HOUSE DOCKET, NO. 1764 FILED ON: 1/20/2011

HOUSE . . . . . No. 1521

The Commonwealth of Massachusetts

PRESENTED BY:

Jeffrey Sánchez

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 to ensure transparency in prescription drug practices in the Commonwealth.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Jeffrey Sánchez	*15th Suffolk*
Jason M. Lewis	*31st Middlesex*
Bruce E. Tarr	☐ *[District]* ☐
John W. Scibak	*2nd Hampshire*

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HOUSE . . . . . No. 1521

By Mr. Sánchez of Boston, a petition (accompanied by bill, House, No. 1521) of Jeffrey Sánchez and others for legislation to ensure transparency in prescription drug practices. Public Health.

The Commonwealth of Massachusetts

An Act to ensure transparency in prescription drug practices in the Commonwealth.

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. Purpose.

It is the intent of the legislature to ensure transparency in contracts and in prescription drug pricing, fair dealing between pharmacy benefit managers and their clients, and protection of consumers, including health plans and insurers by regulating the trade practices of pharmacy benefit managers in the commonwealth.

Section 2. Definitions. For the purposes of this chapter:

(a) "Covered entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization licensed pursuant to the health insurance laws of the commonwealth; a health program administered by the commonwealth in the capacity of provider of health coverage; or an employer, labor union or other group of persons organized in the commonwealth that provides health coverage to covered individuals who are employed or reside in the commonwealth. "Covered entity" does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long-term care or other limited benefit health insurance policies and contracts.

(b) “Covered individual” means a member, participant, enrollee, contract holder or policy holder or beneficiary of a covered entity who is provided health coverage by the covered entity and includes a dependent or other person provided health coverage through a policy, contract or plan for a covered individual.

(c) "Generic drug" means a chemically equivalent copy of a brand-name drug with an expired patent.

22 (d) “Individual identifying information” means information which directly or indirectly
23 identifies a prescriber or a patient, where the information is derived from or relates to a
24 prescription for any prescribed product.

25 (e) "Labeler" means an entity or person that receives prescription drugs from a
26 manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler
27 code from the federal Food and Drug Administration under 21 Code of Federal Regulations,
28 270.20 (1999).

29 (f) “Marketing” means any activity by a pharmacy benefit manager, alone or in
30 collaboration with a company making or selling prescribed products, which is intended to
31 influence prescribing or purchasing choices of the products, including but not limited to:

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

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

35 (3) planning the substance of a sales representative visit or communication or the
36 substance of an advertisement or other promotional message or document;

37 (4) evaluating or compensating sales representatives;

38 (5) identifying individuals to receive any form of gift, product sample, consultancy, or
39 any other item, service, compensation or employment of value;

40 (6) advertising or promoting prescribed products directly to patients, including through
41 refill reminders or information about alternative products.

42 (g) "Pharmacy benefits management" means the procurement of prescription drugs at a
43 negotiated rate for dispensation within the commonwealth to covered individuals, the
44 administration or management of prescription drug benefits provided by a covered entity for the
45 benefit of covered individuals or any of the following services provided with regard to the
46 administration of pharmacy benefits:

47 (1) Mail service pharmacy;

48 (2) Claims processing, retail network management and payment of claims to pharmacies
49 for prescription drugs dispensed to covered individuals;

50 (3) Clinical formulary development and management services;

51 (4) Rebate contracting and administration;

52 (5) Certain patient compliance, therapeutic intervention and generic substitution
53 programs; and

54 (6) Disease management programs

55 (h) "Pharmacy benefits manager" means an entity that performs pharmacy benefits
56 management. "Pharmacy benefits manager" includes a person or entity acting for a pharmacy
57 benefits manager in a contractual or employment relationship in the performance of pharmacy
58 benefits management for a covered entity and includes mail service pharmacy.

59 (i) “Prescribed product” includes a biological product as defined in section 351 of the
60 Public Health Service Act, 42 U.S.C. §262 and a device or a drug as defined in section 201 of the
61 Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321.

