SENATE DOCKET, NO. 2517 FILED ON: 1/17/2025

SENATE . . . . . No. 895

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:
Mark C. Montigny	*Second Bristol and Plymouth*

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SENATE . . . . . No. 895

By Mr. Montigny, a petition (accompanied by bill, Senate, No. 895) of Mark C. Montigny 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. *783* OF 2023-2024.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Fourth General Court
(2025-2026)

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:

SECTION 1. Section 1 of chapter 6D of the General Laws, as most recently amended by chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of "Alternative payment methodologies or methods" the following 2 definitions:-

"Biosimilar", a drug that is produced or distributed under a biologics license application approved under 42 U.S.C. 262(k)(3).

"Brand name drug", a drug that is: (i) produced or distributed pursuant to an original new drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that is pharmaceutically equivalent, as that term is defined by the United States Food and Drug

10 Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug
11 application that was approved by the United States Secretary of Health and Human Services
12 under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the
13 date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of
14 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42
15 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved
16 under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the carrier as a brand name drug based on
17 available data resources such as Medi-Span.

18 SECTION 2. Said section 1 of chapter 6D is hereby amended by inserting after the
19 definition of "Physician" the following definition:-

20 "Pipeline drug", a prescription drug product containing a new molecular entity for which
21 the sponsor has submitted a new drug application or biologics license application and received an
22 action date from the United States Food and Drug Administration.

23 SECTION 2. Said chapter 6D is hereby amended by inserting after section 15 the
24 following section:-

25 Section 15A. (a) A pharmaceutical manufacturing company shall provide early notice to
26 the commission in a manner described in this section for a: (i) pipeline drug; (ii) generic drug; or
27 (iii) biosimilar drug. The commission shall provide nonconfidential information received under
28 this section to the office of Medicaid, the division of insurance and the group insurance
29 commission.

30 Early notice under this subsection shall be submitted to the commission in writing not
31 later than 30 days after receipt of the United States Food and Drug Administration approval date.

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

37 For each pipeline drug, early notice shall include whether the drug has been designated
38 by the United States Food and Drug Administration: (i) as an orphan drug; (ii) for fast track; (iii)
39 as a breakthrough therapy; (iv) for accelerated approval; or (v) for priority review for a new
40 molecular entity; provided, however, that notwithstanding clause (v), submissions for drugs in
41 development that are designated as new molecular entities by the United States Food and Drug
42 Administration shall be provided as soon as practical upon receipt of the relevant designations.
43 For each generic drug, early notice shall include a copy of the drug label approved by the United
44 States Food and Drug Administration.

45 (b) A pharmaceutical manufacturing company shall provide early notice to the
46 commission if it plans to increase the wholesale acquisition cost of a: (i) brand-name drug by
47 more than 15 per cent per wholesale acquisition cost unit during any 12-month period; or (ii)
48 generic drug or biosimilar drug with a significant price increase as determined by the
49 commission during any 12-month period. The commission shall provide non-confidential
50 information received under this section to the office of Medicaid, the division of insurance and
51 the group insurance commission.

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

54 A pharmaceutical manufacturing company required to notify the commission of a price
55 increase under this subsection shall, not less than 30 days before the planned effective date of the
56 increase, report to the commission any information regarding the price increase that is relevant to
57 the commission including, but not limited to: (i) drug identification information; (ii) drug sales
58 volume information; (iii) wholesale price and related information for the drug; (iv) net price and
59 related information for the drug; (v) drug acquisition information, if applicable; (vi) revenue
60 from the sale of the drug; and (vii) manufacturer costs.

