

SENATE No. 2397

The Commonwealth of Massachusetts

—————
In the One Hundred and Ninety-First General Court
(2019-2020)
—————

SENATE, November 7, 2019

The committee on Ways and Means to whom was referred the Senate Bill relative to consumer protection for prescription drug purchases (Senate, No. 733),-- reports, recommending that the same ought to pass with an amendment substituting a new draft entitled “An Act relative to pharmaceutical access, costs and transparency” (Senate, No. 2397).

For the committee,
Michael J. Rodrigues

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**In the One Hundred and Ninety-First General Court
(2019-2020)**

An Act relative to pharmaceutical access, costs and transparency.

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

1 SECTION 1. Section 1 of chapter 6D of the General Laws, as appearing in the 2018
2 Official Edition, is hereby amended by inserting after the definition of “Alternative payment
3 methodologies or methods” the following 2 definitions:-

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

6 “Brand name drug”, a drug that is: (i) produced or distributed pursuant to an original new
7 drug application approved under 21 U.S.C. 355(c) except for an authorized generic as defined by
8 42 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application
9 approved under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the health benefit plan as a brand
10 name drug based on available data resources such as Medi-Span.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

79 SECTION 10. Section 6 of said chapter 6D, as so appearing, is hereby amended by
80 adding the following paragraph:-

81 Pharmaceutical and biopharmaceutical manufacturing companies and pharmacy benefit
82 managers shall, in a manner and distribution determined by the commission, pay to the
83 commonwealth an amount of the estimated expenses of the commission attributable to the
84 commission’s activities under sections 8, 9, 15A, 15B, 20 and 21. A pharmacy benefit manager
85 that is a surcharge payor subject to the preceding paragraph and manages its own prescription
86 drug benefits shall not be subject to additional assessment under this paragraph.

87 SECTION 11. Section 8 of said chapter 6D, as so appearing, is hereby amended by
88 inserting after the word “organization”, in lines 6 and 7, the following words:- , pharmacy benefit
89 manager, pharmaceutical manufacturing company.

90 SECTION 12. Said section 8 of said chapter 6D, as so appearing, is hereby further
91 amended by inserting after the word “organizations”, in line 14, the following words:- ,
92 pharmacy benefit managers, pharmaceutical manufacturing companies.

93 SECTION 13. Said section 8 of said chapter 6D, as so appearing, is hereby further
94 amended by striking out, in line 32, the words “and (xi)” and inserting in place thereof the
95 following words:- (xi) not less than 3 representatives of the pharmaceutical industry; (xii) at least
96 1 pharmacy benefit manager; and (xiii).

97 SECTION 14. Said section 8 of said chapter 6D, as so appearing, is hereby further
98 amended by striking out, in line 48, the first time it appears, the word “and”.

99 SECTION 15. Said section 8 of said chapter 6D, as so appearing, is hereby further
100 amended by inserting after the word “commission”, in line 59, the first time it appears, the
101 following words:- ; and (iii) in the case of pharmacy benefit managers and pharmaceutical
102 manufacturing companies, testimony concerning factors underlying prescription drug costs and

103 price increases including, but not limited to, the initial prices of drugs coming to market and
104 subsequent price increases, changes in industry profit levels, marketing expenses, reverse
105 payment patent settlements, the impact of manufacturer rebates, discounts and other price
106 concessions on net pricing, the availability of alternative drugs or treatments and any other
107 matters as determined by the commission.

108 SECTION 16. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is
109 hereby amended by striking out the second sentence and inserting in place thereof the following
110 sentence:- The report shall be based on the commission's analysis of information provided at the
111 hearings by witnesses, providers, provider organizations, payers, pharmaceutical manufacturing
112 companies and pharmacy benefit managers, registration data collected under section 11, data
113 collected or analyzed by the center under sections 8, 9, 10, and 10A of chapter 12C and any other
114 available information that the commission considers necessary to fulfill its duties under this
115 section as defined in regulations promulgated by the commission.

116 SECTION 17. Section 9 of said chapter 6D, as so appearing, is hereby amended by
117 inserting after the word "organization", in line 72, the following words:- , pharmacy benefit
118 manager, pharmaceutical manufacturing company.

119 SECTION 18. Said chapter 6D is hereby further amended by inserting after section 15
120 the following 2 sections:-

121 Section 15A. (a) The commission shall develop, implement and promote an evidence-
122 based outreach and education program to support the therapeutic and cost-effective utilization of
123 prescription drugs for health care practitioners authorized to prescribe and dispense prescription
124 drugs including, but not limited to, physicians, podiatrists and pharmacists.

