

HOUSE No. 945

The Commonwealth of Massachusetts

PRESENTED BY:

Christine P. Barber and Jon Santiago

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

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

An Act to ensure prescription drug cost transparency and affordability.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Christine P. Barber</i>	<i>34th Middlesex</i>	<i>1/19/2023</i>
<i>Jon Santiago</i>	<i>9th Suffolk</i>	<i>1/19/2023</i>
<i>Lindsay N. Sabadosa</i>	<i>1st Hampshire</i>	<i>1/19/2023</i>
<i>Mindy Domb</i>	<i>3rd Hampshire</i>	<i>1/19/2023</i>
<i>Carmine Lawrence Gentile</i>	<i>13th Middlesex</i>	<i>1/25/2023</i>
<i>David Paul Linsky</i>	<i>5th Middlesex</i>	<i>1/26/2023</i>
<i>Lenny Mirra</i>	<i>2nd Essex</i>	<i>1/26/2023</i>
<i>Peter Capano</i>	<i>11th Essex</i>	<i>1/27/2023</i>
<i>Susannah M. Whipps</i>	<i>2nd Franklin</i>	<i>1/27/2023</i>
<i>Brian W. Murray</i>	<i>10th Worcester</i>	<i>1/29/2023</i>
<i>Jack Patrick Lewis</i>	<i>7th Middlesex</i>	<i>2/1/2023</i>
<i>Vanna Howard</i>	<i>17th Middlesex</i>	<i>2/1/2023</i>
<i>Patricia A. Duffy</i>	<i>5th Hampden</i>	<i>2/2/2023</i>
<i>Kevin G. Honan</i>	<i>17th Suffolk</i>	<i>2/3/2023</i>
<i>Jennifer Balinsky Armini</i>	<i>8th Essex</i>	<i>2/4/2023</i>
<i>David Henry Argosky LeBoeuf</i>	<i>17th Worcester</i>	<i>2/6/2023</i>
<i>Jason M. Lewis</i>	<i>Fifth Middlesex</i>	<i>2/7/2023</i>
<i>Patrick M. O'Connor</i>	<i>First Plymouth and Norfolk</i>	<i>2/8/2023</i>

<i>Colleen M. Garry</i>	<i>36th Middlesex</i>	<i>2/13/2023</i>
<i>James C. Arena-DeRosa</i>	<i>8th Middlesex</i>	<i>2/13/2023</i>
<i>James B. Eldridge</i>	<i>Middlesex and Worcester</i>	<i>2/16/2023</i>
<i>Kate Lipper-Garabedian</i>	<i>32nd Middlesex</i>	<i>2/22/2023</i>
<i>Natalie M. Higgins</i>	<i>4th Worcester</i>	<i>2/23/2023</i>
<i>Tram T. Nguyen</i>	<i>18th Essex</i>	<i>2/27/2023</i>

HOUSE No. 945

By Representatives Barber of Somerville and Santiago of Boston, a petition (accompanied by bill, House, No. 945) of Christine P. Barber, Jon Santiago and others for legislation to ensure prescription drug cost transparency and affordability. Financial Services.

The Commonwealth of Massachusetts

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

An Act to ensure prescription drug cost transparency and affordability.

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 so appearing, is
2 hereby amended by inserting after the definition of “Alternative payment methodologies or
3 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 “Fiscal year” the following definition:-

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

18 SECTION 3. Said section 1 of said chapter 6D, as so appearing, is hereby further
19 amended by striking out, in line 189, the words “not include excludes ERISA plans” and
20 inserting in place thereof the following words:- include self-insured plans to the extent allowed
21 under the federal Employee Retirement Income Security Act of 1974.

22 SECTION 4. Said section 1 of said chapter 6D, as so appearing, is hereby further
23 amended by inserting after the definition of “Performance penalty” the following 2 definitions:-

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

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

35 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
36 management services shall include, but not be limited to, the processing and payment of claims
37 for prescription drugs, the performance of drug utilization review, the processing of drug prior
38 authorization requests, pharmacy contracting, the adjudication of appeals or grievances related to
39 prescription drug coverage contracts, formulary administration, drug benefit design, mail and
40 specialty drug pharmacy services, cost containment, clinical, safety and adherence programs for
41 pharmacy services and managing the cost of covered prescription drugs; provided further, that
42 “pharmacy benefit manager” shall include a health benefit plan that does not contract with a
43 pharmacy benefit manager and manages its own prescription drug benefits unless specifically
44 exempted by the commission.

45 SECTION 5. Said section 1 of said chapter 6D, as so appearing, is hereby further
46 amended by adding the following definition:-

47 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
48 1395w-3a(c)(6)(B).

