

The Commonwealth of Massachusetts

PRESENTED BY:

Christine P. Barber

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:
<i>Christine P. Barber</i>	<i>34th Middlesex</i>
<i>Carmine Lawrence Gentile</i>	<i>13th Middlesex</i>
<i>Lori A. Ehrlich</i>	<i>8th Essex</i>
<i>Maria Duaimé Robinson</i>	<i>6th Middlesex</i>
<i>Carolyn C. Dykema</i>	<i>8th Middlesex</i>
<i>Ruth B. Balser</i>	<i>12th Middlesex</i>
<i>Natalie M. Blais</i>	<i>1st Franklin</i>
<i>Michael D. Brady</i>	<i>Second Plymouth and Bristol</i>
<i>Michelle L. Ciccolo</i>	<i>15th Middlesex</i>
<i>Mike Connolly</i>	<i>26th Middlesex</i>
<i>Marjorie C. Decker</i>	<i>25th Middlesex</i>
<i>Mindy Domb</i>	<i>3rd Hampshire</i>
<i>William J. Driscoll, Jr.</i>	<i>7th Norfolk</i>
<i>Michelle M. DuBois</i>	<i>10th Plymouth</i>
<i>James B. Eldridge</i>	<i>Middlesex and Worcester</i>
<i>Nika C. Elugardo</i>	<i>15th Suffolk</i>
<i>Tricia Farley-Bouvier</i>	<i>3rd Berkshire</i>
<i>Dylan A. Fernandes</i>	<i>Barnstable, Dukes and Nantucket</i>

<i>Sean Garballay</i>	<i>23rd Middlesex</i>
<i>Denise C. Garlick</i>	<i>13th Norfolk</i>
<i>Colleen M. Garry</i>	<i>36th Middlesex</i>
<i>Carlos Gonzalez</i>	<i>10th Hampden</i>
<i>Tami L. Gouveia</i>	<i>14th Middlesex</i>
<i>James K. Hawkins</i>	<i>2nd Bristol</i>
<i>Stephan Hay</i>	<i>3rd Worcester</i>
<i>Jonathan Hecht</i>	<i>29th Middlesex</i>
<i>Natalie M. Higgins</i>	<i>4th Worcester</i>
<i>Patricia D. Jehlen</i>	<i>Second Middlesex</i>
<i>Patrick Joseph Kearney</i>	<i>4th Plymouth</i>
<i>Mary S. Keefe</i>	<i>15th Worcester</i>
<i>Kay Khan</i>	<i>11th Middlesex</i>
<i>David Henry Argosky LeBoeuf</i>	<i>17th Worcester</i>
<i>Jack Patrick Lewis</i>	<i>7th Middlesex</i>
<i>Jay D. Livingstone</i>	<i>8th Suffolk</i>
<i>Adrian C. Madaro</i>	<i>1st Suffolk</i>
<i>Elizabeth A. Malia</i>	<i>11th Suffolk</i>
<i>Liz Miranda</i>	<i>5th Suffolk</i>
<i>Frank A. Moran</i>	<i>17th Essex</i>
<i>Mathew J. Muratore</i>	<i>1st Plymouth</i>
<i>Brian W. Murray</i>	<i>10th Worcester</i>
<i>Tram T. Nguyen</i>	<i>18th Essex</i>
<i>James J. O'Day</i>	<i>14th Worcester</i>
<i>Denise Provost</i>	<i>27th Middlesex</i>
<i>Rebecca L. Rausch</i>	<i>Norfolk, Bristol and Middlesex</i>
<i>David Allen Robertson</i>	<i>19th Middlesex</i>
<i>David M. Rogers</i>	<i>24th Middlesex</i>
<i>Lindsay N. Sabadosa</i>	<i>1st Hampshire</i>
<i>Jon Santiago</i>	<i>9th Suffolk</i>
<i>Alan Silvia</i>	<i>7th Bristol</i>
<i>Thomas M. Stanley</i>	<i>9th Middlesex</i>
<i>José F. Tosado</i>	<i>9th Hampden</i>
<i>Steven Ultrino</i>	<i>33rd Middlesex</i>

By Ms. Barber of Somerville, a petition (accompanied by bill, House, No. 1133) of Christine P. Barber and others relative to the pricing of prescription drugs. Health Care Financing.

The Commonwealth of Massachusetts

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

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 in the 2016
2 Official Edition, is hereby amended by inserting after the definition of “Alternative payment
3 methodologies or methods” the following two 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 produced or distributed pursuant to: (1) an original new
7 drug application, approved under 21 U.S.C. §355(c) except for an authorized generic as defined
8 by 42 C.F.R. § 447.502; or (2) a biologics license application, approved under 42 U.S.C. §
9 262(a)(C).

10 SECTION 2. Said Section 1 of chapter 6D of the General Laws, as appearing in the 2016
11 Official Edition, is hereby amended by inserting after the definition of “Fiscal year” the
12 following definition:

13 “Generic drug”, a retail drug that is marketed or distributed pursuant to: (1) an
14 abbreviated new drug application, approved under 21 U.S.C. § 355(j); or (2) an authorized
15 generic as defined by 42 C.F.R. § 447.502; or (3) a drug that entered the market before 1962 that
16 was not originally marketed under a new drug application.

17 SECTION 3. Said Section 1 of chapter 6D of the General Laws, as appearing in the 2016
18 Official Edition, is hereby amended by inserting after the definition of “Performance penalty” the
19 following two definitions:

20 “Pharmacy benefit manager”, a third-party administrator under contract to a health
21 insurance sponsor for management of prescription drug benefits including claims processing and
22 payment, pharmacy contracting, and drug manufacturer price concession negotiation. “Pharmacy
23 benefit manager” shall include a health benefit plan that does not contract with a pharmacy
24 benefit manager and manages its own prescription drug benefits, unless specifically exempted by
25 the center.

26 “Pharmaceutical manufacturing company”, an entity engaged in producing, preparing,
27 marketing, compounding, processing, packaging, repackaging, or labeling a brand-name or
28 generic drug, and who sets or changes the wholesale acquisition cost of the prescription drug it
29 manufactures or markets, but does not include an entity that is engaged in the preparation and
30 dispensing of a brand-name or generic drug pursuant to a prescription.

31 SECTION 4. Said Section 1 of chapter 6D of the General Laws, as appearing in the 2016
32 Official Edition, is hereby amended by inserting after the definition of “Third party
33 administration” the following definition:

34 “Thirty-day supply”, the amount of a drug that is (1) a drug supply lasting a patient for a
35 period consisting of 30 consecutive days based on the recommended dosage in the FDA-
36 approved labeling; or (2) a drug supply lasting fewer than thirty days if such dosage is
37 recommended in the FDA-approved labeling for such drug; or (3) one unit of the drug if there is
38 no finite dosage in the FDA-approved labeling.

