

# HOUSE BILL 1014

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CF SB 690

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By: **Delegates Kipke, Krebs, Morgan, and Saab**

Introduced and read first time: February 10, 2022

Assigned to: Health and Government Operations

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## A BILL ENTITLED

1 AN ACT concerning

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

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

12 BY repealing and reenacting, with amendments,

13 Article – Insurance

14 Section 15–1601, 15–1606, 15–1611, 15–1611.1, 15–1612, 15–1613, 15–1622,  
15 15–1628(a), 15–1628.3, 15–1629, 15–1630, and 15–1633.1

16 Annotated Code of Maryland

17 (2017 Replacement Volume and 2021 Supplement)

18 BY repealing

19 Article – Insurance

20 Section 15–1633

21 Annotated Code of Maryland

22 (2017 Replacement Volume and 2021 Supplement)

23 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

24 That the Laws of Maryland read as follows:

25 **Article – Insurance**

26 15–1601.

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

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

4 (c) “Beneficiary” means an individual who receives prescription drug coverage or  
5 benefits from a purchaser.

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

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

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

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

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

19 [(f) (E) “Contracted pharmacy” means a pharmacy that participates in the  
20 network of a pharmacy benefits manager through a contract with:

21 (1) the pharmacy benefits manager; or

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

24 [(g) “ERISA” has the meaning stated in § 8–301 of this article.]

25 [(h) (F) “Formulary” means a list of prescription drugs used by a purchaser.

26 [(i) (G) (1) “Manufacturer payments” means any compensation or  
27 remuneration a pharmacy benefits manager receives from or on behalf of a pharmaceutical  
28 manufacturer.

29 (2) “Manufacturer payments” includes:

30 (i) payments received in accordance with agreements with

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

2 (ii) rebates, regardless of how categorized;

3 (iii) market share incentives;

4 (iv) commissions;

5 (v) fees under products and services agreements;

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

8 (vii) administrative or management fees.

9 (3) “Manufacturer payments” does not include purchase discounts based on  
10 invoiced purchase terms.

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

13 [(k)] (I) “Nonresident pharmacy” has the meaning stated in § 12–403 of the  
14 Health Occupations Article.

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

17 [(m)] (K) “Pharmacist” has the meaning stated in § 12–101 of the Health  
18 Occupations Article.

19 [(n)] (L) “Pharmacy” has the meaning stated in § 12–101 of the Health  
20 Occupations Article.

21 [(o)] (M) “Pharmacy and therapeutics committee” means a committee  
22 established by a pharmacy benefits manager to:

23 (1) objectively appraise and evaluate prescription drugs; and

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

26 [(p)] (N) (1) “Pharmacy benefits management services” means:

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

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

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

5 1. mail service pharmacy;

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

8 3. clinical formulary development and management services;

9 4. rebate contracting and administration;

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

12 6. disease management programs.

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

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

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

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

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

23 (1) a trade secret;

24 (2) confidential commercial information; or

25 (3) confidential financial information.

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

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

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

4 [(t)] (R) “Rebate sharing contract” means a contract between a pharmacy  
5 benefits manager and a purchaser under which the pharmacy benefits manager agrees to  
6 share manufacturer payments with the purchaser.

7 [(u)] (S) (1) “Therapeutic interchange” means any change from one  
8 prescription drug to another.

9 (2) “Therapeutic interchange” does not include:

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

11 (ii) a change initiated for patient safety reasons;

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

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

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

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

20 [(w)] (U) “Trade secret” has the meaning stated in § 11–1201 of the Commercial  
21 Law Article.

22 15–1606.

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

25 15–1611.

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

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

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

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

7 (3) if a more affordable drug is available than one on the purchaser's  
8 formulary and the requirements for a therapeutic interchange under §§ [15–1633.1]  
9 **15–1633** through 15–1639 of this subtitle are met, selling the more affordable alternative  
10 to the beneficiary.

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

13 15–1611.1.

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

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

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

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

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

25 15–1612.

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

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

29 (1) for specialty drugs;

30 (2) for mail order drugs; or

31 (3) to a chain pharmacy with more than 15 stores or a pharmacist who is

1 an employee of the chain pharmacy.

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

6 15–1613.

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

10 15–1622.

11 [(a)] Except as provided for in subsection (b) of this section, the provisions of §§  
12 15–1623 and 15–1624 of this subtitle apply only to a pharmacy benefits manager that  
13 provides pharmacy benefits management services on behalf of a carrier.

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

18 15–1628.

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

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

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

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

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

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

31 (ii) For purposes of credentialing a pharmacy or a pharmacist as a  
32 condition for participating in a pharmacy benefits manager's **OR PURCHASER'S** network

1 [for a carrier], the pharmacy benefits manager **OR PURCHASER** may not:

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

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

6 15-1628.3.

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

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

17 15-1629.

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

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

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

25 [(d)] **(C)** A pharmacy benefits manager may not schedule an onsite audit to begin  
26 during the first 5 calendar days of a month unless requested by the pharmacy or  
27 pharmacist.

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

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

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

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

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

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

9 (i) written; or

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

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

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

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

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

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

26 (i) within 6 months after delivery of the preliminary audit report if  
27 the pharmacy or pharmacist does not request an internal appeal under subsection [(k)] (J)  
28 of this section; or

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

32 [(f)] (E) If a contract between a pharmacy or pharmacist and a pharmacy  
33 benefits manager specifies a period of time in which a pharmacy or pharmacist is allowed  
34 to withdraw and resubmit a claim and that period of time expires before the pharmacy  
35 benefits manager delivers a preliminary audit report that identifies discrepancies, the

1 pharmacy benefits manager shall allow the pharmacy or pharmacist to withdraw and  
2 resubmit a claim within 30 days after:

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

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

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

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

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

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

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

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

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

19 (i) required by federal or State law;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

35 (3) A pharmacy benefits manager shall remit any money due to a pharmacy  
36 or pharmacist as a result of an underpayment of a claim within 30 working days after the

1 final audit report has been delivered to the pharmacy or pharmacist.

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

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

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

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

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

13 15-1630.

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

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

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

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

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

30 **[(f)] (E)** This section may not be construed to limit the ability of a pharmacy and  
31 a pharmacy benefits manager to contractually agree that a pharmacy may have more than  
32 180 calendar days to request an internal review of a failure of the pharmacy benefits  
33 manager to pay the contractual amount of a submitted claim.

1 [15-1633.

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

5 [15-1633.1.] **15-1633.**

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

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

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

12           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
13 January 1, 2023.