

SENATE No. 804

The Commonwealth of Massachusetts

PRESENTED BY:

Mark C. Montigny

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 promote transparency and prevent price gouging of pharmaceutical drug prices.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	
<i>Mark C. Montigny</i>	<i>Second Bristol and Plymouth</i>	
<i>Christopher Hendricks</i>	<i>11th Bristol</i>	<i>2/26/2021</i>
<i>Michael J. Barrett</i>	<i>Third Middlesex</i>	<i>2/26/2021</i>
<i>Michael O. Moore</i>	<i>Second Worcester</i>	<i>3/8/2021</i>

SENATE No. 804

By Mr. Montigny, a petition (accompanied by bill, Senate, No. 804) of Mark C. Montigny, Christopher Hendricks, Michael J. Barrett and Michael O. Moore for legislation to promote transparency and prevent price gouging of pharmaceutical drug prices. Health Care Financing.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. 712 OF 2019-2020.]

The Commonwealth of Massachusetts

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

An Act to promote transparency and prevent price gouging of pharmaceutical drug prices.

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

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

4 “Pharmaceutical manufacturing company”, an entity engaged in the production,
5 preparation, propagation, conversion or processing of prescription drugs, directly or indirectly,
6 by extraction from substances of natural origin or independently by means of chemical synthesis
7 or by a combination of extraction and chemical synthesis or an entity engaged in the packaging,
8 repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that
9 "Pharmaceutical manufacturing company" shall not include a wholesale drug distributor licensed

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

12 “Pharmacy benefit manager”, a person or entity that administers: (i) a prescription drug,
13 prescription device or pharmacist services; or (ii) a prescription drug and device and pharmacist
14 services portion of a health benefit plan on behalf of a plan sponsor including, but not limited to,
15 self-insured employers, insurance companies and labor unions; provided, however, that
16 “Pharmacy benefit manager” shall include a health benefit plan that does not contract with a
17 pharmacy benefit manager and administers its own: (a) prescription drug, prescription device or
18 pharmacist services; or (b) prescription drug and device and pharmacist services portion, unless
19 specifically exempted by the center.

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

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

25 SECTION 3. Section 6 of said chapter 6D, as so appearing, is hereby amended by adding
26 the following paragraph:-

27 If the analysis of spending trends with respect to the pharmaceutical or biopharmaceutical
28 products increases the expenses of the commission, the estimated increases in the commission’s
29 expenses shall be assessed fully to pharmaceutical manufacturing companies and pharmacy
30 benefit managers in the same manner as the assessment under section 68 of chapter 118E. A
31 pharmacy benefit manager that is a surcharge payor subject to the preceding paragraph and

32 administers its own prescription drug, prescription device or pharmacist services or prescription
33 drug and device and pharmacist services portion shall not be subject to additional assessment
34 under this paragraph.

35 SECTION 4. Section 8 of said chapter 6D, as so appearing, is hereby amended by
36 striking out, in line 32, the words “ and (xi) ” and inserting in place thereof the following words:-
37 (xi) not less than 3 representatives of the pharmaceutical industry; (xii) at least 1 pharmacy
38 benefit manager; and (xiii).

39 SECTION 5. Said section 8 of said chapter 6D of the General Laws, as so appearing, is
40 hereby amended by inserting after the word “commission”, in line 59, the first time it appears,
41 the following words:- ; and (iii) in the case of pharmacy benefit managers and pharmaceutical
42 manufacturing companies, testimony concerning factors underlying prescription drug costs and
43 price increases, the impact of manufacturer rebates, discounts and other price concessions on net
44 pricing, the availability of alternative drugs or treatments and any other matters as determined by
45 the commission.

46 SECTION 6. Said chapter 6D is hereby further amended by inserting after section 15 the
47 following section:-

48 Section 15A. (a) The commission shall conduct an annual study of pharmaceutical
49 manufacturing companies with pipeline drugs, generic drugs or biosimilar drug products that
50 may have a significant impact on statewide health care expenditures; provided, however, that the
51 commission may issue interim studies if it deems it necessary. The commission may contract
52 with a third-party entity to implement this section that has familiarity with the development and

53 approval of pharmaceuticals or biologics or studies and compares the clinical effectiveness and
54 value of prescription drugs.

55 (b) A pharmaceutical manufacturing company shall, provide early notice to the
56 commission for: (i) a pipeline drug; (ii) an abbreviated new drug application for generic drugs,
57 upon submission to the federal Food and Drug Administration; or (iii) a biosimilar biologics
58 license application upon the receipt of an action date from the federal Food and Drug
59 Administration. The commission shall make early notice information available to the office of
60 Medicaid or another agency in addition to acute hospitals, ambulatory surgical centers and
61 surcharge payors, as deemed appropriate.

