HOUSE BILL 357

C3 3lr0778
HB 1014/22 – HGO

By: **Delegate Kipke**
Introduced and read first time: January 26, 2023
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Pharmacy Benefits Managers – Definitions of Carrier, ERISA, and Purchaser

FOR the purpose of repealing the definitions of "carrier" and "ERISA" and altering the definition of "purchaser" for the purpose of applying certain provisions of State insurance law governing pharmacy benefits managers to certain persons that provide prescription drug coverage or benefits in the State through plans or programs subject to the federal Employee Retirement Income Security Act of 1974 (ERISA); repealing a certain provision that restricts applicability of certain provisions of law to pharmacy benefits managers that provide pharmacy benefits management services on behalf of a carrier; and generally relating to pharmacy benefits managers.

BY repealing and reenacting, with amendments,
Article – Insurance
Section 15–1601, 15–1606, 15–1611, 15–1611.1, 15–1612, 15–1613, 15–1622, 15–1628(a), 15–1628.3, 15–1629, 15–1630, and 15–1633.1
Annotated Code of Maryland
(2017 Replacement Volume and 2022 Supplement)

BY repealing
Article – Insurance
Section 15–1633
Annotated Code of Maryland
(2017 Replacement Volume and 2022 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Insurance

15–1601.

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

(a) In this subtitle the following words have the meanings indicated.

(b) "Agent" means a pharmacy, a pharmacist, a mail order pharmacy, or a nonresident pharmacy acting on behalf or at the direction of a pharmacy benefits manager.

(c) "Beneficiary" means an individual who receives prescription drug coverage or benefits from a purchaser.

(d) **[**(1) "Carrier" means the State Employee and Retiree Health and Welfare Benefits Program, an insurer, a nonprofit health service plan, or a health maintenance organization that:

(i) provides prescription drug coverage or benefits in the State; and

(ii) enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefits management services.

(2) "Carrier" does not include a person that provides prescription drug coverage or benefits through plans subject to ERISA and does not provide prescription drug coverage or benefits through insurance, unless the person is a multiple employer welfare arrangement as defined in § 514(b)(6)(A)(ii) of ERISA.

(e)**]** "Compensation program" means a program, policy, or process through which sources and pricing information are used by a pharmacy benefits manager to determine the terms of payment as stated in a participating pharmacy contract.

[(f)**] (E)** "Contracted pharmacy" means a pharmacy that participates in the network of a pharmacy benefits manager through a contract with:

(1) the pharmacy benefits manager; or

(2) a pharmacy services administration organization or a group purchasing organization.

[(g) "ERISA" has the meaning stated in § 8–301 of this article.**]**

[(h)**] (F)** "Formulary" means a list of prescription drugs used by a purchaser.

[(i)**] (G)** (1) "Manufacturer payments" means any compensation or remuneration a pharmacy benefits manager receives from or on behalf of a pharmaceutical manufacturer.

(2) "Manufacturer payments" includes:

(i) payments received in accordance with agreements with

pharmaceutical manufacturers for formulary placement and, if applicable, drug utilization;

(ii) rebates, regardless of how categorized;

(iii) market share incentives;

(iv) commissions;

(v) fees under products and services agreements;

(vi) any fees received for the sale of utilization data to a pharmaceutical manufacturer; and

(vii) administrative or management fees.

(3) "Manufacturer payments" does not include purchase discounts based on invoiced purchase terms.

[(j)**] (H)** "Nonprofit health maintenance organization" has the meaning stated in § 6–121(a) of this article.

[(k)**] (I)** "Nonresident pharmacy" has the meaning stated in § 12–403 of the Health Occupations Article.

[(l)**] (J)** "Participating pharmacy contract" means a contract filed with the Commissioner in accordance with § 15–1628(b) of this subtitle.

[(m)**] (K)** "Pharmacist" has the meaning stated in § 12–101 of the Health Occupations Article.

[(n)**] (L)** "Pharmacy" has the meaning stated in § 12–101 of the Health Occupations Article.

