1	н. в. 2162
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3	(By Delegates Perdue and Hatfield)
4	[Introduced January 12, 2011; referred to the
5	Committee on Health and Human Resources then Finance.]
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L 0	A BILL to amend the Code of West Virginia, 1931, as amended, by
L1	adding thereto a new article, designated §33-25G-1, §33-25G-2,
L2	§33-25G-3, §33-25G-4, §33-25G-5, §33-25G-6, §33-25G-7, §33-
L3	25G-8, §33-25G-9, §33-25G-10, §33-25G-11, §33-25G-12, §33-25G-
L 4	13 and §33-25G-14, all relating to pharmacy benefit managers;
L 5	requiring licensure, providing requirements for license
L 6	application; defining terms; requiring certain disclosures;
L 7	establishing fees; requiring retention of records; providing
L 8	for annual statement; authorizing access to records;
L 9	establishing special revenue account; requiring certain
20	information be maintained as confidential; establishing
21	criminal and civil penalties for violations; authorizing
22	proposal of rules; requiring annual report to the Legislature
23	and Governor; and setting effective date.

24 Be it enacted by the Legislature of West Virginia:

- 1 That the Code of West Virginia, 1931, as amended, be amended
- 2 by adding thereto a new article, designated \$33-25G-1, \$33-25G-2,
- 3 §33-25G-3, §33-25G-4, §33-25G-5, §33-25G-6, §33-25G-7, §33-25G-8,
- 4 §33-25G-9, §33-25G-10, §33-25G-11, §33-25G-12, §33-25G-13 and §33-
- 5 25G-14, all to read as follows:
- 6 ARTICLE 25G. PHARMACY BENEFIT MANAGER LICENSING AND REGULATION.
- 7 §33-25G-1. Short title and purpose.
- 8 <u>(a) This article may be cited as the "Pharmacy Benefit Manager</u>
- 9 Licensing and Regulation Act."
- 10 (b) The purpose of this article is to establish standards and
- 11 criteria for the licensing and regulation of pharmacy benefit
- 12 managers. This article is designed to promote, preserve and
- 13 protect the public health, safety and welfare by and through
- 14 <u>licensing</u> and effective regulation of pharmacy benefit managers.
- 15 **§33-25G-2**. **Definitions**.
- As used in this article, unless the context otherwise
- 17 indicates, the following terms have the following meanings:
- 18 <u>(1) "Commissioner" means the In</u>surance Commissioner of West
- 19 Virginia;
- 20 (2) "Covered entity" means a nonprofit hospital or medical
- 21 service corporation, health insurer, health benefit plan or health
- 22 <u>maintenance organizati</u>on licensed pursuant to the provisions of
- 23 <u>article twenty-five-a of this chapter; a health</u> program
- 24 administered by the state in the capacity of provider of health

- 1 coverage; or an employer, labor union or other group of persons
- 2 organized in the state that provides health coverage to covered
- 3 individuals who are employed or reside in the state. "Covered
- 4 entity" does not include a self-funded plan that is exempt from
- 5 state regulation pursuant to the federal Employee Retirement Income
- 6 Security Act (ERISA), 29 U.S.C. §§1001 et seq., a health plan that
- 7 provides coverage only for accidental injury, specified disease,
- 8 hospital indemnity, Medicare supplement, disability income, long-
- 9 term care or other limited benefit health insurance policies and
- 10 contracts.
- 11 (3) "Covered person" means a member, participant, enrollee,
- 12 contract holder or policy holder or beneficiary of a covered entity
- 13 who is provided health coverage by the covered entity. "Covered
- 14 <u>individual</u>" includes a dependent or other person provided health
- 15 coverage through a policy, contract or plan for a covered
- 16 individual.
- 17 (4) "Pharmacy benefit management" means the procurement of
- 18 prescription drugs at a negotiated rate for dispensation within
- 19 this state to covered individuals, the administration or management
- 20 of prescription drug benefits provided by a covered entity for the
- 21 benefit of covered individuals or any of the following services
- 22 provided with regard to the administration of pharmacy benefits:
- 23 (A) Mail service pharmacy;
- 24 (B) Claims processing, retail network management and payment

- 1 of claims to pharmacies for prescription drugs dispensed to covered
- 2 individuals;
- 3 (C) Clinical formulary development and management services;
- 4 (D) Rebate contracting and administration;
- 5 (E) Certain patient compliance, therapeutic intervention and
- 6 generic substitution programs; and
- 7 <u>(F) Disease management programs.</u>
- 8 (5) "Pharmacy benefit manager" means an entity that performs
- 9 pharmacy benefit management. "Pharmacy benefit manager" includes
- 10 a person or entity acting for a pharmacy benefit manager in a
- 11 contractual or employment relationship in the performance of
- 12 pharmacy benefit management services, including mail service
- 13 pharmacy.
- 14 §33-25G-3. Applicability and scope.
- This article applies to a pharmacy benefit manager that
- 16 provides claims processing services, other prescription drug or
- 17 device services, or both, to covered persons who are residents of
- 18 this state.
- 19 §33-25G-4. Licensing requirement.
- 20 (a) A person or organization may not act or operate as a
- 21 pharmacy benefit manager in this state without obtaining a
- 22 certificate of licensure from the commissioner. Renewal of
- 23 certificates of licensure are required on an annual basis.
- 24 (b) Each person or organization seeking licensure shall file

