with the highest
626 year-over-year price increases, net of rebates. The report shall not contain any data that is likely
627 to compromise the financial, competitive or proprietary nature of the information contained in
628 the report. The report shall be published on the website of the center.

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

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

633 “Public health essential drug”, a prescription drug, biologic or biosimilar approved by the
634 United States Food and Drug Administration that: (i) appears on the Model List of Essential
635 Medicines most recently adopted by the World Health Organization; (ii) is selected pursuant to
636 section 17T of chapter 32A, section 10R of chapter 118E, section 47UU of chapter 175, section
637 8VV of chapter 176A, section 4VV of chapter 176B and section 4NN of chapter 176G; or (iii) is
638 deemed an essential medicine by the commission due to its efficacy in treating a life-threatening
639 health condition or a chronic health condition that substantially impairs an individual’s ability to
640 engage in activities of daily living or because limited access to a certain population would pose a
641 public health challenge. “Public health essential drug” shall also include all continuous glucose
642 monitoring system components, all components of the continuous glucose monitoring system of
643 which the component is a part and delivery devices selected pursuant to section 17T of chapter
644 32A, section 10R of chapter 118E, section 47UU of chapter 175, section 8VV of chapter 176A,
645 section 4VV of chapter 176B and section 4NN of chapter 176G.

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

651 SECTION 40. Chapter 29 of the General Laws is hereby amending by inserting after
652 section 2DDDDDD the following section:-

653 2EEEEEE. (a) There shall be a Prescription Drug Cost Assistance Trust Fund. The
654 secretary of health and human services shall administer the fund and shall make expenditures
655 from the fund, without further appropriation, to provide financial assistance to residents of the
656 commonwealth for the cost of prescription drugs through the prescription drug costs assistance
657 program established under section 245 of chapter 111. For the purpose of this section,
658 "prescription drug" shall include the prescription drug and any drug delivery device needed to
659 administer the drug that is not included as part of the underlying drug prescription.

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

666 (b) Annually, not later than March 1, the secretary shall report on the fund's activities
667 detailing expenditures from the previous calendar year. The report shall include: (i) the number

668 of individuals who received financial assistance from the fund; (ii) the breakdown of fund
669 recipients by race, gender, age range, geographic region and income level; (iii) a list of all
670 prescription drugs that were covered by money from the fund; and (iv) the total cost savings
671 received by all fund recipients and the cost savings broken down by race, gender, age range and
672 income level. The report shall be submitted to the clerks of the senate and house of
673 representatives, senate and house committees on ways and means and the joint committee on
674 health care financing; provided, however, that annually, not later than March 1, the report shall
675 be published on the website of the executive office of health and human services.

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

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

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

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

690 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
691 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
692 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
693 based on available data resources such as Medi-Span.

694 “Continuous glucose monitoring system”, a system to continuously sense, transmit and
695 display blood glucose levels.

696 “Continuous glucose monitoring system component”, a component of a system to
697 continuously monitor blood glucose levels such as a sensor, transmitter or display.

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

700 “Diabetes treatment supplies”, supplies for the treatment of diabetes including, but not
701 limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home
702 use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips,
703 lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose
704 monitors for use by the legally blind and visual magnifying aids for use by the legally blind;
705 provided, however, that “diabetes treatment supplies” shall not include a brand name drug, a
706 generic drug, a continuous glucose monitoring system component, or a delivery device.

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

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

715 (b) The commission shall select 1 generic drug and 1 brand name drug used to treat each
716 of the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 3 most prevalent heart
717 conditions that disproportionately impact a particular demographic group, including people of
718 color, as determined by the center for health information analysis; provided, however, that for
719 diabetes, the commission shall also select a continuous glucose monitoring system component.

720 The commission shall select insulin as the drug used to treat diabetes. In selecting 1
721 insulin brand name drug and 1 insulin generic drug per dosage and type, including rapid-acting,
722 short-acting, intermediate-acting, long-acting, ultra long-acting and premixed, subject to such
723 generic drug’s availability.

724 (c) In selecting the 1 generic drug, the 1 brand name drug and the delivery device, when
725 applicable, used to treat each chronic condition pursuant to subsection (b), the commission shall
726 select a drug that is among the top 3 of the commission’s most prescribed or of the highest
727 volume for the chronic condition and shall consider whether the drug is:

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

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

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

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

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

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

738 (d) The continuous glucose monitoring system component shall be selected in the same
739 manner in which the 1 generic drug and 1 brand name drug are selected.

740 (e)(1) The commission shall provide coverage for the brand name drugs and generic
741 drugs selected pursuant to subsection (b). Coverage for the selected generic drugs shall not be
742 subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to
743 any deductible. Coverage for selected brand name drugs shall not be subject to any deductible or
744 co-insurance and any co-payment shall not exceed \$25 per 30-day supply; provided, however,
745 that nothing in this section shall prevent co-payments for a 30-day supply of the selected brand
746 name drugs from being reduced below the amount specified in this section.

747 (2) If use of a brand name drug or generic drug that the commission selects requires a
748 separate delivery device, the commission shall select a delivery device for that drug in
749 accordance with the criteria established in subsection (c) for selecting brand name drugs and
750 generic drugs, to the extent possible. The commission shall provide coverage for the delivery
751 device and the delivery device shall not be subject to any cost-sharing, including co-payments
752 and co-insurance, and shall not be subject to any deductible.

753 (3) The commission shall provide coverage for the continuous glucose monitoring system
754 component selected pursuant to subsection (b) and all components of the blood glucose
755 monitoring system of which the selected component is a part. All components of the applicable
756 continuous glucose monitoring system shall not be subject to any cost-sharing, including co-
757 payments and co-insurance, and shall not be subject to any deductible.

758 (4) The commission shall provide coverage for necessary diabetes treatment supplies.
759 Such supplies shall not be subject to any cost-sharing, including co-payments and co-insurance,
760 and shall not be subject to any deductible.

761 (f) A member and their prescribing health care provider shall have access to a clear,
762 readily accessible and convenient process to request to use a different brand name drug or
763 generic drug of the same pharmacological class in place of a brand name drug or generic drug
764 selected under subsection (b). Such request for an exception shall be granted if: (i) the brand
765 name drugs and generic drugs selected under subsection (b) are contraindicated or will likely
766 cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name drugs
767 and generic drugs selected under subsection (b) are expected to be ineffective based on the
768 known clinical characteristics of the member and the known characteristics of the prescription
769 drug regimen; (iii) the member or prescribing health care provider: (A) has provided
770 documentation to the commission establishing that the member has previously tried the brand
771 name drugs and generic drugs selected under subsection (b) ; and (B) such prescription drug was
772 discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or
773 (iv) the member or prescribing health care provider has provided documentation to the
774 commission establishing that the member: (A) is stable on a prescription drug prescribed by the
775 health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical

776 or mental harm to the member. This subsection shall apply to continuous glucose monitoring
777 system components and, when applicable, delivery devices.

778 (g) The commission shall implement a continuity of coverage policy for members that are
779 new to the commission, which shall provide coverage for a 90-day fill of a United States Food
780 and Drug Administration-approved drug reimbursed through a pharmacy benefit that the member
781 has already been prescribed and on which the member is stable, upon documentation by the
782 member's prescriber, and which was selected by the member's previous payer pursuant to
783 subsection (b); provided, however, that the commission shall not apply any greater deductible,
784 co-insurance, co-payments or out-of-pocket limits than would otherwise apply to other drugs
785 selected pursuant to subsection (b) by the plan; and provided further, that the commission shall
786 provide a member or their prescribing health care provider with information regarding the
787 request pursuant to subsection (f) within 30 days of a member or their health care provider
788 contacting the commission to use a different brand name drug or generic drug of the same
789 pharmacological class as the drugs selected pursuant to subsection (b). This subsection shall
790 apply to continuous glucose monitoring system components and, when applicable, delivery
791 devices.

792 (h) Upon granting a request pursuant to subsection (f) or implementing a continuity of
793 coverage pursuant to subsection (g), the commission shall provide coverage for the prescription
794 drug, continuous glucose monitoring system component or delivery device prescribed by the
795 member's health care provider at the same cost as required under subsection (e). A denial of an
796 exception shall be eligible for appeal by a member.

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

804 (j) The commission shall make changes in selected drugs not more than annually and
805 shall provide notice to the division of insurance not less than 90 days before making changes to
806 the selected drugs and an explanation of such changes. Upon verification by the division of
807 insurance that the selected drugs meet the criteria identified in subsection (c), the commission
808 shall provide notice to its members not less than 30 days before any changes to the selected
809 drugs are made. This subsection shall apply to continuous glucose monitoring system
810 components and, when applicable, delivery devices, in the same manner in which it applies to
811 drugs.

812 (k) The commission shall make public the drugs, continuous glucose monitoring system
813 components, all components of the system of which the component is a part and delivery devices
814 selected pursuant to this section.

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

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

821 Section 245. (a) The department shall establish and administer a prescription drug cost
822 assistance program, which shall be funded by the Prescription Drug Cost Assistance Trust Fund
823 established in section 2EEEEEE of chapter 29. The program shall provide financial assistance
824 for prescription drugs used to treat: (i) chronic respiratory conditions, including, but not limited
825 to, chronic obstructive pulmonary disease and asthma; (ii) chronic heart conditions, including,
826 but not limited to, those heart conditions that disproportionately impact a particular demographic
827 group, including people of color; (iii) diabetes; and (iv) any other chronic condition identified by
828 the department that disproportionately impacts a particular demographic group, including people
829 of color; provided, however, that “prescription drug” shall include the prescription drug and any
830 drug delivery device needed to administer the drug that is not included as part of the underlying
831 drug prescription. Financial assistance shall cover the cost of any copayment, coinsurance and
832 deductible for the prescription drug for an individual who is eligible for the program.

833 (b) An individual shall be eligible for the program if the individual: (i) is a resident of the
834 commonwealth; (ii) has a current prescription from a health care provider for a drug that is used
835 to treat a chronic condition listed in subsection (a); (iii) has a family income of not more than
836 500 per cent of the federal poverty level; and (iv) is not enrolled in MassHealth.

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

841 receiving the application. If necessary for its determination, the department may request
842 additional information from the applicant; provided, however, that the department shall notify
843 the applicant within 5 business days of receipt of the original application as to what specific
844 additional information is being requested. If additional information is requested, the department
845 shall, within 3 business days of receipt of the additional information, determine the applicant's
846 eligibility and notify said applicant of the department's determination.

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

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

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

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

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

873 (f) The department shall compile a report detailing information about the program from
874 the previous calendar year. The report shall include: (i) the number of applications received,
875 approved, denied and appealed; (ii) the total number of applicants approved, and the number of
876 applicants approved broken down by race, gender, age range and income level; (iii) a list of all
877 prescription drugs that qualify for the program under subsection (b) and a list of prescription
878 drugs for which applicants actually received financial assistance; and (iv) the total cost savings
879 received by all approved applicants and the cost savings broken down by race, gender, age range
880 and income level. The report shall be submitted annually, not later than March 1, to the clerks of
881 the senate and house of representatives, the house and senate committees on ways and means and
882 the joint committee on health care financing; provided, however, that annually, not later than
883 March 1, the report shall be published on the website of the department.

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

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

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

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

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

899 (c) The board shall: (i) adopt written policies or procedures or promulgate regulations
900 that the board determines are necessary to implement this section; and (ii) establish standards for
901 special handling, administration, quality, safety, and monitoring of specialty drugs; provided,
902 however, that the board shall define the term “specialty drug” for the purposes of this section;
903 and provided further, that the board shall consult with industry leaders and experts and shall base
904 said policies, procedures or regulations on best evidence-based practices.