39 SECTION 5. Section 8 of chapter 6D of the General Laws, as so appearing, is hereby
40 amended by striking out, in line 32, the words “and (xi) ” and inserting in place thereof the
41 following words:- (xi) not less than 3 representatives of the pharmaceutical industry; (xii) at least
42 1 pharmacy benefit manager; (xiii) a representative of a health care consumer organization and
43 (xiv).

44 SECTION 6. Said section 8 of said chapter 6D, as so appearing, is hereby amended by
45 inserting after the word “commission”, in line 59, the first time it appears, the following words:-
46 ; and (iii) in the case of pharmacy benefit managers and pharmaceutical manufacturing
47 companies, testimony concerning factors underlying prescription drug costs and price increases,
48 including changes in industry profit levels, marketing expenses, reverse payment patent
49 settlements, the impact of manufacturer rebates, discounts and other price concessions on net
50 pricing, the availability of alternative drugs or treatments and any other matters as determined by
51 the commission. Pharmacy benefit managers and pharmaceutical manufacturing companies shall
52 not be required to disclose nonpublic clinical, financial, strategic or operational documents or
53 information except pursuant to section 2A.

54 SECTION 7. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is
55 hereby amended by striking out the second sentence and inserting in place thereof the following

56 sentence:- The report shall be based on the commission's analysis of information provided at the
57 hearings by providers, provider organizations, insurers, pharmaceutical manufacturing
58 companies and pharmacy benefit managers, registration data collected under section 11, data
59 collected or analyzed by the center under sections 8, 9, 10 and 10A of chapter 12C and any other
60 available information that the commission considers necessary to fulfill its duties under this
61 section as defined in regulations promulgated by the commission.

62 SECTION 8. Chapter 6D of the General Laws is hereby amended by inserting after
63 Section 10 the following section:-

64 Section 10A. (a) Upon the receipt of information from the center pursuant to section 10A
65 of chapter 12C that identifies that (i) a prescription drug's cost or proposed or implemented
66 increase in its cost appears to be unreasonable or excessive based on a cost that (1) could lead to
67 an entity increasing health care expenditures above the health care cost growth benchmark
68 established pursuant to section 9 of chapter 6D; or (2) could create significant challenges to the
69 affordability of health care in the commonwealth, including affordability for consumers; or (ii) a
70 prescription drug's cost falls under one of the following categories: (1) brand name drugs and
71 biologics, not including biosimilars, that have a launch wholesale acquisition cost of \$30,000 or
72 more for a year or course of treatment, or a whole sale acquisition cost of \$3,000 or more in any
73 twelve-month period, or course of treatment if less than twelve months; (2) biosimilar drugs that
74 have a launch wholesale acquisition cost that is not at least 15% lower than the referenced brand
75 biologic at the time the biosimilar is launched; or (3) generic drugs with a price increase that
76 results in an increase in the wholesale acquisition cost of the drug that is equal to 200 percent or
77 more during the preceding twelve-month period, and the wholesale acquisition cost of the drug is
78 equal to or greater than \$100, as updated annually in accordance with the consumer price index

79 for all urban consumers, for a thirty-day supply, with the increase defined as the difference
80 between the resulting wholesale acquisition cost and the average of the wholesale acquisition
81 cost reported over the previous twelve months; the commission shall determine if a prescription
82 drug shall be reviewed pursuant to this section. The commission may permit an opportunity for
83 interested parties and members of the public to provide comments prior to a determination to
84 undertake a review. All comments received shall be public records.

85 (b) The commission's review of the drug shall determine if, based on the findings of the
86 center and the review factors listed in subsection (c) the commission shall establish, in
87 consultation with the center, an upper payment limit that applies to all purchasers and payor
88 reimbursements of the prescription drug product in the commonwealth, including uninsured
89 consumers or consumers in a deductible period for the drug in the commonwealth. Failure of the
90 manufacturing company to provide the requested information to the center pursuant to section
91 10A of chapter 12C shall not impede the commission from establishing an upper payment limit
92 under this paragraph.

93 (c) The factors to be considered in the review by the commission may include: (1) the
94 price at which the prescription drug has been or will be sold in the commonwealth; (2) the
95 average monetary price concession, discount or rebate the manufacturer provides or is expected
96 to provide to payors as reported by manufacturers and health plans expressed as a percent of the
97 wholesale acquisition cost for the drug; (3) the price at which therapeutic alternates have been or
98 will be sold; (4) the average monetary price concession, discount, or rebate the manufacturer
99 provides or is expected to provide to payors for therapeutic alternates; (5) the relative clinical
100 merits of the product under review compared to therapeutic alternates; (6) the cost to payors
101 based on patient access consistent with FDA labeled indication or indications or standard

102 medical practice; (7) the impact on patient access resulting from the cost of the product relative
103 to insurance benefit design, including the average cost-sharing for the prescription drug; (8) the
104 relative financial impacts to health, medical and other social services costs, as can be quantified
105 and compared to baseline effects of existing therapeutic alternatives; (9) manufacturer research
106 and development costs as shown on the company's federal tax filing for the most recent tax year,
107 multiplied by the proportion of manufacturer's sales in the commonwealth to U.S. sales; (10) that
108 portion of direct to consumer marketing costs eligible for favorable federal tax treatment in the
109 most recent tax year, which are specific to the prescription drug product under review and that
110 are multiplied by the ratio of total manufacturer sales in the commonwealth to total manufacturer
111 U.S. sales for the product under review; (11) gross and net manufacturer revenues for the most
112 recent tax year; and (12) any additional factors specified in regulations or that the commission
113 considers relevant to the circumstances.

114 (d) Following the review, the commission may, by a majority vote of the board members
115 voting, establish an upper payment limit that applies to all purchasers and payor reimbursements
116 of the prescription drug product in the commonwealth, including uninsured consumers or
117 consumers in a deductible period for the drug in the commonwealth. Payors shall use the
118 established upper payment limit for the prescription drug in developing the benefit design for
119 such drug, including, if applicable, any cost-sharing amounts.

120 (e) This section shall be enforced by the attorney general. Payment transactions that do
121 not comply with the maximum level of reimbursement established under this section shall
122 constitute a violation of chapter 93A. The attorney general shall provide guidance concerning
123 activities that could be considered non-compliant, in addition to payment transactions where
124 drug costs exceed the limit established under this section.

125 (f) Nothing in this section shall be construed to affect: (i) an entity's eligibility for the
126 federal 340B Drug Pricing Program; or (ii) the discounts that are available to an entity that is
127 eligible for the federal 340B Drug Pricing Program.

128 SECTION 9. Said chapter 6D is hereby further amended by inserting after section 15A
129 the following section:-

130 Section 15A. (a) The commission shall develop, implement and promote an evidence-
131 based outreach and education program to support the therapeutic and cost-effective utilization of
132 prescription drugs for physicians, podiatrists, pharmacists and other health care professionals
133 authorized to prescribe and dispense prescription drugs. In developing the program, the
134 commission shall consult with physicians, podiatrists, pharmacists, nurses, private insurers,
135 hospitals, pharmacy benefit managers, the MassHealth drug utilization review board, the
136 University of Massachusetts medical school and researchers and organizations that are engaged
137 in the development, training and deployment of health practitioner education outreach programs.

