## **SENATE BILL 898**

By: Senators Ready and Klausmeier

Introduced and read first time: February 15, 2023

Assigned to: Rules

## A BILL ENTITLED

1 AN ACT concerning

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## Pharmacy Benefits Managers - Definitions of Carrier, ERISA, and Purchaser

- 3 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 4 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 management services on behalf of a carrier; and generally relating to pharmacy 10 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 2022 Supplement)
- 18 BY repealing
- 19 Article Insurance
- 20 Section 15–1633
- 21 Annotated Code of Maryland
- 22 (2017 Replacement Volume and 2022 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.

 ${\bf EXPLANATION: CAPITALS\ indicate\ matter\ added\ to\ existing\ law}.$ 

[Brackets] indicate matter deleted from existing law.



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(i)

1 In this subtitle the following words have the meanings indicated. (a) 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 "Beneficiary" means an individual who receives prescription drug coverage or benefits from a purchaser. 5 6 "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 "Carrier" does not include a person that provides prescription drug coverage or benefits through plans subject to ERISA and does not provide prescription drug 13 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 "Compensation program" means a program, policy, or process through which sources and pricing information are used by a pharmacy benefits manager to determine the 17 18 terms of payment as stated in a participating pharmacy contract. 19 "Contracted pharmacy" means a pharmacy that participates in the [(f)] **(E)** 20 network of a pharmacy benefits manager through a contract with: 21(1) the pharmacy benefits manager; or 22a pharmacy services administration organization or a group purchasing (2) 23organization. 24(g)"ERISA" has the meaning stated in § 8–301 of this article. [(h)] (F) 25 "Formulary" means a list of prescription drugs used by a purchaser. 26 [(i)] **(G)** "Manufacturer payments" means any (1) compensation 27 remuneration a pharmacy benefits manager receives from or on behalf of a pharmaceutical 28manufacturer. 29 "Manufacturer payments" includes: (2)

payments received in accordance with agreements with

pharmaceutical manufacturers for formulary placement and, if applicable, drug utilization; 1 2 (ii) rebates, regardless of how categorized: 3 (iii) market share incentives; 4 (iv) commissions: 5 fees under products and services agreements; (v) 6 any fees received for the sale of utilization data to a (vi) 7 pharmaceutical manufacturer; and 8 administrative or management fees. (vii) 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 "Participating pharmacy contract" means a contract filed with the [(l)] (J) Commissioner in accordance with § 15–1628(b) of this subtitle. 16 "Pharmacist" has the meaning stated in § 12-101 of the Health 17 [(m)] (K) Occupations Article. 18 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 24make recommendations to a purchaser regarding the selection of drugs for the purchaser's formulary. 2526 [(p)] (N) "Pharmacy benefits management services" means: (1) 27 the procurement of prescription drugs at a negotiated rate for (i)

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dispensation within the State to beneficiaries;

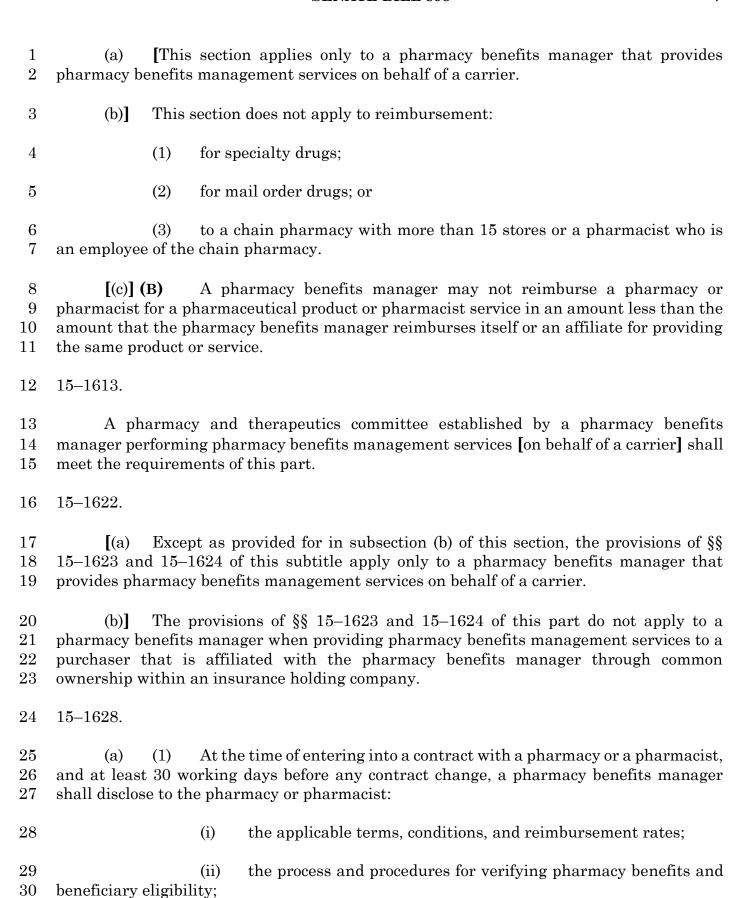
$\frac{1}{2}$	(ii) the administration or management of prescription drug coverage provided by a purchaser for beneficiaries; and			
3 4	(iii) any of the following services provided with regard to the administration of prescription drug coverage:			
5	<ol> <li>mail service pharmacy;</li> </ol>			
6 7	2. claims processing, retail network management, and 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 11	5. patient compliance, therapeutic intervention, and generic substitution programs; or			
12	6. disease management programs.			
13 14 15	(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:			
16 17	(i) is provided solely to a member of the nonprofit health maintenance organization; and			
18 19	(ii) is furnished through the internal pharmacy operations of the nonprofit health maintenance organization.			
20 21	[(q)] (O) "Pharmacy benefits manager" means a person that performs pharmacy 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 27 28 29	[(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:			