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

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

909 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
910 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
911 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
912 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
913 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
914 application that was approved by the United States Secretary of Health and Human Services
915 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
916 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
917 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
918 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
919 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
920 based on available data resources such as Medi-Span.

921 “Continuous glucose monitoring system”, a system to continuously sense, transmit and
922 display blood glucose levels.

923 “Continuous glucose monitoring system component”, a component of a system to
924 continuously monitor blood glucose levels such as a sensor, transmitter or display.

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

927 “Diabetes treatment supplies”, supplies for the treatment of diabetes including, but not
928 limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home
929 use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips,
930 lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose
931 monitors for use by the legally blind and visual magnifying aids for use by the legally blind;
932 provided, however, that diabetes treatment supplies shall not include a brand name drug, a
933 generic drug, a continuous glucose monitoring system component or a delivery device.

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

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

942 (b) The division shall select 1 generic drug and 1 brand name drug used to treat each of
943 the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 3 most prevalent heart
944 conditions that disproportionately impact a particular demographic group, including people of
945 color, determined by the center for health information analysis; provided, however, that for
946 diabetes, the division shall also select a continuous glucose monitoring system component.

947 The division shall select insulin as the drug used to treat diabetes. In selecting 1 insulin
948 brand name drug and 1 insulin generic drug, the division shall select 1 insulin brand name drug

949 per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
950 long-acting and premixed. To the extent possible, the division shall select 1 insulin generic drug
951 per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
952 long-acting and premixed, subject to the generic drug's availability.

953 (c) In selecting the 1 generic drug, the 1 brand name drug and the delivery device, when
954 applicable, used to treat each chronic condition pursuant to subsection (b), the division shall
955 select a drug that is among the top 3 of the division's most prescribed or of the highest volume
956 for the chronic condition and shall consider whether the drug is:

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

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

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

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

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

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

967 (d) The continuous glucose monitoring system component shall be selected in the same
968 manner in which the 1 generic drug and 1 brand name drug are selected.

969 (e)(1) The division shall provide coverage for the brand name drugs and generic drugs
970 selected pursuant to subsection (b). Coverage for the selected generic drugs shall not be subject
971 to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any
972 deductible. Coverage for selected brand name drugs shall not be subject to any deductible or co-
973 insurance and any co-payment per 30-day supply shall not exceed the amount established in the
974 fourth paragraph of subsection (5) of section 25, regardless of whether the beneficiary is enrolled
975 in managed care; provided, however, that nothing in this section shall prevent co-payments for a
976 30-day supply of the selected brand name drugs from being reduced below the amount specified
977 in this section.

978 (2) If use of a brand name drug or generic drug that the division selects requires a
979 separate delivery device, the division shall select a delivery device for that drug in accordance
980 with the criteria established in subsection (c) for selecting brand name drugs and generic drugs,
981 to the extent possible. The division shall provide coverage for the delivery device and the
982 delivery device shall not be subject to any cost-sharing, including co-payments and co-insurance,
983 and shall not be subject to any deductible.

984 (3) The division shall provide coverage for the continuous glucose monitoring system
985 component selected pursuant to subsection (b) and all components of the blood glucose
986 monitoring system of which the selected component is a part. All components of the applicable
987 continuous glucose monitoring system shall not be subject to any cost-sharing, including co-
988 payments and co-insurance, and shall not be subject to any deductible.

989 (4) The division shall provide coverage for necessary diabetes treatment supplies. Such
990 supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and
991 shall not be subject to any deductible.

992 (f) An enrollee and their prescribing health care provider shall have access to a clear,
993 readily accessible and convenient process to request to use a different brand name drug or
994 generic drug of the same pharmacological class in place of a brand name drug or generic drug
995 selected under subsection (b). Such request for an exception shall be granted if: (i) the brand
996 name drugs and generic drugs selected under subsection (b) are contraindicated or will likely
997 cause an adverse reaction in or physical or mental harm to the enrollee; (ii) the brand name drugs
998 and generic drugs selected under subsection (b) are expected to be ineffective based on the
999 known clinical characteristics of the enrollee and the known characteristics of the prescription
1000 drug regimen; (iii) the member or prescribing health care provider: (A) has provided
1001 documentation to the division establishing that the enrollee has previously tried the brand name
1002 drugs and generic drugs selected under subsection (b) while covered by the division or by a
1003 previous health insurance carrier or a health benefit plan; and (B) such prescription drug was
1004 discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or
1005 (iv) the enrollee or prescribing health care provider has provided documentation to the division
1006 establishing that the enrollee: (A) is stable on a prescription drug prescribed by the health care
1007 provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental
1008 harm to the enrollee. This subsection shall apply to continuous glucose monitoring system
1009 components and, when applicable, delivery devices.

1010 (g) This section shall not apply to health plans providing coverage in the Senior Care
1011 Options program to MassHealth-only members who are ages 65 and older.

1012 (h) The division shall implement a continuity of coverage policy for enrollees that are
1013 new to the Medicaid program, which shall provide coverage for a 90-day fill of a United States
1014 Food and Drug Administration-approved drug reimbursed through a pharmacy benefit that the
1015 member has already been prescribed and on which the member is stable, upon documentation by
1016 the member's prescriber, and which was selected by the member's previous payer pursuant to
1017 subsection (b); provided, however, that the division shall not apply any greater deductible,
1018 coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs
1019 covered by the plan; and provided further, that the division shall provide a member or their
1020 prescribing health care provider with information regarding the request pursuant to subsection (f)
1021 within 30 days of a member or their health care provider contacting the division to use a different
1022 brand name drug or generic drug of the same pharmacological class as the drugs selected
1023 pursuant to subsection (b). This subsection shall apply to continuous glucose monitoring system
1024 components and, when applicable, delivery devices.

1025 (i) Upon granting a request pursuant to subsection (f) or implementing a continuity of
1026 coverage pursuant to subsection (h), the division shall provide coverage for the prescription drug,
1027 continuous glucose monitoring system component or delivery device prescribed by the member's
1028 health care provider at the same cost as required under subsection (e). A denial of an exception
1029 shall be eligible for appeal by a member.

1030 (j) The division shall grant or deny a request pursuant to subsection (f) or (h) not more
1031 than 3 business days following the receipt of all necessary information to establish the medical
1032 necessity of the prescribed treatment; provided, however, that if additional delay would result in
1033 significant risk to the member's health or well-being, the division shall respond not more than 24
1034 hours following the receipt of all necessary information to establish the medical necessity of the

1035 prescribed treatment. If a response by the division is not received within the time required under
1036 this subsection, an exception shall be deemed granted.

1037 (k) The division shall make changes in selected drugs not more than once annually and
1038 shall provide notice to the division of insurance not less than 90 days before making changes to
1039 the selected drugs and an explanation of such changes. Upon verification by the division of
1040 insurance that the selected drugs meet the criteria identified in subsection (c), the division shall
1041 provide notice to its enrollees not less than 30 days before any changes to the selected drugs are
1042 made. This subsection shall apply to continuous glucose monitoring system components and,
1043 when applicable, delivery devices in the same manner in which it applies to drugs.

1044 (l) The division shall make public the drugs, continuous glucose monitoring system
1045 components, all components of the system of which the component is a part and delivery devices
1046 selected pursuant to this section.

1047 (m) If a high deductible health plan subject to this section is used to establish a savings
1048 account that is tax-exempt under the federal Internal Revenue Code, the provisions of this
1049 section shall apply to the plan to the maximum extent possible without causing the account to
1050 lose its tax-exempt status.

1051 SECTION 45. Chapter 175 of the General Laws is hereby amended by inserting after
1052 section 47TT the following section:-

1053 Section 47UU. (a) As used in this section, the following words shall have the following
1054 meanings unless the context clearly requires otherwise:

1055 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
1056 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
1057 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
1058 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
1059 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
1060 application that was approved by the United States Secretary of Health and Human Services
1061 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
1062 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
1063 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
1064 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
1065 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
1066 based on available data resources such as Medi-Span.

1067 “Continuous glucose monitoring system”, a system to continuously sense, transmit and
1068 display blood glucose levels.

1069 “Continuous glucose monitoring system component”, a component of a system to
1070 continuously monitor blood glucose levels such as a sensor, transmitter or display.

1071 “Delivery device”, a device that: (i) is used to deliver a brand name drug or a generic
1072 drug; and (ii) an individual can obtain with a prescription.

1073 “Diabetes treatment supplies”, supplies for the treatment of diabetes including, but not
1074 limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home
1075 use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips,
1076 lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose

1077 monitors for use by the legally blind and visual magnifying aids for use by the legally blind;
1078 provided, however, that diabetes treatment supplies shall not include a brand name drug, a
1079 generic drug, a continuous glucose monitoring system component or a delivery device.

1080 “Generic drug”, a retail drug that is: (i) marketed or distributed pursuant to an
1081 abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic
1082 drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962
1083 and was not originally marketed under a new drug application; or (iv) identified by the health
1084 benefit plan as a generic drug based on available data resources such as Medi-Span.

1085 “Separate delivery device”, a device that is used to deliver a brand name drug or a
1086 generic drug and that can be obtained with a prescription separate from, or in addition to, the
1087 brand name drug or generic drug that the device delivers.

1088 (b) Any carrier offering a policy, contract or certificate of health insurance under this
1089 chapter shall select 1 generic drug and 1 brand name drug used to treat each of the following
1090 chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 3 most prevalent heart conditions that
1091 disproportionately impact a particular demographic group, including people of color, determined
1092 by the center for health information analysis; provided, however, that for diabetes, the carrier
1093 shall also select a continuous glucose monitoring system component.

1094 The carrier shall select insulin as the drug used to treat diabetes. In selecting 1 insulin
1095 brand name drug and 1 insulin generic drug, the carrier shall select 1 insulin brand name drug per
1096 dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
1097 long-acting and premixed. To the extent possible, the carrier shall select 1 insulin generic drug

1098 per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
1099 long-acting and premixed, subject to such generic drug's availability.

1100 (c) In selecting the 1 generic drug, the 1 brand name drug and the delivery device, when
1101 applicable, used to treat each chronic condition pursuant to subsection (b), the carrier shall select
1102 a drug that is among the top 3 of the carrier's most prescribed or of the highest volume for the
1103 chronic condition, and shall consider whether the drug is:

1104 (i) of clear benefit and strongly supported by clinical evidence;

1105 (ii) likely to reduce hospitalizations or emergency department visits, reduce future
1106 exacerbations of illness progression or improve quality of life;

1107 (iii) relatively low cost when compared to the cost of an acute illness or incident
1108 prevented or delayed by the use of the service, treatment or drug;

1109 (iv) at low risk for overutilization, abuse, addiction, diversion or fraud;

1110 (v) likely to have a considerable financial impact on individual patients by reducing or
1111 eliminating patient cost-sharing pursuant to this section; and

1112 (vi) likely to enhance equity in disproportionately impacted demographic groups,
1113 including people of color.

1114 (d) The continuous glucose monitoring system component shall be selected in the same
1115 manner in which the 1 generic drug and 1 brand name drug are selected.