[(o)**] (M)** "Pharmacy and therapeutics committee" means a committee established by a pharmacy benefits manager to:

(1) objectively appraise and evaluate prescription drugs; and

(2) make recommendations to a purchaser regarding the selection of drugs for the purchaser's formulary.

[(p)**] (N)** (1) "Pharmacy benefits management services" means:

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

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

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

1. mail service pharmacy;

2. claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to beneficiaries;

3. clinical formulary development and management services;

4. rebate contracting and administration;

5. patient compliance, therapeutic intervention, and generic substitution programs; or

6. disease management programs.

(2) "Pharmacy benefits management services" does not include any service provided by a nonprofit health maintenance organization that operates as a group model, provided that the service:

(i) is provided solely to a member of the nonprofit health maintenance organization; and

(ii) is furnished through the internal pharmacy operations of the nonprofit health maintenance organization.

[(q)**] (O)** "Pharmacy benefits manager" means a person that performs pharmacy benefits management services.

[(r)**] (P)** "Proprietary information" means:

(1) a trade secret;

(2) confidential commercial information; or

(3) confidential financial information.

[(s)**] (Q) (1)** "Purchaser" means a person that offers a plan or program in the State, including the State Employee and Retiree Health and Welfare Benefits Program, **AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION,** that:

[(1)**] (I)** provides prescription drug coverage or benefits in the State; and

[(2)**] (II)** enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefits management services.

(2) "PURCHASER" DOES NOT INCLUDE A NONPROFIT HEALTH MAINTENANCE ORGANIZATION THAT:

(I) OPERATES AS A GROUP MODEL;

(II) PROVIDES SERVICES SOLELY TO MEMBERS OR PATIENTS OF THE NONPROFIT HEALTH MAINTENANCE ORGANIZATION; AND

(III) FURNISHES SERVICES THROUGH THE INTERNAL PHARMACY OPERATIONS OF THE NONPROFIT HEALTH MAINTENANCE ORGANIZATION.

[(t)**] (R)** "Rebate sharing contract" means a contract between a pharmacy benefits manager and a purchaser under which the pharmacy benefits manager agrees to share manufacturer payments with the purchaser.

[(u)**] (S)** (1) "Therapeutic interchange" means any change from one prescription drug to another.

(2) "Therapeutic interchange" does not include:

(i) a change initiated pursuant to a drug utilization review;

(ii) a change initiated for patient safety reasons;

(iii) a change required due to market unavailability of the currently prescribed drug;

(iv) a change from a brand name drug to a generic drug in accordance with § 12–504 of the Health Occupations Article; or

(v) a change required for coverage reasons because the originally prescribed drug is not covered by the beneficiary's formulary or plan.

[(v)**] (T)** "Therapeutic interchange solicitation" means any communication by a pharmacy benefits manager for the purpose of requesting a therapeutic interchange.

[(w)**] (U)** "Trade secret" has the meaning stated in § 11–1201 of the Commercial Law Article.

15–1606.

A **[**carrier**]** **PURCHASER** may not enter into an agreement with a pharmacy benefits manager that has not registered with the Commissioner.

15–1611.

(a) **[**This section applies only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.

(b)**]** A pharmacy benefits manager may not prohibit a pharmacy or pharmacist from:

(1) providing a beneficiary with information regarding the retail price for a prescription drug or the amount of the cost share for which the beneficiary is responsible for a prescription drug;

(2) discussing with a beneficiary information regarding the retail price for a prescription drug or the amount of the cost share for which the beneficiary is responsible for a prescription drug; or

(3) if a more affordable drug is available than one on the purchaser's formulary and the requirements for a therapeutic interchange under §§ **[**15–1633.1**]** **15–1633** through 15–1639 of this subtitle are met, selling the more affordable alternative to the beneficiary.

[(c)**]** **(B)** This section may not be construed to alter the requirements for a therapeutic interchange under §§ **[**15–1633.1**]** **15–1633** through 15–1639 of this subtitle.

15–1611.1.

(a) **[**This section applies only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.