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

51 Section 2A. The commission shall keep confidential all nonpublic clinical, financial,
52 strategic or operational documents or information provided or reported to the commission in
53 connection with any care delivery, quality improvement process, performance improvement plan
54 authorized under sections 7, 10, 14, 15 or 20 of this chapter or under section 2GGGG of chapter
55 29 and shall not disclose the information or documents to any person without the consent of the
56 payer, provider or pharmaceutical manufacturing company providing or reporting the

57 information or documents under said sections 7, 10, 14, 15, or 20 of this chapter or under said
58 section 2GGGG of said chapter 29, except in summary form in evaluative reports of such
59 activities or when the commission believes that such disclosure should be made in the public
60 interest after taking into account any privacy, trade secret or anticompetitive considerations. The
61 confidential information and documents shall not be public records and shall be exempt from
62 disclosure under clause Twenty sixth of section 7 of chapter 4 or section 10 of chapter 66.

63 SECTION 7. Section 6 of said chapter 6D, as so appearing, is hereby amended by
64 inserting after the word “center”, in line 1, the following words:- , pharmaceutical and
65 biopharmaceutical manufacturing company, pharmacy benefit manager.

66 SECTION 8. Said section 6 of said chapter 6D, as so appearing, is hereby further
67 amended by striking out, in lines 5 and 36, the figure “33” and inserting in place thereof, in each
68 instance, the following figure:- 25.

69 SECTION 9. Said section 6 of said chapter 6D, as so appearing, is hereby further
70 amended by adding the following paragraph:-

71 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
72 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
73 appropriated by the general court for the expenses of the commission minus amounts collected
74 from: (i) filing fees; (ii) fees and charges generated by the commission's publication or
75 dissemination of reports and information; and (iii) federal matching revenues received for these
76 expenses or received retroactively for expenses of predecessor agencies. Pharmaceutical and
77 biopharmaceutical manufacturing companies and pharmacy benefit managers shall, in a manner
78 and distribution determined by the commission, pay to the commonwealth an amount of the

79 estimated expenses of the commission attributable to the commission’s activities under sections
80 8, 9 and 20. A pharmacy benefit manager that is a surcharge payor subject to the preceding
81 paragraph and manages its own prescription drug benefits shall not be subject to additional
82 assessment under this paragraph.

83 SECTION 10. Section 8 of said chapter 6D, as so appearing, is hereby amended by
84 inserting after the word “organization”, in lines 6 and 7, the following words:- , pharmacy benefit
85 manager, pharmaceutical manufacturing company.

86 SECTION 11. Said section 8 of said chapter 6D, as so appearing, is hereby further
87 amended by inserting after the word “organizations”, in line 14, the following words:- ,
88 pharmacy benefit managers, pharmaceutical manufacturing companies.

89 SECTION 12. Said section 8 of said chapter 6D, as so appearing, is hereby further
90 amended by striking out, in line 32, the words “and (xi)” and inserting in place thereof the
91 following words:- (xi) at least 3 representatives of the pharmaceutical industry; (xii) at least 1
92 pharmacy benefit manager; and (xiii).

93 SECTION 13. Said section 8 of said chapter 6D, as so appearing, is hereby further
94 amended by inserting after the word “commission”, in line 59, the first time it appears, the
95 following words:- ; and (iii) in the case of pharmacy benefit managers and pharmaceutical
96 manufacturing companies, testimony concerning factors underlying prescription drug costs and
97 price increases including, but not limited to, the initial prices of drugs coming to market and
98 subsequent price increases, changes in industry profit levels, marketing expenses, reverse
99 payment patent settlements, the impact of manufacturer rebates, discounts and other price

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

102 SECTION 14. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is
103 hereby amended by striking out the second sentence and inserting in place thereof the following
104 sentence:- The report shall be based on the commission’s analysis of information provided at the
105 hearings by witnesses, providers, provider organizations, payers, pharmaceutical manufacturing
106 companies and pharmacy benefit managers, registration data collected under section 11, data
107 collected or analyzed by the center under sections 8, 9, 10, and 10A of chapter 12C and any other
108 available information that the commission considers necessary to fulfill its duties under this
109 section as defined in regulations promulgated by the commission.

110 SECTION 15. Section 9 of said chapter 6D, as so appearing, is hereby amended by
111 inserting after the word “organization”, in line 72, the following words:- , pharmacy benefit
112 manager, pharmaceutical manufacturing company.

113 SECTION 16. Said chapter 6D, as so appearing, is hereby further amended by adding the
114 following section:

115 Section 20. (a) For the purposes of this section, “Manufacturer” shall mean an entity that
116 manufactures a pharmaceutical drug.