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

64 (d) If a pharmaceutical manufacturing company fails to timely comply with the
65 requirements under subsection (a) or subsection (b), or otherwise knowingly obstructs the
66 commission's ability to receive early notice under this section, including, but not limited to,
67 providing incomplete, false or misleading information, the commission shall impose appropriate
68 sanctions against the manufacturer, including reasonable monetary penalties not to exceed
69 $1,000,000, in each instance. The commission shall seek to promote compliance with this section
70 and shall only impose a civil penalty on the manufacturer as a last resort. Amounts collected
71 under this section shall be deposited into the Prescription Drug Cost Assistance Trust Fund
72 established in section 2EEEEEE of chapter 29.

73 SECTION 3. Said chapter 6D is hereby further amended by adding the following 2
74 sections:-

75 Section 24. (a) As used in this section, the following words shall have the following
76 meanings unless the context clearly requires otherwise:

77 "Eligible drug", (i) a brand name drug or biologic, not including a biosimilar, that has a
78 launch wholesale acquisition cost of $50,000 or more for a 1-year supply or full course of
79 treatment; (ii) a biosimilar drug that has a launch wholesale acquisition cost that is not at least 15
80 per cent lower than the referenced brand biologic at the time the biosimilar is launched; (iii) a
81 public health essential drug, as defined in subsection (f) of section 13 of chapter 17, with a
82 significant price increase over a defined period of time as determined by the commission by
83 regulation or with a wholesale acquisition cost of $25,000 or more for a 1-year supply or full
84 course of treatment; (iv) all drugs, continuous glucose monitoring system components, all
85 components of the continuous glucose monitoring system of which the component is a part and,
86 when applicable, delivery devices selected pursuant to section 17T of chapter 32A, section 10R
87 of chapter 118E, section 47UU of chapter 175, section 8VV of chapter 176A, section 4VV of
88 chapter 176B and section 4NN of chapter 176G; or (v) other prescription drug products that may
89 have a direct and significant impact and create affordability challenges for the state's health care
90 system and patients, as determined by the commission; provided, however, that the commission
91 shall promulgate regulations to establish the type of prescription drug products classified under
92 clause (v) prior to classification of any such prescription drug product under said clause (v).

93 "Public health essential drug", shall have the same meaning as defined in subsection (f)
94 of section 13 of chapter 17.

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

98 In conducting a review of eligible drugs, the commission may request information
99 relating to the pricing of an eligible drug from the pharmaceutical manufacturing company of
100 said eligible drug. Upon receiving a request for information from the commission, a
101 pharmaceutical manufacturing company shall disclose to the commission, within a reasonable
102 time period, as determined by the commission, applicable information relating to the
103 manufacturer's pricing of an eligible drug.

104 The disclosed information shall be on a standard reporting form developed by the
105 commission and shall include, but not be limited to:

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

108 (ii) the total amount of federal and state tax credits, incentives, grants and other subsidies
109 provided to the pharmaceutical manufacturing company over the previous 10 calendar years that
110 have been used to assist in the research and development of eligible drugs;

111 (iii) the pharmaceutical manufacturing company's aggregate, company-level research and
112 development and other relevant capital expenditures, including facility construction, for the most
113 recent year for which final audited data are available;

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

117 (v) any other information that the pharmaceutical manufacturing company wishes to
118 provide to the commission or that the commission requests.

119 (c) Based on the records provided under subsection (b) and available information from
120 the center for health information and analysis or an outside third party, the commission shall
121 identify a proposed value for the eligible drug. The commission may request additional relevant
122 information that it deems necessary from the pharmaceutical manufacturing company and from
123 other entities, including, but not limited to, payers and pharmacy benefit managers.

