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HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES

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STATE OF MAINE

SENATE

132ND LEGISLATURE

FIRST SPECIAL SESSION

COMMITTEE AMENDMENT " " to S.P. 435, L.D. 1018, "An Act to Protect Health Care for Rural and Underserved Areas by Prohibiting Discrimination by Participants in a Federal Drug Discount Program"

Amend the bill by striking out everything after the enacting clause and inserting the following:

'**Sec. 1. 22 MRSA §1728, sub-§1,** as enacted by PL 2023, c. 276, §1, is repealed.

Sec. 2. 22 MRSA §1728, sub-§1-A is enacted to read:

1-A. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Hospital" means:

(1) An acute care institution licensed and operating in this State as a hospital under section 1811 or the parent of such an institution; or

(2) A hospital subsidiary or hospital affiliate in the State that provides medical services or medically related diagnostic and laboratory services or engages in ancillary activities supporting those services.

B. "340B contract pharmacy" has the same meaning as in Title 24-A, section 7752, subsection 5.

C. "340B drug" has the same meaning as in Title 24-A, section 7752, subsection 6.

D. "340B entity" has the same meaning as in Title 24-A, section 7752, subsection 7.

Sec. 3. 22 MRSA §1728, sub-§2-A is enacted to read:

2-A. Additional reporting by hospitals on participation in federal 340B drug program. In addition to any report required pursuant to subsection 2, beginning July 1, 2026, each hospital participating in the 340B program shall provide an annual report to the Maine Health Data Organization. The Maine Health Data Organization shall post the report on its publicly accessible website. Each hospital shall report in a standardized format, as

agreed upon by the Maine Health Data Organization and the hospital, and include, at a minimum, the following information in the report:

A. The hospital's national provider identification number;

B. The name of the hospital;

C. The address of the hospital for the purpose of accepting service of process;

D. The classification of the hospital;

E. The aggregated acquisition cost for the prescription drugs obtained under the 340B program;

F. The aggregated payment amount received for the prescription drugs obtained under the 340B program and dispensed to patients;

G. The number of pricing units dispensed or administered for prescription drugs described in paragraph F;

H. The aggregated payments made:

(1) To 340B contract pharmacies to dispense 340B drugs;

(2) To any other entity that is not the 340B entity and is not a 340B contract pharmacy for managing any aspect of the hospital's 340B program; and

(3) For all other expenses related to administering the 340B program; and

I. The number of claims for prescription drugs described in paragraph H.

The information required under this subsection must be reported by payor type, including commercial insurance, medical assistance, the MaineCare program and Medicare as required by the Maine Health Data Organization. The information for paragraphs E to G must also be reported at the National Drug Code level for the 50 most frequently dispensed prescription drugs by the hospital under the 340B program. The information must include all physician-administered and physician-dispensed prescription drugs.

Data submitted must also include prescription drugs dispensed by outpatient facilities that are identified as child facilities under the 340B program based on their inclusion on a hospital's Medicare cost report.

Sec. 4. 22 MRSA §1728, sub-§3, as enacted by PL 2023, c. 276, §1, is amended to read:

3. Reporting. The Maine Health Data Organization shall produce and post on its publicly accessible website a report that includes a summary of the aggregate information received from hospitals required to report under subsection 2 and subsection 2-A. The Maine Health Data Organization shall submit the report required by this subsection to the Office of Affordable Health Care, as established in Title 5, section 3122, the Maine Prescription Drug Affordability Board, as established in Title 5, section 12004-G, subsection 14-I, and the joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters.

Sec. 5. 24-A MRSA c. 103 is enacted to read:

CHAPTER 103

PROTECT HEALTH CARE FOR RURAL AND UNDERSERVED COMMUNITIES ACT

§7751. Short title

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

§7752. Definitions

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

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

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

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

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

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

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

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

§7753. Prohibition of certain discriminatory actions by manufacturer or agent related to 340B entities

1. Interference with acquisition or delivery of 340B drugs prohibited. A manufacturer or its agent may not deny, restrict, prohibit or otherwise interfere with, either 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 entity unless receipt of that 340B drug is prohibited by the United States Department of Health and Human Services.

2. Submission of claims or utilization data prohibited. A manufacturer or its agent may not, either directly or indirectly, require a 340B entity to submit any claims or

utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.

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

§7754. Prohibition of certain discriminatory actions with respect to reimbursement of 340B entities

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

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

2. Imposition of different terms and conditions prohibited. Impose any terms or conditions on any 340B entity that differ from such terms or conditions applied to entities that are not 340B entities or pharmacies that are not 340B contract pharmacies because it is a 340B entity including, without limitation:

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

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

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

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

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

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

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

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

5. Discrimination against 340B entity that interferes with patient choice of delivery method. Include any other provision in a contract between a health insurance issuer, pharmacy benefits manager or other 3rd-party payor and a 340B entity that differs from the terms and conditions applied to entities that are not 340B entities that discriminates against the 340B entity that participates in the 340B program or prevents or interferes with a patient's choice to receive a 340B drug from a 340B entity, whether by direct administration, in-person dispensing, direct delivery, mail or other form of shipment;

6. Restrictions or additional charges prohibited. Place a restriction or additional charge on a patient who chooses to receive 340B drugs from a 340B entity if the restriction or additional charge differs from the terms and conditions applied when patients choose to receive drugs that are not 340B drugs from an entity that is not a 340B entity or from a pharmacy that is not a 340B contract pharmacy;

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

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

This section may not be construed to limit a health insurance issuer's ability to use certain preferred pharmacies or develop networks of preferred pharmacies as long as a health insurance issuer's decision is not based on an entity's status as a 340B entity.

§7755. MaineCare program not affected

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

§7756. Contracting under 340B program

As permitted under federal law and regulation, a 340B entity shall, to the extent possible, contract with a 340B contract pharmacy that is located in this State.

§7757. Enforcement

1. Enforcement; violation. Notwithstanding section 12-A, a violation of this chapter is subject to enforcement under the Maine Unfair Trade Practices Act, including any of the remedies provided for in that Act. A violation is committed each time a prohibited act under this chapter occurs. An investigation of a violation by a manufacturer may include a wholesaler or 3rd party that may possess evidence supporting that investigation.

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

§7758. Federal preemption; statutory construction

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

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

A. Applicable federal law and related regulations; or

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

Amend the bill by relettering or renumbering any nonconsecutive Part letter or section number to read consecutively.

SUMMARY

This amendment replaces the bill and prohibits discrimination by pharmaceutical manufacturers, health insurance carriers, pharmacy benefits managers and their agents against pharmacies and health care providers that participate in the federal prescription drug discount program, known as the 340B drug discount program, solely on the basis of participation in the 340B drug discount program. The amendment clarifies that the language prohibiting discrimination does not extend to the use of preferred networks by health insurance carriers and pharmacy benefits managers. The amendment requires that pharmacies and health care providers participating in the program must contract, to the extent possible and as permitted under federal law and regulation, with pharmacies located in this State. The amendment provides that enforcement under the Maine Unfair Trade Practices Act is the exclusive enforcement mechanism and does not authorize a private cause of action for enforcement. These provisions do not apply to the MaineCare program and include language to clarify that the provisions may not be construed or applied in a way that conflicts with federal law.

The amendment also requires hospitals that participate in the 340B drug discount program to annually report additional information to the Maine Health Data Organization related to their participation in the program beginning July 1, 2026.

FISCAL NOTE REQUIRED

(See attached)