

State Corporation Commission 2007 Fiscal Impact Statement

1. **Bill Number** HB1954

House of Origin Introduced Substitute Engrossed

Second House In Committee Substitute Enrolled

2. **Patron** Morgan

3. **Committee** Commerce and Labor

4. **Title** Pharmacy benefits managers; regulation thereof.

5. **Summary/Purpose:** Establishes requirements for the regulation of pharmacy benefits managers. The bill defines “pharmacy benefits management” as the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals, in the administration of pharmacy benefits including:

1. Mail order pharmacy;
2. Claims processing, retail pharmacy network management, and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;
3. Clinical formulary development and management services;
4. Rebate contracting and administration
5. Certain patient compliance, therapeutic intervention, and generic substitution programs; and
6. Disease management programs.

The bill defines “pharmacy benefit manager” as an entity that performs pharmacy benefits management and includes (i) a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefit management for a covered entity, and (ii) a mail service pharmacy owned or operated by a PBM. The bill establishes practices which require that PBMs (i) owe a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law; (ii) shall perform its duties with care, skill, prudence and diligence in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims; (iii) shall make prompt electronic payment of a clean claim within 15 days of receiving the clean claim from a pharmacy provider. The required practice mandates that the average number of days it takes the PBM to process and pay a clean claim from network retail community pharmacies shall not exceed the average number of days it takes the PBM to process and pay valid reimbursement claims received from a mail order pharmacy that is owned or operated by the PBM. The PBM’s records of payment shall be made available to the Commission upon request to determine compliance; (iv) shall notify the covered entity in writing of any activity, policy or practice of PBM that directly or indirectly presents a conflict of interests with the duties imposed by §38.2-3440; (v) a PBM shall provide to a covered entity all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity. A PBM providing information under this subsection may designate that material as confidential. Information designated as

confidential by a PBM and provided to a covered entity under this subsection shall not be disclosed by the covered entity to any person without consent of the PBM, except when the disclosure is ordered by a court of the Commonwealth for good cause shown or made in a court filing under seal unless otherwise ordered by a court. Nothing in this subsection shall limit the authority of the Commission to review such information pursuant to its investigative powers under this title and Title 12.1 to investigate violation of this article.

Requirements for dispensation of substitute prescription drugs for a prescribed drug to a covered individual are:

1. If a PBM makes a substitution in which the substitute drug costs the covered entity or the covered individual more than the prescribed drug, the PBM shall disclose to the covered entity the cost of both drugs and any benefit or payment directly or indirect accruing to the PBM as a result of the substitution.
2. The PBM shall transfer in full to the covered entity any benefit or payment received in any form by the PBM as a result of a prescription drug substitution under subdivision 1.
3. The PBM shall have any substitution approved by the original prescriber and shall notify the covered individual and the pharmacist at the pharmacy where the prescription is on file of the prescriber's authorization and approval of the substitution.

The bill establishes requirements for prompt payment of claims and disclosures and other contractual provisions between PBMs and pharmacy providers. A PBM shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the PBM and a prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing, and pharmacy network fees that are charged from retail pharmacies, and data sales fees; A PBM that derives a rebate, payment or benefit for the dispensation of prescription drugs within the Commonwealth based on sales, substitution, or prescribing for certain prescription drugs or classes or brands of drugs within the Commonwealth shall pass that payment or benefit on in full to the covered entity. A PBM providing information under this paragraph may designate that material as confidential. Information designated as confidential by a PBM that is provided to a covered entity under this paragraph may not be disclosed by the covered entity to any person without consent of the PBM, except when the disclosure is ordered by a court of the Commonwealth for good cause shown or made in a court filing under seal unless otherwise ordered by a court. Nothing in this paragraph shall limit the authority of the Commission to review such information pursuant to its investigative powers under this title and Title 12.1 to investigate violation of this section.

