

HOUSE No. 1201

The Commonwealth of Massachusetts

PRESENTED BY:

Kate Hogan

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 in prescription drug prices.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Kate Hogan</i>	<i>3rd Middlesex</i>	<i>1/18/2023</i>

HOUSE No. 1201

By Representative Hogan of Stow, a petition (accompanied by bill, House, No. 1201) of Kate Hogan relative to the pricing of prescription drugs. Health Care Financing.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. 1272 OF 2021-2022.]

The Commonwealth of Massachusetts

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

An Act to promote transparency in prescription 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 is hereby amended by
2 inserting after the definition of “Performance penalty” the following definition: -

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

11 SECTION 2. Section 8 of said chapter 6D, as so appearing, is further amended by
12 inserting after the word “organization”, in lines 6 and 7, the following words:- , pharmaceutical
13 manufacturing company.

14 SECTION 3. Said section 8 of said chapter 6D, as so appearing, is further amended by
15 inserting after the word “organizations”, in line 14, the following words:- , pharmaceutical
16 manufacturing companies.

17 SECTION 4. Said section 8 of said chapter 6D, as so appearing, is further amended by
18 inserting after the word “commission”, in line 59, the first time it appears, the following words:-
19 ; and (iii) in the case of pharmaceutical manufacturing companies, testimony concerning factors
20 underlying prescription drug costs and price increases including, but not limited to, the initial
21 prices of drugs coming to market and subsequent price increases, changes in industry profit
22 levels, marketing expenses, reverse payment patent settlements, the availability of alternative
23 drugs or treatments and any other matters as determined by the commission

24 SECTION 5. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is
25 hereby amended by striking out the second sentence and inserting in place thereof the following
26 sentence:- The report shall be based on the commission’s analysis of information provided at the
27 hearings by witnesses, providers, provider organizations, payers, and pharmaceutical
28 manufacturing companies, registration data collected under section 11, data collected or analyzed
29 by the center under sections 8, 9, 10, and 10A of chapter 12C and any other available
30 information that the commission considers necessary to fulfill its duties under this section as
31 defined in regulations promulgated by the commission.

32 SECTION 6. Section 9 of said chapter 6D, as so appearing, is hereby amended by
33 inserting after the word “organization”, in line 72, the following words:- , pharmaceutical
34 manufacturing company.

35 SECTION 7. Said chapter 6D is further amended by inserting after section 19 the
36 following new section:-

37 SECTION 20. Pharmaceutical Cost Transparency

38 (a) As used in this section, the following terms shall have the following meanings:-

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

47 “Prescription drug”, as defined in 21 U.S.C. § 321.

48 (b)(1) The Health Policy Commission, in collaboration with the Center for Health
49 Information and Analysis, shall identify annually up to 25 prescription drugs on which the State
50 spends significant health care dollars and for which the wholesale acquisition cost has increased
51 by 50 percent or more over the past five years or by 15 percent or more over the past 12
52 months, or is a new drug whose price may have a significant impact on the cost growth

53 benchmark. When determining whether a drug price may have a significant impact on the cost
54 growth benchmark, the commission shall consider both the volume of prescriptions issued in the
55 commonwealth and single dose wholesale acquisition cost.

56 The drugs identified shall represent different drug classes.

57 (2) The Commission shall provide to the Office of the Attorney General the list of
58 prescription drugs developed pursuant to this subsection and the percentage of the wholesale
59 acquisition cost increase for each drug and shall make the information available to the public on
60 the Commission's website.

61 (c)(1) For each prescription drug identified pursuant to subsection (b) of this section, the
62 commission shall require the drug's pharmaceutical manufacturing company to provide a
63 justification for the increase in the wholesale acquisition cost of the drug in a format that the
64 commission determines to be understandable and appropriate. The pharmaceutical manufacturing
65 company shall submit to the commission all relevant information and supporting documentation
66 necessary to justify the manufacturer's wholesale acquisition cost increase, which may include:

67 (A) all factors that have contributed to the wholesale acquisition cost increase;

68 (B) the percentage of the total wholesale acquisition cost increase attributable to each
69 factor; and

70 (C) an explanation of the role of each factor in contributing to the wholesale acquisition
71 cost increase.