(b)**]** Except as provided in subsection **[**(c)**]** **(B)** of this section, a pharmacy benefits manager may not require that a beneficiary use a specific pharmacy or entity to fill a prescription if:

(1) the pharmacy benefits manager or a corporate affiliate of the pharmacy benefits manager has an ownership interest in the pharmacy or entity; or

(2) the pharmacy or entity has an ownership interest in the pharmacy benefits manager or a corporate affiliate of the pharmacy benefits manager.

[(c)**]** **(B)** A pharmacy benefits manager may require a beneficiary to use a specific pharmacy or entity for a specialty drug as defined in § 15–847 of this title.

15–1612.

(a) **[**This section applies only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.

(b)**]** This section does not apply to reimbursement:

(1) for specialty drugs;

(2) for mail order drugs; or

(3) to a chain pharmacy with more than 15 stores or a pharmacist who is an employee of the chain pharmacy.

[(c)**] (B)** A pharmacy benefits manager may not reimburse a pharmacy or pharmacist for a pharmaceutical product or pharmacist service in an amount less than the amount that the pharmacy benefits manager reimburses itself or an affiliate for providing the same product or service.

15–1613.

A pharmacy and therapeutics committee established by a pharmacy benefits manager performing pharmacy benefits management services **[**on behalf of a carrier**]** shall meet the requirements of this part.

15–1622.

[(a) Except as provided for in subsection (b) of this section, the provisions of §§ 15–1623 and 15–1624 of this subtitle apply only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.

(b)**]** The provisions of §§ 15–1623 and 15–1624 of this part do not apply to a pharmacy benefits manager when providing pharmacy benefits management services to a purchaser that is affiliated with the pharmacy benefits manager through common ownership within an insurance holding company.

15–1628.

(a) (1) At the time of entering into a contract with a pharmacy or a pharmacist, and at least 30 working days before any contract change, a pharmacy benefits manager shall disclose to the pharmacy or pharmacist:

(i) the applicable terms, conditions, and reimbursement rates;

(ii) the process and procedures for verifying pharmacy benefits and beneficiary eligibility;

(iii) the dispute resolution and audit appeals process; and

(iv) the process and procedures for verifying the prescription drugs included on the formularies used by the pharmacy benefits manager.

(2) (i) This paragraph does not apply to a requirement that a specialty pharmacy obtain national certification to be considered a specialty pharmacy in a pharmacy benefits manager's or **[**carrier's**]** **PURCHASER'S** network.

(ii) For purposes of credentialing a pharmacy or a pharmacist as a condition for participating in a pharmacy benefits manager's **OR PURCHASER'S** network **[**for a carrier**]**, the pharmacy benefits manager **OR PURCHASER** may not:

1. require a pharmacy or pharmacist to renew credentialing more frequently than once every 3 years; or

2. charge a pharmacy or pharmacist a fee for the initial credentialing or renewing credentialing.

15–1628.3.

(a) A pharmacy benefits manager or a **[**carrier**]** **PURCHASER** may not directly or indirectly charge a contracted pharmacy, or hold a contracted pharmacy responsible for, a fee or performance–based reimbursement related to the adjudication of a claim or an incentive program.

(b) A pharmacy benefits manager or **[**carrier**]** **PURCHASER** may not make or allow any reduction in payment for pharmacy services by a pharmacy benefits manager or **[**carrier**]** **PURCHASER** or directly or indirectly reduce a payment for a pharmacy service under a reconciliation process to an effective rate of reimbursement, including generic effective rates, brand effective rates, direct and indirect remuneration fees, or any other reduction or aggregate reduction of payments.

15–1629.

(a) **[**This section applies only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.

(b)**]** This section does not apply to an audit that involves probable or potential fraud or willful misrepresentation by a pharmacy or pharmacist.

[(c)**]** **(B)** A pharmacy benefits manager shall conduct an audit of a pharmacy or pharmacist under contract with the pharmacy benefits manager in accordance with this section.

[(d)**]** **(C)** A pharmacy benefits manager may not schedule an onsite audit to begin

during the first 5 calendar days of a month unless requested by the pharmacy or pharmacist.

