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HOUSE BILL NO. 1954

Offered January 10, 2007

Prefiled January 5, 2007

A BILL to amend the Code of Virginia by adding in Chapter 34 of Title 38.2 an article numbered 6, consisting of sections numbered 38.2-3438 through 38.2-3443, relating to the regulation of pharmacy benefits managers.

Patron—Morgan

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 34 of Title 38.2 an article numbered 6, consisting of sections numbered 38.2-3438 through 38.2-3443 as follows:

Article 6.

Regulation of Pharmacy Benefits Managers.

§ 38.2-3438. Definitions.

As used in this article, unless the context indicates otherwise:

"Clean claim" has the same meaning ascribed to the term in subsection A of § 38.2-3407.15.

"Covered entity" means (i) an insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical, and surgical or major medical coverage on an expense-incurred basis, (ii) a corporation providing individual or group accident and sickness subscription contracts, (iii) a health maintenance organization providing a health care plan for health care services, (iv) a health program administered by the Commonwealth or an agency of the Commonwealth in the capacity of provider of health coverage, or (v) an employer, labor union, or other group of persons organized in the Commonwealth that provides health coverage to covered individuals who are employed or reside in the Commonwealth.

"Covered individual" means a member, participant, enrollee, contract holder, policyholder, or beneficiary of a policy, contract or plan of a covered entity who is provided health coverage by a covered entity. "Covered individual" includes a dependent or other person provided health coverage through a policy, contract or plan for a covered individual.

"Generic drug" means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name. "Generic drug" includes but is not limited to a chemically equivalent copy of a brand-name drug with an expired patent.

"Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages them for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations Part 270.20.

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals, which may include any of the following services provided concerning the administration of pharmacy benefits:

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.

"Pharmacy benefits manager" means an entity that performs pharmacy benefits management and includes (i) a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity, and (ii) a mail service pharmacy owned or operated by a pharmacy benefits manager.

§ 38.2-3439. Applicability.

A. The provisions of this article shall not apply to short-term travel or 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.

B. Pharmacy benefits managers shall, and contracts for pharmacy benefits management shall comply with the requirements of this article. Compliance with the requirements of this section is required in all contracts for pharmacy benefits management entered into in the Commonwealth or by a covered entity

in the Commonwealth.

§ 38.2-3440. Required practices.

A. A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law.

B. A pharmacy benefits manager shall perform its duties with care, skill, prudence, and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims.

C. A pharmacy benefits manager shall make prompt electronic payment of a clean claim within 15 days of receiving the clean claim from a pharmacy provider. Notwithstanding this provision, the average number of days in which a pharmacy benefits manager processes and pays a clean claim from network retail community pharmacies shall not exceed the average number of days in which the pharmacy benefits manager processes and pays valid reimbursement claims received from a mail order pharmacy that is owned or operated by the pharmacy benefits manager. The pharmacy benefits manager's records of payments shall be made available to the Commission upon request to determine compliance with this requirement.

D. A pharmacy benefits manager shall notify the covered entity in writing of any activity, policy, or practice of the pharmacy benefits manager that directly or indirectly presents a conflict of interests with the duties imposed by this section.

E. A pharmacy benefits manager 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 pharmacy benefits manager providing information under this subsection may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager and provided to a covered entity under this subsection shall not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager, except when 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 violations of this article.

§ 38.2-3441. Requirements for dispensation of substitute prescription drugs.

Concerning the dispensation of a substitute prescription drug for a prescribed drug to a covered individual:

1. If a pharmacy benefits manager makes a substitution in which the substitute drug costs the covered entity or the covered individual more than the prescribed drug, the pharmacy benefits manager shall disclose to the covered entity the cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution.

2. The pharmacy benefits manager shall transfer in full to the covered entity any benefit or payment received in any form by the pharmacy benefits manager as a result of a prescription drug substitution under subdivision 1.

3. The pharmacy benefits manager 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.

§ 38.2-3442. Disclosure.

A. A pharmacy benefits manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager 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.

B. A pharmacy benefits manager 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 pharmacy benefits manager providing information under this paragraph may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager that is provided to a covered entity under this paragraph may not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager, except when 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 violations of this section.

§ 38.2-3443. Effective date.

This section applies to contracts executed or renewed on or after July 1, 2007. For the purposes of this section, 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.