- 1 an application, furnished by the commissioner, which shall include,
- 2 but is not limited to, the following:
- 3 (1) All basic organizational documents, including the articles
- 4 of incorporation, articles of association, bylaws, partnership
- 5 agreement, trade name certification, trust agreement, shareholder
- 6 agreement and other applicable documents, including amendments;
- 7 (2) The names, addresses, official positions and professional
- 8 qualifications of the individuals who are responsible for the
- 9 conduct of the affairs of the pharmacy benefit manager, including
- 10 all members of the board of directors, board of trustees, executive
- 11 committee, other governing board or committee, the principal
- 12 officers in the case of a corporation, the partners or members in
- 13 the case of a partnership or association and any other person who
- 14 exercises control or influence over the affairs of the pharmacy
- 15 benefit manager;
- 16 (3) Annual audited statements for the most recent year, or
- 17 other information the commissioner requires in order to review the
- 18 current financial condition of the applicant;
- 19 (4) If the applicant is not currently acting as a pharmacy
- 20 benefit manager, a statement of the amounts and sources of funds
- 21 available for organization expenses and the proposed arrangements
- 22 for reimbursement and compensation of incorporators for other
- 23 principals;
- 24 (5) The name and address of the agent for service of process

- 1 in the state;
- 2 (6) A detailed description of the claims processing services,
- 3 pharmacy services, insurance services, other prescription drug or
- 4 device services, audit procedures for network pharmacies or other
- 5 administrative services to be provided;
- 6 (7) Any other information the commissioner requires; and
- 7 (8) A filing fee of \$200.
- 8 (c) The applicant shall make available for inspection by the
- 9 commissioner, copies of all contracts with insurers, pharmaceutical
- 10 manufacturers or other persons using the services of the pharmacy
- 11 benefit manager for pharmacy benefit management services.
- 12 (d) The commissioner may withhold or revoke a license if it is
- 13 determined that the pharmacy benefit manager or any principal of
- 14 the manager is not financially sound or has had a license revoked
- 15 or denied for cause in any state.
- 16 (e) The commissioner may require a surety bond in an amount
- 17 and in a form as the commissioner considers appropriate to ensure
- 18 the financial solvency of the pharmacy benefit manager.
- 19 §33-25G-5. Disclosure of ownership or affiliation and certain
- agreements.
- 21 (a) Each pharmacy benefit manager shall disclose to the
- 22 commissioner any ownership interest or affiliation of any kind with
- 23 any insurance company responsible for providing benefits directly
- 24 or through reinsurance to any plan for which the pharmacy benefit

- 1 manager provides services or any parent companies, subsidiaries and
- 2 other entities or businesses relative to the provision of pharmacy
- 3 services, other prescription drug or device services or a
- 4 pharmaceutical manufacturer.
- 5 (b) A pharmacy benefit manager shall notify the commissioner
- 6 in writing within thirty days of any material change in its
- 7 <u>ownership.</u>
- 8 (c) A pharmacy benefit manager shall disclose the following
- 9 agreements, and any changes to the agreements, within thirty days
- 10 of the change:
- 11 (1) All incentive arrangement or programs such as rebates,
- 12 discounts, disbursements or any other similar financial program or
- 13 arrangement relating to income or consideration received or
- 14 negotiated, directly or indirectly, with any pharmaceutical
- 15 company, that relates to prescription drug or device services,
- 16 including at a minimum, information on the formula or other method
- 17 for calculation and amount of the incentive arrangements, rebates
- 18 or other disbursements, the identity of the associated drug or
- 19 device and the dates and amounts of the disbursements;
- 20 (2) Any agreement with a pharmaceutical manufacturer to share
- 21 manufacturer rebates and discounts with the pharmacy benefit
- 22 manager or to pay money or other economic benefits to the pharmacy
- 23 benefit manager;
- 24 (3) Any agreement or practice to bill a health plan for

- 1 prescription drugs at a cost higher than the pharmacy benefit
- 2 manager pays the pharmacy;
- 3 (4) Any agreement to share revenue with a mail order or
- 4 Internet pharmacy company; and
- 5 (5) Any agreement to sell prescription drug data including
- 6 data concerning the prescribing practices of the health care
- 7 providers in the state.
- 8 §33-25G-6. Maintenance of records; access; confidentiality;
- 9 financial examination.
- 10 (a) A pharmacy benefit manager shall maintain all books and
- 11 records of all transactions between the pharmacy benefit manager,
- 12 insurers and covered entities for three years beyond the
- 13 termination of the contract period, unless any other law prescribes
- 14 <u>a greater time period</u>.
- 15 (b) The pharmacy benefit manager shall give the commissioner
- 16 access to the books and records maintained by the pharmacy benefit
- 17 manager for the purposes of examination, audit and inspection.
- 18 (c) The commissioner may conduct examinations of any pharmacy
- 19 benefit manager in this state whenever the commissioner considers
- 20 it necessary to ensure an appropriate level of regulatory
- 21 oversight. The pharmacy benefit manager shall pay the cost of the
- 22 examination which shall be deposited into the special revenue fund,
- 23 created in section nine of this article, to provide all expenses
- 24 for the regulation under this article.