138 (b) The program shall arrange for physicians, podiatrists, pharmacists and nurses to
139 conduct face-to-face visits with prescribers, utilizing evidence-based materials and borrowing
140 methods from behavioral science, educational theory and, where appropriate, pharmaceutical
141 industry data and outreach techniques; provided, however, that, to the extent possible, the
142 program shall inform prescribers about drug marketing that is intended to circumvent
143 competition from generic or other therapeutically-equivalent pharmaceutical alternatives or other
144 evidence-based treatment options. The program shall be designed to provide outreach to:
145 physicians, podiatrists and other health care practitioners who participate in MassHealth, the
146 subsidized catastrophic prescription drug insurance program established in section 39 of chapter

147 19A, other publicly-funded, contracted or subsidized health care programs, academic medical
148 centers and other prescribers. The commission shall, to the extent possible, utilize or incorporate
149 into its program other independent educational resources or models proven effective in
150 promoting high quality, evidenced-based, cost-effective information regarding the effectiveness
151 and safety of prescription drugs including, but not limited to: (i) the Pennsylvania
152 Pharmaceutical Assistance Contract for the Elderly Independent Drug Information Service
153 affiliated with Harvard University; (ii) the Academic Detailing Program through the University
154 of Vermont Larner College of Medicine's Office of Primary Care and Area Health Education
155 Centers Program; (iii) the Drug Effectiveness Review Project coordinated by the Center for
156 Evidence-based Policy at Oregon Health and Science University; and (iv) the North Carolina
157 evidence-based peer-to-peer education program outreach program.

158 (c) The commission shall make an annual report, not later than April 1, on the operation
159 of the program. The report shall be made publicly available on the commission's website and
160 include information on the outreach and education components of the program, revenues,
161 expenditures and balances and savings attributable to the program in health care programs
162 funded by the commonwealth.

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

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

169 SECTION 10. Section 11N of chapter 12 of the General Laws, as so appearing, is hereby
170 amended by striking out subsection (a) and inserting in place thereof the following subsection:-

171 (a) The attorney general shall monitor trends in the health care market including, but not
172 limited to, trends in provider organization size and composition, consolidation in the provider
173 market, payer contracting trends, patient access and quality issues in the health care market and
174 prescription drug cost trends. The attorney general may obtain the following information from a
175 private health care payer, public health care payer, pharmaceutical manufacturing company,
176 pharmacy benefit manager, provider or provider organization as any of those terms may be
177 defined in section 1 of chapter 6D: (i) any information that is required to be submitted under
178 sections 8, 9 10 and 10A of chapter 12C; (ii) filings, applications and supporting documentation
179 related to any cost and market impact review under section 13 of said chapter 6D; (iii) filings,
180 applications and supporting documentation related to a determination of need application filed
181 under section 25C of chapter 111; and (iv) filings, applications and supporting documentation
182 submitted to the federal Centers for Medicare and Medicaid Services or the Office of the
183 Inspector General for any demonstration project. Under section 17 of said chapter 12C and
184 section 8 of said chapter 6D and subject to the limitations stated in those sections, the attorney
185 general may require that any provider, provider organization, pharmaceutical manufacturing
186 company, pharmacy benefit manager, private health care payer or public health care payer
187 produce documents, answer interrogatories and provide testimony under oath related to health
188 care costs and cost trends, pharmaceutical costs, pharmaceutical cost trends, the factors that
189 contribute to cost growth within the commonwealth's health care system and the relationship
190 between provider costs and payer premium rates and the relationship between pharmaceutical
191 drug costs and payer premium rates.

192 (b) The attorney general may investigate any provider organization referred to the
193 attorney general by the health policy commission under section 13 of chapter 6D to determine
194 whether the provider organization engaged in unfair methods of competition or anticompetitive
195 behavior in violation of chapter 93A or any other law and, if appropriate, take action under said
196 chapter 93A or any other law to protect consumers in the health care market.

197 (c) The attorney general may investigate a pharmaceutical manufacturing company or
198 pharmacy benefit manager referred to the attorney general by the center for health information
199 and analysis under section 11 of chapter 12C to determine whether the pharmaceutical
200 manufacturing company or pharmacy benefit manager engaged in unfair methods of competition
201 or anticompetitive behavior in violation of chapter 93A or any other law and, if appropriate, take
202 action under said chapter 93A or any other law to protect consumers in the health care market.

203 (d) The attorney general may intervene or otherwise participate in efforts by the
204 commonwealth to obtain exemptions or waivers from certain federal laws regarding provider
205 market conduct, including, from the federal Office of the Inspector General, a waiver or
206 expansion of the safe harbors' provided for under 42 U.S.C. § 1320a-7b and obtaining from the
207 federal Office of the Inspector General a waiver of or exemption from 42 U.S.C. § 1395nn
208 subsections (a) to (e), inclusive.

209 (e) Nothing in this section shall limit the authority of the attorney general to protect
210 consumers in the health care market under any other law.

211 SECTION 11. Section 1 of chapter 12C of the General Laws, as appearing in the 2016
212 Official Edition, is hereby amended by inserting after the definition of “Acute hospital” the
213 following definition:

214 “Aggregate retained rebate percentage”, the percentage of all rebates received from a
215 manufacturer or other entity to a pharmacy benefit manager for prescription drug utilization
216 which is not passed on to pharmacy benefit managers’ carrier clients. The percentage shall be
217 calculated for each carrier for rebates in the prior calendar years as follows: (i) the sum total
218 dollar amount of rebates received from all pharmaceutical manufacturers for all utilization of
219 covered persons of a health carrier that was not passed through to the carrier; and (ii) divided by
220 the sum total dollar amount of all rebates received from all pharmaceutical manufacturers for
221 members of a health carrier.

222 SECTION 12. Said section 1 of chapter 12C of the General Laws, as appearing in the
223 2016 Official Edition, is hereby amended by inserting after the definition of “Ambulatory
224 surgical center services” the following two definitions:

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

227 “Brand name drug”, a drug that is produced or distributed pursuant to: (1) an original new
228 drug application, approved under 21 U.S.C. §355(c) except for an authorized generic as defined
229 by 42 C.F.R. § 447.502; or (2) a biologics license application, approved under 42 U.S.C. §
230 262(a)(C).

231 SECTION 13. Said section 1 of chapter 12C of the General Laws, as appearing in the
232 2016 Official Edition, is hereby amended by inserting after the definition of “General health
233 supplies, care or rehabilitative services and accommodations” the following definition:

234 “Generic drug”, a retail drug that is marketed or distributed pursuant to: (1) an
235 abbreviated new drug application, approved under 21 U.S.C. § 355(j); or (2) an authorized

236 generic as defined by 42 C.F.R. § 447.502; or (3) a drug that entered the market before 1962 that
237 was not originally marketed under a new drug application.