125 The commission shall develop the program in consultation with health care practitioners
126 authorized to prescribe and dispense prescription drugs including, but not limited to, physicians,
127 podiatrists, pharmacists, nurses, private insurers, hospitals, pharmacy benefit managers,
128 consumers, the MassHealth drug utilization review board, the University of Massachusetts
129 medical school and researchers and organizations engaged in the development, training and
130 deployment of health practitioner education outreach programs.

131 (b) The program shall provide outreach to: (i) health care practitioners who participate in:
132 (A) MassHealth; (B) the subsidized catastrophic prescription drug insurance program established
133 in section 39 of chapter 19A; and (C) other publicly-funded, contracted or subsidized health care
134 programs; (ii) academic medical centers; and (iii) other health care practitioners authorized to
135 prescribe and dispense prescription drugs.

136 The program shall include in-person visits to prescribers by physicians, podiatrists,
137 pharmacists and nurses that utilize evidence-based materials and borrowing methods from
138 behavioral science, educational theory and, where appropriate, pharmaceutical industry data and
139 outreach techniques; provided, however, that the program shall inform prescribers about drug
140 marketing intended to circumvent competition from generic or other therapeutically-equivalent
141 pharmaceutical alternatives or other evidence-based treatment options, if applicable.

142 The commission shall, to the extent possible, utilize or incorporate into its program other
143 independent educational resources or models proven effective in promoting high quality,
144 evidenced-based, cost-effective information regarding the effectiveness and safety of
145 prescription drugs.

146 (c) Annually, not later than April 1, the commission shall report on the operation of the
147 program including, but not limited to, information on the outreach and education components of

148 the program, revenues, expenditures and balances, including an accounting of the estimated
149 expenses of the program for the following year, and savings attributable to the program in health
150 care programs funded by the commonwealth. The report shall be made publicly available on the
151 commission's website.

152 (d) The commission shall undertake a public education initiative to inform residents of
153 the commonwealth about clinical trials and drug safety information.

154 (e) The commission may establish and collect fees for subscriptions and contracts with
155 private health care payers related to this section. The commission may seek funding from
156 nongovernmental health access foundations and undesignated drug litigation settlement funds
157 associated with pharmaceutical marketing and pricing practices.

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

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

167 For each prescription drug product, early notice shall include a brief description of the: (i)
168 primary disease, health condition or therapeutic area being studied and the indication; (ii) route
169 of administration being studied; (iii) clinical trial comparators; and (iv) estimated year of market

170 entry. To the extent possible, information shall be collected using data fields consistent with
171 those used by the federal National Institutes of Health for clinical trials.

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

178 (b) A pharmaceutical manufacturing company shall provide early notice to the
179 commission if it plans to increase the wholesale acquisition cost of a: (i) brand-name drug by
180 more than 20 per cent per wholesale acquisition cost unit during any 12-month period; or (ii)
181 generic drug priced at \$100 or more per wholesale acquisition cost unit by 200 per cent or more
182 during any 12-month period. The commission shall make non-confidential early notice
183 information available to the office of Medicaid or another agency, as the commission deems
184 appropriate.

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

187 A pharmaceutical manufacturing company required to notify the commission of a price
188 increase under this subsection shall, not less than 30 days before the planned effective date of the
189 increase, report to the commission any information regarding the price increase that is relevant to
190 the commission including, but not limited to: (i) drug identification information; (ii) drug sales
191 volume information; (iii) wholesale price and related information for the drug; (iv) drug

192 acquisition information, if applicable; (v) revenue from the sale of the drug; and (vi)
193 manufacturer costs.

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

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

200 SECTION 19. Said chapter 6D is hereby further amended by adding the following 2
201 sections:-

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

204 “Eligible drug”, a (i) brand name drug or biologic, not including a biosimilar, that has a
205 launch wholesale acquisition cost of \$50,000 or more for a 1-year supply or full course of
206 treatment; (ii) biosimilar drug that has a launch wholesale acquisition cost that is not at least 15
207 per cent lower than the referenced brand biologic at the time the biosimilar is launched; or (iii)
208 public health essential drug, as defined in section 239 of chapter 111, with a significant price
209 increase over a defined period of time as determined by the commission by regulation or with a
210 wholesale acquisition cost of \$25,000 or more for a 1-year supply or full course of treatment.