62 Early notice shall be submitted to the commission not later than 60 days after receipt of
63 the federal Food and Drug Administration action date or after the submission of an abbreviated
64 new drug application to the federal Food and Drug Administration action.

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

70 For each pipeline drug, early notice shall include whether the drug has been designated
71 by the federal Food and Drug Administration: (i) orphan drug; (ii) fast track; (iii) breakthrough
72 therapy; (iv) for accelerated approval; or (v) priority review for a new molecular entity.

73 Notwithstanding the foregoing, submissions for drugs in development that receive such a
74 designation by the federal Food and Drug Administration for new molecular entities shall be
75 provided as soon as practical upon receipt of the relevant designation.

76 (c) The commission shall assess pharmaceutical manufacturing companies for the
77 implementation of this section in a similar manner to the annual registration fees and other
78 assessments related to the annual marketing disclosure reports required under section 2A of
79 chapter 111N.

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

83 SECTION 7. Said chapter 6D is hereby further amended by adding the following 2
84 sections:-

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

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

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

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

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

100 In order to conduct a review of eligible drugs, the commission may require a
101 manufacturer to disclose to the commission within a reasonable time period information relating
102 to the manufacturer’s pricing of an eligible drug. The disclosed information shall be on a
103 standard reporting form developed by the commission with the input of the manufacturers and
104 shall include, but not be limited to:

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

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

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

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

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

118 Any information, analyses or reports regarding an eligible drug review shall be provided
119 to the manufacturer. The commission shall consider any clarifications or data provided by the
120 manufacturer with respect to the eligible drug. The commission shall not base its determination
121 on the proposed value of the eligible drug solely on the analysis or research of an outside third
122 party.

123 (d) If, after review of an eligible drug and after receiving information from the
124 manufacturer under subsections (b) or (e), the commission determines that the manufacturer's
125 pricing of the eligible drug does not substantially exceed the proposed value of the drug, the
126 commission shall notify the manufacturer, in writing, of its determination and shall evaluate
127 other ways to mitigate the eligible drug's cost in order to improve patient access to the eligible
128 drug. The commission may engage with the manufacturer and other relevant stakeholders,
129 including, but not limited to, patients, patient advocacy organizations, providers, provider
130 organizations and payers, to explore options for mitigating the cost of the eligible drug. Upon the
131 conclusion of a stakeholder engagement process under this subsection, the commission shall
132 issue recommendations on ways to reduce the cost of the eligible drug for the purpose of
133 improving patient access to the eligible drug. Recommendations may include, but not be limited
134 to: (i) an alternative payment plan or methodology; (ii) a bulk purchasing program; (iii) co-pay,
135 deductible, coinsurance or other cost-sharing restrictions; and (iv) a reinsurance program to
136 subsidize the cost of the eligible drug. The recommendations shall be publicly posted on the

137 commission's website and provided to the clerks of the house of representatives and senate, the
138 joint committee on health care financing and the house and senate committees on ways and
139 means.

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

145 (f) Not later than 60 days after receiving information from the manufacturer under
146 subsections (b) or (e), the commission shall confidentially issue a determination on whether the
147 manufacturer's pricing of an eligible drug substantially exceeds the commission's proposed
148 value of the drug. If the commission determines that the manufacturer's pricing of an eligible
149 drug substantially exceeds the proposed value of the drug, the commission shall confidentially
150 notify the manufacturer, in writing, of its determination and require the manufacturer to enter
151 into an access improvement plan under section 21.

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

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

163 (h) If the manufacturer fails to timely comply with the commission's request for records
164 under subsections (b) or (e), or otherwise knowingly obstructs the commission's ability to issue
165 its determination under subsection (f), including, but not limited to, by providing incomplete,
166 false or misleading information, the commission may impose appropriate sanctions against the
167 manufacturer, including reasonable monetary penalties not to exceed \$1,000,000, in each
168 instance. The commission shall seek to promote compliance with this section and shall only
169 impose a civil penalty on the manufacturer as a last resort.

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

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

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

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

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

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

195 (e) Upon approval of the proposed access improvement plan, the commission shall notify
196 the manufacturer to begin immediate implementation of the access improvement plan. All
197 manufacturers implementing an approved access improvement plan shall be subject to additional
198 reporting requirements and compliance monitoring as determined by the commission. The
199 commission shall provide assistance to the manufacturer in the successful implementation of the
200 access improvement plan.

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

204 (g) At the conclusion of the timetable established in the access improvement plan, the
205 manufacturer shall report to the commission regarding the outcome of the access improvement
206 plan. If the commission determines that the access improvement plan was unsuccessful, the
207 commission shall: (i) extend the implementation timetable of the existing access improvement
208 plan; (ii) approve amendments to the access improvement plan as proposed by the manufacturer;
209 (iii) require the manufacturer to submit a new access improvement plan; or (iv) waive or delay
210 the requirement to file any additional access improvement plans.

