

2025 -- H 5634 SUBSTITUTE A AS AMENDED

LC000919/SUB A

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2025

A N A C T

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

Introduced By: Representatives J. Brien, Baginski, Cotter, Hopkins, and Place

Date Introduced: February 26, 2025

Referred To: House 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
- 5-19.3-1. Short title.**
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- This chapter shall be known and may be cited as the "Defending Affordable Prescription
- 7
- Drug Costs Act".
- 8
- 5-19.3-2. Definitions.**
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- As used in this chapter, the following terms have the following meanings:
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- (1) "340B drug" means a drug that has been subject to any offer for reduced prices by a
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- manufacturer pursuant to 42 U.S.C. § 256b and is purchased by a covered entity as defined in 42
- 12
- U.S.C. § 256b(a)(4).
- 13
- (2) "340B contract pharmacy" means a pharmacy, as defined in §5-19.1-2, that dispenses
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- 340B drugs on behalf of a 340B-covered entity under contract.
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- (3) "340B covered entity" means an entity participating or authorized to participate in the
- 16
- federal 340B drug discount program, as described in 42 U.S.C. § 256b.
- 17
- (4) "Health insurer" means every nonprofit medical service corporation, hospital service
- 18
- corporation, health maintenance organization, or other insurer offering or insuring health services.

1 (5) "Pharmaceutical manufacturer" means any person or entity that manufactures or sells
2 prescription drugs, directly or through another person or entity, in this state.

3 (6) "Pharmacy benefit manager" or "PBMs" means an entity doing business in the state
4 that contracts to administer or manage prescription-drug benefits on behalf of any carrier that
5 provides prescription-drug benefits to residents of this state.

6 **5-19.3-3. Prohibition of certain discriminatory actions related to reimbursement of**
7 **340B covered entities and 340B contract pharmacies.**

8 (a) With respect to reimbursement to a 340B covered entity for 340B drugs, a health
9 insurer, pharmacy benefit manager, manufacturer, other third-party payor, or its agent shall not do
10 any of the following:

11 (1) Establish a lower reimbursement amount to a 340B covered entity or 340B contract
12 pharmacy for a 340B drug than it would be paid for a non-340B drug, based solely on the drug's
13 340B status;

14 (2) Impose fees, chargebacks, adjustments, or conditions on reimbursement to 340B
15 covered entity, that differs from such terms or conditions applied to a non-340B entity, based on
16 340B status and participation in the federal 340B drug discount program set forth in 42 U.S.C. §
17 256b;

18 (3) Deny or limit participation in standard or preferred pharmacy networks based on 340B
19 status;

20 (4) Impose requirements relating to the frequency or scope of audits of inventory
21 management systems inconsistent with the federal 340B drug pricing program;

22 (5) Require submission of claims-level data or documentation that identifies 340B drugs
23 as a condition of reimbursement or pricing, unless it is required by the Centers for Medicare and
24 Medicaid Services;

25 (6) Require a 340B covered entity to reverse, resubmit, or clarify a claim after the initial
26 adjudication unless these actions are in the normal course of pharmacy business and not related to
27 340B drug pricing;

28 (7) Interfere with, or limit, a 340B covered entity's choice to use a contract pharmacy for
29 drug distribution or dispensing;

30 (8) Include any other provision in a contract between a health insurer, pharmacy benefit
31 manager, manufacturer, or other third-party payor and a 340B covered entity that differ from the
32 terms and conditions applied to entities that are not 340B covered entities, that discriminates against
33 the 340B covered entity or prevents or interferes with an individual's choice to receive a
34 prescription drug from a 340B covered entity, including the administration of such drugs in person

1 or via direct delivery, mail, or other form of shipment, or create a restriction or additional charge
2 on a patient who chooses to receive drugs from a 340B covered entity;

3 (9) Place a restriction or additional charge on a patient who chooses to receive 340B drugs
4 from a 340B covered entity if such restriction or additional charge differs from the terms and
5 conditions applied where patients choose to receive drugs that are not 340B drugs from an entity
6 that is not a 340B covered entity or from a pharmacy that is not a 340B contract pharmacy;

7 (10) Exclude any 340B covered entity from a health insurer, pharmacy benefit manager, or
8 other third-party payor network or refuse to contract with a 340B covered entity for reasons other
9 than those that apply equally to a non-340B entity;

10 (11) Impose any other restrictions, requirements, practices, or policies that are not imposed
11 on a non-340B entity.

12 (b) Nothing in this section is intended to limit a health insurer or pharmacy benefit
13 manager's ability to use preferred pharmacies or develop preferred networks so long as participation
14 is not based on an entity's status as a 340B covered entity and participation in the network is subject
15 to the same terms and conditions as a non-340B covered entity.

16 **5-19.3-4. Exclusion.**

17 Nothing in this chapter applies to the Medicaid program as payor when Medicaid provides
18 reimbursement for covered outpatient drugs as defined in 42 U.S.C. § 1396r-8(k).