- 1 (d) In conducting examinations pursuant to this section, the
- 2 commissioner has the same powers set forth in subsection (h),
- 3 section nine, article two of this chapter.
- 4 §33-25G-7. Annual statement and filing fee required.
- 5 (a) Each pharmacy benefit manager with a license shall file
- 6 with the commissioner an annual audited statement on or before June
- 7 1 of each year. The statement shall be in the form and contain
- 8 information and material the commissioner prescribes and shall
- 9 include the filing fee of \$200. The statement must include the
- 10 total number of persons subject to management by the pharmacy
- 11 benefit manager during the previous year, or portion of the year,
- 12 and the dollar value of the claims processed.
- 13 (b) The statement shall disclose all incentive arrangements or
- 14 programs such as rebates, discounts, disbursements or any other
- 15 similar financial program or arrangement relating to income or
- 16 consideration received or negotiated, directly or indirectly, with
- 17 any pharmaceutical company, that relates to prescription drug or
- 18 device services, including at a minimum information on the formula
- 19 or other method for calculation and amount of the incentive
- 20 arrangements, rebates or other disbursements, the identity of the
- 21 associated drug or device and the dates and amounts of the
- 22 <u>disbursements.</u>
- 23 §33-25G-8. Confidentiality of submitted information.
- 24 Any information submitted in compliance with this article that

- 1 the pharmacy benefit manager believes is proprietary information
- 2 shall be clearly marked as such. The commissioner is only entitled
- 3 to disclose that information in accordance with state and federal
- 4 law.
- 5 §33-25G-9. Special revenue account.
- 6 There is created in the State Treasury a special revenue
- 7 account, designated the "Pharmacy Benefit Managers Licensure Fund",
- 8 which is an interest bearing account and may be invested in the
- 9 manner permitted by the provisions of article six, chapter twelve
- 10 of this code, with the interest income a proper credit to the fund.
- 11 The account shall contain any funds received by the commissioner
- 12 pursuant to this article and any funds appropriated by the
- 13 Legislature. The commissioner may expend funds received in the
- 14 Pharmacy Benefit Managers Licensure Fund only for the purposes of
- 15 administration of this article.
- 16 §33-25G-10. Unauthorized business.
- 17 The unauthorized conduct of the business of a pharmacy benefit
- 18 manager shall be treated as unauthorized insurance business and is
- 19 subject to the same criminal and civil penalties as provided in
- 20 article forty-four of this chapter for violation of the
- 21 unauthorized insurers act.
- 22 **§33-25G-11**. **Violations**.
- 23 The provisions of section eleven, article three of this
- 24 chapter apply to any violations of this article by a pharmacy

- 1 benefit manager.
- 2 §33-25G-12. Promulgation of rules.
- 3 The commissioner may propose rules for legislative approval in
- 4 accordance with the provisions of article three, chapter twenty-
- 5 <u>nine-a of this code</u>, including emergency rules, pursuant to the
- 6 provisions of article three, chapter twenty-nine-a of this code to
- 7 implement the provisions of this article, and the rules may include
- 8 the establishment of fees.
- 9 §33-25G-13. Commissioner's reporting requirements.
- 10 On or before January 1, 2012, and every year after that, the
- 11 commissioner shall submit a report to the Legislature and the
- 12 Governor detailing the implementation of the licensure process and
- 13 the information collected. All information contained in the report
- 14 shall be de-identified or reported as aggregate data only. The
- 15 report shall include, but is not limited to, the following
- 16 information:
- 17 (1) The number of pharmacy benefit managers licensed in this
- 18 state;
- 19 (2) The number of persons in this state served by the pharmacy
- 20 benefit manager annually;
- 21 (3) The number of contracts to provide services in this state;
- 22 (4) The aggregate amount of rebates, discounts or
- 23 disbursements received from pharmaceutical manufacturers;
- 24 (5) The aggregate amount of rebates, discounts or

- 1 disbursements returned to the client; and
- 2 (6) Any other information the commissioner considers necessary
- 3 to report.
- 4 §33-25G-14. Effective date.
- 5 Any pharmacy benefit manager doing business within this state
- 6 shall obtain a license as required in section four of this article
- 7 within one hundred twenty days from the effective date of this
- 8 article.

NOTE: The purpose of this bill is to require the licensure of pharmacy benefit managers and to establish related regulatory requirements.

This article is new; therefore, it has been completely underscored.