The bill does not apply to short-term travel, accident-only policies, short-term nonrenewable policies of not more than six months' duration, or where the policy subscription contract or health care plan does not include coverage for prescription drugs. PBMs shall, and contracts for pharmacy benefits management shall comply with the requirements of this article. Compliance with the requirements section is required in all contracts for pharmacy benefits management entered into in the Commonwealth or by a covered entity in the Commonwealth. The bill applies to contracts executed or renewed on or after July 1, 2007. A contract executed pursuant to a

memorandum of agreement executed prior to July 1, 2007 is considered to have been executed before July 1, 2007 even if the contract was executed after that date.

6. No Fiscal Impact on the State Corporation Commission

7. Budget amendment necessary: No

8. Fiscal implications: None on the State Corporation Commission

9. Specific agency or political subdivisions affected: State Corporation Commission Bureau of Insurance

10. Technical amendment necessary: Throughout proposed §§ 38.2-3441 and 38.2-3442, there are references to disclosures, notifications, or transfers from a PBM to a covered entity. There are no standards identifying when or how disclosures, notifications or transfers are to occur (i.e. monthly, quarterly, etc.). No parameters are included in the proposal. Section 38.2-3441 3 requires the PBM to “have any substitution approved by the original prescriber and shall notify the covered individual and the pharmacist at the pharmacy where the prescription is on file of the prescriber’s authorization and approval of the substitution.” The bill does not address emergency situations, nor does it address what happens when/if the “original prescriber” does not approve the substitution.

11. Other comments: The proposal is placed into Chapter 34 of Title 38.2 of the Code of Virginia. Chapter 34 is applicable to “insurance policies or contracts of the class described in 38.2-109” (accident and sickness insurance). This bill, however, is not directed at insurance policies or contracts; rather, it is directed at third parties (PBMs), and the contracts which they make with “covered entities” (defined in the bill as insurers, HMOs, health services plans, the state health plan, and employers, labor unions and organizations that provide health care coverage to covered individuals in the Commonwealth). The Bureau of Insurance suggested placement of the proposal within a separate chapter of Title 38.2. The Bureau advised the patron that if it was his intention for the Commission to exercise oversight as implied in the bill’s reference to “investigative powers.” an expansion of the bill to include a mechanism for identifying and examining PBMs would more effectively provide the Commission with the means to administer the bill’s provisions.

Under the current framework of this bill, the Commission would have no way of identifying PBMs operating in Virginia. A registration requirement similar to that which is applied to continuing care providers may be an effective means to address this concern (refer to §§ 38.2-4901 and 38.2-4902). While the bill addresses certain activities of PBMs that would be regulated, and also refers to the Commission’s investigative powers, it does not establish any requirements for the examinations of PBMs, a critical component in ensuring ongoing regulatory compliance. In the bill’s current form (placed within Chapter 34 of Title 38.2), the existing requirements for the examination of insurance companies would not apply to PBMs. A separate chapter within Title 38.2 with clear references within that chapter to the application of §§ 38.2-1317.1, 38.2-1318 and 38.2-1319, and inclusion of provisions similar to those found in Chapter 49 of Title 38.2 would address the Bureau’s concerns about the Commission’s ability to administer the bill. Chapter 49 is the chapter by which the Commission regulates continuing care retirement communities (CCRCs), which are registered as opposed to licensed by the Commission as would

be the case with PBMs. Applicable provisions of Chapter 49 concerning the promulgation of regulations, cease and desist orders, and penalties should also be included. Finally, by placing this legislation within its own new chapter (as opposed to Chapter 34), the PBMs essentially qualify as regulated entities, thereby subjecting the PBMs to the penalty provisions applicable to other entities regulated under Title 38.2 (refer to §§ 38.2-218 and 38.2-219), as well as general requirements relating to trade practices and claim settlements.

Date: 01/21 /07 / V. Tompkins

cc: Secretary of Commerce and Trade

Secretary of Health and Human Resources