[(e)**] (D)** When conducting an audit, a pharmacy benefits manager shall:

(1) if the audit is onsite, provide written notice to the pharmacy or pharmacist at least 2 weeks before conducting the initial onsite audit for each audit cycle;

(2) employ the services of a pharmacist if the audit requires the clinical or professional judgment of a pharmacist;

(3) permit its auditors to enter the prescription area of a pharmacy only when accompanied by or authorized by a member of the pharmacy staff;

(4) allow a pharmacist or pharmacy to use any prescription, or authorized change to a prescription, that meets the requirements of COMAR 10.34.20.02 to validate claims submitted for reimbursement for dispensing of original and refill prescriptions;

(5) for purposes of validating the pharmacy record with respect to orders or refills of a drug, allow the pharmacy or pharmacist to use records of a hospital or a physician or other prescriber authorized by law that are:

(i) written; or

(ii) transmitted electronically or by any other means of communication authorized by contract between the pharmacy and the pharmacy benefits manager;

(6) audit each pharmacy and pharmacist under the same standards and parameters as other similarly situated pharmacies or pharmacists audited by the pharmacy benefits manager;

(7) only audit claims submitted or adjudicated within the 2–year period immediately preceding the audit, unless a longer period is authorized under federal or State law;

(8) deliver the preliminary audit report to the pharmacy or pharmacist within 120 calendar days after the completion of the audit, with reasonable extensions allowed;

(9) in accordance with subsection **[**(k)**] (J)** of this section, allow a pharmacy or pharmacist to produce documentation to address any discrepancy found during the audit; and

(10) deliver the final audit report to the pharmacy or pharmacist:

(i) within 6 months after delivery of the preliminary audit report if

the pharmacy or pharmacist does not request an internal appeal under subsection **[**(k)**]** **(J)** of this section; or

(ii) within 30 days after the conclusion of the internal appeals process under subsection **[**(k)**]** **(J)** of this section if the pharmacy or pharmacist requests an internal appeal.

[(f)**]** **(E)** If a contract between a pharmacy or pharmacist and a pharmacy benefits manager specifies a period of time in which a pharmacy or pharmacist is allowed to withdraw and resubmit a claim and that period of time expires before the pharmacy benefits manager delivers a preliminary audit report that identifies discrepancies, the pharmacy benefits manager shall allow the pharmacy or pharmacist to withdraw and resubmit a claim within 30 days after:

(1) the preliminary audit report is delivered if the pharmacy or pharmacist does not request an internal appeal under subsection **[**(k)**]** **(J)** of this section; or

(2) the conclusion of the internal appeals process under subsection **[**(k)**]** **(J)** of this section if the pharmacy or pharmacist requests an internal appeal.

[(g)**]** **(F)** During an audit, a pharmacy benefits manager may not disrupt the provision of services to the customers of a pharmacy.

[(h)**]** **(G)** (1) A pharmacy benefits manager may not:

(i) use the accounting practice of extrapolation to calculate overpayments or underpayments; or

(ii) Except as provided in paragraph (2) of this subsection:

1. share information from an audit with another pharmacy benefits manager; or

2. use information from an audit conducted by another pharmacy benefits manager.

(2) Paragraph (1)(ii) of this subsection does not apply to the sharing of information:

(i) required by federal or State law;

(ii) in connection with an acquisition or merger involving the pharmacy benefits manager; or

(iii) at the payor's request or under the terms of the agreement between the pharmacy benefits manager and the payor.

[(i)**] (H)** The recoupment of a claims payment from a pharmacy or pharmacist by a pharmacy benefits manager shall be based on an actual overpayment or denial of an audited claim unless the projected overpayment or denial is part of a settlement agreed to by the pharmacy or pharmacist.

[(j)**] (I)** (1) In this subsection, "overpayment" means a payment by the pharmacy benefits manager to a pharmacy or pharmacist that is greater than the rate or terms specified in the contract between the pharmacy or pharmacist and the pharmacy benefits manager at the time that the payment is made.

(2) A clerical error, record–keeping error, typographical error, or scrivener's error in a required document or record may not constitute fraud or grounds for recoupment of a claims payment from a pharmacy or pharmacist by a pharmacy benefits manager if the prescription was otherwise legally dispensed and the claim was otherwise materially correct.