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

212 “Public health essential drug”, shall have the same meaning as defined in section 239 of
213 chapter 111.

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

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

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

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

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

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

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

235 Any information, analyses or reports regarding an eligible drug review shall be provided
236 to the manufacturer. The commission shall consider any clarifications or data provided by the

237 manufacturer with respect to the eligible drug. The commission shall not base its determination
238 on the proposed value of the eligible drug solely on the analysis or research of an outside third
239 party.

240 (d) If, after review of an eligible drug and after receiving information from the
241 manufacturer under subsections (b) or (e), the commission determines that the manufacturer's
242 pricing of the eligible drug does not substantially exceed the proposed value of the drug, the
243 commission shall notify the manufacturer, in writing, of its determination and shall evaluate
244 other ways to mitigate the eligible drug's cost in order to improve patient access to the eligible
245 drug. The commission may engage with the manufacturer and other relevant stakeholders,
246 including, but not limited to, patients, patient advocacy organizations, providers, provider
247 organizations and payers, to explore options for mitigating the cost of the eligible drug. Upon the
248 conclusion of a stakeholder engagement process under this subsection, the commission shall
249 issue recommendations on ways to reduce the cost of the eligible drug for the purpose of
250 improving patient access to the eligible drug. Recommendations may include, but not be limited
251 to: (i) an alternative payment plan or methodology; (ii) a bulk purchasing program; (iii) co-pay,
252 deductible, coinsurance or other cost-sharing restrictions; and (iv) a reinsurance program to
253 subsidize the cost of the eligible drug. The recommendations shall be publicly posted on the
254 commission's website and provided to the clerks of the house of representatives and senate, the
255 joint committee on health care financing and the house and senate committees on ways and
256 means.

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

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

262 (f) Not later than 60 days after receiving information from the manufacturer under
263 subsections (b) or (e), the commission shall confidentially issue a determination on whether the
264 manufacturer's pricing of an eligible drug substantially exceeds the commission's proposed
265 value of the drug. If the commission determines that the manufacturer's pricing of an eligible
266 drug substantially exceeds the proposed value of the drug, the commission shall confidentially
267 notify the manufacturer, in writing, of its determination and request the manufacturer to enter
268 into an access improvement plan under section 21.

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

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

280 (h) If the manufacturer fails to timely comply with the commission's request for records
281 under subsections (b) or (e), or otherwise knowingly obstructs the commission's ability to issue
282 its determination under subsection (f), including, but not limited to, by providing incomplete,

283 false or misleading information, the commission may impose appropriate sanctions against the
284 manufacturer, including reasonable monetary penalties not to exceed \$500,000, in each instance.
285 The commission shall seek to promote compliance with this section and shall only impose a civil
286 penalty on the manufacturer as a last resort.

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

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

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

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

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

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

312 (e) Upon approval of the proposed access improvement plan, the commission shall notify
313 the manufacturer to begin immediate implementation of the access improvement plan. All
314 manufacturers implementing an approved access improvement plan shall be subject to additional
315 reporting requirements and compliance monitoring as determined by the commission. The
316 commission shall provide assistance to the manufacturer in the successful implementation of the
317 access improvement plan.

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

321 (g) At the conclusion of the timetable established in the access improvement plan, the
322 manufacturer shall report to the commission regarding the outcome of the access improvement
323 plan. If the commission determines that the access improvement plan was unsuccessful, the
324 commission shall: (i) extend the implementation timetable of the existing access improvement
325 plan; (ii) approve amendments to the access improvement plan as proposed by the manufacturer;

326 (iii) require the manufacturer to submit a new access improvement plan; or (iv) waive or delay
327 the requirement to file any additional access improvement plans.

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

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

334 (j) The commission may assess a civil penalty to a manufacturer of not more than
335 \$500,000, in each instance, if the commission determines that the manufacturer: (i) willfully
336 neglected to file an access improvement plan with the commission under subsection (a); (ii)
337 failed to file an acceptable access improvement plan in good faith with the commission; (iii)
338 failed to implement the access improvement plan in good faith; or (iv) knowingly failed to
339 provide information required by this section to the commission or knowingly falsified the
340 information,. The commission shall seek to promote compliance with this section and shall only
341 impose a civil penalty as a last resort.

