

HOUSE No. 01521

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 bill:

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

PETITION OF:

NAME:	DISTRICT/ADDRESS:
<i>Jeffrey Sánchez</i>	<i>15th Suffolk</i>
<i>Jason M. Lewis</i>	<i>31st Middlesex</i>
<i>Bruce E. Tarr</i>	<i>First Essex and Middlesex</i>
<i>John W. Scibak</i>	<i>2nd Hampshire</i>

HOUSE No. 01521

By Mr. Jeffrey Sánchez of Boston, petition (accompanied by bill, House, No. 01521) of Jeffrey Sánchez and others for legislation to ensure transparency in prescription drug practices.. Joint Committee on Public Health.

The Commonwealth of Massachusetts

In the Year Two Thousand Eleven

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:

1 Section 1. Purpose.

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

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

7 (a) "Covered entity" means a nonprofit hospital or medical service organization, insurer, health
8 coverage plan or health maintenance organization licensed pursuant to the health insurance laws
9 of the commonwealth; a health program administered by the commonwealth in the capacity of
10 provider of health coverage; or an employer, labor union or other group of persons organized in
11 the commonwealth that provides health coverage to covered individuals who are employed or

12 reside in the commonwealth. "Covered entity" does not include a health plan that provides
13 coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement,
14 disability income, long-term care or other limited benefit health insurance policies and contracts.

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

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

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

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

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

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

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

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

35 (4) evaluating or compensating sales representatives;

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

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

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

45 (1) Mail service pharmacy;

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

48 (3) Clinical formulary development and management services;

49 (4) Rebate contracting and administration;

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

51 (6) Disease management programs

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

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

59 Section 3. Registration of Pharmacy Benefit Managers.

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

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

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

69 Section 4. Fiduciary Duty.

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

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

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

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

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

81 Section 5. Transparency.

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

90 (b) A pharmacy benefits manager shall disclose to the covered entity all financial terms and
91 arrangements for remuneration of any kind that apply between the pharmacy benefits manager
92 and any prescription drug manufacturer or labeler, including, without limitation, formulary

93 management and drug-substitution programs, educational support, claims processing and
94 pharmacy network fees that are charged from retail pharmacies and data sales fees.

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

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

103 Section 6. Prescription Drug Substitutions and Formulary Management.

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

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

110 (2) The pharmacy benefits manager shall transfer in full to the covered entity any benefit or
111 payment received in any form by the pharmacy benefits manager either as a result of a
112 prescription drug substitution under subsection (1) or as a result of the pharmacy benefits

113 manager substituting a lower priced generic and therapeutically equivalent drug for a higher
114 priced prescribed drug.

115 (b) Pharmacy benefit managers shall notify a covered entity 10 days in advance of any changes
116 to the entity's drug formulary or preferred drug list, except in case of emergency recall of a drug.
117 Pharmacy benefit managers shall provide the covered entity an explanation for the changes,
118 including but not limited to the medical and financial reasons for the addition, removal, or
119 change in a drug on the formulary or preferred drug list.

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

124 Section 8. Privacy Protections.

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

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

132 Section 9. Audits.

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

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

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

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

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

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

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

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

161 Section 10. Enforcement.

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

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

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

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

176 Section 13. Application. This act applies to contracts executed or renewed on or after July 1,
177 2010. For purposes of this section, a contract executed pursuant to a memorandum of agreement
178 executed prior to July 1, 2010 is deemed to have been executed prior to July 1, 2010 even if the
179 contract was executed after that date