

GENERAL ASSEMBLY OF NORTH CAROLINA  
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SENATE BILL DRS15184-MG-96

Short Title: Fair Pricing & Trnspncy/340B Covered Entities. (Public)

Sponsors: Senators Galey, Burgin, and Sawrey (Primary Sponsors).

Referred to:

A BILL TO BE ENTITLED  
AN ACT ESTABLISHING FAIR PRICING AND TRANSPARENCY REQUIREMENTS FOR  
340B COVERED ENTITIES.

The General Assembly of North Carolina enacts:

**SECTION 1.(a)** Chapter 131E of the General Statutes is amended by adding a new  
Article to read:

"Article 11C.

"340B Covered Entities.

"Part 1. Fair Pricing of 340B Drugs by Hospitals.

**"§ 131E-214.50. Definitions.**

The following definitions apply in this Part:

- (1) 340B drug. – A drug that meets the definition of a "covered drug" under 42 U.S.C. § 256b(b)(2).
- (2) 340B Program. – The federal 340B Drug Pricing Program authorized under 42 U.S.C. § 256b and 42 C.F.R. Part 10, as both are from time to time amended.
- (3) Acquisition cost. – The amount paid by a covered entity to acquire a 340B drug.
- (4) Covered entity. – Any entity described in 42 U.S.C. § 256b(a)(4)(L) or 42 U.S.C. § 256b(a)(4)(M).

**"§ 131E-214.52. Fair pricing of 340B drugs by hospitals.**

A covered entity that acquires a 340B drug for a discounted price under the 340B Program shall not accept an amount greater than the acquisition cost for the 340B drug as payment for dispensing, administering, or otherwise delivering the 340B drug to a patient.

**"§ 131E-214.54. Violations constitute unfair or deceptive trade practice.**

Any violation of this Part constitutes an unfair or deceptive trade practice in violation of G.S. 75-1.1 and is subject to all of the enforcement and penalty provisions of an unfair or deceptive trade practice under Article 1 of Chapter 75 of the General Statutes.

"Part 2. 340B Covered Entity Transparency.

**"§ 131E-214.60. Definitions.**

The following definitions apply in this Part:

- (1) 340B drug. – A covered outpatient drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. § 256b, and is purchased by a covered entity.
- (2) 340B pricing. – Any price offered by a manufacturer to a covered entity for a covered outpatient drug pursuant to 42 U.S.C. § 256b.



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- (3) 340B Program. – The federal 340B Drug Pricing Program authorized under 42 U.S.C. § 256b and 42 C.F.R. Part 10, as both are from time to time amended.
- (4) Charity care. – The costs reported on Form CMS-2552-10, Worksheet S–10, Line 23 or any successor form.
- (5) Covered entity. – A covered entity, as defined in 42 U.S.C. § 256b(a)(4).
- (6) Covered outpatient drug. – A covered outpatient drug, as defined in 42 U.S.C. § 1396r-8(k)(2).

**"§ 131E-214.62. Annual reporting requirements.**

(a) Annually by October 1, each covered entity shall report to the Department, in the form and manner required by the Department, the following information regarding the preceding calendar year for the covered entity and each offsite outpatient facility, clinic, eligible offsite location, or other site associated with the covered entity:

- (1) Delineated by form of insurance or payor type, including, but not limited to, Medicaid, Medicare, commercial insurance, and uninsured:
- a. Aggregate acquisition cost paid for all 340B drugs.
- b. Aggregate payments received by individuals, insurers, or payors for all 340B drugs. For the purpose of this sub-subdivision, aggregate payments include cost-sharing amounts.
- c. The total number of prescriptions and what percentage of the covered entity's prescriptions were filled with 340B drugs.
- (2) Attestation as to whether the covered entity did any of the following:
- a. Passed on 340B Program discounts to patients of the covered entity in the form of lower cost-sharing for 340B drugs at the point of dispensing or administration.
- b. Provided a sliding fee scale for 340B drugs for patients whose family income is less than two hundred percent (200%) of the federal poverty level established pursuant to 42 U.S.C. § 9902.
- (3) Total operating costs of the covered entity, including itemized costs, for each of the following:
- a. Implementation of the policies described in subdivision (2) of this subsection, if applicable.
- b. Charity care.
- (4) Total payments made by the covered entity or any agent of the covered entity to any of the following:
- a. Any pharmacies under contract with the covered entity to dispense 340B drugs for 340B program-related services and other functions.
- b. Third-party administrators, including pharmacy benefits managers, for managing any components of the covered entity's participation in the 340B Program.
- c. Any other third parties in connection with 340B program-related compliance, legal, educational, or administrative costs.
- (5) Total number of pharmacies under contract with the covered entity to dispense 340B drugs, and among those, the following information:
- a. The number of pharmacies located out-of-state and the states in which the out-of-state pharmacies are located.
- b. Total number of prescriptions and orders for 340B drugs filled by the covered entity and by each offsite outpatient facility associated with the covered entity, and the percentage of such prescriptions or orders that were filled at such pharmacies, delineated by in-State and out-of-state pharmacies.

1                   c.     Total remuneration paid to or retained by such pharmacies or their  
2                         affiliates for any 340B program-related services performed on behalf  
3                         of the covered entity and each offsite outpatient facility associated  
4                         with the covered entity.

5                   d.     The percentage change in remuneration described in sub-subdivision  
6                         (4)c. of this subsection for the preceding calendar year compared to  
7                         the year before that.

8           (b)     An officer of the covered entity shall certify to the completeness and accuracy of the  
9                 report submitted pursuant to subsection (a) of this section.

10     **"§ 131E-214.64. Posting of annual reports.**

11                 The Department shall make all the reports received by covered entities pursuant to  
12                 G.S. 131E-214.62 available to the public on the Department's internet website."

13                 **SECTION 1.(b)** Part 1 of Article 11C of Chapter 131E of the General Statutes, as  
14                 enacted by this section, applies to any covered drug, as defined by 42 U.S.C. § 256b(b)(2), that  
15                 is dispensed, administered, or otherwise delivered to a patient by a covered entity on or after the  
16                 date this act becomes law. As used in this subsection, the term "covered entity" has the same  
17                 meaning as in G.S. 131E-214.50.

18                 **SECTION 1.(c)** Covered entities subject to Part 2 of Article 11C of Chapter 131E  
19                 of the General Statutes, as enacted by this section, shall submit the first report due under  
20                 G.S. 131E-214.62 by October 1, 2026.

21                 **SECTION 2.** This act is effective when it becomes law.