

Pharmacy Benefits Managers Registration

Pharmacy Benefits Managers (PBMs) are businesses that administer and manage prescription drug benefit plans either through health insurance products or separately. Approximately 95 percent of all patients with prescription drug coverage receive benefits through a PBM. In recent years, concerns have been raised by consumer organizations and states regarding the business practices of PBMs. Some of these business practices, such as switching patients from one brand-name drug to another brand-name drug, led to multistate settlement agreements between PBMs and state attorney generals. Demands for greater transparency in financial relationships between PBMs and drug manufacturers have prompted states to propose regulation of PBM activities.

This draft legislation requires a PBM to register with the state Insurance Commissioner before providing pharmacy benefits management services in the state. Registration is effective for two years and may be renewed for an additional two years. Subject to hearing provisions, the Insurance Commissioner may deny, suspend, revoke, or refuse to renew a registration under specified circumstances. The Insurance Commissioner is authorized to assess a civil penalty of up to \$10,000 against any person that violates the registration requirements or require PBMs that violate the Act to cease and desist; take specific affirmative corrective action; or make restitution of money, property, or other assets. A PBM may not ship, mail, or deliver drugs or devices to a person in the state through a non-resident pharmacy unless the non-resident pharmacy holds a pharmacy permit from the state Board of Pharmacy. A PBM that is operating in the state on October 1, 2008, may continue to operate as a PBM if the PBM registers with the Insurance Commissioner by July 1, 2009, and complies with all other applicable registration provisions.

Submitted as:
Maryland
HB 419 (Chapter 202, 2008)
Status: Enacted into law in 2008.

Suggested State Legislation

(Title, enacting clause, etc.)

1 Section 1. [*Short Title.*] This Act shall be cited as “The Pharmacy Benefits Managers
2 Registration Act.”

3
4 Section 2. [*Definitions.*] As used in this Act:

5 (1) “Beneficiary” means an individual who receives prescription drug coverage or
6 benefits from a purchaser.

7 (2) “ERISA” has the meaning stated in [insert citation].

8 (3) “Nonprofit health maintenance organization” has the meaning stated in [insert
9 citation].

10 (4) (a) “Pharmacy benefits management services” means:

11 (i) the procurement of prescription drugs at a negotiated rate for
12 dispensation within the state to beneficiaries;

13 (ii) the administration or management of prescription drug coverage
14 provided by a purchaser for beneficiaries; and

15 (iii) any of the following services provided with regard to the
16 administration of prescription drug coverage:

- 17 I. mail service pharmacy;
- 18 II. claims processing, retail network management, and payment of
19 claims to pharmacies for prescription drugs dispensed to beneficiaries;
- 20 III. clinical formulary development and management services;
- 21 IV. rebate contracting and administration;
- 22 V. patient compliance, therapeutic intervention, and generic
23 substitution programs; or
- 24 VI. disease management programs.

25 (b) “Pharmacy benefits management services” does not include any service
26 provided by a nonprofit health maintenance organization that operates as a group model,
27 provided that the service:

- 28 (i) is provided solely to a member of the nonprofit health maintenance
29 organization; and
- 30 (ii) is furnished through the internal pharmacy operations of the nonprofit
31 health maintenance organization.

32 (5) “Pharmacy benefits manager” means a person that performs pharmacy benefits
33 management services.

34 (6) (a) “Purchaser” means the state employee and retiree health and welfare benefits
35 program, an insurer, a nonprofit health service plan, or a health maintenance organization that:

- 36 (i) provides prescription drug coverage or benefits in the state; and
- 37 (ii) enters into an agreement with a pharmacy benefits manager for the
38 provision of pharmacy benefits management services.

39 (b) “Purchaser” does not include a person that provides prescription drug
40 coverage or benefits through plans subject to ERISA and does not provide prescription drug
41 coverage or benefits through insurance, unless the person is a Multiple Employer Welfare
42 Arrangement as defined in § 514(B)(6)(A)(II) of ERISA.

43 44 Section 3. [*Registering Pharmacy Benefits Managers.*]

45 (A) A pharmacy benefits manager shall register with the [commissioner] as a pharmacy
46 benefits manager before providing pharmacy benefits management services in the state to
47 purchasers.

48 (B) An applicant for registration shall:

- 49 (1) file with the [commissioner] an application on the form that the
50 [commissioner] provides; and
- 51 (2) pay to the [commissioner] a registration fee set by the [commissioner].

52 (C) Subject to the provisions of section 5 of this Act, the [commissioner] shall register
53 each pharmacy benefits manager that meets the requirements of this section.

54 55 Section 4. [*Renewing a Pharmacy Benefits Manager’s Registration*]

56 (A) A pharmacy benefits manager registration expires on the anniversary date that occurs
57 on the date [2] years following the date the [commissioner] issued the registration, unless it is
58 renewed as provided under this section.

59 (B) A pharmacy benefits manager may renew its registration for an additional [2–year]
60 term, if the pharmacy benefits manager:

- 61 (1) otherwise is entitled to be registered;

62 (2) files with the [commissioner] a renewal application on the form that the
63 [commissioner] requires; and

64 (3) pays to the [commissioner] a renewal fee set by the [commissioner].