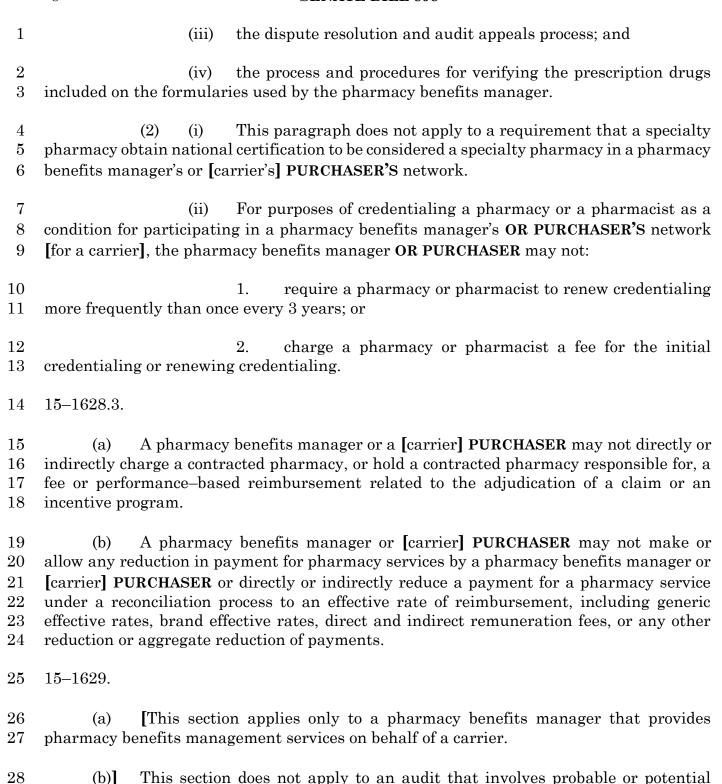
1	[(1)]	(I)	provides prescription drug coverage or benefits in the State; and	
2 3	[(2)] the provision of ph		enters into an agreement with a pharmacy benefits manager for y benefits management services.	
4 5	(2) MAINTENANCE O		RCHASER" DOES NOT INCLUDE A NONPROFIT HEALTH ZATION THAT:	
6		(I)	OPERATES AS A GROUP MODEL;	
7 8	THE NONPROFIT	(II) HEAL	PROVIDES SERVICES SOLELY TO MEMBERS OR PATIENTS OF TH MAINTENANCE ORGANIZATION; AND	
9	OPERATIONS OF	(III) THE N	FURNISHES SERVICES THROUGH THE INTERNAL PHARMACY ONPROFIT HEALTH MAINTENANCE ORGANIZATION.	
11 12 13	[(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.			
14 15	[(u)] (S) prescription drug	٠,,	"Therapeutic interchange" means any change from one her.	
16	(2)	"Ther	rapeutic interchange" does not include:	
17		(i)	a change initiated pursuant to a drug utilization review;	
18		(ii)	a change initiated for patient safety reasons;	
19 20	prescribed drug;	(iii)	a change required due to market unavailability of the currently	
21 22	with § 12–504 of the	(iv) he Hea	a change from a brand name drug to a generic drug in accordance lth Occupations Article; or	
23 24	prescribed drug is	(v) not co	a change required for coverage reasons because the originally vered by the beneficiary's formulary or plan.	
25 26	[(v)] (T) pharmacy benefits		rapeutic interchange solicitation" means any communication by a ger for the purpose of requesting a therapeutic interchange.	
27	[(w)] (U)	"Trad	le secret" has the meaning stated in § 11–1201 of the Commercial	

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15-1606.