342 (k) If a manufacturer declines to enter into an access improvement plan under this
343 section, the commission may publicly post the proposed value of the eligible drug, hold a public
344 hearing on the proposed value of the eligible drug and solicit public comment. The manufacturer
345 shall appear and testify at any hearing held on the eligible drug's proposed value. Upon the
346 conclusion of a public hearing under this subsection, the commission shall issue
347 recommendations on ways to reduce the cost of an eligible drug for the purpose of improving
348 patient access to the eligible drug. The recommendations shall be publicly posted on the

349 commission’s website and provided to the clerks of the house of representatives and senate, the
350 joint committee on health care financing and the house and senate committees on ways and
351 means.

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

353 SECTION 20. Section 1 of chapter 12C of the General Laws, as appearing in the 2018
354 Official Edition, is hereby amended by inserting after the definition of “Ambulatory surgical
355 center services” the following 3 definitions:-

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

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

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

366 SECTION 21. Said section 1 of said chapter 12C, as so appearing, is hereby further
367 amended by inserting after the definition of “General health supplies, care or rehabilitative
368 services and accommodations” the following definition:-

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

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

374 SECTION 22. Said section 1 of said chapter 12C, as so appearing, is hereby further
375 amended by inserting after the definition of “Patient-centered medical home” the following 2
376 definitions:-

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

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

395 “pharmacy benefit manager” shall include a health benefit plan that does not contract with a
396 pharmacy benefit manager and manages its own prescription drug benefits unless specifically
397 exempted by the commission.

398 SECTION 23. Said section 1 of said chapter 12C, as so appearing, is hereby further
399 amended by adding the following definition:-

400 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
401 1395w-3a(c)(6)(B).

402 SECTION 24. Section 3 of said chapter 12C, as so appearing, is hereby amended by
403 inserting after the word “organizations”, in lines 13 and 14, the following words:- ,
404 pharmaceutical manufacturing companies, pharmacy benefit managers.

405 SECTION 25. Said section 3 of said chapter 12C, as so appearing, is hereby further
406 amended by striking out, in line 24, the words “and payer” and inserting in place thereof the
407 following words:- , payer, pharmaceutical manufacturing company and pharmacy benefit
408 manager.

409 SECTION 26. Section 5 of said chapter 12C, as so appearing, is hereby amended by
410 striking out, in lines 11 and 12, the words “and public health care payers” and inserting in place
411 thereof the following words:- , public health care payers, pharmaceutical manufacturing
412 companies and pharmacy benefit managers.

413 SECTION 27. Said section 5 of said chapter 12C, as so appearing, is hereby further
414 amended by striking out, in line 15, the words “and affected payers” and inserting in place
415 thereof the following words:- affected payers, affected pharmaceutical manufacturing companies
416 and affected pharmacy benefit managers.

417 SECTION 28. Section 7 of said chapter 12C, as so appearing, is hereby amended by
418 adding the following paragraph:-

419 Pharmaceutical and biopharmaceutical manufacturing companies and pharmacy benefit
420 managers shall, in a manner and distribution determined by the center, pay to the commonwealth
421 an amount of the estimated expenses of the center attributable to the center's activities under
422 sections 3, 10A, 12 and 16. A pharmacy benefit manager that is a surcharge payor subject to the
423 preceding paragraph and manages its own prescription drug benefits shall not be subject to
424 additional assessment under this paragraph.

425 SECTION 29. Said chapter 12C is hereby further amended by inserting after section 10
426 the following section:-

427 Section 10A. (a) The center shall promulgate the regulations necessary to ensure the
428 uniform reporting of information from pharmaceutical manufacturing companies that enables the
429 center to analyze: (i) year-over-year changes in wholesale acquisition cost and average
430 manufacturer price for prescription drug products; (ii) year-over-year trends in net expenditures;
431 (iii) net expenditures on subsets of biosimilar, brand name and generic drugs identified by the
432 center; (iv) trends in estimated aggregate drug rebates, discounts or other remuneration paid or
433 provided by a pharmaceutical manufacturing company to a pharmacy benefit manager,
434 wholesaler, distributor, health carrier client, health plan sponsor or pharmacy in connection with
435 utilization of the pharmaceutical drug products offered by the pharmaceutical manufacturing
436 company; (v) discounts provided by a pharmaceutical manufacturing company to a consumer in
437 connection with utilization of the pharmaceutical drug products offered by the pharmaceutical
438 manufacturing company, including any discount, rebate, product voucher, coupon or other

439 reduction in a consumer's out-of-pocket expenses including co-payments and deductibles under
440 section 3 of chapter 175H; and (vi) any other information deemed necessary by the center.

