1	H.266
2	Introduced by Representative Black of Essex
3	Referred to Committee on
4	Date:
5	Subject: Health; prescription drugs; 340B drug pricing program; 340B covered
6	entities; 340B contract pharmacies
7	Statement of purpose of bill as introduced: This bill proposes to protect 340B
8	covered entities and 340B contract pharmacies, and their patients, from
9	discrimination or interference by drug manufacturers and by health insurers,
10	pharmacy benefit managers, and other payors.
11	An and 1 in a securious for 240D covered entities and 240D contract
12	An act relating to the 340B prescription drug pricing program
13	It is hereby enacted by the General Assembly of the State of Vermont:
14	Sec. 1. 18 W.S. A. chapter 01, subchapter 6 is added to read:
15	Subchapter 6. 340B Drug Pricing Program
16	§ 4681. DEFINITIONS
17	As used in this subchapter.

1	(1) "3/10P contract pharmacy" means a pharmacy that has a contract
2	with a 340B covered entity to receive and dispense 340B drugs to the 340B
3	covered entity's patients on the covered entity's behalf.
4	(2) '\$40B covered entity" means an entity participating or authorized to
5	participate in the federal 340B drug pricing program, as described in 42 U.S.C
6	§ 256b. The term includes a 340B covered entity's pharmacy.
7	(3) "340B drug" means a drug that has been subject to any offer for
8	reduced prices by a manufacturer pursuant to 42 U.S.C. § 256b and is
9	purchased by a 340B covered entity.
10	(4) "Discount" means a reduction in the amount a 340B covered entity
11	is charged for a 340B drug at the time of purchase.
12	(5) "Health insurer" has the same meaning as in section 9402 of this
13	title.
14	(6) "Manufacturer" has the same meaning as in 26 V.S.A. § 2022.
15	(7) "Pharmacy" means a place licensed by the Vermont Board of
16	Pharmacy at which drugs, chemicals, medicines, prescriptions, and poisons are
17	compounded, dispensed, or sold at retail.
18	(8) "Pharmacy benefit manager" has the same meaning as in vection
19	3602 of this title.
20	(9) "Rebate" means a discount in which the terms are fixed and are
21	disclosed in writing to a 340D covered entity at the time of the initial purchase

1	of the 210P drug to which the discount applies, but which discount is not
2	applied at the time of purchase.
3	§ 4682. DISCRIMINATION AGAINST 340B ENTITIES PROHIBITED
4	(a) A monufacturer or its agent shall not deny, restrict, prohibit, or
5	otherwise interfere with, directly or indirectly, the acquisition of a 340B drug
6	by or delivery of a 340B drug to a 340B contract pharmacy on behalf of a
7	340B covered entity unless receipt by the 340B contract pharmacy is
8	prohibited by the U.S. Department of Health and Human Services.
9	(b) A manufacturer or its agent shall not directly or indirectly require a
10	340B covered entity to submit any laims, utilization, encounter, purchase, or
11	other data as a condition for allowing the acquisition of a 340B drug by or
12	delivery of a 340B drug to a 340B contract pharmacy unless the claims or
13	utilization data-sharing is required by the U.S. Department of Health and
14	Human Services.
15	(c) A manufacturer or its agent shall not interfere with the ability of a
16	pharmacy contracted with a 340B covered entity to dispense 340B drugs to
17	eligible patients of the 340B covered entity.
18	(d) A manufacturer or its agent shall offer or otherwise make available
19	340B drug pricing to a 340B covered entity or 340B contract pharmacy in the
20	form of a discount at the time of purchase and shall not offer or otherwise
21	make avanable 340B drug pricing in the form of a rebate.

