HOUSE BILL 1274

J52lr2276 By: Delegate Kipke Introduced and read first time: February 11, 2022 Assigned to: Health and Government Operations Committee Report: Favorable with amendments House action: Adopted Read second time: March 26, 2022 CHAPTER AN ACT concerning Prescription Drugs - Pharmacy Benefits Managers and Purchasers - Federal 340B Program FOR the purpose of establishing requirements and prohibitions on pharmacy benefits managers and purchasers related to the federal 340B Program, including requirements related to coverage and reimbursement for drugs purchased under the Program; and generally relating to prescription drugs, purchasers, and pharmacy benefits managers. BY adding to Article – Insurance Section 15-1611.2 Annotated Code of Maryland (2017 Replacement Volume and 2021 Supplement) SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows: Article - Insurance 15-1611.2. (A) <u>(1)</u> IN THIS SECTION, THE FOLLOWING WORDS HAVE THE MEANINGS

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

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INDICATED.

Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.



- 1 (2) "COVERED ENTITY" HAS THE MEANING STATED IN § 602 OF THE 2 FEDERAL VETERANS HEALTH CARE ACT OF 1992.
- 3 (3) "PHARMACIES OR PHARMACISTS THAT PARTICIPATE IN THE 340B
 4 PROGRAM" MEANS:
- 5 (I) A PHARMACY OWNED OR OPERATED BY A COVERED ENTITY
 6 THAT IS ELIGIBLE TO OR IS ACTIVELY PARTICIPATING IN THE 340B PROGRAM; OR
- 7 (II) A PHARMACY OR PHARMACIST UNDER CONTRACT WITH A
 8 COVERED ENTITY TO DISPENSE DRUGS PURCHASED UNDER THE 340B PROGRAM TO
 9 PATIENTS OF THE COVERED ENTITY.
- 10 (4) "340B PROGRAM" MEANS THE DRUG PRICING PROGRAM
 11 ESTABLISHED UNDER § 602 OF THE FEDERAL VETERANS HEALTH CARE ACT OF
 12 1992.
- 13 (B) BEFORE ALLOWING A BENEFICIARY TO USE A MAIL-ORDER PHARMACY
 14 THAT PARTICIPATES IN THE 340B PROGRAM, A PHARMACY BENEFITS MANAGER OR
 15 A PURCHASER SHALL OBTAIN A SIGNED WAIVER FROM THE BENEFICIARY STATING
 16 THAT THE BENEFICIARY IS NOT REQUIRED TO USE THE MAIL-ORDER PHARMACY.
- 17 (C) (B) A PHARMACY BENEFITS MANAGER OR A PURCHASER SHALL:
- 18 (1) MAKE FORMULARY AND COVERAGE DECISIONS FOR A PHARMACY
 19 OR PHARMACIST THAT PARTICIPATES IN THE 340B PROGRAM BASED ON THE
 20 NORMAL COURSE OF BUSINESS OF THE PHARMACY BENEFITS MANAGER OR
 21 PURCHASER; AND
- 22 (2) ALLOW A BENEFICIARY TO USE ANY <u>IN-NETWORK</u> PHARMACY OR 23 PHARMACIST THAT THE BENEFICIARY CHOOSES, WITHOUT REGARD TO WHETHER 24 THE PHARMACY OR PHARMACIST PARTICIPATES IN **340B** PROGRAM.
- 25 (D) (C) A PHARMACY BENEFITS MANAGER OR A PURCHASER MAY NOT:
- 26 (1) TRANSFER 340B PROGRAM SAVINGS FROM A PHARMACY OR PHARMACIST THAT PARTICIPATES IN THE 340B PROGRAM TO A PHARMACY BENEFITS MANAGER OR PURCHASER;
- 29 (2) OFFER LOWER REIMBURSEMENT FOR A PRESCRIPTION DRUG 30 PURCHASED UNDER THE 340B PROGRAM THAN THE REIMBURSEMENT IT OFFERS 31 FOR THE SAME PRESCRIPTION DRUG IF IT IS NOT PURCHASED UNDER THE 340B
- 32 PROGRAM;

