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S.P. 435

In Senate, March 13, 2025

**An Act to Protect Health Care for Rural and Underserved Areas by
Prohibiting Discrimination by Participants in a Federal Drug
Discount Program**

Received by the Secretary of the Senate on March 12, 2025. Referred to the Committee on Health Coverage, Insurance and Financial Services pursuant to Joint Rule 308.2 and ordered printed.

A handwritten signature in black ink, appearing to read 'D M Grant'.

DAREK M. GRANT
Secretary of the Senate

Presented by Senator BAILEY of York.
Cosponsored by Representative MORRIS of Turner and
Senators: BALDACCI of Penobscot, President DAUGHTRY of Cumberland, MOORE of
Washington, Representatives: DUCHARME of Madison, FREDERICKS of Sanford,
MASTRACCIO of Sanford, MATHIESON of Kittery, NUTTING of Oakland.

1 **Be it enacted by the People of the State of Maine as follows:**

2 **Sec. 1. 24-A MRSA c. 101** is enacted to read:

3 **CHAPTER 101**

4 **PROTECT HEALTH CARE FOR RURAL AND UNDERSERVED**
5 **COMMUNITIES ACT**

6 **§7701. Short title**

7 This chapter may be known and cited as "the Protect Health Care for Rural and
8 Underserved Communities Act."

9 **§7702. Definitions**

10 As used in this chapter, unless the context otherwise indicates, the following terms
11 have the following meanings.

12 **1. Health insurance issuer.** "Health insurance issuer" has the same meaning as
13 "carrier" as defined in section 4301-A, subsection 3.

14 **2. Manufacturer.** "Manufacturer" has the same meaning as in Title 32, section
15 13702-A, subsection 19.

16 **3. Pharmacy.** "Pharmacy" has the same meaning as in Title 32, section 13702-A,
17 subsection 24.

18 **4. Pharmacy benefits manager.** "Pharmacy benefits manager" has the same meaning
19 as in section 4347, subsection 17.

20 **5. 340B contract pharmacy.** "340B contract pharmacy" means a pharmacy that has a
21 contract with a 340B entity to receive and dispense 340B drugs to the 340B entity's patients
22 on behalf of the 340B entity. For the purposes of this chapter, a record of a current 340B
23 contract pharmacy relationship between the 340B entity and the 340B contract pharmacy
24 that is on the 340B United States Department of Health and Human Services, Health
25 Resources and Services Administration, Office of Pharmacy Affairs 340B Information
26 System website, or such publicly accessible successor website maintained by the United
27 States Department of Health and Human Services, is prima facie evidence of such a
28 contract.

29 **6. 340B drug.** "340B drug" means a drug that is purchased or eligible for purchase
30 under Section 340B of the federal Public Health Service Act, 42 United States Code,
31 Section 256b(a)(3).

32 **7. 340B entity.** "340B entity" means an entity participating or authorized to participate
33 in the federal 340B drug discount program, as described in 42 United States Code, Section
34 256b, including its pharmacy, or any pharmacy contracted with the participating entity to
35 dispense drugs purchased through the federal 340B drug discount program.

36 **§7703. Prohibition of certain discriminatory actions by manufacturer or agent related**
37 **to 340B entities**

1 **1. Interference with acquisition or delivery of 340B drugs prohibited.** A
2 manufacturer or its agent may not deny, restrict, prohibit or otherwise interfere with, either
3 directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a
4 340B contract pharmacy on behalf of a 340B entity unless receipt of that 340B drug is
5 prohibited by the United States Department of Health and Human Services.

6 **2. Submission of claims or utilization data prohibited.** A manufacturer or its agent
7 may not, either directly or indirectly, require a 340B entity to submit any claims or
8 utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery
9 of a 340B drug to, a 340B entity unless the claims or utilization data sharing is required by
10 the United States Department of Health and Human Services.

11 **3. Other interference prohibited.** A manufacturer or distributor may not otherwise
12 interfere with a 340B entity unless expressly authorized by the United States Department
13 of Health and Human Services.

14 **§7704. Prohibition of certain discriminatory actions with respect to reimbursement**
15 **of 340B entities**

16 With respect to reimbursement of a 340B entity for 340B drugs, a health insurance
17 issuer, pharmacy benefits manager or other 3rd-party payor or agent may not:

18 **1. Reimbursement at lower rate prohibited.** Reimburse a 340B entity for 340B drugs
19 at a rate lower than that paid for the same drug to entities that are not 340B entities or lower
20 the reimbursement amount for a claim on the basis that the claim is for a 340B drug;

21 **2. Imposition of different terms and conditions prohibited.** Impose any terms or
22 conditions on any 340B entity that differ from such terms or conditions applied to entities
23 that are not 340B entities or pharmacies that are not 340B contract pharmacies including,
24 without limitation:

25 A. Fees, charges, clawbacks or other adjustments or assessments. For purposes of this
26 paragraph, "other adjustment or assessment" includes, without limitation, placing any
27 additional requirements, restrictions or burdens upon the 340B entity that result in
28 administrative costs or fees to the 340B entity that are not placed upon entities that are
29 not 340B entities, including affiliate pharmacies of the health insurance issuer,
30 pharmacy benefits manager or other 3rd-party payor;