124 Any information, analyses or reports regarding an eligible drug review shall be provided
125 to the pharmaceutical manufacturing company. The commission shall consider any clarifications
126 or data provided by the pharmaceutical manufacturing company with respect to the eligible drug.
127 The commission shall not base its determination on the proposed value of the eligible drug solely
128 on the analysis or research of an outside third party and shall not employ a measure or metric that
129 assigns a reduced value to the life extension provided by a treatment based on a pre-existing
130 disability or chronic health condition of the individuals whom the treatment would benefit. If the
131 commission relies upon a third party to provide cost-effectiveness analysis or research related to
132 the proposed value of the eligible drug, such analysis or research shall also include, but not be
133 limited to: (i) a description of the methodologies and models used in its analysis; (ii) any
134 assumptions and potential limitations of research findings in the context of the results; and (iii)
135 outcomes for affected subpopulations that utilize the drug, including, but not limited to, potential

136 impacts on individuals of marginalized racial or ethnic groups and on individuals with specific
137 disabilities or health conditions who regularly utilize the eligible drug.

138 (d) If, after review of an eligible drug and after receiving information from the
139 pharmaceutical manufacturing company under subsection (b) or subsection (e), the commission
140 determines that the pharmaceutical manufacturing company's pricing of the eligible drug does
141 not substantially exceed the proposed value of the drug, the commission shall notify the
142 pharmaceutical manufacturing company, in writing, of its determination and shall evaluate other
143 ways to mitigate the eligible drug's cost in order to improve patient access to the eligible drug.
144 The commission may engage with the pharmaceutical manufacturing company and other
145 relevant stakeholders, including, but not limited to, patients, patient advocacy organizations,
146 consumer advocacy organizations, providers, provider organizations and payers, to explore
147 options for mitigating the cost of the eligible drug. Upon the conclusion of a stakeholder
148 engagement process under this subsection, the commission shall issue recommendations on ways
149 to reduce the cost of the eligible drug for the purpose of improving patient access to the eligible
150 drug. Recommendations may include but shall not be limited to: (i) an alternative payment plan
151 or methodology; (ii) a bulk purchasing program; (iii) co-payment, deductible, co-insurance or
152 other cost-sharing restrictions; and (iv) a reinsurance program to subsidize the cost of the eligible
153 drug. The recommendations shall be publicly posted on the commission's website and provided
154 to the clerks of the house of representatives and senate, the joint committee on health care
155 financing and the house and senate committees on ways and means; provided, however, that the
156 report shall be published on the website of the commission.

157 (e) If, after review of an eligible drug, the commission determines that the pharmaceutical
158 manufacturing company's pricing of the eligible drug substantially exceeds the proposed value

159 of the drug, the commission shall request that the pharmaceutical manufacturing company
160 provide further information related to the pricing of the eligible drug and the pharmaceutical
161 manufacturing company's reasons for the pricing not later than 30 days after receiving the
162 request.

163 (f) Not later than 60 days after receiving information from the pharmaceutical
164 manufacturing company under subsection (b) or subsection (e), the commission shall
165 confidentially issue a determination on whether the pharmaceutical manufacturing company's
166 pricing of an eligible drug substantially exceeds the commission's proposed value of the drug. If
167 the commission determines that the pharmaceutical manufacturing company's pricing of an
168 eligible drug substantially exceeds the proposed value of the drug, the commission shall
169 confidentially notify the manufacturer, in writing, of its determination and may require the
170 manufacturer to enter into an access and affordability improvement plan under section 25.

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

179 Any request for further information made by the commission under subsection (e) or any
180 determination issued or written notification made by the commission under subsection (f) shall

181 not be public records under said clause Twenty-sixth of said section 7 of said chapter 4 or under
182 said chapter 66.

183 (h) The commission's proposed value of an eligible drug and the commission's
184 underlying analysis of the eligible drug is not intended to be used to determine whether any
185 individual patient meets prior authorization or utilization management criteria for the eligible
186 drug. The proposed value and underlying analysis shall not be the sole factor in determining
187 whether a drug is included in a formulary or whether the drug is subject to step therapy.