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

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

217 (j) The commission shall assess a civil penalty to a manufacturer of not more than
218 \$500,000, in each instance, if the commission determines that the manufacturer: (i) willfully
219 neglected to file an access improvement plan with the commission under subsection (a); (ii)
220 failed to file an acceptable access improvement plan in good faith with the commission; (iii)
221 failed to implement the access improvement plan in good faith; or (iv) knowingly failed to
222 provide information required by this section to the commission or knowingly falsified the

223 information,. The commission shall seek to promote compliance with this section and shall only
224 impose a civil penalty as a last resort.

225 (k) If a manufacturer fails to enter into an access improvement plan under this section, the
226 commission may publicly post the proposed value of the eligible drug, hold a public hearing on
227 the proposed value of the eligible drug and solicit public comment. The manufacturer shall
228 appear and testify at any hearing held on the eligible drug's proposed value. Upon the conclusion
229 of a public hearing under this subsection, the commission shall issue recommendations on ways
230 to reduce the cost of an eligible drug for the purpose of improving patient access to the eligible
231 drug. The recommendations shall be publicly posted on the commission's website and provided
232 to the clerks of the house of representatives and senate, the joint committee on health care
233 financing and the house and senate committees on ways and means.

234 (l) Amounts collected under this section shall be deposited in to the Prevention and
235 Wellness Trust Fund established in section 2G of chapter 111.

236 (m) The commission shall promulgate regulations necessary to implement this section.

237 SECTION 8. Chapter 12 of the General Laws, as so appearing, is hereby amended by
238 striking out section 11N and inserting in place thereof the following section:-

239 Section 11N. (a) The attorney general shall monitor trends in the health care market
240 including, but not limited to, trends in provider organization size and composition, consolidation
241 in the provider market, payer contracting trends, patient access and quality issues in the health
242 care market and prescription drug cost trends. The attorney general may obtain the following
243 information from a private health care payer, public health care payer, pharmaceutical
244 manufacturing company, pharmacy benefit manager, provider or provider organization as any of

245 those terms may be defined in section 1 of chapter 6D: (i) any information that is required to be
246 submitted under sections 8, 9 10 and 10A of chapter 12C; (ii) filings, applications and supporting
247 documentation related to any cost and market impact review under section 13 of said chapter 6D;
248 (iii) filings, applications and supporting documentation related to a determination of need
249 application filed under section 25C of chapter 111; and (iv) filings, applications and supporting
250 documentation submitted to the federal Centers for Medicare and Medicaid Services or the
251 Office of the Inspector General for any demonstration project. Under section 17 of said chapter
252 12C and section 8 of said chapter 6D and subject to the limitations stated in those sections, the
253 attorney general may require that any provider, provider organization, pharmaceutical
254 manufacturing company, pharmacy benefit manager, private health care payer or public health
255 care payer produce documents, answer interrogatories and provide testimony under oath related
256 to health care costs and cost trends, pharmaceutical costs, pharmaceutical cost trends, the factors
257 that contribute to cost growth within the commonwealth's health care system and the relationship
258 between provider costs and payer premium rates and the relationship between pharmaceutical
259 drug costs and payer premium rates.

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

266 (c) The attorney general may intervene or otherwise participate in efforts by the
267 commonwealth to obtain exemptions or waivers from certain federal laws regarding provider

268 market conduct, including, from the federal Office of the Inspector General, a waiver or
269 expansion of the safe harbors' provided for under 42 U.S.C. § 1320a-7b and obtaining from the
270 federal Office of the Inspector General a waiver of or exemption from 42 U.S.C. § 1395nn
271 subsections (a) to (e), inclusive.

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

274 SECTION 9. Chapter 12C of the General Laws, as so appearing, is hereby amended by
275 inserting after section 10 the following section:-

276 Section 10A. (a) The center shall promulgate regulations necessary to ensure the uniform
277 analysis of information regarding pharmaceutical manufacturing companies and pharmacy
278 benefit managers and that enable the center to analyze: (i) year-over-year wholesale acquisition
279 cost changes; (ii) year-over-year trends in net expenditures; (iii) net expenditures on subsets of
280 brand and generic pharmaceuticals identified by the center; (iv) research and development costs
281 as a percentage of revenue, costs paid with public funds and costs paid by third parties, to the
282 extent such costs are attributable to a specific product or set of products; (v) annual marketing
283 and advertising costs, identifying costs for direct-to-consumer advertising; (vi) annual profits
284 over the most recent 5-year period; (vii) information regarding trends of estimated aggregate
285 drug rebates and other price reductions paid by a pharmaceutical manufacturing company in
286 connection with utilization of all pharmaceutical drug products offered by the pharmaceutical
287 manufacturing company; (viii) information regarding trends of estimated aggregate drug rebates
288 and other price reductions paid by a pharmacy benefit manager in connection with utilization of
289 all drugs offered through the pharmacy benefit manager; (ix) information regarding pharmacy

