

SENATE No.

The Commonwealth of Massachusetts

PRESENTED BY:

Montigny, Mark (SEN)

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:

Montigny, Mark (SEN)

DISTRICT/ADDRESS:

Second Bristol and Plymouth

The Commonwealth of Massachusetts

In the Year Two Thousand and Nine

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, insurer,
8 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 policy
17 holder or beneficiary of a covered entity who is provided health coverage by the covered entity
18 and includes a dependent or other person provided health coverage through a policy, contract or
19 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 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;

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

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

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41 (4) evaluating or compensating sales representatives;

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

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

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

53 (1) Mail service pharmacy;

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

56 (3) Clinical formulary development and management services;

57 (4) Rebate contracting and administration;

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

60 (6) Disease management programs.

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

65 (i) "Prescribed product" includes a biological product as defined in section 351 of the
66 Public Health Service Act, 42 U.S.C. §262 and a device or a drug as defined in section 201 of the
67 Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321.
68

69 **Section 3. Registration of Pharmacy Benefit Managers.**

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

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

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

79 **Section 4. Fiduciary Duty.**

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

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

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

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

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

91 **Section 5. Transparency.**

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

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

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

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

113 **Section 6. Prescription Drug Substitutions and Formulary Management.**

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

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

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

123 pharmacy benefits manager substituting a lower priced generic and therapeutically
124 equivalent drug for a higher priced prescribed drug.

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

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

135 **Section 8. Privacy Protections.**

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

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

143 **Section 9. Audits.**

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

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

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

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

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

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

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

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

175 **Section 10. Enforcement.**

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

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

186 **Section 11. Rules.** The board of registration in pharmacy shall make rules for the
187 implementation of this chapter.

188 **Section 12. Severability.** If any provision of this act or its application to any person or
189 circumstance is held invalid, the remainder of the act or the application of the provision to other
190 persons or circumstances is not affected.

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192 **Section 13. Application.** This act applies to contracts executed or renewed on or after July 1,
193 2009. For purposes of this section, a contract executed pursuant to a memorandum of agreement

194 executed prior to July 1, 2009 is deemed to have been executed prior to July 1, 2009 even if the
195 contract was executed after that date.