117 (b) The commission may require a manufacturer specified in subsection (c) to disclose to
118 the commission within a reasonable time information relating to the manufacturer’s pricing of
119 that drug, on a standard reporting form developed by the commission with the input of the
120 manufacturers, which includes, but shall not be limited to, the following:

121 (1) A schedule of the drug's wholesale acquisition cost increases over the previous 5
122 calendar years;

123 (2) The manufacturer's aggregate, company-level research and development and other
124 relevant capital expenditures, including facility construction, for the most recent year for which
125 final audited data are available;

126 (3) A written, narrative description, suitable for public release, of factors that contributed
127 to reported changes in wholesale acquisition cost during the previous 5 calendar years; and

128 (4) Any other information that the manufacturer wishes to provide to the commission.

129 Based on the records furnished, the commission may identify a proposed value for a
130 prescribed drug specified in subsection (c). The Commission may request additional relevant
131 information that it deems necessary.

132 (c) A manufacturer of a drug for which the commission has received a referral from the
133 center under subsection (b) of section 25 of chapter 12C shall comply with the requirements set
134 forth in this section; provided that the commission may select or prioritize a subset of the
135 referred drugs for the commission's review.

136 (d) Records disclosed by a manufacturer under this section shall: (i) be accompanied by
137 an attestation that all information provided is true and correct; (ii) not be public records under
138 section 7 of chapter 4 or chapter 66; and (iii) remain confidential; provided, however, that the
139 commission may produce reports summarizing any findings; provided that any such report shall
140 not be in a form that identifies specific prices charged for or rebate amounts associated with

141 drugs by a manufacturer, or in a manner that is likely to compromise the financial, competitive or
142 proprietary nature of the information.

143 (e) If, after review of any records furnished to the commission under subsection (b), the
144 commission determines that the manufacturer's pricing of the drug is potentially unreasonable or
145 excessive in relation to the commission's proposed value under subsection (b), the commission
146 shall require that the manufacturer provide within 30 days further information related to the
147 pricing of the prescribed drug and the manufacturer's justification for the pricing. In addition to
148 the manufacturer, the commission may identify other relevant parties including but not limited to
149 patients, providers, provider organizations and payers who may provide information to the
150 commission.

151 (f) The commission shall provide to the manufacturer for review and input any
152 information, analyses or reports regarding a particular drug reviewed or relied on by the
153 commission in assessing the proposed value of the drug shall be provided to the manufacturer.
154 The commission shall consider any clarifications or data provided by the manufacturer with
155 respect to its drug. The commission may not rely solely on the analysis or research of an outside
156 third party in reaching its determination regarding the proposed value or the reasonableness of
157 the drug pricing.

158 (g) If the commission relies upon a third party to provide cost-effectiveness analysis or
159 research related to the proposed value, such analysis or research shall also provide, without
160 limitation (i) a description of the methodologies and models used by the third party in its
161 analysis; (ii) any assumptions and potential limitations of research findings in the context of the
162 results; and (iii) outcomes for affected subpopulations that utilize the drug, including but not

163 limited to potential impacts on individuals of minority racial or ethnic groups, and on individuals
164 with specific disabilities or health conditions who regularly utilize the eligible drug.

165 (h) Not later than 60 days after receiving information from the manufacturer, as required
166 under subsections (b) or (e), the commission shall issue a determination on whether the
167 manufacturer's pricing of a drug is unreasonable or excessive in relation to the commission's
168 proposed value of the drug. Following the determination, the commission shall issue
169 recommendations on measures to reduce the cost of the drug and to improve the affordability of
170 the drug for patients. Recommendations may include, but not be limited to: (i) an alternative
171 purchasing plan or value-based payment methodology; (ii) a bulk purchasing program; (iii)
172 changes to co-pay, deductibles, coinsurance or other cost-sharing requirements; or (iv) a
173 reinsurance program to subsidize the cost of the eligible drug. The commission shall make its
174 determination and recommendations public and shall post them on its website and shall provide
175 them to private and public health care payers.

176 (i) If the manufacturer fails to timely comply with the commission's request for records
177 under subsections (b) or (e), or otherwise knowingly obstructs the commission's ability to issue
178 its determination under subsection (h), including, but not limited to, providing incomplete, false
179 or misleading information, the commission may assess a civil penalty to a manufacturer of not
180 more than \$500,000. A civil penalty assessed under this subsection shall be deposited into the
181 Payment Reform Fund established pursuant to section 100 of chapter 194 of the acts of 2011.
182 The commission shall seek to promote compliance with this section and shall only impose a civil
183 penalty on the manufacturer as a last resort.

