2024 -- S 2725 AS AMENDED

LC005419

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2024

AN ACT

RELATING TO BUSINESSES AND PROFESSIONS -- DEFENDING AFFORDABLE PRESCRIPTION DRUG COSTS ACT

Introduced By: Senators Valverde, and Pearson

Date Introduced: March 05, 2024

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

1	SECTION 1. Title 5 of the General Laws entitled "BUSINESSES AND PROFESSIONS"
2	is hereby amended by adding thereto the following chapter:
3	CHAPTER 19.3
4	DEFENDING AFFORDABLE PRESCRIPTION DRUG COSTS ACT
5	<u>5-19.3-1. Short title.</u>
6	This chapter shall be known and may be cited as the "Defending Affordance Prescription
7	Drug Costs Act".
8	<u>5-19.3-2. Definitions.</u>
9	As used in this chapter, the following terms have the following meanings:
10	(1) "340B drug" means a drug that has been subject to any offer for reduced prices by a
11	manufacturer pursuant to 42 U.S.C. § 256b and is purchased by a covered entity as defined in 42
12	<u>U.S.C.</u> § 256b(a)(4).
13	(2) "340B entity" means an entity participating or authorized to participate in the federal
14	340B drug discount program, as described in 42 U.S.C. § 256b, including its pharmacy, or any
15	pharmacy contracted with the participating entity to dispense drugs purchased through the 340B
16	drug discount program.
17	(3) "Health insurer" means every nonprofit medical service corporation, hospital service
18	corporation, health maintenance organization, or other insurer offering or insuring health services;

1	the term shall, in addition, include any entity defined as an "insurer" under § 42-62-4 and any third-
2	party administrator when interacting with health care providers and enrollees on behalf of the
3	<u>insurer.</u>
4	(4) "Pharmaceutical manufacturer" means a person that manufactures a prescription drug
5	and sells, directly or through another person, the prescription drug for distribution in this state.
6	(5) "Pharmacy" has the meaning set forth in § 5-19.1-2.
7	(6) "Pharmacy benefit manager (PBMs)" means a person or entity employed by for-profit
8	companies that manage prescription drug benefits on behalf of private insurers, Medicare Part D
9	drug plans, government employee plans, large employers, and Medicaid managed care
10	organizations (MCOs).
11	(7) "Rebate(s)" means all price concessions paid by a manufacturer or any other third party
12	to PBMs including rebates, discounts, credits, fees, manufacturer administrative fees, or other
13	payments that are based on actual or estimated utilization of a covered drug or price concessions
14	based on the effectiveness of a covered drug.
15	5-19.3-3. Prohibition of certain discriminatory actions related to reimbursement of
16	340B entities.
17	(a) With respect to reimbursement to a 340B entity for 340B drugs, a health insurer,
18	pharmacy benefit manager, other third-party payor, or its agent shall not do any of the following:
19	(1) Reimburse a 340B entity for 340B drugs at a rate lower than that paid for the same drug
20	to entities that are not 340B entities or lower reimbursement for a claim on the basis that the claim
21	is for a 340B drug.
22	(2) Impose any terms or conditions on any 340B entity with respect to any of the following
23	that differ from such terms or conditions applied to non-340B entities on the basis that the entity
24	participates in the federal 340B drug discount program set forth in 42 U.S.C. § 256b or that a drug
25	is a 340B drug including, without limitation, any of the following:
26	(i) Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this
27	section, the term "other adjustment" includes placing any additional requirements, restrictions, or
28	unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B
29	entity that are not placed upon other entities that do not participate in the 340B drug discount
30	program, including affiliate pharmacies of the health insurer, pharmacy benefit manager, or other
31	third-party payor.
32	(ii) Dispensing fees that are less than the dispensing fees for non-340B entities.
33	(iii) Restrictions or requirements regarding participation in standard or preferred pharmacy
34	networks.