72 (2) Nothing in this section shall be construed to restrict the legal ability of a
73 pharmaceutical manufacturing company to changes prices to the extent permitted under federal
74 law.

75 (d) The commission shall publish an Annual Prescription Drug Transparency Report on
76 or before December 1 of each year based on the information received from pharmaceutical
77 manufacturing companies pursuant to this section.

78 (e) In carrying out this section, the commission shall ensure the protection of confidential
79 commercial information and trade secrets.

80 (f) The commission shall promulgate regulations to implement and enforce this section
81 and may impose financial penalties on a pharmaceutical manufacturing company that fails to
82 provide the information required by subsection (c) of this section in an amount not to exceed
83 \$10,000.00 per violation. Each unlawful failure to provide information shall constitute a separate
84 violation.

85 SECTION 8. Said chapter 6D, as so appearing, is further amended by inserting after
86 section 20 the following new section:-

87 SECTION 20A. Transparency in Patient Advocacy

88 The commission shall require a pharmaceutical manufacturing company to annually
89 disclose payments and other transfers of value provided to a patient advocacy organization,
90 consumer advocacy organization, voluntary health agency, or a coalition of such organizations,
91 including a disease-specific advocacy organization. The commission shall issue an annual report
92 identifying the payments or other transfers of value made by manufacturers to a patient advocacy

93 organization, consumer advocacy organization, voluntary health agency, or a coalition of such
94 organizations, including a disease-specific advocacy organization and analyzing the impact of
95 such payments or transfers of value on health care public policy in the commonwealth.

96 SECTION 9. Said chapter 6D is further amended by inserting after section 20 the
97 following new section:-

98 SECTION 21. Early Notice of High Cost Drugs

99 (a) As used in this section, the following terms have the following meanings:-

100 "Average Manufacturer Price", as defined in section 1927(k)(1) of the Social Security
101 Act (42 U.S.C. 1396r-8(k)(1)).

102 "Pharmaceutical manufacturing company", an entity engaged in the: (i) production,
103 preparation, propagation, compounding, conversion or processing of prescription drugs, directly
104 or indirectly, by extraction from substances of natural origin, independently by means of
105 chemical synthesis or by a combination of extraction and chemical synthesis; or (ii) packaging,
106 repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that
107 "pharmaceutical manufacturing company" shall not include a wholesale drug distributor licensed
108 under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said
109 chapter 112.

110 (b)(1) A pharmaceutical manufacturing company shall submit a report to the commission
111 notifying the commission of each price increase of a prescription drug that will result in an
112 increase in the average manufacturer price of that drug that is equal to 10 percent or more over a
113 12-month period, or the introduction of a new drug whose price may threaten the cost benchmark

114 either due to anticipated volume of prescriptions filled in the commonwealth or the increase in
115 the average manufacturer price for a single dose.

116 (2) Each report described in paragraph (1) shall be submitted to the commission not later
117 than 30 days prior to the planned effective date of such price increase.

118 (c) A report under subsection (b) shall, at a minimum, include:

119 (1) With respect to the prescription drug—

120 (A) the percentage by which the pharmaceutical manufacturing company will raise the
121 average manufacturer price of the drug on the planned effective date of such price increase;

122 (B) a justification for, and description of, each pharmaceutical manufacturing company's
123 price increase that occurred during the 12-month period described in subsection (b)(1);

124 (C) the identity of the initial developer of the drug;

125 (D) a description of the history of the pharmaceutical manufacturing company's price
126 increases for the drug since the approval of the application for the drug under section 505 of the
127 Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section
128 351, or since the pharmaceutical manufacturing company acquired such approved application or
129 license;

130 (E) the current list price of the drug;