184 (j) Neither the proposed value, nor the analysis produced via the process to determine a
185 proposed value, is intended to be used by MassHealth, health insurance carriers, managed care
186 organizations, accountable care organizations, hospitals or pharmacies to determine whether a
187 treatment should be approved for an individual patient, whether any individual patient should be
188 subjected to step therapy or other utilization management methodology,

189 (k) The commission shall adopt any written policies, procedures or regulations that the
190 commission determines necessary to implement this section.

191 SECTION 17. Section 11N of chapter 12 of the General Laws, as so appearing, is hereby
192 amended by striking out subsection (a) and inserting in place thereof the following subsection:-

193 (a) The attorney general shall monitor trends in the health care market including, but not
194 limited to, trends in provider organization size and composition, consolidation in the provider
195 market, payer contracting trends, patient access and quality issues in the health care market and
196 prescription drug cost trends. The attorney general may obtain the following information from a
197 private health care payer, public health care payer, pharmaceutical manufacturing company,
198 pharmacy benefit manager, provider or provider organization as any of those terms may be
199 defined in section 1 of chapter 6D: (i) any information that is required to be submitted under
200 sections 8, 9 10 and 10A of chapter 12C; (ii) filings, applications and supporting documentation
201 related to any cost and market impact review under section 13 of said chapter 6D; (iii) filings,
202 applications and supporting documentation related to a determination of need application filed
203 under section 25C of chapter 111; and (iv) filings, applications and supporting documentation
204 submitted to the federal Centers for Medicare and Medicaid Services or the Office of the
205 Inspector General for any demonstration project. Under section 17 of said chapter 12C and

206 section 8 of said chapter 6D and subject to the limitations stated in those sections, the attorney
207 general may require that any provider, provider organization, pharmaceutical manufacturing
208 company, pharmacy benefit manager, private health care payer or public health care payer
209 produce documents, answer interrogatories and provide testimony under oath related to health
210 care costs and cost trends, pharmaceutical costs, pharmaceutical cost trends, the factors that
211 contribute to cost growth within the commonwealth's health care system and the relationship
212 between provider costs and payer premium rates and the relationship between pharmaceutical
213 drug costs and payer premium rates.

214 SECTION 18. Section 1 of chapter 12C of the General Laws, as so appearing, is hereby
215 amended by inserting after the definition of “Ambulatory surgical center services” the following
216 3 definitions:-

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

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

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

227 SECTION 19. Said section 1 of said chapter 12C, as so appearing, is hereby further
228 amended by inserting after the definition of “General health supplies, care or rehabilitative
229 services and accommodations” the following definition:-

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

235 SECTION 20. Said section 1 of said chapter 12C, as so appearing, is hereby further
236 amended by inserting after the definition of “Patient-centered medical home” the following 2
237 definitions:-

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

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

249 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
250 management services shall include, but not be limited to, the processing and payment of claims
251 for prescription drugs, the performance of drug utilization review, the processing of drug prior
252 authorization requests, pharmacy contracting, the adjudication of appeals or grievances related to
253 prescription drug coverage contracts, formulary administration, drug benefit design, mail and
254 specialty drug pharmacy services, cost containment, clinical, safety and adherence programs for
255 pharmacy services and managing the cost of covered prescription drugs; provided further, that
256 “pharmacy benefit manager” shall include a health benefit plan that does not contract with a
257 pharmacy benefit manager and manages its own prescription drug benefits unless specifically
258 exempted by the commission.

259 SECTION 21. Said section 1 of said chapter 12C, as so appearing, is hereby further
260 amended by adding the following definition:-

261 “Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C.
262 1395w-3a(c)(6)(B).

263 SECTION 22. Section 3 of said chapter 12C, as so appearing, is hereby amended by
264 inserting after the word “organizations”, in lines 13 and 14, the following words:- ,
265 pharmaceutical manufacturing companies, pharmacy benefit managers.

266 SECTION 23. Said section 3 of said chapter 12C, as so appearing, is hereby further
267 amended by striking out, in line 24, the words “and payer” and inserting in place thereof the
268 following words:- , payer, pharmaceutical manufacturing company and pharmacy benefit
269 manager.

270 SECTION 24. Section 5 of said chapter 12C, as so appearing, is hereby amended by
271 striking out, in lines 11 and 12, the words “and public health care payers” and inserting in place
272 thereof the following words:- , public health care payers, pharmaceutical manufacturing
273 companies and pharmacy benefit managers.

274 SECTION 25. Said section 5 of said chapter 12C, as so appearing, is hereby further
275 amended by striking out, in line 15, the words “and affected payers” and inserting in place
276 thereof the following words:- affected payers, affected pharmaceutical manufacturing companies
277 and affected pharmacy benefit managers.