- A [carrier] **PURCHASER** may not enter into an agreement with a pharmacy benefits manager that has not registered with the Commissioner.
- 3 15–1611.
- 4 (a) [This section applies only to a pharmacy benefits manager that provides 5 pharmacy benefits management services on behalf of a carrier.
- 6 (b)] A pharmacy benefits manager may not prohibit a pharmacy or pharmacist 7 from:
- 8 (1) providing a beneficiary with information regarding the retail price for 9 a prescription drug or the amount of the cost share for which the beneficiary is responsible 10 for a prescription drug;
- 11 (2) discussing with a beneficiary information regarding the retail price for 12 a prescription drug or the amount of the cost share for which the beneficiary is responsible 13 for a prescription drug; or
- 14 (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] 16 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.
- 20 15–1611.1.
- 21 (a) [This section applies only to a pharmacy benefits manager that provides 22 pharmacy benefits management services on behalf of a carrier.
- 23 (b) Except as provided in subsection [(c)] (B) of this section, a pharmacy benefits 24 manager may not require that a beneficiary use a specific pharmacy or entity to fill a 25 prescription if:
- 26 (1) the pharmacy benefits manager or a corporate affiliate of the pharmacy 27 benefits manager has an ownership interest in the pharmacy or entity; or
- 28 (2) the pharmacy or entity has an ownership interest in the pharmacy 29 benefits manager or a corporate affiliate of the pharmacy benefits manager.
- 30 **[(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.
- 32 15–1612.





section.

pharmacist under contract with the pharmacy benefits manager in accordance with this

fraud or willful misrepresentation by a pharmacy or pharmacist.

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[(c)] **(B)** 

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

A pharmacy benefits manager shall conduct an audit of a pharmacy or

- during the first 5 calendar days of a month unless requested by the pharmacy or pharmacist.
- 3 [(e)] (D) When conducting an audit, a pharmacy benefits manager shall:
- 4 (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;
- 6 (2) employ the services of a pharmacist if the audit requires the clinical or 7 professional judgment of a pharmacist;
- 8 (3) permit its auditors to enter the prescription area of a pharmacy only 9 when accompanied by or authorized by a member of the pharmacy staff;
- 10 (4) allow a pharmacist or pharmacy to use any prescription, or authorized 11 change to a prescription, that meets the requirements of COMAR 10.34.20.02 to validate 12 claims submitted for reimbursement for dispensing of original and refill prescriptions;
- 13 (5) for purposes of validating the pharmacy record with respect to orders 14 or refills of a drug, allow the pharmacy or pharmacist to use records of a hospital or a 15 physician or other prescriber authorized by law that are:
- 16 (i) written; or
- 17 (ii) transmitted electronically or by any other means of 18 communication authorized by contract between the pharmacy and the pharmacy benefits 19 manager;
- 20 (6) audit each pharmacy and pharmacist under the same standards and 21 parameters as other similarly situated pharmacies or pharmacists audited by the 22 pharmacy benefits manager;
- 23 (7) only audit claims submitted or adjudicated within the 2-year period 24 immediately preceding the audit, unless a longer period is authorized under federal or State 25 law;
- 26 (8) deliver the preliminary audit report to the pharmacy or pharmacist 27 within 120 calendar days after the completion of the audit, with reasonable extensions 28 allowed;
- 29 (9) in accordance with subsection **[(k)] (J)** of this section, allow a pharmacy 30 or pharmacist to produce documentation to address any discrepancy found during the audit; 31 and
- 32 (10) deliver the final audit report to the pharmacy or pharmacist:
- 33 (i) within 6 months after delivery of the preliminary audit report if

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pharmacy benefits manager; or

