

1 **H. B. 2331**

2
3 (By Delegate Perdue)

4 [Introduced February 13, 2013; referred to the
5 Committee on Health and Human Resources then Finance.]

6 **FISCAL**
7 **NOTE**

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9
10 A BILL to amend the Code of West Virginia, 1931, as amended, by
11 adding thereto a new article, designated §33-25H-1, §33-25H-2,
12 §33-25H-3, §33-25H-4, §33-25H-5, §33-25H-6, §33-25H-7,
13 §33-25H-8, §33-25H-9, §33-25H-10, §33-25H-11, §33-25H-12,
14 §33-25H-13 and §33-25H-14, all relating to creating the
15 "Pharmacy Benefit Manager Licensing and Regulation Act;"
16 establishing standards and criteria for the licensing and
17 regulation of pharmacy benefit managers; requiring a filing
18 fee; defining terms; requiring the disclosure of ownership or
19 affiliation and certain agreements; establishing fees;
20 requiring the retention of records; providing for annual
21 statements; authorizing access to records; establishing a
22 special revenue account designated the "Pharmacy Benefit
23 Managers Licensure Fund;" requiring certain information be
24 maintained as confidential; establishing criminal and civil

1 penalties, including felonies; authorizing rule-making;
2 requiring annual reports to the Legislature and Governor; and
3 setting an effective date.

4 *Be it enacted by the Legislature of West Virginia:*

5 That the Code of West Virginia, 1931, as amended, be amended
6 by adding thereto a new article, designated §33-25H-1, §33-25H-2,
7 §33-25H-3, §33-25H-4, §33-25H-5, §33-25H-6, §33-25H-7, §33-25H-8,
8 §33-25H-9, §33-25H-10, §33-25H-11, §33-25H-12, §33-25H-13 and
9 §33-25H-14, all to read as follows:

10 **ARTICLE 25H. PHARMACY BENEFIT MANAGER LICENSING AND REGULATION.**

11 **§33-25H-1. Short title and purpose.**

12 (a) This article may be cited as the "Pharmacy Benefit Manager
13 Licensing and Regulation Act."

14 (b) The purpose of this article is to establish standards and
15 criteria for the licensing and regulation of pharmacy benefit
16 managers. This article is designed to promote, preserve and protect
17 the public health, safety and welfare by and through licensing and
18 effective regulation of pharmacy benefit managers.

19 **§33-25H-2. Definitions.**

20 As used in this article, unless the context otherwise
21 indicates, the following terms have the following meanings:

22 (1) "Commissioner" means the Insurance Commissioner of West
23 Virginia;

1 (2) "Covered entity" means a nonprofit hospital or medical
2 service corporation, health insurer, health benefit plan or health
3 maintenance organization having been issued a certificate of
4 authority pursuant to article twenty-five-a of this chapter; a
5 health program administered by the state in the capacity of
6 provider of health coverage; or an employer, labor union or other
7 group of persons organized in the state that provides health
8 coverage to covered individuals who are employed or reside in the
9 state. "Covered entity" does not include a self-funded plan that is
10 exempt from state regulation pursuant to the federal Employee
11 Retirement Income Security Act (ERISA), 29 U.S.C. §1001 et seq., a
12 health plan that provides coverage only for accidental injury,
13 specified disease, hospital indemnity, Medicare supplement,
14 disability income, long-term care or other limited benefit health
15 insurance policies and contracts.

16 (3) "Covered person" or "covered individual" means a member,
17 participant, enrollee, contract holder or policy holder or
18 beneficiary of a covered entity who is provided health coverage by
19 the covered entity. "Covered individual" includes a dependent or
20 other person provided health coverage through a policy, contract or
21 plan for a covered individual.

22 (4) "Pharmacy benefit management" means the procurement of
23 prescription drugs at a negotiated rate for dispensation within
24 this state to covered individuals, the administration or management

1 of prescription drug benefits provided by a covered entity for the
2 benefit of covered individuals or any of the following services
3 provided with regard to the administration of pharmacy benefits:

4 (A) Mail service pharmacy;

5 (B) Claims processing, retail network management and payment
6 of claims to pharmacies for prescription drugs dispensed to covered
7 individuals;

8 (C) Clinical formulary development and management services;

9 (D) Rebate contracting and administration;

10 (E) Certain patient compliance, therapeutic intervention and
11 generic substitution programs; and

12 (F) Disease management programs.

13 (5) "Pharmacy benefit manager" means an entity that performs
14 pharmacy benefit management. "Pharmacy benefit manager" includes
15 a person or entity acting for a pharmacy benefit manager in a
16 contractual or employment relationship in the performance of
17 pharmacy benefit management services, including mail service
18 pharmacy.