278 SECTION 26. The first paragraph of section 7 of said chapter 12C, as so appearing, is
279 hereby amended by adding the following sentence:-

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

283 SECTION 27. Said section 7 of said chapter 12C, as so appearing, is hereby further
284 amended by striking out, in lines 8 and 42, the figure “33” and inserting in place thereof, in each
285 instance, the following figure:- 25.

286 SECTION 28. Said section 7 of said chapter 12C, as so appearing, is hereby further
287 amended by adding the following paragraph:-

288 The assessed amount for pharmaceutical and biopharmaceutical manufacturing
289 companies and pharmacy benefit managers shall be not less than 25 per cent of the amount
290 appropriated by the general court for the expenses of the center minus amounts collected from:

291 (i) filing fees; (ii) fees and charges generated by the commission's publication or dissemination
292 of reports and information; and (iii) federal matching revenues received for these expenses or
293 received retroactively for expenses of predecessor agencies. Pharmaceutical and
294 biopharmaceutical manufacturing companies and pharmacy benefit managers shall, in a manner
295 and distribution determined by the center, pay to the commonwealth an amount of the estimated
296 expenses of the center attributable to the center's activities under sections 3, 10A, 12 and 16. A
297 pharmacy benefit manager that is a surcharge payor subject to the preceding paragraph and
298 manages its own prescription drug benefits shall not be subject to additional assessment under
299 this paragraph.

300 SECTION 29. Subsection (b) of section 10 of chapter 12C of the General Laws, as so
301 appearing, is hereby amended by striking out, in line 55, the word "and".

302 SECTION 30. Said subsection (b) of said section 10 of said chapter 12C is hereby further
303 amended by adding the following words:- ; (12) information about prescription drug utilization
304 and spending for all covered drugs, including for generic drugs, brand-name drugs, and specialty
305 drugs provided in an outpatient setting or sold in a retail setting, including but not limited to
306 information sufficient to show (i) highest utilization drugs, (ii) drugs with the greatest increases
307 in utilization, (iii) drugs that are most impactful on plan spending, net of rebates, and (iv) drugs
308 with the highest year-over-year price increases, net of rebates; and (13) information on claims
309 and non-claims based payments to providers for the provision of primary care and behavioral
310 health, including mental health and substance use disorder, services, as defined by the center.

311 SECTION 31. Subsection (c) of said section 10 of said chapter 12C, as so appearing, is
312 hereby amended by striking out, in line 91, the words “()” and inserting in place thereof the
313 following words:- (10).

314 SECTION 32. Said subsection (c) of said section 10 of said chapter 12C, as so appearing,
315 is hereby further amended by striking out, in line 99, the word “and”.

316 SECTION 33. Said subsection (c) of said section 10 of said chapter 12C, as so appearing,
317 is hereby further amended by adding the following words:- ; (12) information, to the extent
318 permissible under 42 U.S.C. 1396r-8(b)(3)(D), about prescription drug utilization and spending
319 for all covered drugs, including for generic drugs, brand-name drugs, and specialty drugs
320 provided in an outpatient setting or sold in a retail setting, including but not limited to
321 information sufficient to show (i) highest utilization drugs, (ii) drugs with the greatest increases
322 in utilization, (iii) drugs that are most impactful on plan spending, net of rebates, and (iv) drugs
323 with the highest year-over-year price increases, net of rebates; and (13) information on claims
324 and non-claims based payments to providers for the provision of primary care and behavioral
325 health, including mental health and substance use disorder services, as defined by the center.

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

328 Section 10A. (a) The center shall promulgate regulations necessary to ensure the uniform
329 annual reporting of information from pharmacy benefit managers certified under chapter 175N,
330 including but not limited to information on: (1) prices charged to payers on average by pharmacy
331 benefits managers for select prescription drug products, net of any rebate, discounts, fees or other
332 payments from the manufacturer to the pharmacy benefits manager and from the pharmacy

