

HOUSE No. 1162

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>1/14/2019</i>
<i>Carolyn C. Dykema</i>	<i>8th Middlesex</i>	<i>1/24/2019</i>
<i>Ann-Margaret Ferrante</i>	<i>5th Essex</i>	<i>1/24/2019</i>
<i>Steven S. Howitt</i>	<i>4th Bristol</i>	<i>1/24/2019</i>
<i>Michael O. Moore</i>	<i>Second Worcester</i>	<i>1/30/2019</i>
<i>Stephan Hay</i>	<i>3rd Worcester</i>	<i>1/30/2019</i>
<i>Dean A. Tran</i>	<i>Worcester and Middlesex</i>	<i>2/1/2019</i>
<i>James K. Hawkins</i>	<i>2nd Bristol</i>	<i>2/1/2019</i>

HOUSE No. 1162

By Ms. Hogan of Stow, a petition (accompanied by bill, House, No. 1162) of Kate Hogan 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 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. Chapter 6D is amended by adding the following new Sections:

2 Section 19. PHARMACEUTICAL COST TRANSPARENCY

3 (a) As used in this section:

4 (1) “Manufacturer” means the person that holds the application for a drug approved under
5 section 505 of the Federal Food, Drug, and Cosmetic Act or the license issued under section 351
6 of the Public Health Service Act, or who is responsible for setting the price for the drug.

7 (2) “Prescription drug” means a drug as defined in 21 U.S.C. § 321.

8 (b)(1) The Health Policy Commission, in collaboration with the Center for Health
9 Information and Analysis, shall identify annually up to 15 prescription drugs on which the State
10 spends significant health care dollars and for which the wholesale acquisition cost has increased

11 by 50 percent or more over the past five years or by 15 percent or more over the past 12 months,
12 or is a new drug whose price may have a significant impact on the cost benchmark.

13 The drugs identified shall represent different drug classes.

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

18 (c)(1) For each prescription drug identified pursuant to subsection (b) of this section, the
19 Office of the Attorney General shall require the drug's manufacturer to provide a justification for
20 the increase in the wholesale acquisition cost of the drug in a format that the Attorney General
21 determines to be understandable and appropriate. The manufacturer shall submit to the Office of
22 the Attorney General all relevant information and supporting documentation necessary to justify
23 the manufacturer's wholesale acquisition cost increase, which may include:

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

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

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

29 (2) Nothing in this section shall be construed to restrict the legal ability of a prescription
30 drug manufacturer to change prices to the extent permitted under federal law.

31 (d) The Attorney General shall provide an Annual Prescription Drug Transparency
32 Report to the Legislature, the Health Policy Commission and the Center for Health Information
33 and Analysis on or before December 1 of each year based on the information received from
34 manufacturers pursuant to this section. The Attorney General shall also post the report on the
35 Office of the Attorney General’s website.

36 (e) (2) In carrying out this section the Attorney General and the Health Policy
37 Commission shall ensure the protection of confidential commercial information and trade
38 secrets.

39 (f) The Attorney General may bring an action for injunctive relief, costs, and attorney’s
40 fees, and to impose on a manufacturer that fails to provide the information required by
41 subsection (c) of this section a civil penalty of no more than \$10,000.00 per violation. Each
42 unlawful failure to provide information shall constitute a separate violation.

43 Section 20. REPORT ON PRICE INCREASES

44 (a) As used in this section:

45 (1) Average Manufacturer Price has the meaning given the term in section 1927(k)(1) of
46 the Social Security Act (42 U.S.C. 1396r-8(k)(1)). (2) “Manufacturer” means the person that
47 holds the application for a drug approved under section 505 of the Federal Food, Drug, and
48 Cosmetic Act or the license issued under section 351 of the Public Health Service Act, or who is
49 responsible for setting the price for the drug.

50 (b)(1) The manufacturer of a prescription drug shall submit a report to the Health Policy
51 Commission for each price increase of a prescription drug that will result in an increase in the

52 average manufacturer price of that drug that is equal to 10 percent or more over a 12-month
53 period or the introduction of a new drug whose price may threaten the cost benchmark. (2) Each
54 report described in paragraph (1) shall be submitted to the Health Policy Commission not later
55 than 30 days prior to the planned effective date of such price increase.