131 (F) the total expenditures of the pharmaceutical manufacturing company on—

132 (i) materials and manufacturing for such drug; and

133 (ii) acquiring patents and licensing for such drug;

134 (G) the percentage of total expenditures of the pharmaceutical manufacturing company
135 on research and development for such drug that was derived from Federal funds;

136 (H) the total expenditures of the pharmaceutical manufacturing company on research and
137 development for such drug that is used for—

138 (i) basic and preclinical research;

139 (ii) clinical research;

140 (iii) new drug development;

141 (iv) pursuing new or expanded indications for such drug through supplemental
142 applications under section 505 of the Federal Food, Drug, and Cosmetic Act; and

143 (v) carrying out post market requirements related to such drug, including those under
144 section 505(o)(3) of such Act;

145 (I) the total revenue and the net profit generated from the prescription drug for each
146 calendar year since the approval of the application for the drug under section 505 of the Federal
147 Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351, or
148 since the pharmaceutical manufacturing company acquired such approved application or license;
149 and

150 (J) the total costs associated with marketing and advertising for the prescription drug;

151 (2) With respect to the pharmaceutical manufacturing company:

152 (A) the total revenue and the net profit of the pharmaceutical manufacturing company for
153 the 12-month period described in subsection (b)(1);

154 (B) the amount the pharmaceutical manufacturing company has spent on dividends and
155 stock repurchases and the specific metrics used by the pharmaceutical manufacturing company to
156 determine executive compensation, including any stock-based performance metrics, for the 12-
157 month period described in subsection (b)(1); and

158 (C) the amount the pharmaceutical manufacturing company has provided in funding to
159 consumer and disease advocacy groups for the 12-month period described in subsection (b)(1);

160 (D) any additional information the manufacturer chooses to provide related to drug
161 pricing decisions, such as total expenditures on—

162 (i) drug research and development; or

163 (ii) clinical trials on drugs that failed to receive approval by the Food and Drug
164 Administration; and

165 (3) such other related information as the commission considers appropriate.

166 (d) The commission shall promulgate regulations to implement and enforce this section
167 and may impose financial penalties on a pharmaceutical manufacturing company that fails to
168 provide the information required by subsection (c) of this section in an amount not to exceed
169 \$10,000.00 per violation. Each unlawful failure to provide information shall constitute a separate
170 violation.

171 (e)(1) Not later than 30 days after the submission of a report under subsection (b), the
172 commission shall post the report on the public website of the commission.

173 (2) In carrying out this section, the commission shall ensure the protection of confidential
174 commercial information and trade secrets.

175 SECTION 10. Section 1 of chapter 12C of the General Laws, as so appearing, is hereby
176 amended by inserting after the definition of “Patient-centered medical home” the following
177 definition:-

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

186 SECTION 11. Section 3 of said chapter 12C, as so appearing, is hereby amended by
187 inserting after the word “organizations”, in lines 13 and 14, the following words:- ,
188 pharmaceutical manufacturing companies.

189 SECTION 12. Said section 3 of said chapter 12C, as so appearing, is hereby further
190 amended by striking out, in line 24, the words “and payer” and inserting in place thereof the
191 following words:- , payer, and pharmaceutical manufacturing company.

192 SECTION 13. Section 5 of said chapter 12C, as so appearing, is hereby further amended
193 by striking out, in line 15, the words “and affected payers” and inserting in place thereof the
194 following words:- affected payers, and affected pharmaceutical manufacturing companies.

