

SENATE No. 00280

The Commonwealth of Massachusetts

PRESENTED BY:

Mark C. Montigny

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 protect against unfair prescription drug practices..

PETITION OF:

NAME:

Mark C. Montigny

DISTRICT/ADDRESS:

Second Bristol and Plymouth

SENATE No. 00280

By Mr. Montigny, a petition (accompanied by bill, Senate, No. 280) of Mark C. Montigny for legislation to protect against unfair prescription drug practices. [Public Health]

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE
□ SENATE
□ , NO. 316 OF 2009-2010.]

The Commonwealth of Massachusetts

In the Year Two Thousand Eleven

An act to protect against unfair prescription drug practices..

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,
8 insurer, health coverage plan or health maintenance organization licensed pursuant to the health

9 insurance laws of the commonwealth; a health program administered by the commonwealth in
10 the capacity of provider of health coverage; or an employer, labor union or other group of
11 persons organized in the commonwealth that provides health coverage to covered individuals
12 who are employed or reside in the commonwealth. "Covered entity" does not include a health
13 plan that provides coverage only for accidental injury, specified disease, hospital indemnity,
14 Medicare supplement, disability income, long-term care or other limited benefit health insurance
15 policies and contracts.?

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

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

22 (d) ?Individual identifying information? means information which directly or
23 indirectly 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
33 product;

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

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

39 (4) evaluating or compensating sales representatives;

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

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

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

49 (1) Mail service pharmacy;

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

52 (3) Clinical formulary development and management services;

53 (4) Rebate contracting and administration;

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

56 (6) Disease management programs.

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

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

64 Section 3. Registration of Pharmacy Benefit Managers.

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

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

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

74 Section 4. Fiduciary Duty.

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

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

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

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

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

86 Section 5. Transparency.

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

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

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

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

108 Section 6. Prescription Drug Substitutions and Formulary Management.

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

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

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

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

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

129 Section 8. Privacy Protections.

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

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

137 Section 9. Audits.

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

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

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

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

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

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

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

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

170 Section 10. Enforcement.

171 (a) In addition to any other remedy provided by law, a violation of this chapter shall
172 be a violation of section 2 of chapter 93A as an unfair or deceptive act in trade or commerce and

173 may be enforced by the attorney general acting on behalf of the commonwealth, or by an
174 individual. All rights, authority, and remedies available to the attorney general and private
175 parties to enforce the unfair trade practices act shall be available to enforce the provisions of this
176 subchapter.

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

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

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

186 Section 13. Application. This act applies to contracts executed or renewed on or after
187 July 1, 2009. For purposes of this section, a contract executed pursuant to a memorandum of
188 agreement executed prior to July 1, 2009 is deemed to have been executed prior to July 1, 2009
189 even if the contract was executed after that date.