19 **5-19.3-5. Prohibition on certain discriminatory actions by a pharmaceutical**
20 **manufacturer, agent, or affiliate of such manufacturer related to 340B entities.**

21 (a) A pharmaceutical manufacturer, agent, or affiliate of such manufacturer shall not deny,
22 restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B
23 drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B covered entity
24 and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered
25 entity unless such receipt is prohibited by the United States department of health and human
26 services.

27 (b) A pharmaceutical manufacturer, agent, or affiliate of such manufacturer shall not
28 interfere with a 340B contract pharmacy that is actively contracted with a 340B covered entity.

29 (c) A pharmaceutical manufacturer, agent, or affiliate of such manufacturer shall not
30 impose additional terms or limitations not required by federal law as a condition of 340B
31 participation.

32 **5-19.3-6. Reporting and audit.**

33 Annually on or before April 1, each 340B covered entity participating in the federal 340B
34 drug pricing program established by 42 U.S.C. § 256b shall submit to the office of the governor,

1 the speaker of the house of representatives, the president of the senate, and auditor general a report
2 detailing the 340B covered entity's participation in the program during the previous calendar year,
3 which report shall be posted on the state auditor general's website and which shall contain at least
4 the following information:

5 (1) The aggregated acquisition cost for all prescription drugs that the 340B covered entity
6 obtained through the 340B program during the previous calendar year.

7 (2) The aggregated payment amount that the 340B covered entity received for drugs, under
8 the 340B program and dispensed or administered to patients enrolled in commercial and Medicare
9 Supplemental plans.

10 (3) The aggregated payment amount that the 340B covered entity made:

11 (i) To contract pharmacies to dispense drugs to its patients under the 340B program during
12 the previous calendar year;

13 (ii) To any other outside vendor for managing, administering, or facilitating any aspect of
14 the 340B covered entity's drug program during the previous calendar year; and

15 (iii) For all other expenses related to administering the 340B program, including staffing,
16 operational, and administrative expenses, during the previous calendar year.

17 (4) The names of all vendors, including split billing vendors, and contract pharmacies, with
18 which the 340B covered entity contracted to provide services associated with the covered entity's
19 340B program participation during the previous calendar year;

20 (5) The number of claims for all prescription drugs the 340B covered entity obtained
21 through the 340B program during the previous calendar year, including the total number of claims
22 and the number of claims reported by commercial and Medicare Supplemental plans;

23 (6) A description of the ways in which the 340B entity uses savings from its participation
24 in the 340B program to benefit patients and/or its community through programs, projects, and
25 services funded in whole or in part by savings from the 340B program;

26 (7) A description of any and all material breach, change in 340B eligibility status, and/or
27 the U.S. Department of Health and Human Services, Health Resources and Services
28 Administration's ("HRSA") 340B program or manufacturer audits during the previous calendar
29 year;

30 (8) A description of the 340B covered entity's self-audit and oversight of its participation
31 in the 340B program in compliance with the HRSA 340B program rules and guidance; and

32 (9) Such additional information as the general assembly or auditor general may request.

33 **5-19.3-7. Compliance and enforcement.**

34 The office of the state auditor general shall have the authority to:

1 (1) Investigate complaints and take appropriate actions to ensure compliance with this
2 chapter.

3 (2) Promulgate rules and regulations necessary to carry out the provisions of this chapter.

4 **5-19.3-8. Violations.**

5 (a) A violation of chapter 13.1 of title 6 ("deceptive trade practices") shall occur each time
6 a prohibited act is committed.

7 (b) The commission of any act prohibited by this chapter is considered a violation of
8 chapter 13.1 of title 6 ("unfair sales practices"), as may be amended from time to time, and subject
9 to any penalties thereunder.

10 **5-19.3-9. Federal preemption.**

11 (a) Nothing in this chapter is to be construed or applied to be less restrictive than federal
12 law for a person or entity regulated by this chapter.

13 (b) Nothing in this chapter is to be construed or applied to be in conflict with any of the
14 following:

15 (1) Applicable federal law and related regulations.

16 (2) Other laws of this state if the state law is compatible with applicable federal law.

17 (c) Limited distribution of a drug required under 21 U.S.C. § 355-1 is not to be construed
18 as a violation of this chapter.

19 SECTION 2. This act shall take effect on October 1, 2025.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
A N A C T
RELATING TO BUSINESSES AND PROFESSIONS -- DEFENDING AFFORDABLE
PRESCRIPTION DRUG COSTS ACT

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- This act would prohibit any health insurer, pharmacy benefit manager, manufacturer, or other third-party payor from discriminating against any 340B covered entity participating in a drug discount program. This act would further prohibit a pharmaceutical manufacturer or wholesaler from denying, restricting, prohibiting or otherwise interfering, directly or indirectly, with any contract pharmacy to dispense or receive 340B drugs. Violation of the provisions of this act would be considered a violation of chapter 13.1 of title 6 ("unfair sales practices").
- This act would take effect on October 1, 2025.

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