290 benefit manager practices in passing drug rebates or other price reductions received by the
291 pharmacy benefit manager to a private or public health care payer or to the consumer; (x)
292 information regarding discount or free product vouchers that a retail pharmacy provides to a
293 consumer in connection with a pharmacy service, item or prescription transfer offer or to any
294 discount, rebate, product voucher or other reduction in an individual's out-of-pocket expenses,
295 including co-payments and deductibles under section 3 of chapter 175H; (xi) cost disparities
296 between prices charged to purchasers in the commonwealth and purchasers outside of the United
297 States and (xii) any other information deemed necessary by the center.

298 (b) The center shall require the submission of available data and other information from
299 pharmaceutical manufacturing companies and pharmacy benefit managers including, but not
300 limited to: (i) changes in wholesale acquisition costs for prescription drug products as identified
301 by the center; (ii) aggregate, company-level and product-specific research and development to
302 the extent attributable to a specific product or products and other relevant capital expenditures
303 for the most recent year for which final audited data are available for prescription drug products
304 as identified by the center; (iii) the price paid by the manufacturer to acquire the prescription
305 drug product if not developed by the manufacturer; (iv) the 5-year history of any increases in the
306 wholesale acquisition costs; (v) annual marketing and advertising expenditures apportioned by
307 activities directed to consumers and prescribers for prescription drug products as identified by
308 the center; and (vi) a description, suitable for public release, of factors that contributed to
309 reported changes in wholesale acquisition costs for prescription drug products as identified by
310 the center.

311 SECTION 10. Section 11 of said chapter 12C is hereby amended by striking out in its
312 entirety and inserting in place thereof the following:-

313 Section 11. The center shall ensure the timely reporting of information required under
314 sections 8, 9, 10 and 10A. The center shall notify payers, providers, provider organizations,
315 pharmacy benefit managers and pharmaceutical manufacturing companies of any applicable
316 reporting deadlines. The center shall notify, in writing, a private health care payer, provider,
317 provider organization, pharmacy benefit manager or pharmaceutical manufacturing company that
318 it has failed to meet a reporting deadline and that failure to respond within 2 weeks of the receipt
319 of the notice shall result in penalties. The center shall assess a penalty against a private health
320 care payer, provider, provider organization, pharmacy benefit manager or pharmaceutical
321 manufacturing company that fails, without just cause, to provide the requested information
322 within 2 weeks following receipt of the written notice required under this paragraph of up to
323 \$20,000 per week for each week of delay after the 2-week period following receipt of the written
324 notice; provided, however, that the maximum annual penalty against a private health care payer,
325 provider, provider organization, pharmacy benefit manager or pharmaceutical manufacturing
326 company under this section shall be \$1,000,000. Amounts collected under this section shall be
327 deposited in the Healthcare Payment Reform Fund established in section 100 of chapter 194 of
328 the acts of 2011.

329 The center shall notify the attorney general of any pharmaceutical manufacturing
330 company or pharmacy benefit manager that fails to comply with this section for further action
331 pursuant to section 11N of chapter 12 or any other law.

332 For the purposes of this section, the center may promulgate regulations to define “just
333 cause”.

334 SECTION 11. Said chapter 12C is hereby further amended by striking out section 17, as
335 so appearing, and inserting thereof the following section:-

336 Section 17. The attorney general may review and analyze any information submitted to
337 the center under sections 8, 9, 10, 10A and the health policy commission under section 8 of
338 chapter 6D. The attorney general may require that any provider, provider organization,
339 pharmaceutical manufacturing company, pharmacy benefit manager or payer produce
340 documents, answer interrogatories and provide testimony under oath related to health care costs
341 and cost trends, pharmaceutical cost trends, factors that contribute to cost growth within the
342 commonwealth's health care system and the relationship between provider costs and payer
343 premium rates. The attorney general shall keep confidential all nonpublic information and
344 documents obtained under this section and shall not disclose the information or documents to any
345 person without the consent of the provider, pharmaceutical manufacturing company, pharmacy
346 benefit manager or payer that produced the information or documents except in a public hearing
347 under said section 8 of said chapter 6D, a rate hearing before the division of insurance or in a
348 case brought by the attorney general, if the attorney general believes that such disclosure will
349 promote the health care cost containment goals of the commonwealth and that the disclosure
350 shall be made in the public interest after taking into account any privacy, trade secret or
351 anticompetitive considerations. The confidential information and documents shall not be public
352 records and shall be exempt from disclosure under clause Twenty-sixth of section 7 of chapter 4
353 or section 10 of chapter 66.

354 SECTION 12. Chapter 111 of the General Laws is hereby amended by adding the
355 following section:-

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

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

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