441 The center shall require the submission of available data and other information from
442 pharmaceutical manufacturing companies including, but not limited to: (i) changes in wholesale
443 acquisition costs and average manufacturer prices for prescription drug products as identified by
444 the center; (ii) aggregate, company-level research and development costs to the extent
445 attributable to a specific product and other relevant capital expenditures for the most recent year
446 for which final audited data are available for prescription drug products as identified by the
447 center; and (iii) a description, suitable for public release, of factors that contributed to reported
448 changes in wholesale acquisition costs and average manufacturer prices for prescription drug
449 products as identified by the center.

450 (b) The center shall promulgate the regulations necessary to ensure the uniform reporting
451 of information from pharmacy benefit managers that enables the center to analyze: (i) trends in
452 estimated aggregate drug rebates and other drug price reductions, if any, provided by a pharmacy
453 benefit manager to a health carrier client or health plan sponsor or passed through from a
454 pharmacy benefit manager to a health carrier client or health plan sponsor in connection with
455 utilization of the drugs offered through the pharmacy benefit manager and a measure of lives
456 covered by each health carrier client or health plan sponsor; (ii) pharmacy benefit manager
457 practices with regard to drug rebates and other drug price reductions, if any, provided by a
458 pharmacy benefit manager to a health carrier client or to the consumer or passed through from a
459 pharmacy benefit manager to a health carrier client or to the consumer; and (iii) any other
460 information deemed necessary by the center.

461 The center shall require the submission of available data and other information from
462 pharmacy benefit managers including, but not limited to: (i) the amount of all rebates that the
463 pharmacy benefit manager received from all pharmaceutical manufacturing companies for all
464 health carrier clients in the aggregate and for each health carrier client individually; (ii) the
465 administrative fees that the pharmacy benefit manager received from all health carrier clients in
466 the aggregate and for each health carrier client individually; (iii) the aggregate amount of all
467 retained rebates that the pharmacy benefit manager received from all pharmaceutical
468 manufacturing companies and did not pass through to the pharmacy benefit manager's health
469 carrier clients; (iv) the aggregate amount of rebates a pharmacy benefit manager: (A) retains
470 based on its contractual arrangement with its client; and (B) passes through to its clients; and (v)
471 the percentage of contracts that a pharmacy benefit manager holds where the pharmacy benefit
472 manager: (A) retains all rebates; (B) passes all rebates through to the client; and (C) shares
473 rebates with the client.

474 (c) Except as specifically provided otherwise by the center or under this chapter, data
475 collected by the center pursuant to this section from pharmaceutical manufacturing companies
476 and pharmacy benefit managers shall not be a public record under clause Twenty-sixth of section
477 7 of chapter 4 or under chapter 66.

478 SECTION 30. Said chapter 12C is hereby further amended by striking out section 11, as
479 appearing in the 2018 Official Edition, and inserting in place thereof the following section:-

480 Section 11. The center shall ensure the timely reporting of information required under
481 sections 8, 9, 10 and 10A. The center shall notify payers, providers, provider organizations,
482 pharmacy benefit managers and pharmaceutical manufacturing companies of any applicable
483 reporting deadlines. The center shall notify, in writing, a private health care payer, provider,

484 provider organization, pharmacy benefit manager or pharmaceutical manufacturing company that
485 it has failed to meet a reporting deadline and that failure to respond within 2 weeks of the receipt
486 of the notice may result in penalties. The center may assess a penalty against a private health care
487 payer, provider, provider organization, pharmacy benefit manager or pharmaceutical
488 manufacturing company that fails, without just cause, to provide the requested information
489 within 2 weeks following receipt of the written notice required under this section of not more
490 than \$1,000 per week for each week of delay after the 2-week period following receipt of the
491 written notice. Amounts collected under this section shall be deposited in the Healthcare
492 Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

493 SECTION 31. Section 12 of said chapter 12C, as so appearing, is hereby amended by
494 striking out, in line 2, the words “and 10” and inserting in place thereof the following words:- ,
495 10 and 10A.