238 SECTION 14. Said section 1 of chapter 12C of the General Laws, as appearing in the
239 2016 Official Edition, is hereby amended by inserting after the definition of “Patient-centered
240 medical home” the following 3 definitions:

241 “Pharmacy benefit manager”, a third-party administrator under contract to a health
242 insurance sponsor for management of prescription drug benefits including claims processing and
243 payment, pharmacy contracting, and drug manufacturer price concession negotiation. “Pharmacy
244 benefit manager” shall include a health benefit plan that does not contract with a pharmacy
245 benefit manager and manages its own prescription drug benefits, unless specifically exempted by
246 the center.

247 “Pharmaceutical manufacturing company”, an entity engaged in producing, preparing,
248 marketing, compounding, processing, packaging, repackaging, or labeling a brand-name or
249 generic drug, and who sets or changes the wholesale acquisition cost of the prescription drug it
250 manufactures or markets, but does not include an entity that is engaged in the preparation and
251 dispensing of a brand-name or generic drug pursuant to a prescription.

252 “Pipeline drugs”, a prescription drug for which an FDA regulated entity has submitted a
253 new drug application or biologics license application and received an action date from the federal
254 Food and Drug Administration.

255 SECTION 15. Said section 1 of chapter 12C of the General Laws, as appearing in the
256 2016 Official Edition, is hereby amended by inserting after the definition of “Quality measures”
257 the following definition:

258 “Rebates or fees”, all fees or price concessions paid by a manufacturer to a pharmacy
259 benefit manager or carrier, including rebates, discounts, and other price concessions that are
260 based on actual or estimated utilization of a prescription drug. Rebates also include price
261 concessions based on the effectiveness a drug as in a value-based or performance-based contract.

262 SECTION 16. Said section 1 of chapter 12C of the General Laws, as appearing in the
263 2016 Official Edition, is hereby amended by inserting after the definition of “Third party payer”
264 the following definition:

265 “Thirty-day supply”, the amount of a drug that is (1) a drug supply lasting a patient for a
266 period consisting of 30 consecutive days based on the recommended dosage in the FDA-
267 approved labeling; or (2) a drug supply lasting fewer than thirty days if such dosage is
268 recommended in the FDA-approved labeling for such drug; or (3) one unit of the drug if there is
269 no finite dosage in the FDA-approved labeling.

270 SECTION 17. Section 5 of said chapter 12C, as so appearing, is hereby amended by
271 inserting after the word “payers”, in line 11, the following words:- , pharmaceutical
272 manufacturing companies, pharmacy benefit managers.

273 SECTION 18. Said section 5 of said chapter 12C, as so appearing, is hereby further
274 amended by inserting after the word “organizations”, in line 15, the following words:- , affected
275 pharmaceutical manufacturing companies, affected pharmacy benefit managers.

276 SECTION 19. Section 7 of said chapter 12C, as so appearing, is hereby amended by
277 adding the following paragraph:-

278 To the extent that the analysis of pharmaceutical manufacturing companies and pharmacy
279 benefit managers pursuant to section 10A increases the expenses of the center, the estimated
280 increase in the center's expenses shall be fully assessed to pharmaceutical manufacturing
281 companies and pharmacy benefit managers in the same manner as the assessment under section
282 68 of chapter 118E. For pharmaceutical manufacturing companies, such assessments shall be
283 determined based upon each manufacturer's relative share of drug gross revenue in the state. A
284 pharmacy benefit manager that is a surcharge payor subject to the preceding paragraph and
285 administers either its own: (i) prescription drug, prescription device or pharmacist services; or
286 (ii) prescription drug and device and pharmacist services portion shall not be subject to
287 additional assessment under this paragraph.

288 SECTION 20. Said chapter 12C is hereby further amended by inserting after section 10
289 the following section[s]:-

290 Section 10A. (a) The center shall study of the impact of pharmaceutical manufacturing
291 company pricing factors and methodologies and the pharmacy benefit manager business model
292 on drug costs, including patented drugs, pipeline drugs, generic drugs and biosimilar drug
293 products. The center shall develop a list of critical prescription drugs for which there is a
294 substantial public interest in understanding the development of the drug's pricing. In developing
295 the list, the commission shall include the top twenty selling drugs in the commonwealth, and
296 other drugs based on the following factors: (i) the cost of the drug to public health care programs,
297 including the office of Medicaid and the group insurance commission; (ii) the current cost of the
298 drug in the commonwealth; (iii) the extent of utilization of the drug within the commonwealth;
299 (iv) the seriousness and prevalence of the disease or condition that is treated by the drug; (v)
300 identification of the drug as low comparative value by an independent non-profit organization;

301 and (vi) the potential impact of the cost of the drug on the commonwealth's achievement of the
302 statewide health care cost growth benchmark, as established by section 9. For each prescription
303 drug that the center identifies, the center shall require the manufacturer of said prescription drug
304 to report to the center the information pursuant to paragraph (b). Study findings shall be issued at
305 least annually; provided, however, that the center may issue interim studies if it deems it
306 necessary. The center may contract with a state or third-party entity that can access data available
307 from public or proprietary sources, or collected or compiled by other states that satisfy the
308 requirements of this section. The center shall post a summary of the study findings and the
309 information received pursuant to this section on the center's website at least annually on or
310 before October 1 of each year.

311 (b) The center shall require the submission of available data and other information from
312 pharmaceutical manufacturing companies and pharmacy benefit managers; provided, however,
313 that the center shall make its data requests compatible with the prescription drug transparency
314 systems of other states. The center may obtain the data from information submitted to other
315 states and may modify the specific data requested to take into account information available from
316 public and proprietary data sources and prescription drug transparency information requests of
317 other states. The data and information requested from pharmaceutical manufacturing companies
318 may include, but not be limited to: (i) changes in wholesale acquisition costs for prescription
319 drug products as identified by the center; (ii) aggregate, company-level and product-specific
320 research and development costs to the extent attributable to a specific product or products and
321 other relevant capital expenditures for the most recent year for which final audited data are
322 available for prescription drug products as identified by the center, provided that reasonable
323 estimates may be provided if more precise costs are not available; (iii) the amount paid by the

324 manufacturer to acquire the prescription drug product if not developed by the manufacturer; (iv)
325 the 5-year history of any increases in the wholesale acquisition costs; (v) annual marketing and
326 advertising expenditures apportioned by activities directed to consumers and prescribers for
327 prescription drug products as identified by the center; (vi) the average cost-sharing for each
328 prescription drug; and (vii) a description, suitable for public release, of factors that contributed to
329 reported changes in wholesale acquisition costs for prescription drug products as identified by
330 the center; and (vii) any other information necessary to identify drugs that may be subject to
331 reporting under paragraph (j). The center shall further require pharmacy benefit managers to
332 submit data and information regarding: (i) the aggregate amount of all rebates or fees that the
333 pharmacy benefit manager received from all pharmaceutical manufacturers for all health carrier
334 clients and for each health carrier client; (ii) the aggregate administrative fees that the pharmacy
335 benefit manager received from all manufacturers for all health carrier clients and for each health
336 carrier client; (iii) the aggregate retained rebates that the pharmacy benefit manager received
337 from all pharmaceutical manufacturers and did not pass through to health benefit plans; (iv) the
338 aggregate retained rebate percentage; and (v) the highest, lowest, and mean aggregate retained
339 rebate percentage for all health benefit plan clients and for each health carrier client.