1116 (e)(1) The carrier shall provide coverage for the brand name drugs and generic drugs
1117 selected pursuant to subsection (b). Coverage for the selected generic drugs shall not be subject

1118 to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any
1119 deductible. Coverage for selected brand name drugs shall not be subject to any deductible or co-
1120 insurance and any co-payment shall not exceed \$25 per 30-day supply; provided, however, that
1121 nothing in this section shall prevent co-payments for a 30-day supply of the selected brand name
1122 drugs from being reduced below the amount specified in this section.

1123 (2) If use of a brand name drug or generic drug that the carrier selects requires a separate
1124 delivery device, the carrier shall select a delivery device for that drug in accordance with the
1125 criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the
1126 extent possible. The carrier shall provide coverage for the delivery device and the delivery
1127 device shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1128 shall not be subject to any deductible.

1129 (3) The carrier shall provide coverage for the continuous glucose monitoring system
1130 component selected pursuant to subsection (b) and all components of the blood glucose
1131 monitoring system of which the selected component is a part. All components of the applicable
1132 continuous glucose monitoring system shall not be subject to any cost-sharing, including co-
1133 payments and co-insurance, and shall not be subject to any deductible.

1134 (4) The carrier shall provide coverage for necessary diabetes treatment supplies. Such
1135 supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1136 shall not be subject to any deductible.

1137 (f) A member and their prescribing health care provider shall have access to a clear,
1138 readily accessible and convenient process to request to use a different brand name drug or
1139 generic drug of the same pharmacological class in place of a brand name drug or generic drug

1140 selected under subsection (b). Such request for an exception shall be granted if: (i) the brand
1141 name drugs and generic drugs selected under subsection (b) are contraindicated or will likely
1142 cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name drugs
1143 and generic drugs selected under subsection (b) are expected to be ineffective based on the
1144 known clinical characteristics of the member and the known characteristics of the prescription
1145 drug regimen; (iii) the member or prescribing health care provider: (A) has provided
1146 documentation to the carrier establishing that the member has previously tried the brand name
1147 drugs and generic drugs selected under subsection (b) ; and (B) such prescription drug was
1148 discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or
1149 (iv) the member or prescribing health care provider has provided documentation to the carrier
1150 establishing that the member: (A) is stable on a prescription drug prescribed by the health care
1151 provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental
1152 harm to the member. This subsection shall apply to continuous glucose monitoring system
1153 components and, when applicable, delivery devices.

1154 (g) The carrier shall implement a continuity of coverage policy for members that are new
1155 to the carrier, which shall provide coverage for a 90-day fill of a United States Food and Drug
1156 Administration-approved drug reimbursed through a pharmacy benefit that the member has
1157 already been prescribed and on which the member is stable, upon documentation by the
1158 member's prescriber, and which was selected by the member's previous payer pursuant to
1159 subsection (b); provided, however, that a carrier shall not apply any greater deductible,
1160 coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs
1161 covered by the plan; and provided further, that the carrier shall provide a member or their
1162 prescribing health care provider with information regarding the request pursuant to subsection (f)

1163 within 30 days of a member or their health care provider contacting the carrier to use a different
1164 brand name drug or generic drug of the same pharmacological class as the drugs selected
1165 pursuant to subsection (b). This subsection shall apply to continuous glucose monitoring system
1166 components and, when applicable, delivery devices.

1167 (h) Upon granting a request pursuant to subsection (f) or implementing a continuity of
1168 coverage pursuant to subsection (g), the carrier shall provide coverage for the prescription drug,
1169 continuous glucose monitoring system component or delivery device prescribed by the member's
1170 health care provider at the same cost as required under subsection (e). A denial of an exception
1171 shall be eligible for appeal by a member.

1172 (i) The carrier shall grant or deny a request pursuant to subsection (f) or (g) not more than
1173 3 business days following the receipt of all necessary information to establish the medical
1174 necessity of the prescribed treatment; provided, however, that if additional delay would result in
1175 significant risk to the member's health or well-being, the carrier shall respond not more than 24
1176 hours following the receipt of all necessary information to establish the medical necessity of the
1177 prescribed treatment. If a response by the carrier is not received within the time required under
1178 this subsection, an exception shall be deemed granted.

1179 (j) The carrier shall make changes in selected drugs not more than once annually and
1180 shall provide notice to the division of insurance not less than 90 days before making changes to
1181 the selected drugs and an explanation of such changes. Upon verification by the division of
1182 insurance that the selected drugs meet the criteria identified in subsection (c), the carrier shall
1183 provide notice to its members not less than 30 days before any changes to the selected drugs are

1184 made. This subsection shall apply to continuous glucose monitoring system components and,
1185 when applicable, delivery devices in the same manner in which it applies to drugs.

1186 (k) The carrier shall make public the drugs, continuous glucose monitoring system
1187 components, all components of the system of which the component is a part and delivery devices
1188 selected pursuant to this section.

1189 (l) If a high deductible health plan subject to this section is used to establish a savings
1190 account that is tax-exempt under the federal Internal Revenue Code, the provisions of this
1191 section shall apply to the plan to the maximum extent possible without causing the account to
1192 lose its tax-exempt status.

1193 SECTION 45A. Said chapter 175 of the General Laws is hereby further amended by
1194 inserting after section 47UU, inserted by section 45, the following section:-

1195 Section 47VV. (a) As used in this section, the following words shall have the following
1196 meanings unless the context clearly requires otherwise:

1197 “340B drug”, a drug that has been subject to any offer for reduced prices by a
1198 manufacturer pursuant to 42 U.S.C. 256b and is purchased by a 340B grantee as defined in this
1199 section.

1200 “340B grantee”, a federally qualified health center, a non-state, government public safety
1201 net hospital system established pursuant to chapter 147 of the acts of 1996 or a non-profit acute
1202 care hospital in the commonwealth that received not less than 60 per cent of its gross patient
1203 service revenue in fiscal year 2021 from government payers, including Medicare, MassHealth
1204 and the Health Safety Net Trust Fund based on the hospital’s fiscal year 2021 cost report and that

1205 is also authorized to participate in the federal drug discount program under 42 U.S.C 256b,
1206 including its pharmacies or any contracted pharmacy.

1207 “Distributor”, a person engaged in the sale, distribution or delivery, at wholesale, of
1208 drugs or medicines within the commonwealth, including entities operating outside of the
1209 commonwealth that cause deliveries of drugs or medicines to be made within the
1210 commonwealth.

1211 “Federally qualified health center”, an entity receiving a grant under 42 U.S.C. 254(b).

1212 “Manufacturer”, an entity engaged in the production, preparation, propagation,
1213 compounding, conversion or processing of prescription drugs or medical devices, either directly
1214 or indirectly, by extraction from substances of natural origin, or independently by means of
1215 chemical synthesis or by a combination of extraction and chemical synthesis, or any entity
1216 engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs.

1217 “Pharmacy”, an entity engaged in the drug business, as defined in section 37 of chapter
1218 112, or engaged in the practice of compounding to fulfill a practitioner prescription.

1219 (b) A manufacturer or distributor shall not:

1220 (i) deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the
1221 acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract
1222 with a 340B grantee and is authorized under such contract to receive and dispense 340B drugs on
1223 behalf of the covered entity unless such receipt is prohibited by the United States Department of
1224 Health and Human Services; or

1225 (ii) interfere with a contract between a pharmacy and a 340B grantee.

1226 (c) The commission of any act prohibited under subsection (b) of this section shall
1227 constitute an unfair or deceptive practice within the meaning of section 2 of chapter 93A. Each
1228 commission of a prohibited act shall constitute a separate violation.

1229 (d) The attorney general shall have jurisdiction, consistent with the provisions of chapter
1230 93A, to enforce the provisions of this section. The attorney general shall issue regulations to
1231 implement this chapter.

1232 (e) The board of registration in pharmacy shall promulgate regulations to implement and
1233 enforce of this section and may investigate any complaint of a violation of this section by an
1234 individual or entity licensed by the board and may impose discipline, suspension or revocation of
1235 any such license.

1236 (f) Nothing in this section shall be construed or applied to be less restrictive than any
1237 federal law as to any person or entity regulated by this section or to conflict with: (i) any
1238 applicable federal law and related regulations; or (ii) any other general law that is compatible
1239 with applicable federal law.

1240 (g) Limited distribution of a drug required under 21 U.S.C. 355-1 shall not be a violation
1241 of this section.

1242 SECTION 46. Section 226 of said chapter 175, as appearing in the 2022 Official Edition,
1243 is hereby amended by striking out subsection (a) and inserting in place thereof the following
1244 subsection:-

1245 (a) For the purposes of this section, the term “pharmacy benefit manager” shall mean a
1246 person, business or other entity, however organized, that directly or through a subsidiary

1247 provides pharmacy benefit management services for prescription drugs and devices on behalf of
1248 a health benefit plan sponsor, including, but not limited to, a self-insurance plan, labor union or
1249 other third-party payer; provided, however, that pharmacy benefit management services shall
1250 include, but not be limited to: (i) the processing and payment of claims for prescription drugs;
1251 (ii) the performance of drug utilization review; (iii) the processing of drug prior authorization
1252 requests; (iv) pharmacy contracting; (v) the adjudication of appeals or grievances related to
1253 prescription drug coverage contracts; (vi) formulary administration; (vii) drug benefit design;
1254 (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x) clinical, safety and
1255 adherence programs for pharmacy services; and (xi) managing the cost of covered prescription
1256 drugs; provided further, that “pharmacy benefit manager” shall include a health benefit plan
1257 sponsor that does not contract with a pharmacy benefit manager and manages its own
1258 prescription drug benefits unless specifically exempted.

1259 SECTION 47. Chapter 176A of the General Laws is hereby amended by inserting after
1260 section 8UU the following section:-

1261 Section 8VV. (a) As used in this section, the following words shall have the following
1262 meanings unless the context clearly requires otherwise:

1263 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
1264 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
1265 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
1266 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
1267 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
1268 application that was approved by the United States Secretary of Health and Human Services

1269 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
1270 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
1271 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
1272 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
1273 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
1274 based on available data resources such as Medi-Span.

1275 “Continuous glucose monitoring system”, a system to continuously sense, transmit and
1276 display blood glucose levels.

1277 “Continuous glucose monitoring system component”, a component of a system to
1278 continuously monitor blood glucose levels such as a sensor, transmitter or display.

1279 “Delivery device”, a device that: (i) is used to deliver a brand name drug or a generic
1280 drug; and (ii) an individual can obtain with a prescription.

1281 “Diabetes treatment supplies”, supplies for the treatment of diabetes including, but not
1282 limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home
1283 use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips,
1284 lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose
1285 monitors for use by the legally blind and visual magnifying aids for use by the legally blind;
1286 provided, however, that diabetes treatment supplies shall not include a brand name drug, a
1287 generic drug, a continuous glucose monitoring system component, or a delivery device.

1288 “Generic drug”, a retail drug that is: (i) marketed or distributed pursuant to an
1289 abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic
1290 drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962

1291 and was not originally marketed under a new drug application; or (iv) identified by the health
1292 benefit plan as a generic drug based on available data resources such as Medi-Span.

1293 “Separate delivery device”, a device that is used to deliver a brand name drug or a
1294 generic drug and that can be obtained with a prescription separate from, or in addition to, the
1295 brand name drug or generic drug that the device delivers.

1296 (b) Any carrier offering a policy, contract or certificate of health insurance under this
1297 chapter shall select 1 generic drug and 1 brand name drug used to treat each of the following
1298 chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 3 most prevalent heart conditions that
1299 disproportionately impact a particular demographic group, including people of color, determined
1300 by the center for health information analysis; provided, however, that for diabetes, the carrier
1301 shall also select a continuous glucose monitoring system component.