65 (C) An application for renewal of a pharmacy benefits manager registration shall be
66 considered made in a timely manner if it is postmarked on or before the date the pharmacy
67 benefits manager's registration expires.

68 (D) Subject to the provisions of section 5 of this Act, the [commissioner] shall renew the
69 registration of each pharmacy benefits manager that meets the requirements of this section.

70
71 Section 5. [*Denying Registration to a Pharmacy Benefits Manager Applicant.*]

72 (A) Subject to the hearing provisions of [insert citation], the [commissioner] may deny a
73 registration to a pharmacy benefits manager applicant or refuse to renew, suspend, or revoke the
74 registration of a pharmacy benefits manager if the pharmacy benefits manager, or an officer,
75 director, or employee of the pharmacy benefits manager:

76 (1) makes a material misstatement or misrepresentation in an application for
77 registration;

78 (2) fraudulently or deceptively obtains or attempts to obtain a registration;

79 (3) in connection with the administration of pharmacy benefits management
80 services, commits fraud or engages in illegal or dishonest activities; or

81 (4) violates any provision of this Act or a regulation adopted under this Act.

82 (B) This section does not limit any other regulatory authority of the [commissioner]
83 under this Act.

84
85 Section 6. [*Nonresident Pharmacies.*] A pharmacy benefits manager may not ship, mail,
86 or deliver prescription drugs or devices to a person in the state through a nonresident pharmacy
87 unless the nonresident pharmacy holds a permit issued in accordance with the provisions of
88 [insert citation].

89
90 Section 7. [*Auditing Pharmacy Benefits Managers.*]

91 (A) Whenever the [commissioner] considers it advisable, the [commissioner] may
92 examine the affairs, transactions, accounts, and records of a registered pharmacy benefits
93 manager.

94 (B) The examination shall be conducted in accordance with [insert citation].

95 (C) The expense of the examination shall be paid in accordance with [insert citation].

96 (D) The reports of the examination and investigation shall be issued in accordance with
97 [insert citation].

98
99 Section 8. [*Pharmacy Benefits Manager Bookkeeping and Record Keeping.*]

100 (A) A pharmacy benefits manager shall maintain adequate books and records about each
101 purchaser for which the pharmacy benefits manager provides pharmacy benefits management
102 services:

103 (1) in accordance with prudent standards of record keeping;

104 (2) for the duration of the agreement between the pharmacy benefits manager and
105 the purchaser; and

106 (3) for [3] years after the pharmacy benefits manager ceases to provide pharmacy
107 benefits management services for the purchaser.

108
109 Section 9. [*Penalties for Violating this Act.*]

110 (A) If the [commissioner] determines that a pharmacy benefits manager has violated any
111 provision of this Act or any regulation adopted under this Act the [commissioner] may issue an
112 order that requires the pharmacy benefits manager to:

- 113 (1) cease and desist from the identified violation and further similar violations;
114 (2) take specific affirmative action to correct the violation; or
115 (3) make restitution of money, property, or other assets to a person that has
116 suffered financial injury because of the violation.

117 (B) An order of the [commissioner] issued under this section may be served on a
118 pharmacy benefits manager that is registered under this Act in the manner provided in [insert
119 citation].

120 (C) An order of the [commissioner] issued under this section may be served on a
121 pharmacy benefits manager that is not registered under this Act in the manner provided in [insert
122 citation] for service on an unauthorized insurer that does an act of insurance business in the state.

123 (D) A request for a hearing on any order issued under this section does not stay that
124 portion of the order that requires the pharmacy benefits manager to cease and desist from
125 conduct identified in the order.

126 (E) The [commissioner] may file a petition in the [circuit court] of any county to enforce
127 an order issued under this section, whether or not a hearing has been requested or, if requested,
128 whether or not a hearing has been held.

129 (F) If the [commissioner] prevails in an action brought under this section, the
130 [commissioner] may recover, for the use of the state, reasonable attorney's fees and the costs of
131 the action.

132 (G) In addition to any other enforcement action taken by the [commissioner] under this
133 section, the [commissioner] may impose a civil penalty not exceeding [\$10,000] for each
134 violation of this Act.

135 (H) This section does not limit any other regulatory authority of the [commissioner]
136 under this Act.

137

138 Section 10. [*Purchasers.*] A purchaser may not enter into an agreement with a pharmacy
139 benefits manager that has not registered with the [commissioner].

140

141 Section 11. [*Exceptions to Registering A Pharmacy Benefits Manager.*] A person acting
142 as a pharmacy benefits manager in the state on the effective date of this Act may continue to act
143 as a pharmacy benefits manager in the state without being registered with the [commissioner], as
144 required under this Act, if the person registers with the [commissioner] on or before [insert date];
145 and complies with all other applicable provisions of this Act.

146

147 Section 12. [*Applicability of this Act to Health Maintenance Organizations.*] The
148 provisions of [insert sections] of this Act apply to health maintenance organizations.

149

150 Section 13. [*Severability.*] [Insert severability clause.]

151

152 Section 14. [*Repealer.*] [Insert repealer clause.]

153

154 Section 15. [*Effective Date.*] [Insert effective date.]