340 (c) The study shall include, to the extent supported by available information, the
341 following: (i) annual changes in wholesale acquisition costs and net expenditures for products
342 identified by the center, including manufacturing and distribution costs; (ii) annual marketing
343 and advertising costs, identifying costs for consumer-directed advertising; (iii) gross revenue,
344 volume and profits derived from sales in the commonwealth during the previous five years; (iv)
345 research and development costs as a percentage of revenue, including research costs received
346 from public sources, including costs paid by grants from the federal Department of Health and

347 Human Services and Department of Defense, tax credits received in connection with research
348 and development or marketing, and costs paid by third parties, to the extent such costs are
349 attributable to a specific product or set of products; (viii) estimated aggregate drug rebates and
350 other price reductions paid by a pharmaceutical manufacturing company in connection with
351 purchase of drugs produced by the pharmaceutical manufacturing company; (ix) information
352 regarding trends of estimated aggregate rebates or fees and other price reductions paid by a
353 pharmacy benefit manager in connection with utilization of all drugs offered through the
354 pharmacy benefit manager; (x) information regarding pharmacy benefit manager practices in
355 passing drug rebates or other price reductions received by the pharmacy benefit manager to a
356 private or public health care payer or to the consumer; (xi) information regarding discount or free
357 product coupons that a pharmacy provides to a consumer in connection with a pharmacy service,
358 item or prescription transfer offer or to any discount, rebate, product voucher or other reduction
359 in an individual's out-of-pocket expenses, including co-payments and deductibles under section
360 3 of chapter 175H; (xii) disparities between costs for purchasers in the commonwealth and
361 purchasers outside of the United States and (xiii) any other information deemed necessary by the
362 center.

363 (d) A pharmaceutical manufacturing company shall provide early notice to the center for:
364 (i) a pipeline drug; (ii) an abbreviated new drug application for generic drugs, upon submission
365 to the federal Food and Drug Administration; or (iii) a biosimilar biologics license application
366 upon the receipt of an action date from the federal Food and Drug Administration. The center
367 may arrange to receive notices required by this subsection from publicly available information or
368 subscription data sources. The center shall make early notice information available to the office
369 of Medicaid or another agency and to acute hospitals, ambulatory surgical centers and surcharge

370 payors, as deemed appropriate. Early notice shall be submitted to the center not later than 60
371 days after receipt of the federal Food and Drug Administration action date or after the
372 submission of an abbreviated new drug application to the federal Food and Drug Administration
373 action. For each prescription drug product, early notice shall include a brief description of the: (i)
374 primary disease, health condition or therapeutic area being studied and the indication; (ii) route
375 of administration being studied; (iii) clinical trial comparators; and (iv) estimated year of market
376 entry. To the extent possible, information shall be collected using data fields consistent with
377 those used by the federal National Institutes of Health for clinical trials. For each pipeline drug,
378 early notice shall include whether the drug has been designated by the federal Food and Drug
379 Administration: (i) orphan drug; (ii) fast track; (iii) breakthrough therapy; (iv) for accelerated
380 approval; or (v) priority review for a new molecular entity. Notwithstanding the foregoing,
381 submissions for drugs in development that receive such a designation by the federal Food and
382 Drug Administration for new molecular entities shall be provided as soon as practical upon
383 receipt of the relevant designation.

384 (e) A pharmaceutical manufacturing company shall provide notice to the center for any
385 drug purchased or reimbursed by a health insurance plan or a pharmacy benefit manager in the
386 commonwealth with a wholesale acquisition cost over forty dollars for a course of therapy if the
387 wholesale acquisition cost will increase by more than 10 percent, including any increases in the
388 previous two calendar years. The notice shall specify the amount of the proposed increase, the
389 cumulative increase in the past 24-month period, the date that the increase will take effect, and
390 the current wholesale acquisition cost of the drug. The notice required by this subsection shall be
391 provided at least sixty days before the planned increase. The notice provided under this
392 subsection shall be accompanied by a statement providing the specific financial and non-

393 financial factors used to make the decision to increase the wholesale acquisition cost of the drug,
394 including pricing of competitive drugs, policy changes, changes in treatment, any improved
395 clinical efficacy and any other information as required by the center. The center shall publish the
396 information it receives pursuant to this subsection on its public internet site in a format that
397 allows members of the public to be informed when new notices are published on the site.

398 (f) The center shall report on the operation of the United States generic market, including
399 a review of physician-administered drugs. Such report shall consider: (1) the prices of generic
400 drugs on a year over year basis; (2) the degree to which generic drug prices affect yearly
401 insurance premium changes; (3) annual changes in insurance cost-sharing for generic drugs; (4)
402 the potential for and history of drug shortages; (5) the degree to which generic drug prices affect
403 yearly state Medicaid spending; and (6) any other relevant study questions.

404 (g) The center shall promulgate regulations necessary to ensure the uniform analysis of
405 information regarding pharmaceutical manufacturing companies and pharmacy benefit managers
406 and that enable the center to receive the required information necessary to perform the analysis
407 and reporting required by this section. The center may obtain data from information submitted to
408 other states and may modify the specific data requested to take into account information
409 available from public and proprietary data sources and prescription drug transparency
410 information requests of other states.

411 (h) The center shall notify pharmacy benefit managers and pharmaceutical manufacturing
412 companies of any applicable reporting deadlines under this section. The center shall notify, in
413 writing, a pharmacy benefit manager or pharmaceutical manufacturing company that it has failed
414 to meet a reporting deadline and that failure to respond within two weeks of the receipt of the

415 notice shall result in penalties. The center shall assess a penalty against a pharmacy benefit
416 manager or pharmaceutical manufacturing company that fails, without just cause, to provide the
417 requested information within two weeks following receipt of the written notice required under
418 this paragraph of up to \$10,000 per day for each week of delay after the two-week period
419 following receipt of the written notice; provided, however, that the maximum annual penalty
420 against a pharmacy benefit manager or pharmaceutical manufacturing company under this
421 section shall be \$1,000,000. Amounts collected under this section shall be deposited in the
422 Healthcare Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.
423 The center may additionally identify any such pharmaceutical manufacturing company that fails,
424 without just cause, to provide the requested information within two weeks following receipt of
425 the written notice required under this paragraph and may recommend any drug manufactured by
426 such manufacturing company for automatic review by the commission pursuant to paragraph (j).
427 The center shall notify the attorney general of any pharmaceutical manufacturing company or
428 pharmacy benefit manager that fails to comply with this section for further action pursuant to
429 section 11N of chapter 12 or any other law. For the purposes of this section, the center may
430 promulgate regulations to define “just cause”.