1302 The carrier shall select insulin as the drug used to treat diabetes. In selecting 1 insulin
1303 brand name drug and 1 insulin generic drug, the carrier shall select 1 insulin brand name drug per
1304 dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
1305 long-acting and premixed. To the extent possible, the carrier shall select 1 insulin generic drug
1306 per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
1307 long-acting and premixed, subject to such generic drug’s availability.

1308 (c) In selecting the 1 generic drug, the 1 brand name drug and the delivery device, when
1309 applicable, used to treat each chronic condition pursuant to subsection (b), the carrier shall select
1310 a drug that is among the top 3 of the carrier’s most prescribed or of the highest volume for the
1311 chronic condition and shall consider whether the drug is:

1312 (i) of clear benefit and strongly supported by clinical evidence;

1313 (ii) likely to reduce hospitalizations or emergency department visits, reduce future
1314 exacerbations of illness progression or improve quality of life;

1315 (iii) relatively low cost when compared to the cost of an acute illness or incident
1316 prevented or delayed by the use of the service, treatment or drug;

1317 (iv) at low risk for overutilization, abuse, addiction, diversion or fraud;

1318 (v) likely to have a considerable financial impact on individual patients by reducing or
1319 eliminating patient cost-sharing pursuant to this section; and

1320 (vi) likely to enhance equity in disproportionately impacted demographic groups,
1321 including people of color.

1322 (d) The continuous glucose monitoring system component shall be selected in the same
1323 manner in which the 1 generic drug and 1 brand name drug are selected.

1324 (e)(1) The carrier shall provide coverage for the brand name drugs and generic drugs
1325 selected pursuant to subsection (b). Coverage for the selected generic drugs shall not be subject
1326 to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any
1327 deductible. Coverage for selected brand name drugs shall not be subject to any deductible or co-
1328 insurance and any co-payment shall not exceed \$25 per 30-day supply; provided, however, that
1329 nothing in this section shall prevent co-payments for a 30-day supply of the selected brand name
1330 drugs from being reduced below the amount specified in this section.

1331 (2) If use of a brand name drug or generic drug that the carrier selects requires a separate
1332 delivery device, the carrier shall select a delivery device for that drug in accordance with the
1333 criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the

1334 extent possible. The carrier shall provide coverage for the delivery device and the delivery
1335 device shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1336 shall not be subject to any deductible.

1337 (3) The carrier shall provide coverage for the continuous glucose monitoring system
1338 component selected pursuant to subsection (b) and all components of the blood glucose
1339 monitoring system of which the selected component is a part. All components of the applicable
1340 continuous glucose monitoring system shall not be subject to any cost-sharing, including co-
1341 payments and co-insurance, and shall not be subject to any deductible.

1342 (4) The carrier shall provide coverage for necessary diabetes treatment supplies. Such
1343 supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1344 shall not be subject to any deductible.

1345 (f) A member and their prescribing health care provider shall have access to a clear,
1346 readily accessible and convenient process to request to use a different brand name drug or
1347 generic drug of the same pharmacological class in place of a brand name drug or generic drug
1348 selected under subsection (b). Such request for an exception shall be granted if: (i) the brand
1349 name drugs and generic drugs selected under subsection (b) are contraindicated or will likely
1350 cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name drugs
1351 and generic drugs selected under said subsection (b) are expected to be ineffective based on the
1352 known clinical characteristics of the member and the known characteristics of the prescription
1353 drug regimen; (iii) the member or prescribing health care provider: (A) has provided
1354 documentation to the carrier establishing that the member has previously tried the brand name
1355 drugs and generic drugs selected under subsection (b) ; and (B) such prescription drug was

1356 discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or
1357 (iv) the member or prescribing health care provider has provided documentation to the carrier
1358 establishing that the member: (A) is stable on a prescription drug prescribed by the health care
1359 provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental
1360 harm to the member. This subsection shall apply to continuous glucose monitoring system
1361 components and, when applicable, delivery devices.

1362 (g) The carrier shall implement a continuity of coverage policy for members that are new
1363 to the carrier, which shall provide coverage for a 90-day fill of a United States Food and Drug
1364 Administration-approved drug reimbursed through a pharmacy benefit that the member has
1365 already been prescribed and on which the member is stable, upon documentation by the
1366 member's prescriber, and which was selected by the member's previous payer pursuant to
1367 subsection (b); provided, however, that a carrier shall not apply any greater deductible,
1368 coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs
1369 covered by the plan; and provided further, that the carrier shall provide a member or their
1370 prescribing health care provider with information regarding the request pursuant to subsection (f)
1371 within 30 days of a member or their health care provider contacting the carrier to use a different
1372 brand name drug or generic drug of the same pharmacological class as the drugs selected
1373 pursuant to subsection (b). This subsection shall apply to continuous glucose monitoring system
1374 components and, when applicable, delivery devices.

1375 (h) Upon granting a request pursuant to subsection (f) or implementing a continuity of
1376 coverage pursuant to subsection (g), the carrier shall provide coverage for the prescription drug,
1377 continuous glucose monitoring system component or delivery device prescribed by the member's

1378 health care provider at the same cost as required under subsection (e). A denial of an exception
1379 shall be eligible for appeal by a member.

1380 (i) The carrier shall grant or deny a request pursuant to subsection (f) or (g) not more than
1381 3 business days following the receipt of all necessary information to establish the medical
1382 necessity of the prescribed treatment; provided, however, that if additional delay would result in
1383 significant risk to the member's health or well-being, the carrier shall respond not more than 24
1384 hours following the receipt of all necessary information to establish the medical necessity of the
1385 prescribed treatment. If a response by the carrier is not received within the time required under
1386 this subsection, an exception shall be deemed granted.

1387 (j) The carrier shall make changes in selected drugs not more than once annually and
1388 shall provide notice to the division of insurance not less than 90 days before making changes to
1389 the selected drugs and an explanation of such changes. Upon verification by the division of
1390 insurance that the selected drugs meet the criteria identified in subsection (c), the carrier shall
1391 provide notice to its members not less than 30 days before any changes to the selected drugs are
1392 made. This subsection shall apply to continuous glucose monitoring system components and,
1393 when applicable, delivery devices in the same manner in which it applies to drugs.

1394 (k) The carrier shall make public the drugs, continuous glucose monitoring system
1395 components, all components of the system of which the component is a part and delivery devices
1396 selected pursuant to this section.

1397 (l) If a high deductible health plan subject to this section is used to establish a savings
1398 account that is tax-exempt under the federal Internal Revenue Code, the provisions of this

1399 section shall apply to the plan to the maximum extent possible without causing the account to
1400 lose its tax-exempt status.

1401 SECTION 48. Chapter 176B of the General Laws is hereby amended by inserting after
1402 section 4UU the following section:-

1403 Section 4VV. (a) As used in this section, the following words shall have the following
1404 meanings unless the context clearly requires otherwise:

1405 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
1406 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
1407 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
1408 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
1409 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
1410 application that was approved by the United States Secretary of Health and Human Services
1411 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
1412 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
1413 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
1414 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
1415 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
1416 based on available data resources such as Medi-Span.

1417 “Continuous glucose monitoring system”, a system to continuously sense, transmit and
1418 display blood glucose levels.

1419 “Continuous glucose monitoring system component”, a component of a system to
1420 continuously monitor blood glucose levels such as a sensor, transmitter or display.

1421 “Delivery device”, a device that: (i) is used to deliver a brand name drug or a generic
1422 drug; and (ii) an individual can obtain with a prescription.

1423 “Diabetes treatment supplies”, supplies for the treatment of diabetes including, but not
1424 limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home
1425 use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips,
1426 lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose
1427 monitors for use by the legally blind and visual magnifying aids for use by the legally blind;
1428 provided, however, that diabetes treatment supplies shall not include a brand name drug, a
1429 generic drug, a continuous glucose monitoring system component or a delivery device.

1430 “Generic drug”, a retail drug that is: (i) marketed or distributed pursuant to an
1431 abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic
1432 drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962
1433 and was not originally marketed under a new drug application; or (iv) identified by the health
1434 benefit plan as a generic drug based on available data resources such as Medi-Span.

1435 “Separate delivery device”, a device that is used to deliver a brand name drug or a
1436 generic drug and that can be obtained with a prescription separate from, or in addition to, the
1437 brand name drug or generic drug that the device delivers.

1438 (b) Any carrier offering a policy, contract or certificate of health insurance under this
1439 chapter shall select 1 generic drug and 1 brand name drug used to treat each of the following
1440 chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 3 most prevalent heart conditions that
1441 disproportionately impact a particular demographic group, including people of color, determined

1442 by the center for health information analysis; provided, however, that for diabetes, the carrier
1443 shall also select a continuous glucose monitoring system component.

1444 The carrier shall select insulin as the drug used to treat diabetes. In selecting 1 insulin
1445 brand name drug and 1 insulin generic drug, the carrier shall select 1 insulin brand name drug per
1446 dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
1447 long-acting and premixed. To the extent possible, the carrier shall select 1 insulin generic drug
1448 per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
1449 long-acting and premixed, subject to such generic drug's availability.

1450 (c) In selecting the 1 generic drug, the 1 brand name drug and the delivery device, when
1451 applicable, used to treat each chronic condition pursuant to subsection (b), the carrier shall select
1452 a drug that is among the top 3 of the carrier's most prescribed or of the highest volume for the
1453 chronic condition, and shall consider whether the drug is:

1454 (i) of clear benefit and strongly supported by clinical evidence;

1455 (ii) likely to reduce hospitalizations or emergency department visits, reduce future
1456 exacerbations of illness progression or improve quality of life;

1457 (iii) relatively low cost when compared to the cost of an acute illness or incident
1458 prevented or delayed by the use of the service, treatment or drug;

1459 (iv) at low risk for overutilization, abuse, addiction, diversion or fraud;

1460 (v) likely to have a considerable financial impact on individual patients by reducing or
1461 eliminating patient cost-sharing pursuant to this section; and

1462 (vi) likely to enhance equity in disproportionately impacted demographic groups,
1463 including people of color.

1464 (d) The continuous glucose monitoring system component shall be selected in the same
1465 manner in which the 1 generic drug and 1 brand name drug are selected.

1466 (e)(1) The carrier shall provide coverage for the brand name drugs and generic drugs
1467 selected pursuant to subsection (b). Coverage for the selected generic drugs shall not be subject
1468 to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any
1469 deductible. Coverage for selected brand name drugs shall not be subject to any deductible or co-
1470 insurance and any co-payment shall not exceed \$25 per 30-day supply; provided, however, that
1471 nothing in this section shall prevent co-payments for a 30-day supply of the selected brand name
1472 drugs from being reduced below the amount specified in this section.

1473 (2) If use of a brand name drug or generic drug that the carrier selects requires a separate
1474 delivery device, the carrier shall select a delivery device for that drug in accordance with the
1475 criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the
1476 extent possible. The carrier shall provide coverage for the delivery device and the delivery
1477 device shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1478 shall not be subject to any deductible.

1479 (3) The carrier shall provide coverage for the continuous glucose monitoring system
1480 component selected pursuant to subsection (b) and all components of the blood glucose
1481 monitoring system of which the selected component is a part. All components of the applicable
1482 continuous glucose monitoring system shall not be subject to any cost-sharing, including co-
1483 payments and co-insurance, and shall not be subject to any deductible.