(3) Notwithstanding paragraph (2) of this subsection, claims remain subject to recoupment of overpayment or payment of any discovered underpayment by the pharmacy benefits manager.

[(k)**] (J)** (1) A pharmacy benefits manager shall establish an internal appeals process under which a pharmacy or pharmacist may appeal any disputed claim in a preliminary audit report.

(2) Under the internal appeals process, a pharmacy benefits manager shall allow a pharmacy or pharmacist to request an internal appeal within 30 working days after receipt of the preliminary audit report, with reasonable extensions allowed.

(3) The pharmacy benefits manager shall include in its preliminary audit report a written explanation of the internal appeals process, including the name, address, and telephone number of the person to whom an internal appeal should be addressed.

(4) The decision of the pharmacy benefits manager on an appeal of a disputed claim in a preliminary audit report by a pharmacy or pharmacist shall be reflected in the final audit report.

(5) The pharmacy benefits manager shall deliver the final audit report to the pharmacy or pharmacist within 30 calendar days after conclusion of the internal appeals process.

[(l)**] (K)** (1) A pharmacy benefits manager may not recoup by setoff any money for an overpayment or denial of a claim until:

(i) the pharmacy or pharmacist has an opportunity to review the pharmacy benefits manager's findings; and

(ii) if the pharmacy or pharmacist concurs with the pharmacy benefits manager's findings of overpayment or denial, 30 working days have elapsed after the date the final audit report has been delivered to the pharmacy or pharmacist.

(2) If the pharmacy or pharmacist does not concur with the pharmacy benefits manager's findings of overpayment or denial, the pharmacy benefits manager may not recoup by setoff any money pending the outcome of an appeal under subsection **[**(k)**]** **(J)** of this section.

(3) A pharmacy benefits manager shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within 30 working days after the final audit report has been delivered to the pharmacy or pharmacist.

(4) Notwithstanding the provisions of paragraph (1) of this subsection, a pharmacy benefits manager may withhold future payments before the date the final audit report has been delivered to the pharmacy or pharmacist if the identified discrepancy for all disputed claims in a preliminary audit report for an individual audit exceeds $25,000.

[(m)**]** **(L)** (1) The Commissioner may adopt regulations regarding:

(i) the documentation that may be requested during an audit; and

(ii) the process a pharmacy benefits manager may use to conduct an audit.

(2) On request of the Commissioner or the Commissioner's designee, a pharmacy benefits manager shall provide a copy of its audit procedures or internal appeals process.

15–1630.

(a) **[**This section applies only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.

(b)**]** A pharmacy benefits manager shall establish a reasonable internal review process for a pharmacy to request the review of a failure to pay the contractual reimbursement amount of a submitted claim.

[(c)**]** **(B)** A pharmacy may request a pharmacy benefits manager to review a failure to pay the contractual reimbursement amount of a claim within 180 calendar days after the date the submitted claim was paid by the pharmacy benefits manager.

[(d)**]** **(C)** The pharmacy benefits manager shall give written notice of its review decision within 90 calendar days after receipt of a request for review from a pharmacy under this section.

[(e)**] (D)** If the pharmacy benefits manager determines through the internal review process established under subsection **[**(b)**] (A)** of this section that the pharmacy benefits manager underpaid a pharmacy, the pharmacy benefits manager shall pay any money due to the pharmacy within 30 working days after completion of the internal review process.

[(f)**] (E)** This section may not be construed to limit the ability of a pharmacy and a pharmacy benefits manager to contractually agree that a pharmacy may have more than 180 calendar days to request an internal review of a failure of the pharmacy benefits manager to pay the contractual amount of a submitted claim.

[15–1633.

The provisions of §§ 15–1633.1 through 15–1639 of this subtitle apply only to a pharmacy benefits manager performing pharmacy benefits management services on behalf of a carrier.**]**

[15–1633.1.**] 15–1633.**

A pharmacy benefits manager or its agent may not request a therapeutic interchange unless:

(1) the proposed therapeutic interchange is for medical reasons that benefit the beneficiary; or

(2) the proposed therapeutic interchange will result in financial savings and benefits to the purchaser or the beneficiary.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect January 1, 2024.