188 (i) If the pharmaceutical manufacturing company fails to timely comply with the
189 commission's request for records under subsection (b) or subsection (e), or otherwise knowingly
190 obstructs the commission's ability to issue its determination under subsection (f), including, but
191 not limited to, by providing incomplete, false or misleading information, the commission shall
192 impose appropriate sanctions against the pharmaceutical manufacturing company, including
193 reasonable monetary penalties not to exceed $1,000,000, in each instance. The commission shall
194 seek to promote compliance with this section and shall only impose a civil penalty on the
195 manufacturer as a last resort. Penalties collected under this subsection shall be deposited into the
196 Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29.

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

199 Section 25. (a) The commission shall establish procedures to assist manufacturers in
200 filing and implementing an access and affordability improvement plan.

201 Upon providing written notice provided under subsection (f) of section 24, the
202 commission may require that a pharmaceutical manufacturing company whose pricing of an

203 eligible drug substantially exceeds the commission's proposed value of the drug file an access
204 and affordability improvement plan with the commission. Not later than 45 days after receipt of a
205 notice under said subsection (f) of said section 24, a pharmaceutical manufacturing company
206 shall: (i) file an access and affordability improvement plan; or (ii) provide written notice
207 declining participation in the access and affordability improvement plan.

208 (b) An access and affordability improvement plan shall: (i) be generated by the
209 pharmaceutical manufacturing company; (ii) identify the reasons for the pharmaceutical
210 manufacturing company's drug price; and (iii) include, but not be limited to, specific strategies,
211 adjustments and action steps the pharmaceutical manufacturing company proposes to implement
212 to address the cost of the eligible drug in order to improve the accessibility and affordability of
213 the eligible drug for patients and the state's health system. The proposed access and affordability
214 improvement plan shall include specific identifiable and measurable expected outcomes and a
215 timetable for implementation. The timetable for an access and affordability improvement plan
216 shall not exceed 18 months.

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

221 (d) If the commission determines that the proposed access and affordability improvement
222 plan is unacceptable or incomplete, the commission may provide consultation on the criteria that
223 have not been met and may allow an additional time period of not more than 30 calendar days for
224 resubmission; provided, however, that all aspects of the access plan shall be proposed by the

225 pharmaceutical manufacturing company and the commission shall not require specific elements
226 for approval.

227 (e) Upon approval of the proposed access and affordability improvement plan, the
228 commission shall notify the pharmaceutical manufacturing company to begin immediate
229 implementation of the access and affordability improvement plan. Public notice shall be
230 provided by the commission on its website, identifying that the pharmaceutical manufacturing
231 company is implementing an access and affordability improvement plan; provided, however, that
232 upon the successful completion of the access and affordability improvement plan, the identity of
233 the pharmaceutical manufacturing company shall be removed from the commission's website.
234 All pharmaceutical manufacturing companies implementing an approved access improvement
235 plan shall be subject to additional reporting requirements and compliance monitoring as
236 determined by the commission. The commission shall provide assistance to the pharmaceutical
237 manufacturing company in the successful implementation of the access and affordability
238 improvement plan.

239 (f) All pharmaceutical manufacturing companies shall work in good faith to implement
240 the access and affordability improvement plan. At any point during the implementation of the
241 access and affordability improvement plan, the pharmaceutical manufacturing company may file
242 amendments to the access improvement plan, subject to approval of the commission.

243 (g) At the conclusion of the timetable established in the access and affordability
244 improvement plan, the pharmaceutical manufacturing company shall report to the commission
245 regarding the outcome of the access and affordability improvement plan. If the commission
246 determines that the access and affordability improvement plan was unsuccessful, the commission

247 shall: (i) extend the implementation timetable of the existing access and affordability
248 improvement plan; (ii) approve amendments to the access and affordability improvement plan as
249 proposed by the pharmaceutical manufacturing company; (iii) require the pharmaceutical
250 manufacturing company to submit a new access and affordability improvement plan; or (iv)
251 waive or delay the requirement to file any additional access and affordability improvement plans.