1484 (4) The carrier shall provide coverage for necessary diabetes treatment supplies. Such
1485 supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1486 shall not be subject to any deductible.

1487 (f) A member and their prescribing health care provider shall have access to a clear,
1488 readily accessible and convenient process to request to use a different brand name drug or
1489 generic drug of the same pharmacological class in place of a brand name drug or generic drug
1490 selected under subsection (b). Such request for an exception shall be granted if: (i) the brand
1491 name drugs and generic drugs selected under said subsection (b) are contraindicated or will
1492 likely cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name
1493 drugs and generic drugs selected under said subsection (b) are expected to be ineffective based
1494 on the known clinical characteristics of the member and the known characteristics of the
1495 prescription drug regimen; (iii) the member or prescribing health care provider: (A) has provided
1496 documentation to the carrier establishing that the member has previously tried the brand name
1497 drugs and generic drugs selected under said subsection (b) while covered by the carrier or by a
1498 previous health insurance carrier or a health benefit plan; and (B) such prescription drug was
1499 discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or
1500 (iv) the member or prescribing health care provider has provided documentation to the carrier
1501 establishing that the member: (A) is stable on a prescription drug prescribed by the health care
1502 provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental
1503 harm to the member. This subsection shall apply to continuous glucose monitoring system
1504 components and, when applicable, delivery devices.

1505 (g) The carrier shall implement a continuity of coverage policy for members that are new
1506 to the carrier, which shall provide coverage for a 90-day fill of a United States Food and Drug

1507 Administration-approved drug reimbursed through a pharmacy benefit that the member has
1508 already been prescribed and on which the member is stable, upon documentation by the
1509 member's prescriber, and which was selected by the member's previous payer pursuant to
1510 subsection (b); provided, however, that a carrier shall not apply any greater deductible,
1511 coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs
1512 covered by the plan; and provided further, that the carrier shall provide a member or their
1513 prescribing health care provider with information regarding the request pursuant to subsection (f)
1514 within 30 days of a member or their health care provider contacting the carrier to use a different
1515 brand name drug or generic drug of the same pharmacological class as the drugs selected
1516 pursuant to subsection (b). This subsection shall apply to continuous glucose monitoring system
1517 components and, when applicable, delivery devices.

1518 (h) Upon granting a request pursuant to subsection (f) or implementing a continuity of
1519 coverage pursuant to subsection (g), the carrier shall provide coverage for the prescription drug,
1520 continuous glucose monitoring system component or delivery device prescribed by the member's
1521 health care provider at the same cost as required under subsection (e). A denial of an exception
1522 shall be eligible for appeal by a member.

1523 (i) The carrier shall grant or deny a request pursuant to subsection (f) or (g) not more than
1524 3 business days following the receipt of all necessary information to establish the medical
1525 necessity of the prescribed treatment; provided, however, that if additional delay would result in
1526 significant risk to the member's health or well-being, the carrier shall respond not more than 24
1527 hours following the receipt of all necessary information to establish the medical necessity of the
1528 prescribed treatment. If a response by the carrier is not received within the time required under
1529 this subsection, an exception shall be deemed granted.

1530 (j) The carrier shall make changes in selected drugs not more than once annually and
1531 shall provide notice to the division of insurance not less than 90 days before making such
1532 changes to the selected drugs and an explanation of those changes. Upon verification by the
1533 division of insurance that the selected drugs meet the criteria identified in subsection (c), the
1534 carrier shall provide notice to its members not less than 30 days before any changes to the
1535 selected drugs are made. This subsection shall apply to continuous glucose monitoring system
1536 components and, when applicable, delivery devices in the same manner in which it applies to
1537 drugs.

1538 (k) The carrier shall make public the drugs, continuous glucose monitoring system
1539 components, all components of the system of which the component is a part and delivery devices
1540 selected pursuant to this section.

1541 (l) If a high deductible health plan subject to this section is used to establish a savings
1542 account that is tax-exempt under the federal Internal Revenue Code, the provisions of this
1543 section shall apply to the plan to the maximum extent possible without causing the account to
1544 lose its tax-exempt status.

1545 SECTION 49. The fourth paragraph of section 3B of chapter 176D of the General Laws,
1546 as appearing in the 2022 Official Edition, is hereby amended by inserting after the second
1547 sentence the following sentence:- Neither a carrier nor the group insurance commission may
1548 prohibit the dispensing of a specialty drug that is included in its pharmaceutical drug benefits to
1549 an insured by any network specialty pharmacy licensed under section 39K of chapter 112;
1550 provided, however, that the pharmacy: (i) agrees to the in-network reimbursement rate for the
1551 specialty drug; (ii) is able to comply with the standards for special handling, administration,

1552 quality, safety and monitoring established under subsection (c) of said section 39K of said
1553 chapter 112; and (iii) complies with all reasonable carrier network terms and conditions for
1554 dispensing the specialty drug; provided further, that neither a carrier nor the group insurance
1555 commission may impose any terms or conditions on a specialty pharmacy licensed under said
1556 section 39K of said chapter 112 that are unreasonable or prevent the specialty pharmacy from
1557 providing the specialty drug; provided further, that the commissioner may grant a waiver
1558 exempting a carrier from the requirements of this sentence to a carrier whose percentage of
1559 members enrolled in government programs is 80 per cent or more, as indicated in the most recent
1560 enrollment data published by the center for health information and analysis; and provided
1561 further, that for the purposes of this sentence, the term “carrier” shall apply to the division of
1562 medical assistance to the extent allowed under federal law.

1563 SECTION 50. Said section 3B of said chapter 176D, as so appearing, is hereby further
1564 amended by striking out the fifth paragraph and inserting in place thereof the following
1565 paragraph:-

1566 A carrier shall not prohibit a network pharmacy from offering and providing mail
1567 delivery services to an insured; provided, however, that the network pharmacy agrees to the
1568 reimbursement terms and conditions and discloses to the insured any delivery service fee
1569 associated with the delivery service.

1570 SECTION 51. The eighth paragraph of said section 3B of said chapter 176D, as so
1571 appearing, is hereby amended by adding the following sentence:- The term “specialty drugs”
1572 shall mean a specialty drug as defined under section 39K of chapter 112.

1573 SECTION 52. Chapter 176G of the General Laws is hereby amended by inserting after
1574 section 4MM the following section:-

1575 Section 4NN. (a) As used in this section, the following words shall have the following
1576 meanings unless the context clearly requires otherwise:

1577 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
1578 drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an
1579 application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that
1580 is pharmaceutically equivalent, as that term is defined by the United States Food and Drug
1581 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
1582 application that was approved by the United States Secretary of Health and Human Services
1583 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
1584 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
1585 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
1586 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
1587 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand name drug
1588 based on available data resources such as Medi-Span.

1589 “Continuous glucose monitoring system”, a system to continuously sense, transmit and
1590 display blood glucose levels.

1591 “Continuous glucose monitoring system component”, a component of a system to
1592 continuously monitor blood glucose levels such as a sensor, transmitter or display.

1593 “Delivery device”, a device that: (i) is used to deliver a brand name drug or a generic
1594 drug; and (ii) an individual can obtain with a prescription.

1595 “Diabetes treatment supplies”, supplies for the treatment of diabetes including, but not
1596 limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home
1597 use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips,
1598 lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose
1599 monitors for use by the legally blind and visual magnifying aids for use by the legally blind;
1600 provided, however, that diabetes treatment supplies shall not include a brand name drug, a
1601 generic drug, a continuous glucose monitoring system component, or a delivery device.”

1602 “Generic drug”, a retail drug that is: (i) marketed or distributed pursuant to an
1603 abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic
1604 drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962
1605 and was not originally marketed under a new drug application; or (iv) identified by the health
1606 benefit plan as a generic drug based on available data resources such as Medi-Span.

1607 “Separate delivery device”, a device that is used to deliver a brand name drug or a
1608 generic drug and that can be obtained with a prescription separate from, or in addition to, the
1609 brand name drug or generic drug that the device delivers.

1610 (b) Any carrier offering a policy, contract or certificate of health insurance under this
1611 chapter shall select 1 generic drug and 1 brand name drug used to treat each of the following
1612 chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 3 most prevalent heart conditions that
1613 disproportionately impact a particular demographic group, including people of color, determined
1614 by the center for health information analysis; provided, however, that for diabetes, the carrier
1615 shall also select a continuous glucose monitoring system component.

1616 The carrier shall select insulin as the drug used to treat diabetes. In selecting 1 insulin
1617 brand name drug and 1 insulin generic drug, the carrier shall select 1 insulin brand name drug per
1618 dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
1619 long-acting and premixed. To the extent possible, the carrier shall select 1 insulin generic drug
1620 per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra
1621 long-acting and premixed, subject to such generic drug's availability.

1622 (c) In selecting the 1 generic drug, the 1 brand name drug and the delivery device, when
1623 applicable, used to treat each chronic condition pursuant to subsection (b), the carrier shall select
1624 a drug that is among the top 3 of the carrier's most prescribed or of the highest volume for the
1625 chronic condition, and shall consider whether the drug is:

1626 (i) of clear benefit and strongly supported by clinical evidence;

1627 (ii) likely to reduce hospitalizations or emergency department visits, reduce future
1628 exacerbations of illness progression or improve quality of life;

1629 (iii) relatively low cost when compared to the cost of an acute illness or incident
1630 prevented or delayed by the use of the service, treatment or drug;

1631 (iv) at low risk for overutilization, abuse, addiction, diversion or fraud;

1632 (v) likely to have a considerable financial impact on individual patients by reducing or
1633 eliminating patient cost-sharing pursuant to this section; and

1634 (vi) likely to enhance equity in disproportionately impacted demographic groups,
1635 including people of color.

1636 (d) The continuous glucose monitoring system component shall be selected in the same
1637 manner in which the 1 generic drug and 1 brand name drug are selected.

1638 (e)(1) The carrier shall provide coverage for the brand name drugs and generic drugs
1639 selected pursuant to subsection (b). Coverage for the selected generic drugs shall not be subject
1640 to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any
1641 deductible. Coverage for selected brand name drugs shall not be subject to any deductible or co-
1642 insurance and any co-payment shall not exceed \$25 per 30-day supply; provided, however, that
1643 nothing in this section shall prevent co-payments for a 30-day supply of the selected brand name
1644 drugs from being reduced below the amount specified in this section.

1645 (2) If use of a brand name drug or generic drug that the carrier selects requires a separate
1646 delivery device, the carrier shall select a delivery device for that drug in accordance with the
1647 criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the
1648 extent possible. The carrier shall provide coverage for the delivery device and the delivery
1649 device shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1650 shall not be subject to any deductible.

1651 (3) The carrier shall provide coverage for the continuous glucose monitoring system
1652 component selected pursuant to subsection (b) and all components of the blood glucose
1653 monitoring system of which the selected component is a part. All components of the applicable
1654 continuous glucose monitoring system shall not be subject to any cost-sharing, including co-
1655 payments and co-insurance, and shall not be subject to any deductible.

1656 (4) The carrier shall provide coverage for necessary diabetes treatment supplies. Such
1657 supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and
1658 shall not be subject to any deductible.