333 benefits manager to the manufacturer; (2) payments received by pharmacy benefit managers by
334 payers related to drugs provided to Massachusetts residents; (3) payments made by pharmacy
335 benefit managers to pharmacies related to drugs provided to Massachusetts residents; (4) rebates
336 received by pharmacy benefit managers from drug manufacturers related to drugs provided to
337 Massachusetts residents; (5) rebates paid by pharmacy benefit managers to payers related to
338 drugs provided to Massachusetts residents; (6) other payments made or received by pharmacy
339 benefit managers by payers or pharmacies, including but not limited to administrative or
340 performance-based payments, related to doing business in Massachusetts; (7) other rebates paid
341 to or received by pharmacy benefit managers by drug manufacturers or payers related to doing
342 business in Massachusetts; (8) information about prescription drug utilization and spending for
343 all covered drugs, including for generic drugs, brand-name drugs, and specialty drugs provided
344 in an outpatient setting or sold in a retail setting, including but not limited to information
345 sufficient to show: (i) highest utilization drugs; (ii) drugs with the greatest increases in
346 utilization; (iii) drugs that are most impactful on plan spending, net of rebates; and (iv) drugs
347 with the highest year-over-year price increases, net of rebates; (9) the Medicare Maximum Fair
348 Price (42USC Sec 1191(c)) for a prescription drug; and (10) any other information deemed
349 necessary by the center.

350 (b) The center shall analyze the information and data collected under subsection (a) and
351 shall publish an annual report summarizing, at minimum, the information collected under
352 subsection (a) and comparing the information as it relates to each pharmacy benefit manager
353 certified under chapter 175N with respect to drugs provided to Massachusetts residents. The
354 center may also consult with other states collecting similar data to inform their analysis and
355 annual report.

356 (c) Except as provided otherwise by the center or under this chapter, pharmacy benefit
357 manager data collected by the center under this section shall not be a public record under clause
358 Twenty-sixth of section 7 of chapter 4 or under chapter 66. The center may confidentially
359 provide pharmacy benefit manager data collected by the center under this section to the health
360 policy commission.

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

363 Section 11. The center shall ensure the timely reporting of information required under
364 sections 8, 9, 10 and 10A. The center shall notify payers, providers, provider organizations,
365 pharmacy benefit managers and pharmaceutical manufacturing companies of any applicable
366 reporting deadlines. The center shall notify, in writing, a private health care payer, provider,
367 provider organization, pharmacy benefit manager or pharmaceutical manufacturing company that
368 it has failed to meet a reporting deadline and that failure to respond within 2 weeks of the receipt
369 of the notice may result in penalties. The center may assess a penalty against a private health care
370 payer, provider, provider organization, pharmacy benefit manager or pharmaceutical
371 manufacturing company that fails, without just cause, to provide the requested information
372 within 2 weeks following receipt of the written notice required under this section of not more
373 than \$2,000 per week for each week of delay after the 2-week period following receipt of the
374 written notice. Amounts collected under this section shall be deposited in the Healthcare
375 Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

376 SECTION 36. Section 12 of said chapter 12C, as so appearing, is hereby amended by
377 striking out, in line 2, the words “and 10” and inserting in place thereof the following words:- ,
378 10 and 10A.

379 SECTION 37. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby
380 amended by striking out the first sentence and inserting in place thereof the following sentence:-

381 The center shall publish an annual report based on the information submitted under: (i)
382 sections 8, 9, 10 and 10A concerning health care provider, provider organization, private and
383 public health care payer, pharmaceutical manufacturing company and pharmacy benefit manager
384 costs and cost and price trends; (ii) section 13 of chapter 6D relative to market power reviews;
385 and (iii) section 15 of said chapter 6D relative to quality data.

386 SECTION 38. Said chapter 12C is hereby further amended by striking out section 17, as
387 so appearing, and inserting in place thereof the following section:-

388 Section 17. The attorney general may review and analyze any information submitted to
389 the center under sections 8, 9, 10 and 10A and the health policy commission under section 8 of
390 chapter 6D. The attorney general may require that any provider, provider organization,
391 pharmaceutical manufacturing company, pharmacy benefit manager or payer produce
392 documents, answer interrogatories and provide testimony under oath related to health care costs
393 and cost trends, pharmaceutical cost trends, factors that contribute to cost growth within the
394 commonwealth's health care system and the relationship between provider costs and payer
395 premium rates. The attorney general shall keep confidential all nonpublic information and
396 documents obtained under this section and shall not disclose the information or documents to any
397 person without the consent of the provider, pharmaceutical manufacturing company, pharmacy

398 benefit manager or payer that produced the information or documents except in a public hearing
399 under said section 8 of said chapter 6D, a rate hearing before the division of insurance or in a
400 case brought by the attorney general, if the attorney general believes that such disclosure will
401 promote the health care cost containment goals of the commonwealth and that the disclosure
402 shall be made in the public interest after taking into account any privacy, trade secret or
403 anticompetitive considerations. The confidential information and documents shall not be public
404 records and shall be exempt from disclosure under clause Twenty-sixth of section 7 of chapter 4
405 or section 10 of chapter 66.