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

57 (1) With respect to the prescription drug—

58 (A) the percentage by which the manufacturer will raise the average manufacturer price
59 of the drug on the planned effective date of such price increase;

60 (B) a justification for, and description of, each manufacturer's price increase that
61 occurred during the 12-month period described in subsection (b)(1);

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

63 (D) a description of the history of the manufacturer's price increases for the drug since the
64 approval of the application for the drug under section 505 of the Federal Food, Drug, and
65 Cosmetic Act or the issuance of the license for the drug under section 351, or since the
66 manufacturer acquired such approved application or license;

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

68 (F) the total expenditures of the manufacturer on—

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

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

71 (G) the percentage of total expenditures of the manufacturer on research and development
72 for such drug that was derived from Federal funds;

73 (H) the total expenditures of the manufacturer on research and development for such drug
74 that is used for—

75 (i) basic and preclinical research;

76 (ii) clinical research;

77 (iii) new drug development;

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

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

82 (I) the total revenue and the net profit generated from the prescription drug for each
83 calendar year since the approval of the application for the drug under section 505 of the Federal
84 Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351, or
85 since the manufacturer acquired such approved application or license; and

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

87 (2) With respect to the manufacturer:

88 (A) the total revenue and the net profit of the manufacturer for the 12-month period
89 described in subsection (b)(1);

90 (B) the amount the manufacturer has spent on dividends and stock repurchases and the
91 specific metrics used by the manufacturer to determine executive compensation, including any
92 stock-based performance metrics, for the 12-month period described in subsection (b)(1); and

93 (C) the amount the manufacturer has provided in funding to consumer and disease
94 advocacy groups for the 12-month period described in subsection (b)(1);

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

97 (i) drug research and development; or

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

100 (3) such other related information as the Health Policy Commission considers
101 appropriate.

102 (d) The Attorney General may bring an action for injunctive relief, costs, and attorney's
103 fees, and to impose on a manufacturer that fails to provide the information required by
104 subsections (b) and (c) of this section a civil penalty of no more than \$10,000.00 per violation.
105 Each unlawful failure to provide information shall constitute a separate violation.

106 (e)(1) Not later than 30 days after the submission of a report under subsection (b), the
107 Health Policy Commission shall post the report on the public Website of the Commission. (2) In
108 carrying out this section the Health Policy Commission shall ensure the protection of
109 confidential commercial information and trade secrets.

110 SECTION 2. Section 8 of Chapter 6D is amended to read as follows:

111 (a) Not later than October 1 of every year, the commission shall hold public hearings
112 based on the report submitted by the center for health information and analysis under section 16
113 of chapter 12C comparing the growth in total health care expenditures to the health care cost
114 growth benchmark for the previous calendar year. The hearings shall examine health care
115 provider, provider organization, prescription drug manufacturer and private and public health
116 care payer costs, prices and cost trends, with particular attention to factors that contribute to cost
117 growth within the commonwealth's health care system.

118 (b) The attorney general may intervene in such hearings.

119 (c) Public notice of any hearing shall be provided at least 60 days in advance.

120 (d) The commission shall identify as witnesses for the public hearing a representative
121 sample of providers, provider organizations, prescription drug manufacturers, payers and others,
122 including: (i) at least 3 academic medical centers, including the 2 acute hospitals with the highest
123 level of net patient service revenue; (ii) at least 3 disproportionate share hospitals, including the 2
124 hospitals whose largest per cent of gross patient service revenue is attributable to Title XVIII and
125 XIX of the federal Social Security Act or other governmental payers; (iii) community hospitals
126 from at least 3 separate regions of the commonwealth; (iv) freestanding ambulatory surgical
127 centers from at least 3 separate regions of the commonwealth; (v) community health centers from
128 at least 3 separate regions of the commonwealth; (vi) the 5 private health care payers with the
129 highest enrollments in the commonwealth; (vii) any managed care organization that provides
130 health benefits under Title XIX; (viii) the group insurance commission; (ix) at least 3
131 municipalities that have adopted chapter 32B; (x) at least 4 provider organizations, at least 2 of
132 which shall be certified as accountable care organizations, 1 of which has been certified as a

133 model ACO, which shall be from diverse geographic regions of the commonwealth; (xi) the
134 prescription drug manufacturers whose drugs were identified in the latest Attorney General's
135 Annual Prescription Drug Transparency Report and (xii) any witness identified by the attorney
136 general or the center.