1659 (f) A member and their prescribing health care provider shall have access to a clear,
1660 readily accessible and convenient process to request to use a different brand name drug or
1661 generic drug of the same pharmacological class in place of a brand name drug or generic drug
1662 selected under subsection (b). Such request for an exception shall be granted if: (i) the brand
1663 name drugs and generic drugs selected under said subsection (b) are contraindicated or will
1664 likely cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name
1665 drugs and generic drugs selected under said subsection (b) are expected to be ineffective based
1666 on the known clinical characteristics of the member and the known characteristics of the
1667 prescription drug regimen; (iii) the member or prescribing health care provider: (A) has provided
1668 documentation to the carrier establishing that the member has previously tried the brand name
1669 drugs and generic drugs selected under said subsection (b); and (B) such prescription drug was
1670 discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or
1671 (iv) the member or prescribing health care provider has provided documentation to the carrier
1672 establishing that the member: (A) is stable on a prescription drug prescribed by the health care
1673 provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental
1674 harm to the member. This subsection shall apply to continuous glucose monitoring system
1675 components and, when applicable, delivery devices.

1676 (g) The carrier shall implement a continuity of coverage policy for members that are new
1677 to the carrier, which shall provide coverage for a 90-day fill of a United States Food and Drug
1678 Administration-approved drug reimbursed through a pharmacy benefit that the member has

1679 already been prescribed and on which the member is stable, upon documentation by the
1680 member's prescriber, and which was selected by the member's previous payer pursuant to
1681 subsection (b); provided, however, that a carrier shall not apply any greater deductible,
1682 coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs
1683 covered by the plan; and provided further, that the carrier shall provide a member or their
1684 prescribing health care provider with information regarding the request pursuant to subsection (f)
1685 within 30 days of a member or their health care provider contacting the carrier to use a different
1686 brand name drug or generic drug of the same pharmacological class as the drugs selected
1687 pursuant to subsection (b). This subsection shall apply to continuous glucose monitoring system
1688 components and, when applicable, delivery devices.

1689 (h) Upon granting a request pursuant to subsection (f) or implementing a continuity of
1690 coverage pursuant to subsection (g), the carrier shall provide coverage for the prescription drug,
1691 continuous glucose monitoring system component or delivery device prescribed by the member's
1692 health care provider at the same cost as required under subsection (e). A denial of an exception
1693 shall be eligible for appeal by a member.

1694 (i) The carrier shall grant or deny a request pursuant to subsection (f) or (g) not more than
1695 3 business days following the receipt of all necessary information to establish the medical
1696 necessity of the prescribed treatment; provided, however, that if additional delay would result in
1697 significant risk to the member's health or well-being, the carrier shall respond not more than 24
1698 hours following the receipt of all necessary information to establish the medical necessity of the
1699 prescribed treatment. If a response by the carrier is not received within the time required under
1700 this subsection, an exception shall be deemed granted.

1701 (j) The carrier shall make changes in selected drugs not more than once annually and
1702 shall provide notice to the division of insurance not less than 90 days before making such
1703 changes to the selected drugs and an explanation of those changes. Upon verification by the
1704 division of insurance that the selected drugs meet the criteria identified in subsection (c), the
1705 carrier shall provide notice to its members not less than 30 days before any changes to the
1706 selected drugs are made. This subsection shall apply to continuous glucose monitoring system
1707 components and, when applicable, delivery devices in the same manner in which it applies to
1708 drugs.

1709 (k) The carrier shall make public the drugs, continuous glucose monitoring system
1710 components, all components of the system of which the component is a part and delivery device
1711 selected pursuant to this section.

1712 (l) If a high deductible health plan subject to this section is used to establish a savings
1713 account that is tax-exempt under the federal Internal Revenue Code, the provisions of this
1714 section shall apply to the plan to the maximum extent possible without causing the account to
1715 lose its tax-exempt status.

1716 SECTION 53. Section 2 of chapter 176O of the General Laws, as appearing in the 2022
1717 Official Edition, is hereby amended by adding the following subsection:-

1718 (i) Every 3 years, a carrier that contracts with a pharmacy benefit manager shall
1719 coordinate an audit of the operations of the pharmacy benefit manager to ensure compliance with
1720 this chapter and to examine the pricing and rebates applicable to prescription drugs that are
1721 provided to the carrier's covered persons.

1722 SECTION 54. Said chapter 176O is hereby further amended by inserting after section 22
1723 the following section:-

1724 Section 22A. Notwithstanding any other general or special law to the contrary, each
1725 carrier shall require that a pharmacy benefit manager receive a license from the division under
1726 chapter 176Y as a condition of contracting with that carrier.

1727 SECTION 55. Said chapter 176O is hereby further amended by adding the following
1728 section:-

1729 Section 30. (a) For the purposes of this section, the following words shall have the
1730 following meanings unless the context clearly requires otherwise:

1731 “Cost-sharing”, an amount owed by an individual under the terms of the individual’s
1732 health benefit plan.

1733 “Pharmacy retail price”, the amount an individual would pay for a prescription drug at a
1734 pharmacy if the individual purchased that prescription drug at that pharmacy without using a
1735 health benefit plan or any other prescription drug benefit or discount.

1736 (b) At the point of sale, a pharmacy shall charge an individual the lesser of: (i)
1737 appropriate cost-sharing amount; or (ii) pharmacy retail price; provided, however, that a carrier,
1738 or an entity that manages or administers benefits for a carrier, shall not require an individual to
1739 make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser
1740 of the: (A) individual’s cost share; or (B) pharmacy retail price.

1741 (c) A contract shall not: (i) prohibit a pharmacist from complying with this section; or (ii)
1742 impose a penalty on the pharmacist or pharmacy for complying with this section.

1743 SECTION 56. The General Laws are hereby amended by inserting after chapter 176X the
1744 following chapter:-

1745 Chapter 176Y. LICENSING AND REGULATION OF PHARMACY BENEFIT
1746 MANAGERS.

1747 Section 1. As used in this chapter, the following words shall have the following meanings
1748 unless the context clearly requires otherwise:

1749 “Carrier”, an insurer licensed or otherwise authorized to transact accident or health
1750 insurance under chapter 175, a nonprofit hospital service corporation organized under chapter
1751 176A, a non-profit medical service corporation organized under chapter 176B, a health
1752 maintenance organization organized under chapter 176G and an organization entering into a
1753 preferred provider arrangement under chapter 176I; provided, however, that “carrier” shall not
1754 include an employer purchasing coverage or acting on behalf of its employees or the employees
1755 of any subsidiary or affiliated corporation of the employer; and provided further, that unless
1756 otherwise provided, “carrier” shall not include any entity to the extent it offers a policy,
1757 certificate or contract that provides coverage solely for dental care services or vision care
1758 services.

1759 “Center”, the center for health information and analysis established in chapter 12C.

1760 “Commissioner”, the commissioner of insurance.

1761 “Division”, the division of insurance.

1762 “Health benefit plan”, a contract, certificate or agreement entered into, offered or issued
1763 by a carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care

1764 services; provided, however, that the commissioner may by regulation define other health
1765 coverage as a “health benefit plan” for the purposes of this chapter.

1766 “Pharmacy”, a physical or electronic facility under the direction or supervision of a
1767 registered pharmacist that is authorized to dispense prescription drugs and has entered into a
1768 network contract with a pharmacy benefit manager or a carrier.

1769 “Pharmacy benefit manager”, a person, business or other entity, however organized, that
1770 directly or through a subsidiary provides pharmacy benefit management services for prescription
1771 drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-
1772 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
1773 management services shall include, but not be limited to: (i) the processing and payment of
1774 claims for prescription drugs; (ii) the performance of drug utilization review; (iii) the processing
1775 of drug prior authorization requests; (iv) pharmacy contracting; (v) the adjudication of appeals or
1776 grievances related to prescription drug coverage contracts; (vi) formulary administration; (vii)
1777 drug benefit design; (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x)
1778 clinical, safety and adherence programs for pharmacy services; and (xi) managing the cost of
1779 covered prescription drugs; provided further, that “pharmacy benefit manager” shall not include
1780 a health benefit plan sponsor unless otherwise specified by the division.

1781 Section 2. (a) No person, business or other entity shall establish or operate as a pharmacy
1782 benefit manager without obtaining a license from the division pursuant to this section. A license
1783 may be granted only when the division is satisfied that the entity possesses the necessary
1784 organization, background expertise financial integrity to supply the services sought to be offered.
1785 A pharmacy benefit manager license shall be valid for a period of 3 years and shall be renewable

1786 for additional 3-year periods. Initial application and renewal fees for the license shall be
1787 established pursuant to section 3B of chapter 7.

1788 (b) A license granted pursuant to this section and any rights or interests therein shall not
1789 be transferable.

1790 (c) A person, business or other entity licensed as a pharmacy benefit manager shall
1791 submit data and reporting information to the center according to the standards and methods
1792 specified by the center pursuant to section 10A of chapter 12C.

1793 (d) The division may issue or renew a license pursuant to this section, subject to
1794 restrictions in order to protect the interests of consumers. Such restrictions may include: (i)
1795 limiting the type of services that a license holder may provide; (ii) limiting the activities in which
1796 the license holder may be engaged; or (iii) addressing conflicts of interest between pharmacy
1797 benefit managers and health plan sponsors.

1798 (e) The division shall develop an application for licensure of pharmacy benefit managers
1799 that shall include, but not be limited to: (i) the name of the applicant or pharmacy benefit
1800 manager; (ii) the address and contact telephone number for the applicant or pharmacy benefit
1801 manager; (iii) the name and address of the agent of the applicant or pharmacy benefit manager
1802 for service of process in the commonwealth; (iv) the name and address of any person with
1803 management or control over the applicant or pharmacy benefit manager; and (v) any audited
1804 financial statements specific to the applicant or pharmacy benefit manager. An applicant or
1805 pharmacy benefit manager shall report to the division any material change to the information
1806 contained in its application, certified by an officer of the pharmacy benefit manager, within 30
1807 days of such a change.

1808 (f) The division may suspend, revoke, refuse to issue or renew or place on probation a
1809 pharmacy benefit manager license for cause, which shall include, but not be limited to: (i) the
1810 applicant or pharmacy benefit manager engaging in fraudulent activity that is found by a court of
1811 law to be a violation of state or federal law; (ii) the division receiving consumer complaints that
1812 justify an action under this chapter to protect the health, safety and interests of consumers; (iii)
1813 the applicant or pharmacy benefit manager failing to pay an application or renewal fee for a
1814 license; (iv) the applicant or pharmacy benefit manager failing to comply with reporting
1815 requirements of the center under section 10A of chapter 12C; or (v) the applicant pharmacy
1816 benefit manager's failing to comply with a requirement of this chapter.

1817 The division shall provide written notice to the applicant or pharmacy benefit manager
1818 and advise in writing of the reason for any suspension, revocation, refusal to issue or renew or
1819 placement on probation of a pharmacy benefit manager license under this chapter. A copy of the
1820 notice shall be forwarded to the center. The applicant or pharmacy benefit manager may make
1821 written demand upon the division within 30 days of receipt of such notification for a hearing
1822 before the division to determine the reasonableness of the division's action. The hearing shall be
1823 held pursuant to chapter 30A.

1824 The division shall not suspend or cancel a license unless the division has first afforded
1825 the pharmacy benefit manager an opportunity for a hearing pursuant to said chapter 30A.

1826 (g) If a person, business or other entity performs the functions of a pharmacy benefit
1827 manager in violation of this chapter, the person, business or other entity shall be subject to a fine
1828 of \$5,000 per day for each day that the person, business or other entity is found to be in violation.