195 SECTION 14 Said chapter 12C is hereby further amended by inserting after section 10
196 the following new section:-

197 Section 10A. (a) The center shall promulgate regulations necessary to ensure the uniform
198 reporting of information from pharmaceutical manufacturing companies that enables the center
199 to analyze: (i) year-over-year changes in wholesale acquisition cost and average manufacturer
200 price for prescription drug products; (ii) year-over-year trends in net expenditures; (iii) net
201 expenditures on subsets of biosimilar, brand name and generic drugs identified by the center; (iv)
202 trends in estimated aggregated drug rebates, discounts or other remuneration paid or provided by
203 a pharmaceutical manufacturing company to a pharmacy benefit manager, wholesaler,
204 distributor, health carrier client, health plan sponsor or pharmacy in connection with utilization
205 of the pharmaceutical drug products offered by the pharmaceutical manufacturing company; (v)
206 discounts provided by a pharmaceutical manufacturing company to a consumer in connection
207 with utilization of the pharmaceutical drug products offered by the pharmaceutical
208 manufacturing company, including any discount, rebate, product voucher, coupon or other
209 reduction in a consumer's out-of-pocket expenses including co-payments and deductibles under
210 section 3 of chapter 175H; (vi) research and development costs as a percentage of revenue; (vii)
211 annual marketing and advertising costs, identifying costs for direct-to-consumer advertising;
212 (viii) annual profits over the most recent 5-year period; (ix) cost disparities between prices
213 charged to purchasers in the commonwealth and purchasers outside of the United States; and (x)
214 any other information deemed necessary by the center.

215 The center shall require the submission of available data and other information from
216 pharmaceutical manufacturing companies including, but not limited to: (i) changes in wholesale

217 acquisition costs and average manufacturer prices for prescription drug products as identified by
218 the center; (ii) aggregate, company-level research and development costs to the extent
219 attributable to a specific product and other relevant capital expenditures for the most recent year
220 for which final audited data are available for prescription drug products as identified by the
221 center; (iii) annual marketing and advertising expenditures; and (iv) a description, suitable for
222 public release, of factors that contributed to reported changes in wholesale acquisition costs and
223 average manufacturer prices for prescription drug products as identified by the center.

224 (b) Except as specifically provided otherwise by the center or under this chapter, data
225 collected by the center pursuant to this section from pharmaceutical manufacturing companies
226 shall not be a public record under clause Twenty-sixth of section 7 of chapter 4 or under chapter
227 66.

228 SECTION 15. Said chapter 12C is hereby further amended by striking out section 11, as
229 appearing in the 2018 Official Edition, and inserting in place thereof the following section:-

230 Section 11. The center shall ensure the timely reporting of information required under
231 sections 8, 9, 10 and 10A. The center shall notify payers, providers, provider organizations, and
232 pharmaceutical manufacturing companies of any applicable reporting deadlines. The center shall
233 notify, in writing, a private health care payer, provider, provider organization, or pharmaceutical
234 manufacturing company that it has failed to meet a reporting deadline and that failure to respond
235 within 2 weeks of the receipt of the notice may result in penalties. The center may assess a
236 penalty against a private health care payer, provider, provider organization, or pharmaceutical
237 manufacturing company that fails, without just cause, to provide the requested information
238 within 2 weeks following receipt of the written notice required under this section of not more

239 than \$1,000 per week for each week of delay after the 2-week period following receipt of the
240 written notice. Amounts collected under this section shall be deposited in the Healthcare
241 Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

242 SECTION 16. Section 12 of said chapter 12C, as so appearing, is hereby amended by
243 striking out, in line 2, the words “and 10” and inserting in place thereof the following words:- ,
244 10 and 10A.

245 SECTION 17. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby
246 amended by striking out the first sentence and inserting in place thereof the following sentence:-

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

252 SECTION 18. The General Laws are hereby amended by inserting after chapter 63B the
253 following new chapter: -

254 Chapter 63D. Penalty on drug manufacturers for excessive price increases

255 Section 1. As used in this section, the following terms shall have the following
256 meanings:- “Commissioner”, the commissioner of revenue.

257 “Consumer price index”, the consumer price index for all urban consumers for Boston, as
258 most recently reported by the federal Bureau of Labor Statistics.

259 “Drug”, any medication, as identified by a National Drug Code, approved for sale by the
260 U.S. Food and Drug Administration.

