SENATE DOCKET, NO. 1262 FILED ON: 1/20/2011

SENATE . . . . . No. 280

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:

An act to protect against unfair prescription drug practices.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Mark C. Montigny	
	☐ *[District]*
	☐

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SENATE . . . . . No. 280

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

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

The Commonwealth of Massachusetts

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:

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

18 covered entity and includes a dependent or other person provided health coverage through a
19 policy, contract or plan for a covered individual.

20 (c) "Generic drug" means a chemically equivalent copy of a brand-name drug
21 with an 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
33 a 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
38 communication 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
41 sample, 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
45 drugs at 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
51 claims 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
58 benefits management. "Pharmacy benefits manager" includes a person or entity acting for a
59 pharmacy benefits manager in a contractual or employment relationship in the performance of
60 pharmacy benefits management for a covered entity and includes mail service pharmacy.

61 (i) ?Prescribed product? includes a biological product as defined in section
62 351 of the Public Health Service Act, 42 U.S.C. ?262 and a device or a drug as defined in section
63 201 of the 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
66 without first registering with the board of registration in pharmacy on a form and in a manner
67 prescribed by the board of registration in pharmacy.

68 (b) Each pharmacy benefit manager shall pay a registration fee of $3,000.00.
69 Fees 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
72 benefit managers entering into contracts with a covered entity for pharmacy benefit management
73 in the commonwealth.

74 Section 4. Fiduciary Duty.

75 (a) A pharmacy benefits manager owes a fiduciary duty to a covered entity and
76 shall 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,
78 prudence and diligence and in accordance with the standards of conduct applicable to a fiduciary
79 in an enterprise of a like character and with like aims.

80 (c) A pharmacy benefits manager shall notify the covered entity in writing of
81 any activity, policy or practice of the pharmacy benefits manager that directly or indirectly
82 presents 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
85 its rights under this chapter.

86 Section 5. Transparency.

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

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

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

110 Section 6. Prescription Drug Substitutions and Formulary Management.

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

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

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

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

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

132 Section 8. Privacy Protections.

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

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

140 Section 9. Audits.

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

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

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

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

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

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

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

171 (d) ?Financial and contractual information? includes, but is not limited to,
172 financial records, contracts, medical records, agreements, and relationships with subcontractors.

173 Section 10. Enforcement.

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

180 (b) Any person who knowingly fails to comply with the requirements of this
181 chapter or rules adopted pursuant to this chapter shall be subject to a fine of not more than

182 $50,000.00 per violation. Each failure to disclose shall constitute a violation. The office of the
183 attorney general shall take necessary action to enforce payment of penalties assessed under this
184 section.

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

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

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