

HOUSE No.

The Commonwealth of Massachusetts

PRESENTED BY:

Stephen Kulik

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 passage of the accompanying bill:

An Act prohibiting the use of health data for marketing purposes.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Denise Provost	27th Middlesex
Gale D. Candaras	First Hampden and Hampshire
Peter v. Kocot	1st Hampshire

The Commonwealth of Massachusetts

In the Year Two Thousand and Nine

AN ACT PROHIBITING THE USE OF HEALTH DATA FOR MARKETING PURPOSES.

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 118G is hereby amended by inserting after section 33 the following section:—

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3 Section 34. (a) As used in this section the following words shall, unless the context clearly requires
4 otherwise, have the following meanings:—

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6 “Bona-fide clinical trial”, any research project that prospectively assigns human subjects to intervention
7 and comparison groups to study the cause and effect relationship between a medical intervention and
8 health outcome, has received approval from an appropriate Institutional Review Board, and has been
9 registered at ClinicalTrials.gov prior to commencement.

10

11 “Identifying information”, information that can be used to directly or indirectly identify the patient or the
12 prescriber, including, but not limited to, a person’s name, address, telephone number, facsimile number,
13 electronic mail address, photograph or likeness, account, credit card, medical record, social security
14 number, Drug Enforcement Agency (DEA) number, National Provider Identifier (NPI) or any other
15 unique number, characteristic, code or information which is likely to lead to the identification of the
16 patient or prescriber.

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18 “Marketing purpose” means any activity by a company making or selling prescribed products, or such
19 company’s agent, intended to influence prescribing or purchasing choices of its products, including but
20 not limited to:

21

22 (1) advertising, publicizing, promoting or sharing information about a product;

23 (2) identifying individuals to receive a message promoting use of a particular product, including but not
24 limited to an advertisement, brochure, or contact by a sales representative;

- 25 (3) planning the substance of a sales representative visit or communication or the substance of an
26 advertisement or other promotional message or document;
27 (4) evaluating or compensating sales representatives;
28 (5) identifying individuals to receive any form of gift, product sample, consultancy, or any other item,
29 service, compensation or employment of value;
30 (6) advertising or promoting prescribed products directly to patients.

31
32 “Person”, any business, individual, corporation, union, association, firm, partnership, committee, or other
33 organization, individual or group of persons.

34
35 “Pharmacy”, a facility under the direction or supervision of a registered pharmacist which is authorized to
36 dispense controlled substances, including but not limited to retail drug business as defined in Section 1 of
37 Chapter 94C.

38
39 “Prescribed product”, includes a biological product as defined in section 251 of the Public Health Service
40 Act, 42 U.S.C. §262 and a device or a drug as defined in section 201 of the Federal Food, Drug and
41 Cosmetic Act, 21 U.S.C. §321.

42
43 “Prescriber”, a person who is licensed, registered or otherwise authorized to prescribe and administer
44 drugs in the course of professional practice.

45
46 “Regulated transaction”, a prescription for a drug that is written by a prescriber within the commonwealth
47 or that is dispensed within the commonwealth. The commonwealth does not regulate activities that take
48 place wholly outside of the commonwealth.

49
50 (b) No person shall license, use, sell, or transfer for any marketing purpose, prescribed product
51 information related to a regulated transaction that has identifying information. A record of a regulated
52 transaction containing individual identifying information may be transferred to another entity, including
53 to another branch or subsidiary of the same firm, only if it carries satisfactory assurance that the recipient
54 will safeguard the records from being disclosed or used in the commonwealth for marketing purposes

55
56 (c) Nothing in this section shall prohibit the collection use, transfer, or sale of prescribed product
57 information for marketing purposes if:-- (i) the data is aggregated; (ii) the data does not contain
58 identifying information; and (iii) the data cannot be used, directly or indirectly, to obtain identifying
59 information.

60
61 (d) Nothing in this section shall prohibit the collection, use, transfer, or sale of prescribed product
62 information for non-marketing purposes, including, but not limited to, pharmacy reimbursement,
63 prescription drug formulary or prior authorization compliance, patient care, patient care management,
64 utilization review, health care research, bona fide clinical trials, product safety studies, transfer of
65 prescription records that may occur when a pharmacy’s ownership is changed or transferred, transfer of
66 information to the patient or patient’s authorized representative, and as required by law.

67
68 (e) Nothing in this section shall be interpreted to regulate conduct that takes place wholly outside of the

69 commonwealth.

70

71 (f) Nothing in this section shall be interpreted to regulate the content, time, place or manner of any
72 discussion between a prescriber and patient, or a prescriber and any person representing a prescription drug
73 manufacturer.

74

75 (g) Any person who knowingly fails to comply with the requirements of this section shall be subject to an
76 administrative penalty of at least \$10,000 per violation and not more than \$50,000 per violation, as
77 assessed by the division of health care finance and policy. Each unauthorized disclosure shall constitute a
78 violation.

79

80 (h) A violation of this section shall also constitute an unfair or deceptive act or practice in the conduct of
81 trade in violation of Section 2 of Chapter 93A. Any person whose rights under this section have been
82 violated may institute and prosecute in his own name and on his own behalf, or the attorney general,
83 acting on behalf of the commonwealth, may institute a civil action for injunctive and other equitable
84 relief.

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86 (i) If any provision of this act or its application to any person or circumstance is held invalid, the
87 remainder of the act or the application of the provision to other persons or circumstances is not affected.

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89 SECTION 2. This act shall take effect upon passage.

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