431 (i) The center shall keep confidential all nonpublic clinical, financial, strategic or
432 operational documents or information provided or reported in connection with this section and
433 shall not disclose the information or documents to any person without the consent of the entity
434 providing or reporting the information or documents, except in summary form in evaluative
435 reports of such activities or when the center believes that such disclosure should be made in the
436 public interest after taking into account any privacy, trade secret or anticompetitive
437 considerations. The confidential information and documents shall not be public records and shall

438 be exempt from disclosure under clause Twenty-sixth of section 7 of chapter 4 or section 10 of
439 chapter 66.

440 (j) The center shall identify and regularly report to the commission, based on the
441 information gathered and analyzed in this section, the following: (i) any drug or group of drugs
442 whose cost or proposed or implemented cost increase appears to be unreasonable or excessive
443 based on a cost that (1) could lead to an entity increasing health care expenditures above the
444 health care cost growth benchmark established pursuant to section 9 of chapter 6D; or (2) could
445 create significant challenges to the affordability of health care in the commonwealth, including
446 affordability for consumers based on the information received by the center; or (ii) any drug or
447 group of drugs that falls under one of the following categories: (1) brand name drugs and
448 biologics, not including biosimilars, that have a launch wholesale acquisition cost of \$30,000 or
449 more for a year or course of treatment, or a wholesale acquisition cost of \$3,000 or more in any
450 twelve-month period, or course of treatment if less than twelve months; (2) biosimilar drugs that
451 have a launch wholesale acquisition cost that is not at least 15% lower than the referenced brand
452 biologic at the time the biosimilar is launched; or (3) generic drugs with a price increase that
453 results in an increase in the wholesale acquisition cost of the drug that is equal to 200 percent or
454 more during the preceding twelve-month period, and the wholesale acquisition cost of the drug is
455 equal to or greater than \$100, as updated annually in accordance with the consumer price index
456 for all urban consumers, for a thirty-day supply, with the increase defined as the difference
457 between the resulting wholesale acquisition cost and the average of the wholesale acquisition
458 cost reported over the previous twelve months.

459 SECTION 21. Said chapter 12C is hereby further amended by striking out section 17, as
460 so appearing, and inserting in place thereof the following section:-

461 Section 17. The attorney general may review and analyze any information submitted to
462 the center under sections 8, 9, 10 and 10A and the health policy commission under section 8 of
463 chapter 6D. The attorney general may require that any provider, provider organization,
464 pharmaceutical manufacturing company, pharmacy benefit manager or payer produce
465 documents, answer interrogatories and provide testimony under oath related to health care costs
466 and cost trends, pharmaceutical cost trends, factors that contribute to cost growth within the
467 commonwealth's health care system and the relationship between provider costs and payer
468 premium rates. The attorney general shall keep confidential all nonpublic information and
469 documents obtained under this section and shall not disclose the information or documents to any
470 person without the consent of the provider, pharmaceutical manufacturing company, pharmacy
471 benefit manager or payer that produced the information or documents except in a public hearing
472 under said section 8 of said chapter 6D, a rate hearing before the division of insurance or in a
473 case brought by the attorney general, if the attorney general believes that such disclosure will
474 promote the health care cost containment goals of the commonwealth and that the disclosure
475 shall be made in the public interest after taking into account any privacy, trade secret or
476 anticompetitive considerations. The confidential information and documents shall not be public
477 records and shall be exempt from disclosure under clause Twenty-sixth of section 7 of chapter 4
478 or section 10 of chapter 66.

479 SECTION 22. Chapter 94C of the General Laws is hereby amended by inserting after
480 section 21B the following section:-

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

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

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

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

491 (b)(1) A health benefit plan shall (i) not restrict, directly or indirectly, any pharmacy that
492 dispenses a prescription drug to an insured in the plan from informing, or penalize such
493 pharmacy for informing, an insured of any differential between the insured’s cost-sharing
494 amount under the plan with respect to acquisition of the drug and the amount an individual
495 would pay for acquisition of the drug without using any health plan or health insurance coverage;
496 and (ii) ensure that any pharmacy benefit manager under a contract with any such health benefit
497 plan does not, with respect to such plan, restrict, directly or indirectly, a pharmacy that dispenses
498 a prescription drug from informing, or penalize such pharmacy for informing, an insured of any
499 differential between the insured’s cost-sharing amount under the plan with respect to acquisition
500 of the drug and the amount an individual would pay for acquisition of the drug without using any
501 health plan or health insurance coverage. (2) A health benefit plan or a pharmacy benefit
502 manager may not require an insured to make a payment at the point of sale for a covered
503 prescription medication in an amount greater than the lesser of: (i) the applicable copayment for
504 the prescription medication; (ii) the allowable claim amount for the prescription medication;

505 (iii) the amount an insured would pay for the prescription medication if the insured
506 purchased the prescription medication without using a health benefit plan or any other source of
507 prescription medication benefits or discounts; or (iv) the amount the pharmacy will be
508 reimbursed for the drug from pharmacy benefit manager or health benefit plan. (3) A pharmacy
509 shall post a notice informing consumers that a consumer may request, at the point of sale, the
510 current pharmacy retail price for each prescription medication the consumer intends to purchase.
511 If the consumer's cost-sharing amount for a prescription medication exceeds the current
512 pharmacy retail price, the pharmacist, or an authorized individual at the direction of a
513 pharmacist, shall notify the consumer that the pharmacy retail price is less than the patient's cost-
514 sharing amount. The pharmacist shall charge the consumer the applicable cost-sharing amount or
515 the current pharmacy retail price for that prescription medication, as directed by the consumer.
516 (4) A contractual obligation shall not prohibit a pharmacist from complying with this section;
517 provided, however, that a pharmacist shall submit a claim to the insured's health benefit plan or
518 its pharmacy benefit manager if the pharmacist has knowledge that the prescription medication is
519 covered under the insured's health benefit plan. (5) A pharmacy benefit manager shall not
520 require pharmacy or other provider accreditation standards or certification requirements
521 inconsistent with, more stringent than, or in addition to requirements of the board of registration
522 of pharmacy or other state or federal entity. (6) A health benefit plan or pharmacy benefit
523 manager shall not penalize, require, or provide financial incentives, including variations in
524 premiums, deductibles, copayments, or coinsurance, to insureds as incentives to use specific
525 retail, mail order pharmacy, or other network pharmacy provider in which a pharmacy benefit
526 manager has an ownership interest or that has an ownership interest in a pharmacy benefit

527 manager. (7) A violation of this section shall be an unfair or deceptive act or practice under
528 chapter 93A.

