

HOUSE No. 1272

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>2/10/2021</i>

HOUSE No. 1272

By Ms. Hogan of Stow, a petition (accompanied by bill, House, No. 1272) of Kate Hogan relative to the pricing of prescription drugs. Health Care Financing.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. 1162 OF 2019-2020.]

The Commonwealth of Massachusetts

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

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 Chapter 6D is amended by adding the following new Sections:

2 Section 20- 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 21- 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)).

47 (2) "Manufacturer" means the person that holds the application for a drug approved under
48 section 505 of the Federal Food, Drug, and Cosmetic Act or the license issued under section 351
49 of the Public Health Service Act, or who is 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.

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55 (2) Each report described in paragraph (1) shall be submitted to the Health Policy
56 Commission not later than 30 days prior to the planned effective date of such price increase.

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

58 (1) With respect to the prescription drug—

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

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

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

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

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

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

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

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

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

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

76 (i) basic and preclinical research;

77 (ii) clinical research;

78 (iii) new drug development;

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

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

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

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

88 (2) With respect to the manufacturer:

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

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

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

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

98 (i) drug research and development; or

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

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

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

107 (e)(1) Not later than 30 days after the submission of a report under subsection (b), the
108 Health Policy Commission shall post the report on the public website of the Commission.

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110 (2) In carrying out this section the Health Policy Commission shall ensure the protection
111 of confidential commercial information and trade secrets.