- 1 (3) REFUSE TO COVER PRESCRIPTION DRUGS PURCHASED UNDER 2 THE 340B PROGRAM;
- 3 (4) REFUSE TO ALLOW PHARMACIES OR PHARMACISTS THAT
- 4 PARTICIPATE IN THE 340B PROGRAM TO PARTICIPATE IN THE PHARMACY BENEFITS
- 5 MANAGER'S PURCHASER'S NETWORK ON THE SOLE BASIS THAT THE PHARMACY OR
- 6 PHARMACIST PARTICIPATES IN THE 340B PROGRAM;
- 7 (5) CHARGE MORE THAN FAIR MARKET VALUE OR SEEK PROFIT
- 8 SHARING IN EXCHANGE FOR COVERAGE OF SERVICES FOR A PHARMACY OR
- 9 PHARMACIST THAT PARTICIPATES IN THE 340B PROGRAM;
- 10 (6) REQUIRE, AS A CONDITION OF COVERAGE, THAT A BENEFICIARY
- 11 USE A SPECIFIED MAIL ORDER PHARMACY OR PHARMACIST THAT PARTICIPATES IN
- 12 THE 340B PROGRAM OR OTHERWISE COERCE A BENEFICIARY INTO USING A
- 13 SPECIFIC MAIL-ORDER PHARMACY OR PHARMACIST THAT PARTICIPATES IN THE
- 14 **340B Program**;
- 15 (7) (5) IMPOSE DIFFERENT REIMBURSEMENT OR NETWORK
- 16 PARTICIPATION CONTRACT TERMS ON PHARMACIES OR PHARMACISTS THAT
- 17 PARTICIPATE IN A PHARMACY BENEFITS MANAGER'S OR PURCHASER'S NETWORK
- 18 BASED ON WHETHER A PHARMACY OR PHARMACIST PARTICIPATES IN THE 340B
- 19 **PROGRAM**;
- 20 (8) REQUIRE A PHARMACY OR PHARMACIST TO REVERSE, RESUBMIT,
- 21 OR CLARIFY A 340B PROGRAM CLAIM AFTER THE INITIAL ADJUDICATION, UNLESS
- 22 THE ACTIONS ARE IN THE NORMAL COURSE OF BUSINESS OF THE PHARMACY
- 23 BENEFITS MANAGER OR PURCHASER AND ARE NOT RELATED TO WHETHER THE
- 24 PHARMACY OR PHARMACIST PARTICIPATES IN THE 340B PROGRAM:
- 25 (9) REQUIRE A BILLING MODIFIER TO INDICATE THAT THE CLAIM FOR
- 26 A PRESCRIPTION DRUG IS A 340B PROGRAM CLAIM, UNLESS THE PRESCRIPTION
- 27 DRUG IS BEING BILLED TO THE MARYLAND MEDICAL ASSISTANCE PROGRAM OR A
- 28 MANAGED CARE ORGANIZATION:
- 29 (6) IMPOSE DIFFERENT FEES, CHARGEBACKS, OR OTHER
- 30 ADJUSTMENTS ON PHARMACIES OR PHARMACISTS BASED ON WHETHER A
- 31 PHARMACY OR PHARMACIST PARTICIPATES IN THE 340B PROGRAM;
- 32 (10) (7) MODIFY A BENEFICIARY'S COPAYMENT ON THE BASIS OF
- 33 WHETHER A PHARMACY OR PHARMACIST PARTICIPATES IN THE 340B PROGRAM;

1 2 3	(11) (8) ESTABLISH OR SET NETWORK ADEQUACY REQUIREMENTS BASED ON WHETHER A PHARMACY OR PHARMACIST PARTICIPATES IN THE 340B PROGRAM; OR
4 5 6 7 8 9	(12) (9) PROHIBIT AN A COVERED ENTITY AUTHORIZED TO PARTICIPATE IN THE 340B PROGRAM OR A PHARMACY OR PHARMACIST UNDER CONTRACT WITH AN A COVERED ENTITY AUTHORIZED TO PARTICIPATE IN THE 340B PROGRAM FROM PARTICIPATING IN THE PHARMACY BENEFITS MANAGER'S OR PURCHASER'S NETWORK ON THE BASIS OF THE COVERED ENTITY'S PARTICIPATION IN THE 340B PROGRAM.
10 11	(E) (D) A PHARMACY BENEFITS MANAGER OR PURCHASER MAY NOT BASE ♣ FORMULARY OR PRESCRIPTION DRUG COVERAGE DECISIONS ON:
12 13	(1) THE PRICE OF THE PRESCRIPTION DRUG UNDER THE 340B PROGRAM; OR
14 15	(2) WHETHER THE DISPENSING PHARMACY OR PHARMACIST PARTICIPATES IN THE 340B PROGRAM.
16 17 18	(F) A 340B PROGRAM CLAIM PROCESSED BY A PHARMACY OR PHARMACIST THAT PARTICIPATES IN THE 340B PROGRAM IS FINAL AT THE POINT OF ADJUDICATION.
19 20	(G) THE ADMINISTRATION SHALL ADOPT REGULATIONS TO CARRY OUT THIS SECTION.
21 22	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2022.
	Approved:
	Governor.
	Speaker of the House of Delegates.
	President of the Senate.