- 1 the pharmacy or pharmacist does not request an internal appeal under subsection [(k)] (J) 2 of this section: or 3 within 30 days after the conclusion of the internal appeals (ii) process under subsection [(k)] (J) of this section if the pharmacy or pharmacist requests 4 an internal appeal. 5 6 [(f)] **(E)** If a contract between a pharmacy or pharmacist and a pharmacy 7 benefits manager specifies a period of time in which a pharmacy or pharmacist is allowed 8 to withdraw and resubmit a claim and that period of time expires before the pharmacy 9 benefits manager delivers a preliminary audit report that identifies discrepancies, the 10 pharmacy benefits manager shall allow the pharmacy or pharmacist to withdraw and resubmit a claim within 30 days after: 11 12 (1) the preliminary audit report is delivered if the pharmacy or pharmacist 13 does not request an internal appeal under subsection [(k)] (J) of this section; or 14 (2)the conclusion of the internal appeals process under subsection [(k)] (J) 15 of this section if the pharmacy or pharmacist requests an internal appeal. 16 [(g)] **(F)** During an audit, a pharmacy benefits manager may not disrupt the provision of services to the customers of a pharmacy. 17 [(h)] (G) 18 (1) A pharmacy benefits manager may not: 19 (i) use the accounting practice of extrapolation to calculate 20 overpayments or underpayments; or 21Except as provided in paragraph (2) of this subsection: (ii) 22 1. share information from an audit with another pharmacy 23benefits manager; or 242. use information from an audit conducted by another 25pharmacy benefits manager. 26 Paragraph (1)(ii) of this subsection does not apply to the sharing of (2) 27information: 28(i) required by federal or State law; 29 in connection with an acquisition or merger involving the (ii)
- 31 (iii) at the payor's request or under the terms of the agreement 32 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.
- 9 (2) A clerical error, record-keeping error, typographical error, or 10 scrivener's error in a required document or record may not constitute fraud or grounds for 11 recoupment of a claims payment from a pharmacy or pharmacist by a pharmacy benefits 12 manager if the prescription was otherwise legally dispensed and the claim was otherwise 13 materially correct.
- 14 (3) Notwithstanding paragraph (2) of this subsection, claims remain 15 subject to recoupment of overpayment or payment of any discovered underpayment by the 16 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.
- 20 (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.
- 23 (3) The pharmacy benefits manager shall include in its preliminary audit 24 report a written explanation of the internal appeals process, including the name, address, 25 and telephone number of the person to whom an internal appeal should be addressed.
- 26 (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.
- 29 (5) The pharmacy benefits manager shall deliver the final audit report to 30 the pharmacy or pharmacist within 30 calendar days after conclusion of the internal 31 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:
- 34 (i) the pharmacy or pharmacist has an opportunity to review the 35 pharmacy benefits manager's findings; and

- 1 (ii) if the pharmacy or pharmacist concurs with the pharmacy 2 benefits manager's findings of overpayment or denial, 30 working days have elapsed after 3 the date the final audit report has been delivered to the pharmacy or pharmacist.
- 4 (2) If the pharmacy or pharmacist does not concur with the pharmacy 5 benefits manager's findings of overpayment or denial, the pharmacy benefits manager may 6 not recoup by setoff any money pending the outcome of an appeal under subsection [(k)] 7 (J) of this section.
- 8 (3) A pharmacy benefits manager shall remit any money due to a pharmacy 9 or pharmacist as a result of an underpayment of a claim within 30 working days after the 10 final audit report has been delivered to the pharmacy or pharmacist.
- 11 (4) Notwithstanding the provisions of paragraph (1) of this subsection, a 12 pharmacy benefits manager may withhold future payments before the date the final audit 13 report has been delivered to the pharmacy or pharmacist if the identified discrepancy for 14 all disputed claims in a preliminary audit report for an individual audit exceeds \$25,000.
- 15 [(m)] (L) (1) The Commissioner may adopt regulations regarding:
- 16 (i) the documentation that may be requested during an audit; and
- 17 (ii) the process a pharmacy benefits manager may use to conduct an 18 audit.
- 19 (2) On request of the Commissioner or the Commissioner's designee, a 20 pharmacy benefits manager shall provide a copy of its audit procedures or internal appeals 21 process.
- 22 15–1630.
- 23 (a) [This section applies only to a pharmacy benefits manager that provides 24 pharmacy benefits management services on behalf of a carrier.
- 25 (b) A pharmacy benefits manager shall establish a reasonable internal review 26 process for a pharmacy to request the review of a failure to pay the contractual 27 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.
- 31 **[(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 la0 calendar days to request an internal review of a failure of the pharmacy benefits manager to pay the contractual amount of a submitted claim.
- 10 [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.]
- 14 [15–1633.1.] **15–1633.**
- A pharmacy benefits manager or its agent may not request a therapeutic interchange unless:
- 17 (1) the proposed therapeutic interchange is for medical reasons that benefit 18 the beneficiary; or
- 19 (2) the proposed therapeutic interchange will result in financial savings 20 and benefits to the purchaser or the beneficiary.
- SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 22 January 1, 2024.