137 (e) Witnesses shall provide testimony under oath and subject to examination and cross
138 examination by the commission, the executive director of the center and the attorney general at
139 the public hearing in a manner and form to be determined by the commission, including, but not
140 limited to: (i) in the case of providers and provider organizations, testimony concerning payment
141 systems, care delivery models, payer mix, cost structures, administrative and labor costs, capital
142 and technology cost, adequacy of public payer reimbursement levels, reserve levels, utilization
143 trends, relative price, quality improvement and care-coordination strategies, investments in
144 health information technology, the relation of private payer reimbursement levels to public payer
145 reimbursements for similar services, efforts to improve the efficiency of the delivery system,
146 efforts to reduce the inappropriate or duplicative use of technology and the impact of price
147 transparency on prices; (ii) in the case of prescription drug manufacturers, testimony concerning
148 all factors that have contributed to significant cost increases for their drugs, the percentage of
149 cost increase attributable to each factor and an explanation of the role of each factor in
150 contributing to such cost increases and their efforts in moving to value based drug pricing, and
151 (iii) in the case of private and public payers, testimony concerning factors underlying premium
152 cost and rate increases, the relation of reserves to premium costs, efforts by the payer to reduce
153 the use of fee-for-service payment mechanisms, the payer's efforts to develop benefit design,
154 network design and payment policies that enhance product affordability and encourage efficient
155 use of health resources and technology including utilization of alternative payment

156 methodologies, efforts by the payer to increase consumer access to health care information,
157 efforts by the payer to promote the standardization of administrative practices, the impact of
158 price transparency on prices and any other matters as determined by the commission. The
159 commission shall solicit testimony from any payer which has been identified by the center's
160 annual report under subsection (a) of section 16 of chapter 12C as (1) paying providers more
161 than 10 per cent above or more than 10 per cent below the average relative price or (2) entering
162 into alternative payment contracts that vary by more than 10 per cent. Any payer identified by
163 the center's report shall explain the extent of price variation between the payer's participating
164 providers and describe any efforts to reduce such price variation.

165 (f) In the event that the center's annual report under subsection (a) of section 16 of
166 chapter 12C finds that the percentage change in total health care expenditures exceeded the
167 health care cost benchmark in the previous calendar year, the commission may identify
168 additional witnesses for the public hearing. Witnesses shall provide testimony subject to
169 examination and cross examination by the commission, the executive director of the center and
170 attorney general at the public hearing in a manner and form to be determined by the commission,
171 including, but not limited to: (i) testimony concerning unanticipated events that may have
172 impacted the total health care cost expenditures, including, but not limited to, a public health
173 crisis such as an outbreak of a disease, a public safety event or a natural disaster; (ii) testimony
174 concerning trends in patient acuity, complexity or utilization of services; (iii) testimony
175 concerning trends in input cost structures, including, but not limited to, the introduction of new
176 pharmaceuticals, medical devices and other health technologies; (iv) testimony concerning the
177 cost of providing certain specialty services, including, but not limited to, the provision of health
178 care to children, cancer-related health care and medical education; (v) testimony related to

179 unanticipated administrative costs for carriers, including, but not limited to, costs related to
180 information technology, administrative simplification efforts, labor costs and transparency
181 efforts; (vi) testimony related to costs due the implementation of state or federal legislation or
182 government regulation; and (vii) any other factors that may have led to excessive health care cost
183 growth.

184 (g) The commission shall compile an annual report concerning spending trends and
185 underlying factors, along with any recommendations for strategies to increase the efficiency of
186 the health care system. The report shall be based on the commission's analysis of information
187 provided at the hearings by providers, provider organizations and insurers, registration data
188 collected under section 11, data collected by the center for health information and analysis under
189 sections 8, 9 and 10 of chapter 12C and any other information the commission considers
190 necessary to fulfill its duties under this section, as further defined in regulations promulgated by
191 the commission. The report shall be submitted to the chairs of the house and senate committees
192 on ways and means and the chairs of the joint committee on health care financing and shall be
193 published and available to the public not later than December 31 of each year. The report shall
194 include any legislative language necessary to implement the recommendations.