252 (h) The commission shall submit a recommendation for proposed legislation to the joint
253 committee on health care financing if the commission determines that further legislative
254 authority is needed to assist pharmaceutical manufacturing company with the implementation of
255 access and affordability improvement plans or to otherwise ensure compliance with this section.

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

258 (j) The commission shall assess a civil penalty to a pharmaceutical manufacturing
259 company of not more than $1,000,000, in each instance, if the commission determines that the
260 pharmaceutical manufacturing company: (i) declined or willfully neglected to file an access and
261 affordability improvement plan with the commission under subsection (a); (ii) failed to file an
262 acceptable access and affordability improvement plan in good faith with the commission; (iii)
263 failed to implement the access and affordability improvement plan in good faith; or (iv)
264 knowingly failed to provide information required by this section to the commission or knowingly
265 falsified the information. The commission shall seek to promote compliance with this section and
266 shall only impose a civil penalty as a last resort. Penalties collected under this subsection shall be
267 deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE
268 of chapter 29.

269 (k) If a pharmaceutical manufacturing company declines to enter into an access and
270 affordability improvement plan under this section, the commission may publicly post the
271 proposed value of the eligible drug, hold a public hearing on the proposed value of the eligible
272 drug and solicit public comment. The pharmaceutical manufacturing company shall appear and
273 testify at the public hearing held on the eligible drug's proposed value. Upon the conclusion of a
274 public hearing under this subsection, the commission shall issue recommendations on ways to
275 reduce the cost of an eligible drug for the purpose of improving patient access to the eligible
276 drug. The recommendations shall be publicly posted on the commission's website and provided
277 to the clerks of the house of representatives and senate, the joint committee on health care
278 financing and the house and senate committees on ways and means.

279 If a pharmaceutical manufacturing company is deemed to not be acting in good faith to
280 develop an acceptable or complete access and affordability improvement plan, the commission
281 may publicly post the proposed value of the eligible drug, hold a public hearing on the proposed
282 value of the eligible drug and solicit public comment. The pharmaceutical manufacturing
283 company shall appear and testify at any hearing held on the eligible drug's proposed value. Upon
284 the conclusion of a public hearing under this subsection, the commission shall issue
285 recommendations on ways to reduce the cost of an eligible drug for the purpose of improving
286 patient access to the eligible drug. The recommendations shall be publicly posted on the
287 commission's website and provided to the clerks of the house of representatives and senate, the
288 joint committee on health care financing and the house and senate committees on ways and
289 means.

290 Before making a determination that the pharmaceutical manufacturing company is not
291 acting in good faith, the commission shall send a written notice to the pharmaceutical

292 manufacturing company that the commission shall deem the pharmaceutical manufacturing
293 company to not be acting in good faith if the pharmaceutical manufacturing company does not
294 submit an acceptable access and affordability improvement plan within 30 days of receipt of
295 notice; provided, however, that the commission shall not send a notice under this paragraph
296 within 120 calendar days from the date that the commission notified the pharmaceutical
297 manufacturing company of its requirement to enter into the access and affordability improvement
298 plan.

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

300 SECTION 4. Section 13 of chapter 17 of the General Laws is hereby amended by adding
301 the following subsection:-

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

304 "Public health essential drug", a prescription drug, biologic or biosimilar approved by the
305 United States Food and Drug Administration that: (i) appears on the Model List of Essential
306 Medicines most recently adopted by the World Health Organization; or (ii) is deemed an
307 essential medicine by the commission due to its efficacy in treating a life-threatening health
308 condition or a chronic health condition that substantially impairs an individual's ability to engage
309 in activities of daily living or because limited access to a certain population would pose a public
310 health challenge.

311 The commission shall identify and publish a list of public health essential drugs. The list
312 shall be updated not less than annually and be made publicly available on the department's
313 website; provided, however, that the commission may provide an interim listing of a public

314 health essential drug prior to an annual update. The commission shall notify and forward a copy

315 of the list to the health policy commission established under chapter 6D.