\$ 4692 DEIMBURGEMENT OF 240D ENTITIES

1	8 1682 DEIMDIDGEMENT OF 210D ENTITIES
2	(a) With respect to reimbursement to a 340B covered entity or 340B
3	contrac pharmacy for 340B drugs, a health insurer, pharmacy benefit
4	manager, on other third-party payor, or is agent, shall not do any of the
5	<u>following:</u>
6	(1) Reimburse a 340B covered entity or 340B contract pharmacy for a
7	340B drug at a rate lower than that paid for the same drug to pharmacies that
8	are not 340B covered entities or 340B contract pharmacies or provide lower
9	reimbursement for a claim on the basis that the claim is for a 340B drug.
10	(2) Impose any terms or conditions on any 340B covered entity or 340B
11	contract pharmacy that differ from the terms or conditions applied to non-
12	340B covered entities or non-340B contract pharmacies, including any of the
13	following:
14	(A) fees, charges, clawbacks, or other adjustments or assessments,
15	including placing any additional requirements, restrictions, or burdens on the
16	340B covered entity or 340B contract pharmacy that results in administrative
17	costs or fees to the 340B covered entity or 340B contract pharmacy that are
18	not placed on other entities, including affiliate pharmacies of the health
19	insurer, pharmacy benefit manager, or other third-party payor;
20	(B) dispensing fees that are less than the dispensing fees for non-
21	340B covered entities of non-340B contract pharmacies,

1	(C) restrictions or requirements regarding portionation in standard or
2	preferred pharmacy networks;
3	(D) requirements relating to the frequency or scope of audits of
4	inventory n anagement systems;
5	(E) requirements that a claim for a drug include any identification,
6	billing modifier, attestation, or other indication that a drug is a 340B drug in
7	order to be processed of submitted, unless the indication is required by the
8	Centers for Medicare and Medicaid Services or the Agency of Human Services
9	for the administration of the Vermont Medicaid program; or
10	(F) any other restrictions, conditions, practices, or policies that are
11	not imposed on non-340B entities.
12	(3) Require a 340B covered entity of 340B contract pharmacy to
13	reverse, resubmit, or clarify a claim after the initial adjudication unless these
14	actions are in the normal course of pharmacy business and not related to 340B
15	drug pricing.
16	(4)(A) Discriminate against a 340B covered entity of 340B contract
17	pharmacy in a manner that prevents or interferes with any patient's choice to
18	receive drugs from the 340B covered entity or 340B contract pharmacy,
19	including for the administration of the drugs.
20	(B) For purposes of this subdivision (4), it is considered a
21	discriminatory practice that prevents or interferes with a patient's choice to

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hearth insurer, pharmacy benefit manager, or other third-party payor places any additional requirements, restrictions, or unnecessary burdens on the 340B covered entity or 340B contract pharmacy that result in administrative costs or fees to the 340B overed entity or 340B contract pharmacy, including requiring a claim for a drug to include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed, submitted, or resubmitted unless the indication is required by the Centers for Medicare and Medicaid Services or the Agency of Human Services for the administration of the Vermont Medicaid program. (5) Include any other provision in a contract between a health insurer, pharmacy benefit manager, or other third-party payor and a 340B covered entity or 340B contract pharmacy that discriminates gainst the 340B covered entity or 340B contract pharmacy or interferes with a patient's choice to receive a prescription drug from a 340B covered entity or 340B contract pharmacy, including the administration of the drug, in person or through direct

delivery, mail, or other form of shipment or creation of a restriction of

covered entity of 3400 contract pharmacy.

additional charge on a patient who chooses to receive drugs from a 340B

1	(6) Require or compel the 340R covered entity or 340R contract
2	pharmacy to submit ingredient costs or pricing data pertaining to 340B drugs
3	to any health insurer, pharmacy benefit manager, or third-party payor.
4	(7) Exclude any 340B covered entity or 340B contract pharmacy from
5	the health insurer's, pharmacy benefit manager's, or third-party payor network
6	on the basis that the 340B covered entity or 340B contract pharmacy dispenses
7	340B drugs or refusing to contract with a 340B covered entity or 340B
8	contract pharmacy for reasons other than those that apply equally to non-340B
9	entities.
10	§ 4684. MEDICAID UNAFFECTED
11	Nothing in this subchapter shall be deemed to apply to the Vermont
12	Medicaid program as payor.
13	§ 4685. VIOLATIONS
14	(a) A 340B covered entity, 340B contract pharmacy, or other person
15	injured by a manufacturer's, health insurer's, pharmacy benefit manager's,
16	other third-party payor's, or agent's violation of this subchapter may bring an
17	action in Superior Court for injunctive relief, compensatory and punitive
18	damages, costs and reasonable attorney's fees, and other appropriate relief.
19	(b) A violation occurs each time a prohibited act is committed.