496 SECTION 32. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby
497 amended by striking out the first sentence and inserting in place thereof the following sentence:-
498 The center shall publish an annual report based on the information submitted under: (i) sections
499 8, 9, 10 and 10A concerning health care provider, provider organization, private and public
500 health care payer, pharmaceutical manufacturing company and pharmacy benefit manager costs
501 and cost and price trends; (ii) section 13 of chapter 6D relative to market power reviews; and (iii)
502 section 15 of said chapter 6D relative to quality data.

503 SECTION 33. Chapter 94C of the General Laws is hereby amended by inserting after
504 section 21B the following section:-

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

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

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

514 (b) A pharmacy shall provide the consumer, at the point of sale, the current pharmacy
515 retail price and the applicable cost-sharing amount for each prescription medication the
516 consumer is purchasing; provided, however, that the lower cost prescription medication is clearly
517 indicated. The consumer shall affirm by signature in writing that the pharmacy has provided this
518 price information and an opportunity for counseling. The pharmacy shall charge the consumer
519 the applicable cost-sharing amount or the current pharmacy retail price for that prescription
520 medication, as directed by the consumer.

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

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

529 SECTION 34. Chapter 111 of the General Laws is hereby amended by adding the
530 following section:-

531 Section 239. (a) As used in this section, the following words shall have the following
532 meanings unless the context clearly requires otherwise:

533 “Public health essential drug”, a prescription drug, biologic or biosimilar approved by the
534 federal Food and Drug Administration that: (i) appears on the Model List of Essential Medicines
535 most recently adopted by the World Health Organization; or (ii) is deemed an essential medicine
536 by the commissioner due to its efficacy in treating a life-threatening health condition or a chronic
537 health condition that substantially impairs an individual's ability to engage in activities of daily
538 living or because limited access to a certain population would pose a public health challenge.

539 (b) The department shall identify and publish a list of public health essential prescription
540 drugs. The list shall be updated not less than annually and be made publicly available on the
541 department’s website; provided, however, that the department may provide an interim listing of a
542 public health essential drug prior to an annual update. The department shall also notify and
543 forward a copy of the list to the health policy commission established under chapter 6D.

544 SECTION 35. Section 226 of chapter 175 of the General Laws, as appearing in the 2018
545 Official Edition, is hereby amended by striking out subsection (a) and inserting in place thereof
546 the following subsection:-

547 (a) For the purposes of this section, the term “pharmacy benefit manager” shall mean a
548 person, business or other entity, however organized, that, directly or through a subsidiary,
549 provides pharmacy benefit management services for prescription drugs and devices on behalf of
550 a health benefit plan sponsor, including, but not limited to, a self-insurance plan, labor union or
551 other third-party payer; provided, however, that pharmacy benefit management services shall

552 include, but not be limited to, the processing and payment of claims for prescription drugs, the
553 performance of drug utilization review, the processing of drug prior authorization requests,
554 pharmacy contracting, the adjudication of appeals or grievances related to prescription drug
555 coverage contracts, formulary administration, drug benefit design, mail and specialty drug
556 pharmacy services, cost containment, clinical, safety and adherence programs for pharmacy
557 services and managing the cost of covered prescription drugs; provided further, that “pharmacy
558 benefit manager” shall include a health benefit plan that does not contract with a pharmacy
559 benefit manager and manages its own prescription drug benefits unless specifically exempted.

560 SECTION 36. Section 2 of Chapter 176O of the General Laws, as so appearing, is hereby
561 amended by adding the following subsection:-

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

566 SECTION 37. Said chapter 176O of the General Laws is hereby further amended by
567 inserting after section 22 the following section:-

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

571 SECTION 38. The General Laws are hereby amended by inserting after chapter 176W
572 the following chapter:-

Chapter 176X.

LICENSING AND REGULATION OF PHARMACY BENEFIT MANAGERS.

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

575 “Carrier”, an insurer licensed or otherwise authorized to transact accident or health
576 insurance under chapter 175, a nonprofit hospital service corporation organized under chapter
577 176A, a non-profit medical service corporation organized under chapter 176B, a health
578 maintenance organization organized under chapter 176G and an organization entering into a
579 preferred provider arrangement under chapter 176I; provided, however, that the term “carrier”
580 shall not include an employer purchasing coverage or acting on behalf of its employees or the
581 employees of any subsidiary or affiliated corporation of the employer; provided further, that
582 unless otherwise noted the term “carrier” shall not include any entity to the extent it offers a
583 policy, certificate or contract that provides coverage solely for dental care services or vision care
584 services.