1829 Penalties collected under this subsection shall be deposited into the Prescription Drug Cost
1830 Assistance Trust Fund established in section 2EEEEEE of chapter 29.

1831 (h) A pharmacy benefit manager licensed under this section shall notify a health carrier
1832 client in writing of any activity, policy, practice contract or arrangement of the pharmacy benefit
1833 manager that directly or indirectly presents any conflict of interest with the pharmacy benefit
1834 manager's relationship with or obligation to the health carrier client.

1835 (i) The division shall adopt any written policies, procedures or regulations that the
1836 division determines are necessary to implement this section.

1837 Section 3. (a) The commissioner may make an examination of the affairs of a pharmacy
1838 benefit manager when the commissioner deems prudent but not less frequently than once every 3
1839 years. The focus of the examination shall be to ensure that a pharmacy benefit manager is able to
1840 meet its responsibilities under contracts with carriers licensed under chapters 175, 176A, 176B,
1841 or 176G. The examination shall be conducted according to the procedures set forth in paragraph
1842 (6) of section 4 of chapter 175.

1843 (b) The commissioner, a deputy or an examiner may conduct an on-site examination of
1844 each pharmacy benefit manager in the commonwealth to thoroughly inspect and examine its
1845 affairs.

1846 (c) The charge for each such examination shall be determined annually according to the
1847 procedures set forth in paragraph (6) of section 4 of chapter 175.

1848 (d) Not later than 60 days following completion of the examination, the examiner in
1849 charge shall file with the commissioner a verified written report of examination under oath.

1850 Upon receipt of the verified report, the commissioner shall transmit the report to the pharmacy
1851 benefit manager examined with a notice that shall afford the pharmacy benefit manager
1852 examined a reasonable opportunity of not more than 30 days to make a written submission or
1853 rebuttal with respect to any matters contained in the examination report. Within 30 days of the
1854 end of the period allowed for the receipt of written submissions or rebuttals, the commissioner
1855 shall consider and review the reports together with any written submissions or rebuttals and any
1856 relevant portions of the examiner's work papers and enter an order:

1857 (i) adopting the examination report as filed with modifications or corrections and, if the
1858 examination report reveals that the pharmacy benefit manager is operating in violation of this
1859 section or any regulation or prior order of the commissioner, the commissioner may order the
1860 pharmacy benefit manager to take any action the commissioner considers necessary and
1861 appropriate to cure such violation;

1862 (ii) rejecting the examination report with directions to examiners to reopen the
1863 examination for the purposes of obtaining additional data, documentation or information and re-
1864 filing pursuant to this section; or

1865 (iii) calling for an investigatory hearing with not less than 20 days' notice to the
1866 pharmacy benefit manager for purposes of obtaining additional documentation, data, information
1867 and testimony.

1868 (e) Notwithstanding any general or special law to the contrary, including clause Twenty-
1869 sixth of section 7 of chapter 4 and chapter 66, the records of any such audit, examination or other
1870 inspection and the information contained in the records, reports or books of any pharmacy
1871 benefit manager examined pursuant to this section shall be confidential and open only to the

1872 inspection of the commissioner, or the examiners and assistants. Access to such confidential
1873 material may be granted by the commissioner to law enforcement officials of the commonwealth
1874 or any other state or agency of the federal government at any time if the agency or office
1875 receiving the information agrees in writing to keep such material confidential. Nothing in this
1876 subsection shall be construed to prohibit the required production of such records, and
1877 information contained in the reports of such company or organization before any court of the
1878 commonwealth or any master or auditor appointed by any such court, in any criminal or civil
1879 proceeding, affecting such pharmacy benefit manager, its officers, partners, directors or
1880 employees. The final report of any such audit, examination or any other inspection by or on
1881 behalf of the division of insurance shall be a public record.

1882 Section 4. (a) A pharmacy benefit manager shall not make payments to a pharmacy
1883 benefit consultant or broker whose services were obtained by a health plan sponsor to work on
1884 the pharmacy benefit bidding or contracting process if the payment constitutes a conflict of
1885 interest, as determined by the commissioner. For purposes of this section, payments from a
1886 pharmacy benefit manager to a pharmacy benefit consultant or broker shall include, but not be
1887 limited to: (i) shared rebates from pharmaceutical manufacturers; (ii) per prescription fees; (iii)
1888 per member fees; (iv) referral fees; (v) bonuses; or (vi) any other financial arrangement the
1889 commissioner considers to be a conflict of interest.

1890 (b) The division shall adopt any written policies or procedures or promulgate regulations
1891 that the division determines are necessary to implement this section.

1892 Section 5. A pharmacy benefit manager shall not, by contract, written policy or written
1893 procedure, require that a pharmacy designated by the pharmacy benefit manager dispense a

1894 medication directly to a patient with the expectation or intention that the patient will transport the
1895 medication to a physician's office, hospital or clinic for administration.

1896 SECTION 57. (a) Notwithstanding any general or special law to the contrary, the
1897 commonwealth health insurance connector authority, in consultation with the division of
1898 insurance, shall report on the impact of pharmaceutical pricing on health care costs and outcomes
1899 for ConnectorCare and non-group and small group plans offered through the connector and its
1900 members.

1901 The report shall include, but not be limited to: (i) information on the differential between
1902 drug list price and price net of rebates for plans offered and the impact of those differentials on
1903 member premiums; (ii) the relationship between drug list price and member cost-sharing
1904 requirements; (iii) the impact of drug price changes over time on premium and out-of-pocket
1905 costs in plans authorized under section 3 of chapter 176J of the General Laws offered through the
1906 commonwealth health insurance connector authority; (iv) trends in changes in drug list price and
1907 price net of rebates by health plan; (v) an analysis of the impact of member out-of-pocket costs
1908 on drug utilization and member experience; and (vi) an analysis of the impact of drug list price
1909 and price net of rebates on member formulary access to drug. Data collected under this
1910 subsection shall be protected as confidential and shall not be a public record under clause
1911 Twenty-sixth of section 7 of chapter 4 of the General Laws or under chapter 66 of the General
1912 Laws.

1913 The report shall be submitted to the joint committee on health care financing and the
1914 house and senate committees on ways and means not later than July 1, 2025; provided, however,

1915 that the report shall be published on the website of the commonwealth health insurance
1916 connector authority not later than July 1, 2025.

1917 (b) In fiscal year 2024, the amount required to be paid pursuant to the last paragraph of
1918 section 6 of chapter 6D of the General Laws shall be increased by \$500,000; provided, however,
1919 that said \$500,000 shall be provided to the commonwealth health insurance connector authority
1920 not later than March 14, 2024 for data collection and analysis costs associated with the report
1921 required by this section.

1922 SECTION 58. Notwithstanding any general or special law to the contrary, there shall be a
1923 special commission to examine the feasibility of: (i) establishing a system for the bulk
1924 purchasing and distribution of pharmaceutical products with a significant public health benefit
1925 and the potential for significant health care cost savings for consumers through overall increased
1926 purchase capacity; and (ii) making bulk purchase pricing information available to purchasers in
1927 other states.

1928 The commission shall consist of: the commissioner of public health or a designee, who
1929 shall serve as chair; the executive director of the group insurance commission or a designee; the
1930 chief of pharmacy of the state office for pharmacy services; the MassHealth director of
1931 pharmacy; the secretary of technology services and security; and 9 members to be appointed by
1932 the commissioner of public health, 2 of whom shall be health care economists, 1 of whom shall
1933 be an expert in health law and policy innovation, 1 of whom shall be an academic with relevant
1934 expertise in the field, 1 of whom shall be a representative from a community health center, 1 of
1935 whom shall be the chief executive officer of a hospital licensed in the commonwealth, 1 of
1936 whom shall be a representative of the Massachusetts Association of Health Plans, Inc., 1 of

1937 whom shall be a representative of Blue Cross Blue Shield of Massachusetts, Inc. and 1 of whom
1938 shall be a member of the public with experience with health care and consumer protection.

1939 The commission shall hold not less than 3 public hearings in different geographic areas of
1940 the commonwealth, accept input from the public and solicit expert testimony from individuals
1941 representing health insurance carriers, pharmaceutical companies, independent and chain
1942 pharmacies, hospitals, municipalities, health care practitioners, health care technology
1943 professionals, community health centers, substance use disorder providers, public health
1944 educational institutions and other experts identified by the commission.

1945 The commission shall consider: (i) the process by which the commonwealth could make
1946 bulk purchases of pharmaceutical products with a significant public health benefit and the
1947 potential for significant health care cost savings to consumers; (ii) the process by which both
1948 governmental and nongovernmental entities may participate in a collaborative to purchase
1949 pharmaceutical products with a significant public health benefit and the potential for significant
1950 health care cost savings; (iii) the feasibility of developing an electronic information interchange
1951 system to exchange bulk purchase price information with partnering states; (iv) potential sources
1952 of funding available to implement bulk purchases; (v) potential cost savings of bulk purchases to
1953 the commonwealth or other participating nongovernmental entities; (vi) the feasibility of
1954 partnering with the federal government, other states in the New England region or the state of
1955 New York ; and (vii) any other factors that the commission deems relevant.

1956 The commission shall file a report of its analysis, along with any recommended
1957 legislation, if any, to the clerks of the senate and house of representatives, the house and senate
1958 committees on ways and means, the joint committee on health care financing, the joint

1959 committee on public health, the joint committee on elder affairs and the joint committee on
1960 mental health, substance use and recovery not later than September 1, 2024; provided, however,
1961 that the report shall be published on the website of the department of public health not later than
1962 September 1, 2024.

1963 SECTION 59. (a) As used in this section, the following words shall have the following
1964 meanings unless the context clearly requires otherwise:

1965 “Chain pharmacist”, a pharmacist employed by a retail drug organization operating not
1966 less than 10 retail drug stores within the commonwealth under section 39 of chapter 112 of the
1967 General Laws.

1968 “Independent pharmacist”, a pharmacist actively engaged in the business of retail
1969 pharmacy and employed in an organization of not more than 9 registered retail drugstores in the
1970 commonwealth under said section 39 of said chapter 112 that employs not more than a total of
1971 20 full-time pharmacists.

1972 (b) There shall be a task force to: (i) review the drug supply chain and reimbursement
1973 structures including, but not limited to: (A) plan and pharmacy benefit manager reimbursements
1974 to pharmacies; (B) wholesaler prices to pharmacies; (C) pharmacy services administrative
1975 organization fees and contractual relationships with pharmacies; and (D) drug manufacturer
1976 prices to wholesalers; (ii) review ways to recognize the unique challenges of small and
1977 independent pharmacies; (iii) identify methods to increase pricing transparency throughout the
1978 supply chain; (iv) make recommendations on the use of multiple maximum allowable costs lists
1979 and their frequency of use for mail order products; (v) review the utilization of maximum
1980 allowable costs lists or similar reimbursement structures established by a pharmacy benefit

1981 manager or payer; (vi) review the availability of drugs to independent and chain pharmacies on
1982 the maximum allowable cost list or any similar reimbursement structures established by a
1983 pharmacy benefit manager or payer; (vii) review the pharmacy acquisition cost from national or
1984 regional wholesalers that serve pharmacies compared to the reimbursement amount provided
1985 through a maximum allowable cost list or any similar reimbursement structures established by a
1986 pharmacy benefit manager or payer and the conditions under which an adjustment to a
1987 reimbursement is appropriate; (viii) review the timing of pharmacy purchases of products and the
1988 relative risk of list price changes related to the timing of dispensing the products; (ix) assess
1989 ways to increase transparency for chain and independent pharmacists to understand the
1990 methodology used by a pharmacy benefit manager or payer to develop a maximum allowable
1991 cost list or any similar reimbursement structure established by the pharmacy benefit manager or
1992 payer; (x) assess the prevalence and appropriateness of pharmacy benefit managers requiring, or
1993 using financial incentives or penalties to incentivize, customer use of pharmacies with whom the
1994 pharmacy benefit manager has an ownership or financial interest; (xi) examine the impact of the
1995 merger or consolidation of pharmacy benefit managers and health carrier clients on drug costs;
1996 (xii) review current appeals processes for a chain or independent pharmacist to request an
1997 adjustment on a reimbursement subject to a maximum allowable cost list or any similar
1998 reimbursement structure established by a pharmacy benefit manager or payer; and (xiii) evaluate
1999 the effect of differences between pharmacy benefit manager payments to pharmacies and charges
2000 made to health carrier clients on drug price.