1	(iv) Requirements leading to the frequency of scope of addits of inventory management
2	systems.
3	(v) Requirements that a claim for a drug include any identification, billing modifier,
4	attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted
5	unless it is required by the Centers for Medicare and Medicaid Services or the Medicaid program.
6	(vi) Any other restrictions, conditions, practices, or policies that are not imposed on non-
7	340B entities.
8	(3) Require a 340B entity to reverse, resubmit, or clarify a claim after the initial
9	adjudication unless these actions are in the normal course of pharmacy business and not related to
10	340B drug pricing.
11	(4) Discriminate against a 340B entity in a manner that prevents or interferes with any
12	patient's choice to receive such drugs from the 340B entity, including the administration of such
13	drugs. For purposes of this section, it is considered a discriminatory practice that prevents or
14	interferes with a patient's choice to receive drugs at a 340B entity if a health insurer, pharmacy
15	benefit manager, or other third-party payor places any additional requirements, restrictions, or
16	unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B
17	entity including, but not limited to, requiring a claim for a drug to include any identification, billing
18	modifier, attestation or other indication that a drug is a 340B drug in order to be processed or
19	resubmitted unless it is required by the centers for Medicare and Medicaid services or the executive
20	office of health and human services in administration of the Medicaid program.
21	(5) Include any other provision in a contract between a health insurer, pharmacy benefit
22	manager, or other third-party payor and a 340B entity that discriminates against the 340B entity or
23	prevents or interferes with an individual's choice to receive a prescription drug from a 340B entity,
24	including the administration of the drug, in person or via direct delivery, mail, or other form of
25	shipment, or creation of a restriction or additional charge on a patient who chooses to receive drugs
26	from a 340B entity.
27	(6) Require or compel the submission of ingredient costs or pricing data pertaining to 340B
28	drugs to any health insurer, pharmacy benefit manager, or other third-party payor.
29	(7) Exclude any 340B entity from the health insurer, pharmacy benefit manager, or other
30	third-party payor network or refusing to contract with a 340B entity for reasons other than those
31	that apply equally to non-340B entities.
32	<u>5-19.3-4. Exclusion.</u>
33	Nothing in this chapter applies to the Medicaid program as payor when Medicaid provides
34	reimbursement for covered outpatient drugs as defined in 42 U.S.C. § 1396r-8(k).

1	5-19.3-5. Prohibition on certain discriminatory actions by a pharmaceutical
2	manufacturer, agent, or affiliate of such manufacturer related to 340B entities.
3	(a) A pharmaceutical manufacturer, agent, or affiliate of such manufacturer shall not deny,
4	restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B
5	drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is
6	authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity
7	unless such receipt is prohibited by the United States department of health and human services.
8	(b) A pharmaceutical manufacturer, agent, or affiliate of such manufacturer shall not
9	interfere with a pharmacy contracted with a 340B entity.
0	<u>5-19.3-6. Violations.</u>
1	(a) The commission of any act prohibited by this chapter is considered a violation of the
2	Rhode Island deceptive trade practices act set forth in chapter 13.1 of title 6, as may be amended
3	from time to time, and subject to any penalties hereunder; provided, however, that there shall be no
4	right to bring a private or class action pursuant to such chapter 13.1 of title 6.
5	(b) A violation of chapter 13.1 of title 6 ("deceptive trade practices") shall occur each time
6	a prohibited act is committed.
7	5-19.3-7. Federal preemption.
8	(a) Nothing in this chapter is to be construed or applied to be less restrictive than federal
9	law for a person or entity regulated by this chapter.
0	(b) Nothing in this chapter is to be construed or applied to be in conflict with any of the
1	following:
2	(1) Applicable federal law and related regulations.
3	(2) Other laws of this state if the state law is compatible with applicable federal law.
4	(c) Limited distribution of a drug required under 21 U.S.C. § 355-1 is not to be construed
5	as a violation of this chapter.
6	SECTION 2. This act shall take effect upon passage.
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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO BUSINESSES AND PROFESSIONS -- DEFENDING AFFORDABLE PRESCRIPTION DRUG COSTS ACT

L	This act would prohibit any health insurer, pharmacy benefit manager, or other third-party
2	payor from discriminating against any 340B entity participating in a drug discount program. This
3	act would further prohibit a pharmaceutical manufacturer or wholesaler from denying, restricting,
1	prohibiting or otherwise interfering, directly or indirectly, with any contract to dispense or receive
5	340B drugs. Violation of the provisions of this act would be considered a violation of chapter 13.1
5	of title 6 ("deceptive trade practices").
7	This act would take effect upon passage.
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