62 Section 3. Registration of Pharmacy Benefit Managers.

63 (a) A pharmacy benefit manager shall not do business in the commonwealth without first
64 registering with the board of registration in pharmacy on a form and in a manner prescribed by
65 the board of registration in pharmacy.

66 (b) Each pharmacy benefit manager shall pay a registration fee of $3,000.00. Fees
67 collected under this section shall fund the costs of registration by the board of registration in
68 pharmacy and enforcement of this chapter by the attorney general’s office.

69 (c) Compliance with the requirements of this chapter is required for pharmacy benefit
70 managers entering into contracts with a covered entity for pharmacy benefit management in the
71 commonwealth.

72 Section 4. Fiduciary Duty.

73 (a) A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall
74 discharge that duty in accordance with the provisions of state and federal law.

75 (b) A pharmacy benefits manager shall perform its duties with care, skill, prudence and
76 diligence and in accordance with the standards of conduct applicable to a fiduciary in an
77 enterprise of a like character and with like aims.

78 (c) A pharmacy benefits manager shall notify the covered entity in writing of any
79 activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents
80 any conflict of interest with the duties imposed by this section.

81 (d) Covered entities shall have the right to terminate contracts without cause.

82 (e) A pharmacy benefit manager shall provide notice to the covered entity of its rights
83 under this chapter.

84 Section 5. Transparency.

85 (a) A pharmacy benefits manager shall provide to a covered entity all financial and
86 utilization information requested by the covered entity relating to the provision of benefits to
87 covered individuals through that covered entity and all financial and utilization information
88 relating to services to that covered entity. The parties' contract shall specify which third-party
89 entity's database the pharmacy benefits manager contractors must use when calculating the drug
90 costs billed under the contract, the maximum allowable cost applicable to the covered entity, the
91 methodology for calculating rebate amounts, and identify specialty drugs and the pricing
92 mechanism for these drugs.

93 (b) A pharmacy benefits manager shall disclose to the covered entity all financial terms
94 and arrangements for remuneration of any kind that apply between the pharmacy benefits
95 manager and any prescription drug manufacturer or labeler, including, without limitation,
96 formulary management and drug-substitution programs, educational support, claims processing
97 and pharmacy network fees that are charged from retail pharmacies and data sales fees.

98 (c) A pharmacy benefits manager providing information under this section may designate
99 that material as confidential. Information designated as confidential by a pharmacy benefits
100 manager and provided to a covered entity under this paragraph may not be disclosed by the
101 covered entity to any person without the consent of the pharmacy benefits manager, except that
102 disclosure may be made in a court filing, ordered by a court of the commonwealth for good cause
103 shown, or made in a court filing under seal until otherwise ordered by a court.

104 (d) Nothing in this section limits the attorney general's authority under state law
105 including, but not limited to, chapter 93A, to investigate violations of this section.

106 Section 6. Prescription Drug Substitutions and Formulary Management.

107 (a) The following provisions apply to the dispensation of a prescription drug substituted
108 for a prescribed drug to a covered individual:

109 (1) If a pharmacy benefits manager makes a substitution in which the substitute drug
110 costs more than the prescribed drug, the pharmacy benefits manager shall disclose to the
111 covered entity the cost of both drugs and any benefit or payment directly or indirectly accruing to
112 the pharmacy benefits manager as a result of the substitution; and

113 (2) The pharmacy benefits manager shall transfer in full to the covered entity any benefit
114 or payment received in any form by the pharmacy benefits manager either as a result of a
115 prescription drug substitution under subsection (1) or as a result of the pharmacy benefits
116 manager substituting a lower priced generic and therapeutically equivalent drug for a higher
117 priced prescribed drug.

118 (b) Pharmacy benefit managers shall notify a covered entity 10 days in advance of any
119 changes to the entity's drug formulary or preferred drug list, except in case of emergency recall

120 of a drug. Pharmacy benefit managers shall provide the covered entity an explanation for the
121 changes, including but not limited to the medical and financial reasons for the addition, removal,
122 or change in a drug on the formulary or preferred drug list.

