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Bill Analysis

Version: As Introduced

Primary Sponsor: Sen. Hackett

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SUMMARY

- Prohibits health plan issuers and Medicaid managed care organizations (MCOs) from including in a contract with a covered entity that participates in the federal 340B Drug Pricing Program certain provisions that would result in the 340B covered entity not receiving the financial relief it is entitled to by virtue of its participation in the program.
- Requires terminal distributors of dangerous drugs to pay to a 340B covered entity the full amount received from the patient and the patient's health insurer, except for a fee agreed upon in writing between the terminal distributor and the covered entity.

DETAILED ANALYSIS

Reimbursements to 340B covered entities

Generally, the bill prohibits private insurers and Medicaid managed care organizations (MCOs) from including certain provisions related to reimbursement and fees in contracts entered into with 340B covered entities. A 340B covered entity is an entity that under federal law is authorized to participate in the 340B Drug Pricing Program.

340B Drug Pricing Program – federal law background

The 340B Drug Pricing Program resulted from the enactment of the “Veterans Health Care Act of 1992,” which is codified as Section 340B of the Public Health Service Act.¹ Section 340B requires drug manufacturers to sell outpatient drugs at a discount to certain grantees of federal agencies and other entities identified in the statute. Drugs that are covered by the 340B Drug Pricing Program are (1) drugs provided in outpatient settings approved by the U.S. Food and Drug Administration (FDA) that require a prescription, (2) over-the-counter drugs written

¹ 42 United States Code (U.S.C.) 256b.

on a prescription, (3) biological products that can be dispensed only by a prescription (other than vaccines), or (4) FDA-approved insulin.²

The purpose of the program is to provide financial relief to facilities that provide care to the medically underserved. The program is administered by the Office of Pharmacy Affairs of the Health Resources and Services Administration (HRSA), a division of the U.S. Department of Health and Human Services.³

Only “covered entities” as defined in Section 340B are authorized to participate in the 340B Drug Pricing Program. Covered entities are referred to in the bill as “340B covered entities” and include all of the following:⁴

1. FQHCs – This category includes federally qualified health center look-alikes, consolidated health centers, migrant health centers, health care for the homeless, healthy schools/healthy communities, health centers for residents of public housing, and Office of Tribal Programs or urban Indian organizations.
2. A family planning project receiving a grant or contract under Section 1001 of the federal Public Health Service Act;
3. An entity receiving a grant under subpart II of part C of Title XXVI of the federal Ryan White Care Act (relating to categorical grants for outpatient early intervention services for the human immunodeficiency virus (HIV));
4. A state-operated AIDS Drug Assistance Program (ADAP) receiving financial assistance under the Ryan White Care Act;
5. A black lung clinic receiving funds under Section 427(a) of the federal Black Lung Benefits Act;
6. A comprehensive hemophilia diagnostic treatment center receiving a grant under Section 501(a)(2) of the Social Security Act;
7. A Native Hawaiian Health Center receiving funds under the federal Native Hawaiian Health Care Act of 1988;
8. An urban Indian organization receiving funds under Title V of the federal Indian Health Care Improvement Act;
9. Any entity receiving assistance under Title XXVI of the Public Health Service Act (the HIV Health Care Services Program), other than a state or unit of local government, but only if the entity is certified by the U.S. Secretary of Health and Human Services;

² 42 U.S.C. 1396r-8(k)(2).

³ Health Resources and Services Administration, U.S. Department of Health and Human Services, *340B Drug Pricing Program*, <https://www.hrsa.gov/opa/index.html>.

⁴ R.C. 5167.01, citing 42 U.S.C. 256b(a)(4).

10. An entity receiving funds under Section 318 (relating to treatment of sexually transmitted diseases) or Section 317(j)(2) (relating to treatment of tuberculosis) of the Social Security Act through a state or unit of local government, but only if the entity is certified by the U.S. Secretary of Health and Human Services; and
11. Certain hospitals, including children’s hospitals, critical access hospitals, free standing cancer hospitals, rural referral centers, sole community hospitals, and disproportionate share hospitals (often referred to as DSH hospitals).⁵

Insurer and MCO contracts with 340B covered entities

The bill prohibits health plan issuers⁶ and MCOs, including third-party administrators of either, from including any of the following provisions in a contract with a 340B covered entity:⁷

1. A reimbursement or payment rate for a prescription drug that is less than the national average drug acquisition cost rate⁸ for the drug as determined by the U.S. Centers for Medicare and Medicaid Services (CMS) or, if that rate is not available, a reimbursement rate that is less than the wholesale acquisition cost of the drug as defined in federal law, measured at the time the drug is administered or dispensed;
2. A fee that is not imposed on a health care provider that is not a 340B covered entity;
3. A fee that exceeds a fee imposed on a health care provider that is not a 340B covered entity.

Additionally, the bill prohibits a health plan issuer from including in the contract a provision that establishes a dispensing fee reimbursement that is less than the dispensing fee for terminal distributors of dangerous drugs the Medicaid Director establishes for the Medicaid program under current law.⁹

Both health plan issuers and MCOs are prohibited by the bill from discriminating against 340B covered entities in a manner that prevents or interferes with an enrollee or recipient’s choice to receive a prescription drug from a 340B covered entity or its contracted pharmacies.¹⁰

⁵ A “disproportionate share hospital” is a hospital with a disproportionately large share of low-income patients. Health Resources and Services Administration, U.S. Department of Health and Human Services, *Disproportionate Share Hospitals*, <https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals/index.html>.

⁶ R.C. 3922.01, not in the bill.

⁷ R.C. 3902.51(A) and 5167.123(A).

⁸ CMS’ methodology for calculating the national average drug acquisition cost can be found at the following link: <https://www.medicare.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf>.

⁹ R.C. 3902.51(A)(2), referencing R.C. 5164.753, not in the bill.

¹⁰ R.C. 3902.51(B) and 5167.123(B).

The bill specifies that its provisions that are applicable to health plan issuers apply to contracts entered into on and after the bill's effective date.¹¹ For both health plan issuers and MCOs, the bill specifies that any contract provision entered into that is contrary to the prohibitions discussed above is unenforceable and must be replaced with a dispensing fee or reimbursement rate that applies to health care providers that are not 340B covered entities.¹²

Terminal distributor contracts with 340B covered entities

The bill requires contracts between a terminal distributor of dangerous drugs and a 340B covered entity to provide that, when paying a 340B covered entity for dispensing a dangerous drug to a patient, the terminal distributor must pay to the 340B covered entity the full amount the terminal distributor receives from the patient and the patient's health insurer, except that the terminal distributor may deduct not more than a fee agreed upon in writing between the terminal distributor and the 340B covered entity.¹³ A terminal distributor of dangerous drugs is a person engaged in the sale of dangerous drugs at retail, or a person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption.¹⁴ Sites licensed as terminal distributors include pharmacies, hospitals, nursing homes, emergency medical service organizations, and laboratories.

Medicaid state maximum allowable cost

Regarding current law that requires the Medicaid Director to establish a state maximum allowable cost program for purposes of managing Medicaid payments to terminal distributors for certain identified drugs, the bill specifies that the establishment of the program is subject to its prohibitions on MCOs, as discussed above.¹⁵

HISTORY

Action	Date
Introduced	01-27-20

S0263-I-133/ts

¹¹ R.C. 3902.51(A).

¹² R.C. 3902.51(C) and 5167.123(C).

¹³ R.C. 4729.49(B) and (C).

¹⁴ R.C. 4729.01(Q), not in the bill.

¹⁵ R.C. 5164.751(B).