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

586 “Commissioner”, the commissioner of insurance.

587 “Division”, the division of insurance.

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

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

595 “Pharmacy benefit manager”, a person, business or other entity, however organized, that,
596 , directly or through a subsidiary, provides pharmacy benefit management services for
597 prescription drugs and devices on behalf of a health benefit plan sponsor, including, but not
598 limited to, a self-insurance plan, labor union or other third-party payer; provided, however, that
599 pharmacy benefit management services shall include, but not be limited to, the processing and
600 payment of claims for prescription drugs, the performance of drug utilization review, the
601 processing of drug prior authorization requests, pharmacy contracting, the adjudication of
602 appeals or grievances related to prescription drug coverage contracts, formulary administration,
603 drug benefit design, mail and specialty drug pharmacy services, cost containment, clinical, safety
604 and adherence programs for pharmacy services and managing the cost of covered prescription
605 drugs; provided further, that “pharmacy benefit manager” shall not include a health benefit plan
606 unless otherwise specified by the division.

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

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

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

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

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

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

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

641 The division shall notify the pharmacy benefit manager and advise, in writing, of the
642 reason for any suspension, revocation, refusal to issue or renew or placement on probation of a
643 pharmacy benefit manager license under this chapter. A copy of the notice shall be forwarded to
644 the center. The applicant or pharmacy benefit manager may make written demand upon the
645 division within 30 days of receipt of such notification for a hearing before the division to
646 determine the reasonableness of the division's action. The hearing shall be held pursuant to
647 chapter 30A.

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

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

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

657 SECTION 39. Notwithstanding any general or special law to the contrary, there shall be a
658 4-year program to assess the public health utilization and cost impacts of capping co-pays and
659 eliminating deductible and co-insurance requirements for insulin for individuals with diabetes.
660 To implement the program any policy, contract or certificate of health insurance subject to
661 chapters 32A, 118E, 175, 176A, 176B, 176G or 176Q of the General Laws that is delivered,

662 issued or renewed from January 1, 2020 to December 31, 2023, inclusive, shall provide coverage
663 for insulin for the treatment of diabetes. Such coverage shall not be subject to any deductible or
664 co-insurance and any co-pay shall not exceed \$25 per month per insulin prescription.

665 The center for health information and analysis shall collect, analyze and evaluate data at
666 the start of the program and annually thereafter, including, but not limited to: (i) rates of insulin
667 utilization; (ii) average monthly out-of-pocket insulin costs; (iii) annual plan costs and member
668 premiums; (iv) the average price of insulin, net of rebates or discounts received by or accrued
669 directly or indirectly by health insurance carriers; and (v) average and total out-of-pocket
670 expenditures on insulin delivery devices that are not included as part of an insulin prescription.
671 The center shall file an interim 2-year report and a final 4-year report assessing the program's
672 impact on insulin utilization, member premiums and insulin costs and providing data on
673 expenditures on insulin delivery devices separate from insulin prescriptions. The reports shall be
674 filed with the clerks of the house of representatives and senate, the joint committee on public
675 health, the joint committee on health care financing and the house and senate committees on
676 ways and means not later than March 1, 2022 and March 1, 2024, respectively.

677 SECTION 40. (a) Notwithstanding any general or special laws to the contrary, the
678 commonwealth health insurance connector authority, in consultation with the division of
679 insurance, shall report to the joint committee on health care financing and the house and senate
680 committees on ways and means not later than January 15, 2021 on the impact of pharmaceutical
681 pricing on health care costs and outcomes for ConnectorCare and non-group and small group
682 plans offered through the connector and its members.

683 The report shall include, but not be limited to: (i) information on the differential between
684 medication list price and price net of rebates for plans offered and the impact of those

685 differentials on member premiums; (ii) the relationship between medication list price and
686 member cost-sharing requirements; (iii) the impact of medication price changes over time on
687 premium and out-of-pocket costs in plans authorized under section 3 of chapter 176J of the
688 General Laws offered through the commonwealth health insurance connector authority; (iv)
689 trends in changes in medication list price and price net of rebates by health plan; (v) an analysis
690 of the impact of member out-of-pocket costs on medication utilization and health outcomes; and
691 (vi) an analysis of the impact of medication list price and price net of rebates on member
692 formulary access to medications. Data collected under this subsection shall be protected as
693 confidential and shall not be a public record under clause Twenty-sixth of section 7 of chapter 4
694 of the General Laws or under chapter 66 of the General Laws.