529 SECTION 23. Chapter 118E of the General Laws is hereby amended by inserting after
530 section 12 the following section:-

531 Section 12A. (a) As used in this section, the following words shall have the following
532 meanings unless the context clearly indicates otherwise:

533 “Board”, the MassHealth drug utilization review board established in accordance with 42
534 U.S.C. 1396r-8.

535 “Manufacturer”, an entity that manufacturers a pharmaceutical drug covered by
536 MassHealth.

537 “Pharmaceutical spending target”, the reduction in the projected increase in the
538 commonwealth’s net share of pharmaceutical spending for the next fiscal year for the
539 MassHealth program as compared to the current fiscal year.

540 “Secretary”, the secretary of health and human services.

541 (b) The secretary, in consultation with the board, shall establish a pharmaceutical
542 spending target pursuant to the supplemental rebate cost containment efforts set forth in this
543 section. When establishing the pharmaceutical spending target, the board shall annually hold at
544 least 1 public hearing and solicit input from interested stakeholders not later than December 15.
545 The secretary shall provide notice of the pharmaceutical spending target for the next fiscal year
546 not later than January 1 to the clerks of the senate and house of representatives and the chairs of
547 the senate and house committees on ways and means.

548 (c) Notwithstanding any general or special law to the contrary, including 801 CMR 21.00
549 or any successor regulation, and subject to required federal approvals, the secretary may directly
550 negotiate supplemental rebate agreements with manufacturers including, but not limited to,
551 agreements utilizing guaranteed net prices that are (i) reasonable, affordable and sustainable for
552 the commonwealth; and (ii) reflects the public health value of such drugs as determined by an
553 independent third party designated by the secretary or other appropriate measure of value. In
554 requesting a supplemental rebate, the secretary shall consider any data received or analysis
555 performed by the center for health information and analysis pursuant to section 10A of chapter
556 12C and of determinations, including any upper payment limit imposed, of the health policy
557 commission pursuant to section 10A of chapter 6D. A manufacturer may request to enter into
558 negotiations for a supplemental rebate agreement for a prescription drug; provided, however, that
559 the secretary may prioritize other negotiations or refuse to enter into such negotiations. Nothing
560 in this paragraph shall preclude the secretary from entering into a supplemental rebate agreement
561 negotiation with a manufacturer at a later date.

562 (d) If a manufacturer and the secretary are unable to establish a supplemental rebate
563 agreement under subsection (c), the secretary may require the manufacturer to disclose within a
564 reasonable time any records that describe or relate to the manufacturer's pricing of any such
565 drugs that are the subject of a supplemental rebate agreement negotiation. Records disclosed by a
566 manufacturer shall not be public records under section 7 of chapter 4 and under chapter 66 and
567 shall remain confidential; provided, however, that the secretary may produce reports
568 summarizing any findings related to records received under this section to the extent allowable
569 under applicable state and federal laws. The secretary, in conjunction with the board, may hold a
570 public hearing at which the manufacturer shall be required to appear and testify to provide

571 further information related to any prescription drug that is the subject of a negotiation for a
572 supplemental rebate agreement.

573 (e) If a manufacturer does not comply with subsection (d), the secretary may impose a
574 reasonable penalty on the manufacturer which shall not exceed the difference between the gross
575 cost of the pharmaceutical drug subject to the supplemental rebate negotiation in the previous
576 fiscal year and the fiscal year preceding the previous fiscal year; provided, however, that if there
577 is no information available for the preceding 2 fiscal years for the pharmaceutical drug subject to
578 the supplemental rebate, then the maximum penalty shall be the amount of the supplemental
579 rebate first requested by the secretary during a negotiation under subsection (c).

580 (f) If, after review of any records furnished to the executive office under subsection (d),
581 no supplemental rebate agreement is completed and the secretary determines that the
582 manufacturer's pricing of the drug is excessive, the secretary may impose a reasonable penalty
583 against the manufacturer which shall not exceed the difference between the gross cost of the
584 pharmaceutical drug subject to the supplemental rebate negotiation in the previous fiscal year
585 and the fiscal year preceding the previous fiscal year; provided, however, that if there is no
586 information available for the preceding 2 fiscal years for the pharmaceutical drug subject to the
587 supplemental rebate negotiation, then the maximum penalty shall be the amount of the
588 supplemental rebate first requested by the secretary during a negotiation under subsection (c).

589 (g) A penalty assessed under subsection (e) or (f) shall be accompanied by a written
590 determination by the secretary that shall include: (i) the reason for the penalty; (ii) the amount of
591 the penalty; and (iii) a notice outlining the appeals process for the penalty.

592 (h) The secretary may, pursuant to an interagency agreement, share information received
593 under this section with the health policy commission, established under chapter 6D; provided,
594 however, that any shared information shall be held confidential and shall not be a public record
595 under section 7 of chapter 4 and under chapter 66. The health policy commission may use the
596 information received under this subsection in relevant reporting in a de-identified, aggregate
597 format. The secretary may, pursuant to an interagency agreement, share information received
598 under this section with the state office of pharmacy services in the department of public health;
599 provided, however, that any shared information shall be held confidential and shall not be a
600 public record under section 7 of chapter 4 and under chapter 66.

601 (i) Annually, not later than October 15, the secretary shall report to the clerks of the
602 senate and house of representatives, the joint committee on healthcare financing and the house
603 and senate committees on ways and means on activities conducted pursuant to this section which
604 shall include, but not limited to, the following information: (i) whether the pharmaceutical
605 spending target was achieved; (ii) the amount of supplemental rebates received under this
606 section; (iii) the number of pharmaceutical drugs receiving a supplemental rebate under this
607 section, broken down by manufacturer; (iv) a breakdown of the duration of the supplemental
608 rebates received; and (v) a breakdown of the percentage of each supplemental rebate's
609 contribution to meeting the pharmaceutical spending target.

610 (j) The executive office shall adopt regulations necessary to implement this section.

611 SECTION 24. Section 6 of chapter 176J of the General Laws, as so appearing, is
612 hereby amended by striking subsection (c) and inserting in place thereof the following
613 subsection:-

614 (c) Notwithstanding any general or special law to the contrary, carriers offering small
615 group health insurance plans, including carriers licensed under chapters 175, 176A, 176B or
616 176G, shall file small group product base rates and any changes to small group rating factors that
617 are to be effective on January 1 of each year, on or before July 1 of the preceding year. The
618 commissioner shall disapprove any proposed changes to base rates that are excessive, inadequate
619 or unreasonable in relation to the benefits charged. The commissioner shall further disapprove
620 any proposed changes to base rates that do not take into account the upper payment limit
621 established for any prescription drug pursuant to section 10A of chapter 6D. The commissioner
622 shall disapprove any change to small group rating factors that is discriminatory or not actuarially
623 sound. Rates of reimbursement or rating factors included in the rate filing materials submitted for
624 review by the division shall be deemed confidential and exempt from the definition of public
625 records in clause Twenty-sixth of section 7 of chapter 4. The commissioner shall adopt
626 regulations to carry out this section.