261 “Excessive price,” the price of a drug if it exceeds the sum of (a) the reference price of
262 that drug, as adjusted for any increase or decrease in the consumer price index since the
263 reference price was determined, and (b) an additional two percent of the reference price for each
264 twelve-month period that has elapsed since the date on which the reference price was
265 determined. The two percent increment provided in (b) of the preceding sentence shall
266 compound annually on the first day of the first calendar quarter commencing after the end of
267 each 12-month period described therein.

268 “Excessive price increase”, the amount by which the price of a drug exceeds the sum of
269 (a) the reference price of that drug, as adjusted for any increase or decrease in the consumer price
270 index since the reference price was determined, and (b) an additional two percent of the
271 reference price for each twelve-month period that has elapsed since the date on which the
272 reference price was determined. The two percent increment provided in (b) shall compound
273 annually on the first day of the first calendar quarter commencing after the end of each twelve-
274 month period described therein.

275 “Person”, any natural person or legal entity.

276 “Price”, the wholesale acquisition cost of a drug, per unit, as reported to the First Data
277 Bank or other applicable price compendium designated by the commissioner.

278 “Reference price”, the price of a drug as of October 1, 2019, or in the case of any drug
279 first commercially marketed in the United States after October 1, 2019, the price of the drug on
280 the date when first marketed.

281 “Related party”, an entity is a related party with respect to a person if that entity belongs
282 to the same affiliated group as that person under section 1504 of the Internal Revenue Code, as
283 amended and in effect for the taxable year, or if the entity and the person are otherwise under
284 common ownership and control.

285 “Unit”, the lowest dispensable amount of a drug.

286 Section 2. (a) Any person who manufactures and sells drugs, directly or through another
287 person, for distribution in the commonwealth and who establishes an excessive price for any
288 such drug directly or in cooperation with a related party, shall pay a per unit penalty on all units
289 of the drug ultimately dispensed or administered in the commonwealth. The penalty for each unit
290 shall be 80 percent of the excessive price increase for each unit, determined at the beginning of
291 the calendar quarter.

292 (b) A person who establishes an excessive price for a drug as described in subsection (a)
293 shall file a return as provided in section 4 declaring all units of excessively priced drug sold for
294 distribution in the commonwealth during the quarter. In the event that a person filing such a
295 return pays a penalty with regard to one or more units of drug that are ultimately dispensed or
296 administered outside of the commonwealth, the person may claim a credit for such penalty
297 amounts on the return for the tax period during which such units are ultimately dispensed or
298 administered.

299 Section 3. The penalty under section 2 shall apply for any calendar quarter only to a
300 person who maintains a place of business in the commonwealth or whose total sales of all
301 products, directly or through another person, for distribution in the commonwealth were more

302 than \$100,000 in the prior twelve-month period. The penalty shall not apply more than once to
303 any unit of drug sold.

304 Section 4. Any person subject to the penalty under section 2 shall file a return with the
305 commissioner and shall pay the penalty by the fifteenth day of the third month following the end
306 of each calendar quarter, subject to such reasonable extensions of time for filing as the
307 commissioner may allow. The return shall set out the person's total sales subject to penalty in the
308 immediately preceding calendar quarter and shall provide such other information as the
309 commissioner may require.

310 Section 5. The penalty imposed under this chapter shall be in addition to, and not a
311 substitute for or credit against, any other penalty, tax or excise imposed under the General Laws.

312 Section 6. The commissioner may disclose information contained in returns filed under
313 this chapter to the department of public health for purposes of verifying that a filer's sales subject
314 to penalty are properly declared and that all reporting is otherwise correct. Return information so
315 disclosed shall remain confidential and shall not be public record.

316 Section 7. To the extent that a person subject to penalty under section 2 fails to pay
317 amounts due under this chapter, a related party of such person that directly or indirectly
318 distributes in the commonwealth any drug whose sales are subject to this chapter shall be jointly
319 and severally liable for the penalty due.

320 Section 8. The commissioner may promulgate regulations or issue other guidance for the
321 implementation of this chapter.