406 SECTION 39. Said chapter 12C is hereby further amended by adding the following
407 section:-

408 Section 25. (a) The center shall analyze data on Massachusetts drug utilization and
409 spending, including but not limited to data reported under Sections 10 and 10A. Annually, the
410 center shall refer drugs to the health policy commission for review under section 8B of chapter
411 6D that meet any of the following criteria: (i) a current average annual gross cost per utilizer for
412 public and private health care payers in Massachusetts of greater than \$50,000; (ii) a biosimilar
413 drug that has a launch wholesale acquisition cost that is not at least 15 per cent lower than the
414 referenced brand biologic at the time the biosimilar is launched; or (iii) among the 25 drugs
415 determined by the center to have the most impact on health care spending in the most recent year
416 of available data, based upon utilization, price, utilization and price growth, patient cost sharing
417 amounts, net spending and other factors as determined by the center. The center shall provide
418 notice of the referral to the manufacturer of the drug.

419 (b) Not later than May 1, the center shall publish an annual report detailing, at minimum,
420 each drug referred to the health policy commission under subsection (a).

421 (c) The center shall adopt any written policies, procedures or regulations necessary to
422 implement this section.

423 SECTION 40. Chapter 94C of the General Laws is hereby amended by inserting after
424 section 21B the following section:-

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

427 “Cost-sharing”, the amount owed by an insured under the terms of the insured’s health
428 benefit plan or as required by a pharmacy benefit manager, including any copayment,
429 coinsurance or deductible.

430 “Pharmacy retail price”, the amount a pharmacy bills for a prescription medication
431 regardless of whether the individual purchases that prescription medication at that pharmacy
432 using a health benefit plan or any other prescription medication benefit or discount.

433 “Registered pharmacist”, a pharmacist who holds a valid certificate of registration issued
434 by the board of registration in pharmacy pursuant to section 24 of chapter 112.

435 (b) A health benefit plan shall (1) not restrict, directly or indirectly, any pharmacy that
436 dispenses a prescription drug to an insured in the plan from informing, or penalize such
437 pharmacy for informing, an insured of any differential between the insured’s cost-sharing
438 amount under the plan with respect to acquisition of the drug and the amount an individual
439 would pay for acquisition of the drug without using any health plan or health insurance coverage;

440 and (2) ensure that any pharmacy benefit manager under a contract with any such health benefit
441 plan does not, with respect to such plan, restrict, directly or indirectly, a pharmacy that dispenses
442 a prescription drug from informing, or penalize such pharmacy for informing, an insured of any
443 differential between the insured's cost-sharing amount under the plan with respect to acquisition
444 of the drug and the amount an individual would pay for acquisition of the drug without using any
445 health plan or health insurance coverage.

446 (c) A health benefit plan or a pharmacy benefit manager may not require an insured to
447 make a payment at the point of sale for a covered prescription medication in an amount greater
448 than the lesser of: (i) the applicable copayment for the prescription medication; (ii) the allowable
449 claim amount for the prescription medication; (iii) the amount an insured would pay for the
450 prescription medication if the insured purchased the prescription medication without using a
451 health benefit plan or any other source of prescription medication benefits or discounts, to the
452 extent this information is available to the health benefit plan; or (iv) the amount the pharmacy
453 will be reimbursed for the drug from pharmacy benefit manager or health benefit plan.

454 (d) A pharmacy shall affirmatively inform consumers that a consumer may request, at the
455 point of sale, the current pharmacy retail price for each prescription medication the consumer
456 intends to purchase. The pharmacy shall provide the information through verbal indication,
457 posting of a notice, or other methods. If the consumer's cost-sharing amount for a prescription
458 medication exceeds the current pharmacy retail price, the pharmacist, or an authorized individual
459 at the direction of a pharmacist, shall notify the consumer that the pharmacy retail price is less
460 than the patient's cost-sharing amount. The pharmacist shall charge the consumer the applicable
461 cost-sharing amount or the current pharmacy retail price for that prescription medication, as
462 directed by the consumer.

463 (e) A contractual obligation shall not prohibit a pharmacist from complying with this
464 section; provided, however, that a pharmacist shall submit a claim to the insured's health benefit
465 plan or its pharmacy benefit manager if the pharmacist has knowledge that the prescription
466 medication is covered under the insured's health benefit plan.

467 (f) A health benefit plan or pharmacy benefit manager shall not penalize, require, or
468 provide financial incentives, including variations in premiums, deductibles, copayments, or
469 coinsurance, to insureds as incentives to use specific retail, mail order pharmacy, or other
470 network pharmacy provider in which a pharmacy benefit manager has an ownership interest or
471 that has an ownership interest in a pharmacy benefit manager.