31 B. Dispensing fees that are less than the dispensing fees for entities that are not 340B
32 entities or pharmacies that are not 340B contract pharmacies;

33 C. Restrictions or requirements regarding participation in standard or preferred
34 pharmacy networks;

35 D. Requirements relating to inventory management systems or to the frequency or
36 scope of audits;

37 E. Requirements that a claim for a drug include any identification, billing modifier,
38 attestation or other indication that a drug is a 340B drug in order to be processed or
39 submitted or reimbursed unless it is required by the United States Department of Health
40 and Human Services, Centers for Medicare and Medicaid Services or the Department
41 of Health and Human Services for the administration of the MaineCare program; or

42 F. Any other restrictions, conditions, practices or policies that are not imposed on
43 entities that are not 340B entities;

1 **3. Reversal, resubmission or clarification of claims prohibited.** Require a 340B
2 entity to reverse, resubmit or clarify a claim after the initial adjudication unless these
3 actions are in the normal course of pharmacy business and are not related to 340B drug
4 pricing;

5 **4. Discrimination against 340B entity that interferes with patient choice.**
6 Discriminate against a 340B entity in a manner that prevents or interferes with a patient's
7 choice to receive 340B drugs from the 340B entity, including the administration of the
8 drugs. For purposes of this subsection, it is considered a discriminatory practice that
9 prevents or interferes with a patient's choice to receive drugs at a 340B entity if a health
10 insurance issuer, pharmacy benefits manager or other 3rd-party payor places any additional
11 requirements, restrictions or burdens upon the 340B entity that result in administrative costs
12 or fees to the 340B entity, including but not limited to requiring a claim for a drug to include
13 any identification, billing modifier, attestation or other indication that a drug is a 340B drug
14 in order to be processed or resubmitted unless it is required by the United States Department
15 of Health and Human Services, Centers for Medicare and Medicaid Services or the
16 Department of Health and Human Services for the administration of the MaineCare
17 program;

18 **5. Discrimination against 340B entity that interferes with patient choice of**
19 **delivery method.** Include any other provision in a contract between a health insurance
20 issuer, pharmacy benefits manager or other 3rd-party payor and a 340B entity that
21 discriminates against the 340B entity that participates in the 340B program or prevents or
22 interferes with a patient's choice to receive a 340B drug from a 340B entity, whether by
23 direct administration, in-person dispensing, direct delivery, mail or other form of shipment;

24 **6. Restrictions or additional charges prohibited.** Place a restriction or additional
25 charge on a patient who chooses to receive 340B drugs from a 340B entity;

26 **7. Submission of data pertaining to ingredient costs or pricing of 340B drugs**
27 **prohibited.** Require or compel the submission of ingredient costs or pricing data pertaining
28 to 340B drugs from a 340B entity to any health insurance issuer, pharmacy benefits
29 manager or other 3rd-party payor; or

30 **8. Exclusion from pharmacy network prohibited.** Exclude any 340B entity from the
31 health insurance issuer, pharmacy benefits manager or other 3rd-party payor network on
32 the basis that the 340B entity dispenses 340B drugs or refuse to contract with a 340B entity
33 for reasons other than those that apply equally to entities that are not 340B entities.

34 **§7705. MaineCare program not affected**

35 This chapter does not apply to the MaineCare program as a payor when the MaineCare
36 program provides reimbursement for covered outpatient drugs as defined in 42 United
37 States Code, Section 1396r-8(k)(2).

38 **§7706. Enforcement**

39 **1. Enforcement; violation.** A violation of this chapter is subject to enforcement under
40 the Maine Unfair Trade Practices Act, including any of the remedies provided for in that
41 Act. A violation is committed each time a prohibited act under this chapter occurs.

42 **2. Civil action authorized.** A 340B entity may bring a civil action in the Superior
43 Court against a person who violates this chapter.

1 **3. Exemption from enforcement.** The limited distribution of a drug required under 21
2 United States Code, Section 355–1 is not a violation of this chapter.

3 **§7707. Federal preemption; statutory construction**

4 **1. No less restrictive than federal law.** This chapter may not be construed or applied
5 to be less restrictive than federal law for a person or entity regulated by this chapter.

6 **2. No conflict with federal law and regulation or other laws of this State.** This
7 chapter may not be construed or applied in any manner that conflicts with:

8 A. Applicable federal law and related regulations; or

9 B. Other laws of this State if the State law is compatible with applicable federal law.

10 **SUMMARY**

11 This bill prevents discrimination by pharmaceutical manufacturers, health insurance
12 carriers, pharmacy benefits managers and their agents against pharmacies and health care
13 providers that participate in the federal prescription drug discount program, known as the
14 340B drug discount program. The bill's provisions do not apply to the MaineCare program.
15 The bill also includes language to clarify that the provisions may not be construed or
16 applied in any way that conflicts with federal law.