123 Section 7. Sales Volume Discounts. A pharmacy benefits manager that derives any
124 payment or benefit for the dispensation of prescription drugs within the commonwealth based on
125 volume of sales for certain prescription drugs or classes or brands of drugs within the
126 commonwealth shall pass that payment or benefit on in full to the covered entity.

127 Section 8. Privacy Protections.

128 (a) In addition to the disclosure and privacy provisions of the Health Insurance
129 Portability and Accountability Act of 1996, a pharmacy benefit manager shall not knowingly
130 disclose or use records containing individual identifying information for marketing a prescribed
131 product to a patient or prescriber.

132 (b) This section shall not prevent a pharmacy benefit manager from disclosing individual
133 identifying information to the identified individual as long as the information does not include
134 protected information pertaining to any other person.

135 Section 9. Audits.

136 (a) Upon request, pharmacy benefit managers shall allow access by the covered entity,
137 the covered entity's agent, or the state auditor to the pharmacy benefit managers and its
138 contractors' facilities and all financial and contractual information necessary to conduct a
139 complete and independent audit designed to verify costs and discounts associated with drug
140 claims, pharmacy benefit manager contractor compliance with the contract requirements, and
141 services provided by subcontractors, including, but not limited to:

142 (1) the drug prices and rebates received from a pharmaceutical manufacturer associated
143 with all drugs dispensed to covered individuals of the covered entity in both retail and mail order
144 settings or resulting from any of the pharmacy benefit management functions defined in the
145 contract;

146 (2) the drug prices and rebates provided by the pharmacy benefit manager to the covered
147 entity associated with all drugs dispensed to covered individuals in both retail and mail order
148 settings or resulting from any of the pharmacy benefit management functions defined in the
149 contract;

150 (3) all other fees charged or financial remuneration received by the pharmacy benefit
151 manager associated with all drugs dispensed to covered individuals of the covered entity in both
152 retail and mail order settings or resulting from any of the pharmacy benefit management
153 functions defined in the contract, including rebates from pharmaceutical manufacturers; and

154 (4) the full benefits of the pricing arrangements and activities of the pharmacy benefit
155 manager required by the contract.

156 (b) Every contract shall define the reporting requirements for audits that a pharmacy
157 benefit manager contractors performs concerning the conduct of the pharmacy network,
158 including what information should be reported, how often audit results should be reported, and
159 require the pharmacy benefit manager contractor to return recovered overpayments to the
160 covered entity.

161 (c) All audits performed under this section shall comply with auditing standards to
162 ensure the business processes and activities related to the audit objectives are reviewed and
163 tested for compliance and reliability and that there is sufficient, appropriate evidence captured to
164 support the audit's findings and conclusions.

165 (d) "Financial and contractual information" includes, but is not limited to, financial
166 records, contracts, medical records, agreements, and relationships with subcontractors.

167 Section 10. Enforcement.

168 (a) In addition to any other remedy provided by law, a violation of this chapter shall be a
169 violation of section 2 of chapter 93A as an unfair or deceptive act in trade or commerce and may
170 be enforced by the attorney general acting on behalf of the commonwealth, or by an individual.
171 All rights, authority, and remedies available to the attorney general and private parties to enforce
172 the unfair trade practices act shall be available to enforce the provisions of this subchapter.

173 (b) Any person who knowingly fails to comply with the requirements of this chapter or
174 rules adopted pursuant to this chapter shall be subject to a fine of not more than $50,000.00 per
175 violation. Each failure to disclose shall constitute a violation. The office of the attorney general
176 shall take necessary action to enforce payment of penalties assessed under this section.

177 Section 11. Rules. The board of registration in pharmacy shall make rules for the
178 implementation of this chapter.

179 Section 12. Severability. If any provision of this act or its application to any person or
180 circumstance is held invalid, the remainder of the act or the application of the provision to other
181 persons or circumstances is not affected.

182 Section 13. Application. This act applies to contracts executed or renewed on or after
183 July 1, 2010. For purposes of this section, a contract executed pursuant to a memorandum of
184 agreement executed prior to July 1, 2010 is deemed to have been executed prior to July 1, 2010
185 even if the contract was executed after that date