19 **§33-25H-3. Applicability and scope.**

20 This article applies to a pharmacy benefit manager that
21 provides claims processing services, other prescription drug or
22 device services, or both, to covered persons who are residents of
23 this state.

24 **§33-25H-4. Licensing requirement.**

1 (a) A person or organization may not act or operate as a
2 pharmacy benefit manager in this state without obtaining a
3 certificate of licensure from the commissioner. Renewal of
4 certificates of licensure are required on an annual basis.

5 (b) Each person or organization seeking licensure shall file
6 an application, furnished by the commissioner, which shall include,
7 but is not limited to, the following:

8 (1) All basic organizational documents, including the articles
9 of incorporation, articles of association, bylaws, partnership
10 agreement, trade name certification, trust agreement, shareholder
11 agreement and other applicable documents, including amendments;

12 (2) The names, addresses, official positions and professional
13 qualifications of the individuals who are responsible for the
14 conduct of the affairs of the pharmacy benefit manager, including
15 all members of the board of directors, board of trustees, executive
16 committee, other governing board or committee, the principal
17 officers in the case of a corporation, the partners or members in
18 the case of a partnership or association and any other person who
19 exercises control or influence over the affairs of the pharmacy
20 benefit manager;

21 (3) Annual audited statements for the most recent year, or
22 other information the commissioner requires in order to review the
23 current financial condition of the applicant;

24 (4) If the applicant is not currently acting as a pharmacy

1 benefit manager, a statement of the amounts and sources of funds
2 available for organization expenses and the proposed arrangements
3 for reimbursement and compensation of incorporators for other
4 principals;

5 (5) The name and address of the agent for service of process
6 in the state;

7 (6) A detailed description of the claims processing services,
8 pharmacy services, insurance services, other prescription drug or
9 device services, audit procedures for network pharmacies or other
10 administrative services to be provided;

11 (7) Any other information the commissioner requires; and

12 (8) A filing fee of \$200.

13 (c) The applicant shall make available for inspection by the
14 commissioner, copies of all contracts with insurers, pharmaceutical
15 manufacturers or other persons using the services of the pharmacy
16 benefit manager for pharmacy benefit management services.

17 (d) The commissioner may withhold or revoke a license if it is
18 determined that the pharmacy benefit manager or any principal of
19 the manager is not financially sound or has had a license revoked
20 or denied for cause in any state.

21 (e) The commissioner may require a surety bond in an amount
22 and in a form as the commissioner considers appropriate to ensure
23 the financial solvency of the pharmacy benefit manager.

24 **§33-25H-5. Disclosure of ownership or affiliation and certain**

1 **agreements.**

2 (a) Each pharmacy benefit manager shall disclose to the
3 commissioner any ownership interest or affiliation of any kind with
4 any insurance company responsible for providing benefits directly
5 or through reinsurance to any plan for which the pharmacy benefit
6 manager provides services or any parent companies, subsidiaries and
7 other entities or businesses relative to the provision of pharmacy
8 services, other prescription drug or device services or a
9 pharmaceutical manufacturer.

10 (b) A pharmacy benefit manager shall notify the commissioner
11 in writing within thirty days of any material change in its
12 ownership.

13 (c) A pharmacy benefit manager shall disclose the following
14 agreements, and any changes to the agreements, within thirty days
15 of the change:

16 (1) All incentive arrangement or programs such as rebates,
17 discounts, disbursements or any other similar financial program or
18 arrangement relating to income or consideration received or
19 negotiated, directly or indirectly, with any pharmaceutical
20 company, that relates to prescription drug or device services,
21 including at a minimum, information on the formula or other method
22 for calculation and amount of the incentive arrangements, rebates
23 or other disbursements, the identity of the associated drug or
24 device and the dates and amounts of the disbursements;

1 (2) Any agreement with a pharmaceutical manufacturer to share
2 manufacturer rebates and discounts with the pharmacy benefit
3 manager or to pay money or other economic benefits to the pharmacy
4 benefit manager;

5 (3) Any agreement or practice to bill a health plan for
6 prescription drugs at a cost higher than the pharmacy benefit
7 manager pays the pharmacy;

8 (4) Any agreement to share revenue with a mail order or
9 Internet pharmacy company; and

10 (5) Any agreement to sell prescription drug data including
11 data concerning the prescribing practices of the health care
12 providers in the state.

13 **§33-25H-6. Maintenance of records; access; confidentiality;**
14 **financial examination.**

15 (a) A pharmacy benefit manager shall maintain all books and
16 records of all transactions between the pharmacy benefit manager,
17 insurers and covered entities for three years beyond the
18 termination of the contract period, unless any other law prescribes
19 a greater time period.

20 (b) The pharmacy benefit manager shall give the commissioner
21 access to the books and records maintained by the pharmacy benefit
22 manager for the purposes of examination, audit and inspection.