2001 (c) The task force shall consist of: the commissioner of insurance or a designee, who shall
2002 serve as chair; and 9 members to be appointed by the commissioner, 2 of whom shall be
2003 independent pharmacists employed in the independent pharmacy setting or representatives of

2004 independent pharmacies, 2 of whom shall be chain pharmacists employed in the chain pharmacy
2005 setting or representatives of chain pharmacies, 2 of whom shall be representatives of a pharmacy
2006 benefit managers or payers who manage their own pharmacy benefit services, 1 of whom shall
2007 represent the Massachusetts Association of Health Plans, Inc., 1 of whom shall represent Blue
2008 Cross Blue Shield of Massachusetts, Inc. and 1 of whom shall be a representative of wholesalers
2009 or pharmacy services administrative organizations. If more than 1 independent pharmacist is
2010 appointed, each appointee shall represent a distinct practice setting. If more than 1 chain
2011 pharmacist is appointed, each appointee shall represent a distinct practice setting. A pharmacy
2012 benefit manager or payer appointed to the task force shall not be co-owned or have any
2013 ownership relationship with any other payer, pharmacy benefit manager or chain pharmacist also
2014 appointed to the task force.

2015 (d) The commissioner shall file the task force’s findings with the clerks of the house of
2016 representatives and the senate, the joint committee on health care financing and the house and
2017 senate committees on ways and means not later than December 1, 2024; provided, however, that
2018 the findings shall be published on the website of the division of insurance not later than
2019 December 1, 2024.

2020 SECTION 60. The health policy commission shall consult with relevant stakeholders,
2021 including, but not limited to, consumers, consumer advocacy organizations, organizations
2022 representing people with disabilities and chronic health conditions, providers, provider
2023 organizations, payers, pharmaceutical manufacturers, pharmacy benefit managers and health care
2024 economists and other academics, to assist in the development and periodic review of regulations
2025 to implement section 21 of chapter 6D of the General Laws, including, but not limited to: (i)
2026 establishing the criteria and processes for identifying the proposed value of an eligible drug as

2027 defined in said section 21 of said chapter 6D; and (ii) determining the appropriate price increase
2028 for a public health essential drug as described within the definition of eligible drug in said
2029 section 21 of said chapter 6D.

2030 The commission shall hold its first public outreach not more than 45 days after the
2031 effective date of this act and shall, to the extent possible, ensure fair representation and input
2032 from a diverse array of stakeholders.

2033 SECTION 61. Annually, each carrier shall report to the division of insurance the drugs
2034 selected to be provided with no or limited cost-sharing under section 17T of chapter 32A of the
2035 General Laws, section 10R of chapter 118E of the General Laws, section 47UU of chapter 175 of
2036 the General Laws, section 8VV of chapter 176A of the General Laws, section 4VV of chapter
2037 176B of the General Laws and section 4NN of chapter 176G of the General Laws. The division
2038 of insurance shall consult with the health policy commission and the center for health and
2039 information analysis to review the drugs to verify that the selected drugs meet the criteria
2040 identified in said section 17T of said chapter 32A, said section 10R of said chapter 118E, said
2041 section 47UU of said chapter 175, said section 8VV of said chapter 176A, said section 4VV of
2042 said chapter 176B and said section 4NN of said chapter 176G. If a selected drug shall be deemed
2043 by the division to not meet the criteria, the division may require a different drug to be selected.
2044 The division shall disclose the list of drugs selected by each entity annually on the division's
2045 website. This section shall also apply to selected continuous glucose monitoring system
2046 components and, when applicable, delivery devices.

2047 SECTION 62. Notwithstanding subsection (b) of section 15A of chapter 6D of the
2048 General Laws, for the purposes of providing early notice under said section 15A of said chapter

2049 6D, the health policy commission shall determine a significant price increase for a generic drug
2050 to be defined as a generic drug priced at \$100 or more per wholesale acquisition cost unit that
2051 increases in cost by 100 per cent or more during any 12-month period.

2052 SECTION 63. Section 62 is hereby repealed.

2053 SECTION 64. The health policy commission, in consultation with the department of
2054 public health, the office of Medicaid, the group insurance commission and the division of
2055 insurance, shall study and analyze health insurance payer, including public and private payer,
2056 specialty pharmacy networks in the commonwealth. The study shall include: (i) a description of
2057 the type of specialty drugs most often provided by specialty pharmacies; (ii) the impact of
2058 existing health insurance payers' specialty pharmacy networks on patient access, availability of
2059 clinical support, continuity of care, safety, quality, cost sharing and health care costs; and (iii)
2060 any recommendations for increasing patient access to and choice of specialty drugs, maintaining
2061 high-quality specialty pharmacy standards and meeting the commonwealth's health care cost
2062 containment goals.

2063 The commission shall submit a report of its findings and recommendations to the clerks
2064 of the senate and house of representatives, the senate and house committees on ways and means,
2065 the joint committee on health care financing and the joint committee on public health not later
2066 than July 1, 2024.

2067 SECTION 64A. The department of public health, in consultation with the department of
2068 elementary and secondary education, executive office of public safety and security and the center
2069 for health information and analysis established under section 2 of chapter 12C of the General
2070 Laws, shall conduct a study on a state-wide policy on: (i) maintaining a stock supply of non-

2071 patient specific epinephrine in elementary and secondary public schools for use by students in
2072 schools, including students with individualized health care plans prescribing epinephrine
2073 injections, in lieu of a policy that relies on parents and guardians to supply epinephrine for use by
2074 students in schools; and (ii) police stations and fire stations maintaining a stock supply of non-
2075 patient specific epinephrine for emergency community use. The study shall consider: (i) the
2076 impacts of the policy on the health and safety of schools and the community as a whole; (ii) the
2077 impacts of the policy on costs and savings for students' families, municipalities, school districts,
2078 MassHealth and other insurance plans; (iii) the number of types of epinephrine injectors that a
2079 school would be required to stock to ensure student health and safety; (iv) training that would be
2080 necessary to implement the policy, including training related to the use of epinephrine dose
2081 calculation devices; (v) funding and cost-reduction mechanisms for the policy, including bulk
2082 purchasing and an assessment on surcharge payors as defined in section 64 of chapter 118E of
2083 the General Laws; (vi) the number of types of epinephrine injectors that a fire station or police
2084 station would be required to stock to ensure community safety; and (vii) any additional
2085 regulations necessary to implement the policy. The department of public health shall submit a
2086 report of its findings and recommendations to the house and senate committees on ways and
2087 means, the joint committee on education, the joint committee on public safety, the joint
2088 committee on financial services and the joint committee on health care financing not later than
2089 June 30, 2025.

2090 SECTION 64B. The department shall compile a report detailing the effectiveness, safety
2091 and long-term public health impacts of weight loss medication for preventative care including,
2092 but not limited to: (i) heart conditions; (ii) stroke; (iii) asthma; and (iv) diabetes. The report shall
2093 be submitted to the clerks of the senate and house of representatives, the house and senate

2094 committees on ways and means and the joint committee on health care financing not later than
2095 July 1, 2025.

2096 SECTION 64C. The health policy commission, in consultation with the board of
2097 registration in pharmacy and the division of insurance, shall study and analyze the performance
2098 of pharmacists of primary care functions within their authorized scope of practice. The study
2099 shall include, but not be limited to: (i) reimbursements that carriers currently provide to
2100 pharmacists for the performance of primary care services that are authorized in a pharmacist's
2101 scope of practice in the commonwealth; (ii) primary care services that are authorized in a
2102 pharmacist's scope of practice in the commonwealth but are not currently reimbursed or are
2103 inadequately reimbursed by carriers; (iii) primary care services that pharmacists are authorized to
2104 perform; (iv) the extent to which pharmacists currently perform primary care services; (v)
2105 reimbursement rates for comparable services performed by pharmacists in other states; (vi)
2106 impact of pharmacist-provided primary care services on access to health care and overall costs of
2107 the commonwealth's health care system; and (vii) reimbursement levels needed to achieve
2108 sustainability in delivery of primary care services by pharmacists. The commission shall submit a
2109 report of its findings and recommendations to the clerks of the senate and house of
2110 representatives, the senate and house committees on ways and means, the joint committee on
2111 health care financing and the joint committee on public health not later than July 1, 2024. The
2112 report shall be published on the website of the commission.

2113 SECTION 64D. The department of public health, in consultation with the attorney
2114 general, district attorneys, patient advocates, health care practitioners and other relevant
2115 stakeholders, shall analyze the effectiveness and sufficiency of the marketing code of conduct
2116 established pursuant to chapter 111N of the General Laws. The department's analysis shall

2117 include, but not be limited to: (i) an evaluation of the reports, compliance information and data
2118 required under sections 2A, 5 and 6 of said chapter 111N; (ii) a comparison of the marketing
2119 code of conduct with similar rules established in other states; (iii) a review of any enforcement
2120 actions taken for violations of said chapter 111N; (iv) a review of opioid marketing practices and
2121 the direct impact of said practices on increased substance use disorders and related deaths; and
2122 (v) an assessment of the need, and recommendations for implementation, for further
2123 requirements to ensure marketing activities by pharmaceutical and medical device manufacturers
2124 do not influence prescribing patterns in a manner that adversely affects patient care, which shall
2125 include, but not be limited to, requiring the licensing of all pharmaceutical and medical device
2126 representatives, including pharmaceutical or medical device manufacturing agents, as defined in
2127 section 1 of said chapter 111N.

2128 The department shall file a report of its findings with the clerks of the senate and house of
2129 representatives, the joint committee on public health, the joint committee on health care
2130 financing, the senate committee on steering and policy and the senate and house committees on
2131 ways and means not later than May 1, 2024.

2132 SECTION 65. The regulations required by subsection (c) of section 39K of chapter 112
2133 of the General Laws shall be promulgated not later than December 31, 2023.

2134 SECTION 65A. The regulations required by subsections (e) and (f) of section 47VV of
2135 chapter 175 of the General Laws shall be promulgated not later than 3 months after the effective
2136 date of this act.

2137 SECTION 66. Sections 21 and 39 shall take effect on July 1, 2024.

2138 SECTION 67. Sections 41, 44, 45, 47, 48, 52 and 61 shall take effect on July 1, 2025.

2139 SECTION 68. Section 43 shall take effect on April 1, 2024.

2140 SECTION 69. Section 54 shall take effect on July 1, 2024.

2141 SECTION 70. Section 56 shall take effect on March 30, 2024.

2142 SECTION 71. Section 63 shall take effect on January 1, 2025.