l	(1) For numbers of section 1689 of this subchanter a prohibited set is
2	defined as each package of 340B drugs that is subject to a discriminatory
3	action by a manufacturer or its agent.
4	(2) For purposes of section 4683 of this chapter, a prohibited act is
5	defined as each tay that a health insurer, pharmacy benefit manager, third-
6	party payor, or agent engages in a discriminatory action toward a single
7	covered entity.
8	§ 4686. NO CONFLICT WITH FEDERAL LAW
9	Nothing in this subchapter shall be construed or applied to conflict with or
10	to be less restrictive than federal law for a person regulated by this subchapter.
11	Sec. 2. 18 V.S.A. § 3631 is amended to read:
12	§ 3631. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES
13	WITH RESPECT TO PHARMACIES
14	* * *
15	(g)(1) A pharmacy benefit manager or other third party that reimburses a
16	340B covered entity for drugs that are subject to an agreement under 42 U.S.C.
17	§ 256b through the 340B drug pricing program shall not reimburse the 340B
18	covered entity for pharmacy-dispensed drugs at a rate lower than that paid for
19	the same drug to pharmacies that are not 340B covered entities, and the
20	pharmacy benefit manager shall not assess any fee, charge-back, or other

1	adjustment on the 340B covered entity on the basis that the covered entity
2	part cipates in the 340B program as set forth in 42 U.S.C. § 256b.
3	(2) With respect to a patient who is eligible to receive drugs that are
4	subject to an agreement under 42 U.S.C. § 256b through the 340B drug pricing
5	program, a pharmacy benefit manager or other third party that makes payment
6	for the drugs shall not discriminate against a 340B covered entity in a manner
7	that prevents or interferes with the patient's choice to receive the drugs from
8	the 340B covered entity.
9	(3) As used in this section, "other third party" does not include Vermont
10	Medicaid. [Repealed.]
11	(h) A pharmacy benefit manager shall not:
12	(1) require a claim for a drug to include a modifier or supplemental
13	transmission, or both, to indicate that the drug is a 3-0B drug unless the claim
14	is for payment, directly or indirectly, by Medicaid; or
15	(2) restrict access to a pharmacy network or adjust rein bursement rates
16	based on a pharmacy's participation in a 340B contract pharmacy
17	arrangement. [Repealed.]
18	Sec. 3. EFFECTIVE DATE
19	This act shall take effect on passage.

Subchapter 6. 340B Drug Pricing Program

Sec. 1. 18 V.S.A. chapter 91, subchapter 6 is added to read:

§ 4681. DEFINITIONS

As used in this subchapter:

- (1) "340B contract pharmacy" means a pharmacy that has a contract with a 340B covered entity to receive and dispense 340B drugs to the 340B covered entity's patients on the covered entity's behalf.
- (2) "340B covered entity" means an entity participating or authorized to participate in the federal 340B drug pricing program, as described in 42 U.S.C. § 256b. The term includes a 340B covered entity's pharmacy.
- (3) "340B drug" means a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. § 256b and is purchased by a 340B covered entity.
- (4) "Discount" means a reduction in the amount a 340B covered entity is charged for a 340B drug at the time of purchase.
 - (5) "Manufacturer" has the same meaning as in 26 V.S.A. § 2022.
- (6) "Pharmacy" means a place licensed by the Vermont Board of Pharmacy at which drugs, chemicals, medicines, prescriptions, and poisons are compounded, dispensed, or sold at retail.
- (7) "Pharmacy benefit manager" has the same meaning as in section 3602 of this title.
- (8) "Rebate" means a discount in which the terms are fixed and are disclosed in writing to a 340B covered entity at the time of the initial purchase

of the 340B drug to which the discount applies, but which discount is not applied at the time of purchase.