627 SECTION 25. The General Laws are hereby amended by inserting after Chapter 176V
628 the following chapter:-

629 Chapter 176W

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

632 “Carrier”, an insurer licensed or otherwise authorized to transact accident and health
633 insurance under chapter 175; a nonprofit hospital service corporation organized under chapter
634 176A; a non-profit medical service corporation organized under chapter 176B; or a health
635 maintenance organization organized under chapter 176G.

636 “Commissioner”, the commissioner of the division of insurance.

637 “Division”, the division of insurance.

638 “Health benefit plan”, any individual, general, blanket or group policy of health, accident
639 and sickness insurance issued by an insurer licensed under chapter 175; an individual or group
640 hospital service plan issued by a non-profit hospital service corporation under chapter 176A; an
641 individual or group medical service plan issued by a nonprofit medical service corporation under
642 chapter 176B; and an individual or group health maintenance contract issued by a health
643 maintenance organization under chapter 176G. Health benefit plans shall not include: accident
644 only, credit only, limited scope vision or dental benefits if offered separately; hospital indemnity
645 insurance policies that provide a benefit to be paid to an insured or a dependent, including the
646 spouse of an insured, on the basis of a hospitalization of the insured or a dependent, that are sold
647 as a supplement and not as a substitute for a health benefit plan and that meet any requirements
648 set by the commissioner by regulation; disability income insurance; coverage issued as a
649 supplement to liability insurance; specified disease insurance that is purchased as a supplement
650 and not as a substitute for a health plan and meets any requirements the commissioner by
651 regulation may set; insurance arising out of a workers' compensation law or similar law;
652 automobile medical payment insurance; insurance under which benefits are payable with or
653 without regard to fault and which is statutorily required to be contained in a liability insurance
654 policy or equivalent self insurance; long-term care if offered separately; coverage supplemental
655 to the coverage provided under 10 U.S.C. 55 if offered as a separate insurance policy; travel
656 insurance; or any policy subject to chapter 176K or any similar policies issued on a group basis,
657 Medicare Advantage plans or Medicare Prescription drug plans. A health plan issued, renewed or
658 delivered within or without the commonwealth to an individual who is enrolled in a qualifying

659 student health insurance program under section 18 of chapter 15A shall not be considered a
660 health plan for the purposes of this chapter and shall be governed by said chapter 15A. The
661 commissioner may by regulation define other health coverage as a health benefit plan for the
662 purposes of this chapter.

663 "Insured", an enrollee, covered person, insured, member, policyholder or subscriber of a
664 carrier, including an individual whose eligibility as an insured of a carrier is in dispute or under
665 review, or any other individual whose care may be subject to review by a utilization review
666 program or entity as described under other provisions of this chapter.

667 "Mail Order Pharmacy", a pharmacy whose primary business is to receive prescriptions
668 by mail, telefax or through electronic submissions and to dispense medication to insureds
669 through the use of the United States mail or other common or contract carrier services and that
670 provides any consultation with patients electronically rather than face to face.

671 "Network Pharmacy", a retail or other licensed pharmacy provider that contracts with a
672 pharmacy benefit manager.

673 "Pharmacy", a facility, either physical or electronic, under the direction or supervision of
674 a registered pharmacist which is authorized to dispense prescription drugs and has entered into a
675 network contract with a pharmacy benefit manager or a carrier.

676 "Pharmacy benefit manager", a person, business, or other entity that, pursuant to a
677 contract or under an employment relationship with a carrier, a self-insurance plan, or other third-
678 party payer, either directly or through an intermediary, manages the prescription drug coverage
679 provided by the carrier, self-insurance plan, or other third-party payer including, but not limited
680 to, the processing and payment of claims for prescription drugs, the performance of drug

681 utilization review, the processing of drug prior authorization requests, the adjudication of appeals
682 or grievances related to prescription drug coverage, contracting with network pharmacies, and
683 controlling the cost of covered prescription drugs.

684 “Rebates or fees”, all fees or price concessions paid by a manufacturer to a pharmacy
685 benefit manager or carrier, including rebates, discounts, and other price concessions that are
686 based on actual or estimated utilization of a prescription drug. Rebates also include price
687 concessions based on the effectiveness a drug as in a value-based or performance-based contract.

688 “Retail Pharmacy”, a chain pharmacy, a supermarket pharmacy, a mass merchandiser
689 pharmacy, an independent pharmacy, or a network of independent pharmacies that is licensed as
690 a pharmacy by the commonwealth and that dispenses medications to the public.

691 Section 2. (a) Any pharmacy benefit manager contracting with a pharmacy that operates
692 in the commonwealth shall comply with the provisions of this chapter.

693 (b) A pharmacy benefit manager shall receive a license from the division before
694 conducting business in the commonwealth. A license granted pursuant to this section is not
695 transferable.

696 (c) A license may be granted only when the division is satisfied that the entity possesses
697 the necessary organization, background expertise, and financial integrity to supply the services
698 sought to be offered.

699 (d) The division may issue a license subject to restrictions or limitations upon the
700 authorization, including the type of services that may be supplied or the activities in which the
701 entity may be engaged.

702 (e) A license shall be valid for a period of three years.

703 (f) The division shall develop an application for licensure that includes at least the
704 following information: (i) the name of the pharmacy benefit manager; (ii) the address and contact
705 telephone number for the pharmacy benefit manager; (iii) the name and address of the pharmacy
706 benefit manager's agent for service of process in the commonwealth; (iv) the name and address
707 of each person beneficially interested in the pharmacy benefit manager; and (v) the name and
708 address of each person with management or control over the pharmacy benefit manager.

709 (g) The division may suspend, revoke, or place on probation a pharmacy benefit manager
710 license under any of the following circumstances: (i) the pharmacy benefit manager has engaged
711 in fraudulent activity that constitutes a violation of state or federal law; (ii) the division received
712 consumer complaints that justify an action under this chapter to protect the safety and interests of
713 consumers; (iii) the pharmacy benefit manager fails to pay an application fee for the license; or
714 (iv) the pharmacy benefit manager fails to comply with a requirement set forth in this chapter.

715 (h) If an entity performs the functions of pharmacy benefit manager acts without
716 registering, it will be subject to a fine of \$5,000 per day for the period they are found to be in
717 violation.

718 Section 3. (a) A pharmacy benefit manager has a fiduciary duty to a health benefit plan
719 client and shall discharge that duty in accordance with the provisions of state and federal law.

720 (b) A pharmacy benefit manager shall perform its duties with care, skill, prudence,
721 diligence, and professionalism.

722 (c) A pharmacy benefit manager shall notify a carrier client in writing of any activity,
723 policy or practice of the pharmacy benefit manager that directly or indirectly presents any
724 conflict of interest with the duties imposed in this section.