

SENATE No. 728

The Commonwealth of Massachusetts

PRESENTED BY:

Dean A. Tran

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 providing affordable access to generic medicines.

PETITION OF:

NAME:

Dean A. Tran

DISTRICT/ADDRESS:

Worcester and Middlesex

SENATE No. 728

By Mr. Tran, a petition (accompanied by bill, Senate, No. 728) of Dean A. Tran for legislation to provide affordable access to generic medicines . Health Care Financing.

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-First General Court
(2019-2020)**

An Act providing affordable access to generic medicines.

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 23I of the general laws, as appearing in the 2016
2 Official Edition, is hereby amended by inserting after subsection (10) the following subsection:-

3 (11) While recognizing that support of the discovery and launch of new therapies is
4 necessary, it is also declared that increasing access to established therapies including generic
5 medicines by addressing shortages, quality issues, and/or affordability of generic medicines is
6 critical to improve the quality and delivery of health care for the people of the commonwealth as
7 well as supports economic development and job growth not just in the life sciences field but
8 throughout all sectors of the economy; and will reduce financial burden on people, businesses,
9 and the commonwealth.

10 SECTION 2. Section 2 of said chapter 23I, as so appearing, is hereby amended by
11 inserting at the end thereof the following definition:-

12 "Independent Nonprofit Manufacturing Company", a nonprofit manufacturing
13 organization that holds tax-exempt status granted under section 501(c)(3) of the Internal Revenue
14 Code and shall be organized and operated primarily to manufacture, virtually or directly, FDA
15 approved medicines, including generics, to increase access by addressing shortages, quality
16 issues, and/or affordability of medicines.

17 SECTION 3. Subsection (a) of section 5 of said chapter 23I, as so appearing, is hereby
18 amended by inserting after the word "companies", in line 7, the following:- including
19 independent non-profit manufacturing companies.

20 SECTION 4. Subsection (b) of said section 5, as so appearing, is hereby amended by
21 inserting after the word "generate", in line 16, the following:- or for an independent nonprofit
22 manufacturing company healthcare cost savings for the state,

23 SECTION 5. Subsection (b) of said section 5, as so appearing, is hereby further amended
24 by inserting after the word "revenue", in line 19, the following:- Or savings,

25 SECTION 6. Subsection (b) of said section 5, as so appearing, is hereby further amended
26 by inserting after the word "revenue", in line 20, the following:- Or savings,

27 SECTION 7. Subsection (b) of said section 5, as so appearing, is hereby further amended
28 by inserting after the word "received", in line 20, the following:-

29 Or realized,

30 SECTION 8. Subsection (f) of said section 5, as so appearing, is hereby amended by
31 inserting after the word "revenue", in line 154, the following:- or realized savings,

32 SECTION 9. Subsection (c) of section 6 of said chapter 23I, as so appearing, is hereby
33 amended by striking paragraph (2) in its entirety and replacing it with the following paragraph: -

34 (2) to make targeted investments, including research funding, proof of concept funding,
35 funding for the manufacture of generic medicines by an independent non-profit manufacturing
36 company through tax-exempt bonds and funding for the development of devices, drugs or
37 therapeutics and to promote manufacturing activities for new or existing advanced technologies
38 and life sciences research;

39 SECTION 10. Paragraph (3) of subsection (c) of said section 6, as so appearing, is hereby
40 amended by inserting after the word “development”, in line 61, the following:- , increasing
41 access to generic medicines through a non-profit model

42 SECTION 11. Subsection (d) of said section 6, as so appearing, is hereby amended by
43 inserting after paragraph (7) the following paragraph:-

44 (8) increase access to generic medicines experiencing shortages, quality issues, and/or
45 affordability issues.

46 SECTION 12. Paragraph (3) of subsection (e) of said section 6, as so appearing, is hereby
47 amended by inserting after clause (vii) the following clause: -

48 (viii) or when dealing with an independent nonprofit manufacturing company that is
49 addressing generic medicine access issues that the cost savings that can be realized by
50 the commonwealth, businesses, and individuals, and / or improvement in healthcare
51 outcomes will be used in place of clauses (iii), (iv), (v), and (vii).

52 SECTION 13. Paragraph 5 of subsection (e) of said section 6, as so appearing, is hereby
53 amended by inserting after the word “party”, in line 141, the following:- , except when dealing
54 with an independent nonprofit manufacturing company that is addressing generic medicine
55 access issues where this requirement is waived.

56 SECTION 14. Said paragraph 5, as so appearing, is hereby further amended by inserting
57 after the word “opportunities”, in line 146, the following:- , increase access to generic medicines
58 through a non-profit model

59 SECTION 15. Clause (v) of paragraph (3) of subsection (c) of section 7 of said chapter
60 23I, as so appearing, is hereby amended by inserting after the word “enterprise”, in line 60, the
61 following language:- , except when dealing with an independent non-profit manufacturing
62 company that is addressing generic medicine access issues the substantial financial commitment
63 is waived.

64 SECTION 16. Paragraph 4 of subsection (c) of said section 7, as so appearing, is hereby
65 amended by inserting after the word “opportunities”, in line 78, the following:- , increase access
66 to generic medicines through a nonprofit model,

67 SECTION 17. Chapter 23I of the general laws is hereby amended by inserting after
68 section 18, the following new section: -

69 Section 19. The center shall establish a grant program to address access to generic
70 pharmaceuticals. Issues regarding access shall include drug shortages, discontinuations, quality,
71 and/or affordability. To qualify for a grant, an organization must be an independent nonprofit
72 manufacturing company as defined in section 2. The grant funding may be used for startup costs
73 associated with forming an independent nonprofit manufacturing company. To further qualify,

74 an independent nonprofit manufacturing company must abide by all existing state and federal
75 pharmaceutical laws. The center may also create a program to address access to naloxone by
76 those suffering from opioid addiction. This program shall be made available to qualifying
77 independent nonprofit manufacturing companies, but shall not be used to subsidize the
78 purchasing of naloxone. Any qualifying independent nonprofit manufacturing company shall be
79 required to provide to the center all information requested in reference to operating expenses.