§ 4682. DISCRIMINATION AGAINST 340B ENTITIES PROHIBITED

- (a) A manufacturer or its agent shall not deny, restrict, prohibit, or otherwise interfere with, directly or indirectly, the acquisition of a 340B drug by or delivery of a 340B drug to a 340B contract pharmacy on behalf of a 340B covered entity unless receipt by the 340B contract pharmacy is prohibited by the U.S. Department of Health and Human Services.
- (b) A manufacturer or its agent shall not directly or indirectly require a 340B covered entity to submit any claims, utilization, encounter, purchase, or other data as a condition for allowing the acquisition of a 340B drug by or delivery of a 340B drug to a 340B contract pharmacy unless the claims or utilization data-sharing is required by the U.S. Department of Health and Human Services.
- (c) A manufacturer or its agent shall not interfere with the ability of a pharmacy contracted with a 340B covered entity to dispense 340B drugs to eligible patients of the 340B covered entity.
- (d) A manufacturer or its agent shall offer or otherwise make available 340B drug pricing to a 340B covered entity or 340B contract pharmacy in the form of a discount at the time of purchase and shall not offer or otherwise make available 340B drug pricing in the form of a rebate.

§ 4683. MEDICAID UNAFFECTED

Nothing in this subchapter shall be deemed to apply to the Vermont

Medicaid program as payor.

§ 4684. VIOLATIONS

- (a) A 340B covered entity, 340B contract pharmacy, or other person injured by a manufacturer's or its agent's violation of this subchapter may bring an action in Superior Court for injunctive relief, compensatory and punitive damages, costs and reasonable attorney's fees, and other appropriate relief.
- (b) A violation occurs each time a prohibited act is committed. For purposes of section 4682 of this subchapter, a prohibited act is defined as each package of 340B drugs that is subject to a discriminatory action by a manufacturer or its agent.

§ 4685. NO CONFLICT WITH FEDERAL LAW

Nothing in this subchapter shall be construed or applied to conflict with or to be less restrictive than federal law for a person regulated by this subchapter.

Sec. 2. 18 V.S.A. § 9406 is added to read:

§ 9406. REPORTING ON PARTICIPATION IN 340B DRUG PRICING PROGRAM

Annually on or before January 31, each hospital participating in the federal 340B drug pricing program established by 42 U.S.C. § 256b shall submit to

the Green Mountain Care Board a report detailing the hospital's participation in the program during the previous hospital fiscal year, which report shall be posted on the Green Mountain Care Board's website and which shall contain at least the following information:

- (1) The annual estimated savings to the hospital from participating in the 340B program, comparing the acquisition price of drugs under the 340B program to group purchasing organization pricing. If group purchasing organization pricing is not available for a specific drug, the hospital shall compare the acquisition price under the 340B program to the price from another generally accepted pricing source.
- (2) The aggregated payment amount that the hospital made to pharmacies with which the hospital contracted to dispense drugs to its patients under the 340B program during the previous hospital fiscal year.
- (3) The aggregated payment amount that the hospital made to any other outside vendor for managing, administering, or facilitating any aspect of the hospital's 340B drug program during the previous hospital fiscal year.
- (4) The number of claims for all prescription drugs the hospital obtained through the 340B program during the previous hospital fiscal year.
- (5) A description of the ways in which the hospital uses savings from its participation in the 340B program to benefit its community through programs and services funded in whole or in part by savings from the 340B program,

including services that support community access to care that the hospital could not continue without these savings.

(6) A description of the hospital's internal review and oversight of its participation in the 340B program in compliance with the U.S. Department of Health and Human Services, Health Resources and Services Administration's 340B program rules and guidance.

Sec. 3. REPEAL

Sec. 2 (18 V.S.A. § 9406; reporting on participation in 340B drug pricing program) is repealed on January 1, 2031.

Sec. 4. EFFECTIVE DATE

This act shall take effect on passage, with the first report under Sec. 2 (18 V.S.A. § 9406) due on or before January 31, 2026.