

**SENATE . . . . . No. 316**

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**The Commonwealth of Massachusetts**

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**In the Year Two Thousand Nine**  
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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  
3 drug 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;

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  
119 any changes to the entity's drug formulary or preferred drug list, except in case of emergency  
120 recall of a drug. Pharmacy benefit managers shall provide the covered entity an explanation for  
121 the changes, including but not limited to the medical and financial reasons for the addition,  
122 removal, 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  
143 associated with all drugs dispensed to covered individuals of the covered entity in both retail and  
144 mail order settings or resulting from any of the pharmacy benefit management functions defined  
145 in the contract;

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

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



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

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

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

168 Section 10. Enforcement.

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

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

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

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

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