695 (b) In fiscal year 2021, the amount required to be paid pursuant to the last paragraph of
696 section 6 of chapter 6D of the General Laws shall be increased by \$500,000; provided, however,
697 that said \$500,000 shall be provided to the commonwealth health insurance connector authority
698 not later than October 14, 2020 for data collection and analysis costs associated with the report
699 required by this section.

700 SECTION 41. (a) As used in this section, the following words shall have the following
701 meanings unless context clearly requires otherwise:

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

705 “Independent pharmacist”, a pharmacist actively engaged in the business of retail
706 pharmacy and employed in an organization of not more than 9 registered retail drugstores in the

707 commonwealth under said section 39 of said chapter 112 that employs not more than a total of
708 20 full-time pharmacists.

709 (b) There shall be a task force to: (i) review the drug supply chain including, but not
710 limited to: (A) plan and pharmacy benefit manager reimbursements to pharmacies; (B)
711 wholesaler or pharmacy service administrative organization prices to pharmacies; and (C) drug
712 manufacturer prices to pharmacies; (ii) review ways to recognize the unique challenges of small
713 and independent pharmacies; (iii) identify methods to increase pricing transparency throughout
714 the supply chain; (iv) make recommendations on the use of multiple maximum allowable costs
715 lists and their frequency of use for mail order products; (v) review the utilization of maximum
716 allowable costs lists or similar reimbursement structures established by a pharmacy benefit
717 manager or payer; (vi) review the availability of drugs to independent and chain pharmacies on
718 the maximum allowable cost list or any similar reimbursement structures established by a
719 pharmacy benefit manager or payer; (vii) review the pharmacy acquisition cost from national or
720 regional wholesalers that serve pharmacies compared to the reimbursement amount provided
721 through a maximum allowable cost list or any similar reimbursement structures established by a
722 pharmacy benefit manager or payer and the conditions under which an adjustment to a
723 reimbursement is appropriate; (viii) review the timing of pharmacy purchases of products and the
724 relative risk of list price changes related to the timing of dispensing the products; (ix) assess
725 ways to increase transparency for chain and independent pharmacists to understand the
726 methodology used by a pharmacy benefit manager or payer to develop a maximum allowable
727 cost list or any similar reimbursement structure established by the pharmacy benefit manager or
728 payer; and (x) review current appeals processes for a chain or independent pharmacist to request

729 an adjustment on a reimbursement subject to a maximum allowable cost list or any similar
730 reimbursement structure established by a pharmacy benefit manager or payer.

731 (c) The task force shall consist of: the commissioner of insurance or a designee, who shall
732 serve as chair; and 6 members to be appointed by the commissioner, 2 of whom shall be either
733 independent pharmacists employed in the independent pharmacy setting or representatives of
734 independent pharmacies, 2 of whom shall be chain pharmacists employed in the chain pharmacy
735 setting or representatives of chain pharmacies and 2 of whom shall be representatives of a
736 pharmacy benefit managers or payers who manage their own pharmacy benefit services. If more
737 than 1 independent pharmacist is appointed to the task force, each appointee shall represent a
738 distinct practice setting and if more than 1 chain pharmacist is appointed to the task force, each
739 appointee shall represent a distinct practice setting. A pharmacy benefit manager or payer
740 appointed to the task force shall not be co-owned or have any ownership relationship with any
741 other payer, pharmacy benefit manager or chain pharmacist also appointed to the task force.

742 (d) The commissioner shall file the task force's findings with the clerks of the house of
743 representatives and the senate, the joint committee on health care financing and the house and
744 senate committees on ways and means not later than December 1, 2020.

745 SECTION 42. The health policy commission shall consult with relevant stakeholders,
746 including, but not limited to, consumers, consumer advocacy organizations, providers, provider
747 organizations, payers, pharmaceutical manufacturers, pharmacy benefit managers and health care
748 economists and other academics, to assist in the development and periodic review of regulations
749 to implement section 20 of chapter 6D of the General Laws, including, but not limited to: (i)
750 establishing the criteria and processes for identifying the proposed value of an eligible drug as
751 defined in said section 20 of said chapter 6D; and (ii) determining the appropriate price increase

752 for a public health essential drug as described within the definition of eligible drug in said
753 section 20 of said chapter 6D.

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

757 SECTION 43. Sections 19 and 34 shall take effect on July 1, 2021.