23 (c) The commissioner may conduct examinations of any pharmacy
24 benefit manager in this state whenever the commissioner considers

1 it necessary to ensure an appropriate level of regulatory
2 oversight. The pharmacy benefit manager shall pay the cost of the
3 examination which shall be deposited into the special revenue fund,
4 created in section nine of this article, to provide all expenses
5 for the regulation under this article.

6 (d) In conducting examinations pursuant to this section, the
7 commissioner has the same powers set forth in subsection (h),
8 section nine, article two of this chapter.

9 **§33-25H-7. Annual statement and filing fee required.**

10 (a) Each pharmacy benefit manager with a license shall file
11 with the commissioner an annual audited statement on or before June
12 1 of each year. The statement shall be in the form and contain
13 information and material the commissioner prescribes and shall
14 include the filing fee of \$200. The statement must include the
15 total number of persons subject to management by the pharmacy
16 benefit manager during the previous year, or portion of the year,
17 and the dollar value of the claims processed.

18 (b) The statement shall disclose all incentive arrangements or
19 programs such as rebates, discounts, disbursements or any other
20 similar financial program or arrangement relating to income or
21 consideration received or negotiated, directly or indirectly, with
22 any pharmaceutical company, that relates to prescription drug or
23 device services, including at a minimum information on the formula
24 or other method for calculation and amount of the incentive

1 arrangements, rebates or other disbursements, the identity of the
2 associated drug or device and the dates and amounts of the
3 disbursements.

4 **§33-25H-8. Confidentiality of submitted information.**

5 Any information submitted in compliance with this article that
6 the pharmacy benefit manager believes is proprietary information
7 shall be clearly marked as such. The commissioner is only entitled
8 to disclose that information in accordance with state and federal
9 law.

10 **§33-25H-9. Special revenue account.**

11 There is created in the State Treasury a special revenue
12 account, designated the "Pharmacy Benefit Managers Licensure Fund",
13 which is an interest bearing account and may be invested in the
14 manner permitted by article six, chapter twelve of this code, with
15 the interest income a proper credit to the fund. The account shall
16 contain any funds received by the commissioner pursuant to this
17 article and any funds appropriated by the Legislature. The
18 commissioner may expend funds received in the Pharmacy Benefit
19 Managers Licensure Fund only for the purposes of administration of
20 this article.

21 **§33-25H-10. Unauthorized business.**

22 The unauthorized conduct of the business of a pharmacy benefit
23 manager shall be treated as unauthorized insurance business and is
24 subject to the same criminal and civil penalties as provided in

1 article forty-four of this chapter for violation of the
2 unauthorized insurers act.

3 **§33-25H-11. Violations.**

4 Section eleven, article three of this chapter apply to any
5 violations of this article by a pharmacy benefit manager.

6 **§33-25H-12. Promulgation of rules.**

7 The commissioner may propose rules for legislative approval in
8 accordance with article three, chapter twenty-nine-a of this code,
9 including emergency rules, pursuant to article three, chapter
10 twenty-nine-a of this code to implement this article, and the rules
11 may include the establishment of fees.

12 **§33-25H-13. Commissioner's reporting requirements.**

13 On or before January 1, 2014, and every year after that, the
14 commissioner shall submit a report to the Legislature and the
15 Governor detailing the implementation of the licensure process and
16 the information collected. All information contained in the report
17 shall be identified or reported as aggregate data only. The report
18 shall include, but is not limited to, the following information:

19 (1) The number of pharmacy benefit managers licensed in this
20 state;

21 (2) The number of persons in this state served by the pharmacy
22 benefit manager annually;

23 (3) The number of contracts to provide services in this state;

24 (4) The aggregate amount of rebates, discounts or

1 disbursements received from pharmaceutical manufacturers;

2 (5) The aggregate amount of rebates, discounts or
3 disbursements returned to the client; and

4 (6) Any other information the commissioner considers necessary
5 to report.

6 **§33-25H-14. Effective date.**

7 Any pharmacy benefit manager doing business within this state
8 shall obtain a license as required in section four of this article
9 within one hundred twenty days from the effective date of this
10 article.

NOTE: The purpose of this bill is to create the "Pharmacy Benefit Manager Licensing and Regulation Act." The bill establishes standards and criteria for the licensing and regulation of pharmacy benefit managers. The bill requires a filing fee. The bill defines terms. The bill requires the disclosure of ownership or affiliation and certain agreements. The bill establishes fees. The bill requires retention of records. The bill provides for annual statements. The bill authorizes access to records. The bill establishes a special revenue account designated as the "Pharmacy Benefit Managers Licensure Fund." The bill requires certain information be maintained as confidential. The bill establishes criminal and civil penalties, including felonies. The bill authorizes rule-making. The bill requires annual reports be made to the Legislature and Governor. The bill sets an effective date.

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