HOUSE DOCKET, NO. 1189 FILED ON: 1/20/2011

HOUSE . . . . . No. 1497

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:

An Act prohibiting the use of prescriber-identifiable data for marketing purposes .

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Stephen Kulik	*1st Franklin*
Denise Andrews	*2nd Franklin*
Cory Atkins	*14th Middlesex*
Jennifer E. Benson	*37th Middlesex*
John J. Binienda	*17th Worcester*
Cheryl A. Coakley-Rivera	*10th Hampden*
Benjamin B. Downing	*Berkshire, Hampshire, and Franklin*
James J. Dwyer	*30th Middlesex*
Carlos Henriquez	*5th Suffolk*
Kay Khan	*11th Middlesex*
Elizabeth A. Malia	*11th Suffolk*
Alice Hanlon Peisch	*14th Norfolk*
George T. Ross	*2nd Bristol*
John W. Scibak	*2nd Hampshire*
Carl M. Sciortino, Jr.	*34th Middlesex*
David B. Sullivan	*6th Bristol*
Martha M. Walz	*8th Suffolk*
Ruth B. Balser	*12th Middlesex*

Nick Collins	*4th Suffolk*
Carolyn C. Dykema	*8th Middlesex*
James B. Eldridge	☐ *[District]* ☐
Colleen M. Garry	*36th Middlesex*
Patricia D. Jehlen	☐ *[District]* ☐
David Paul Linsky	*5th Middlesex*
Alice K. Wolf	*25th Middlesex*
Michael J. Finn	*6th Hampden*
Gale D. Candaras	☐ *[District]* ☐
Gailanne M. Cariddi	*1st Berkshire*
Linda Dorcena Forry	*12th Suffolk*
Denise Provost	*27th Middlesex*
Stephen Stat Smith	*28th Middlesex*
Theodore C. Speliotis	*13th Essex*
Joyce A. Spiliotis	*12th Essex*
Ellen Story	*3rd Hampshire*

HOUSE DOCKET, NO. 1189 FILED ON: 1/20/2011

HOUSE . . . . . No. 1497

By Mr. Kulik of Worthington, a petition (accompanied by bill, House, No. 1497) of Stephen Kulik and others for legislation to regulate the license, transfer, use, or sale of prescriber-identifiable data only for commercial purposes by pharmacies. Public Health.

The Commonwealth of Massachusetts

An Act prohibiting the use of prescriber-identifiable 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:

Section 1. Chapter 118G is hereby amended by inserting after section 33 the following section:—

Section 34. It is the intent of the legislature to safeguard the confidentiality of prescriber-identifiable data, protect the integrity of the doctor-patient relationship, maintain the integrity and public trust in the medical profession, and further the state interest in protecting public health and lowering the cost of health care. The legislature intends to regulate the license, transfer, use, or sale of prescriber-identifiable data only for commercial purposes by pharmacies and other similar entities. The intent is not to regulate non-commercial uses, such as reimbursement, quality control, and research. .

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

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

"Prescriber-identifiable data", information that can be used to directly or indirectly identify the prescriber, including, but not limited to, a prescriber's name, address, telephone number, facsimile number, electronic mail address, photograph or likeness, account number, social security number, National Provider Identifier (NPI) or any other unique number, characteristic, code or information which is likely to lead to the identification of the patient or prescriber.

"Commercial purpose", includes, but is not limited to,

23 (1) advertising, marketing, promoting, or any activity that could be used to influence
24 sales or market share of a pharmaceutical product;

25 (2) influencing or evaluating the prescribing behavior of an individual prescriber;

26 (3) evaluating the effectiveness of a professional pharmaceutical detailing sales force;

27

28 "Person", any business, individual, corporation, union, association, firm, partnership,
29 committee, or other organization or group of persons.

30 "Pharmacy", a facility under the direction or supervision of a registered pharmacist which
31 is authorized in Massachusetts to dispense pharmaceuticals including, but not limited to, retail
32 drug business as defined in Section 1 of Chapter 94C, mail order or Internet pharmacy, pharmacy
33 benefits manager, insurance company, electronic transmission intermediary, or other similar
34 entities.

35 "Prescriber", a person who is licensed, registered or otherwise authorized to prescribe and
36 administer drugs in the course of professional practice in Massachusetts.

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

40 (b) No pharmacy shall license, use, sell, or transfer for any commercial purpose,
41 prescriber-identifiable data.

42 (c) Nothing in this section shall prohibit a pharmacy from collecting, licensing, using,
43 selling, or transferring data for commercial purposes if the data is de-identified and aggregated
44 into categories, including, but not limited to, zip code, geographic region, or medical purposes.

45 (d) Nothing in this section shall prohibit a pharmacy from licensing, using, selling,
46 transferring, or collecting prescriber-identifiable information for non-commercial purposes,
47 including, but not limited to,

48 (i) pharmacy reimbursement, prescription drug formulary or prior authorization
49 compliance;

50 (ii) the dispensing of prescription medications to a patient or to the patient's authorized
51 representative;

52 (iii)the transfer of information to the patient or patient's authorized representative;

53 (iv) health care research, including, but not limited to, bona fide clinical trials, product
54 safety studies, and utilization reviews;

55 (v) transfer of prescription records that may occur when a pharmacy's ownership is
56 changed or transferred or between licensed pharmacies;

57 (vi) care management educational communications provided to a patient about the
58 patient's health condition;

59

60 (e) Nothing in this section shall be interpreted to regulate conduct that takes place
61 wholly outside of the commonwealth.

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

65 (g) Whoever violates any provision of this section shall be punished by imprisonment for
66 not more than two and one half years in a house of correction, or by a fine of not less than twenty
67 thousand dollars, or by both such fine and imprisonment. Whoever violates any provision of this
68 section after one or more prior convictions of a violation of this section shall be punished by
69 imprisonment in the state prison for not more than 10 years, or by a fine of not more than thirty
70 thousand dollars or by both such fine and imprisonment.

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

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

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