472 (g) A violation of this section shall be an unfair or deceptive act or practice under chapter
473 93A.

474 SECTION 41. Section 226 of chapter 175 of the General Laws, as appearing in the 2018
475 Official Edition, is hereby amended by striking out subsection (a) and inserting in place thereof
476 the following subsection:-

477 (a) For the purposes of this section, the term "pharmacy benefit manager" shall mean a
478 person, business or other entity, however organized, that, directly or through a subsidiary,
479 provides pharmacy benefit management services for prescription drugs and devices on behalf of
480 a health benefit plan sponsor, including, but not limited to, a self-insurance plan, labor union or
481 other third-party payer; provided, however, that pharmacy benefit management services shall
482 include, but not be limited to, the processing and payment of claims for prescription drugs, the
483 performance of drug utilization review, the processing of drug prior authorization requests,
484 pharmacy contracting, the adjudication of appeals or grievances related to prescription drug

485 coverage contracts, formulary administration, drug benefit design, mail and specialty drug
486 pharmacy services, cost containment, clinical, safety and adherence programs for pharmacy
487 services and managing the cost of covered prescription drugs; provided further, that “pharmacy
488 benefit manager” shall include a health benefit plan that does not contract with a pharmacy
489 benefit manager and manages its own prescription drug benefits unless specifically exempted.

490 SECTION 42. Section 2 of Chapter 176O of the General Laws, as so appearing, is hereby
491 amended by adding the following subsection:-

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

496 SECTION 43. Said chapter 176O of the General Laws is hereby further amended by
497 inserting after section 22 the following section:-

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

501 SECTION 44. The General Laws are hereby amended by inserting after chapter 176W
502 the following chapter:-

503 Chapter 176X.

504 LICENSING AND REGULATION OF PHARMACY BENEFIT MANAGERS.

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

507 “Carrier”, an insurer licensed or otherwise authorized to transact accident or health
508 insurance under chapter 175, a nonprofit hospital service corporation organized under chapter
509 176A, a non-profit medical service corporation organized under chapter 176B, a health
510 maintenance organization organized under chapter 176G and an organization entering into a
511 preferred provider arrangement under chapter 176I; provided, however, that the term “carrier”
512 shall not include an employer purchasing coverage or acting on behalf of its employees or the
513 employees of any subsidiary or affiliated corporation of the employer; provided further, that
514 unless otherwise noted the term “carrier” shall not include any entity to the extent it offers a
515 policy, certificate or contract that provides coverage solely for dental care services or vision care
516 services.

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

518 “Commissioner”, the commissioner of insurance.

519 “Division”, the division of insurance.

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

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

527 “Pharmacy benefit manager”, a person, business or other entity, however organized, that,
528 directly or through a subsidiary, provides pharmacy benefit management services for prescription
529 drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-
530 insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit
531 management services shall include, but not be limited to, the processing and payment of claims
532 for prescription drugs, the performance of drug utilization review, the processing of drug prior
533 authorization requests, pharmacy contracting, the adjudication of appeals or grievances related to
534 prescription drug coverage contracts, formulary administration, drug benefit design, mail and
535 specialty drug pharmacy services, cost containment, clinical, safety and adherence programs for
536 pharmacy services and managing the cost of covered prescription drugs; provided further, that
537 “pharmacy benefit manager” shall not include a health benefit plan unless otherwise specified by
538 the division.

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

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

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

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

556 (e) The division shall develop an application for licensure that shall include, but not be
557 limited to: (1) the name of the pharmacy benefit manager; (2) the address and contact telephone
558 number for the pharmacy benefit manager; (3) the name and address of the pharmacy benefit
559 manager's agent for service of process in the commonwealth; (4) the name and address of each
560 person with management or control over the pharmacy benefit manager; and (5) any audited
561 financial statements specific to the pharmacy benefit manager. A pharmacy benefit manager
562 shall report to the division any material change to the information contained in its application,
563 certified by an officer of the pharmacy benefit manager, within 30 days of such a change.

564 (f) The division may suspend, revoke, refuse to issue or renew or place on probation a
565 pharmacy benefit manager license for cause, which shall include, but not be limited to: (1) the
566 pharmacy benefit manager engaging in fraudulent activity that constitutes a violation of state or
567 federal law; (2) the division receiving consumer complaints that justify an action under this
568 chapter to protect the health, safety and interests of consumers; (3) the pharmacy benefit

569 manager failing to pay an application or renewal fee for a license; (4) the pharmacy benefit
570 manager failing to comply with reporting requirements of the center under section 10A of
571 chapter 12C; or (5) the pharmacy benefit manager failing to comply with a requirement of this
572 chapter.

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

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

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

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

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

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