SENATE BILL 257:
Medication Cost Transparency Act.

2021-2022 General Assembly

Committee:		**Date:**	December 8, 2021
Introduced by:		**Prepared by:**	Jason Moran-Bates
Analysis of:	S.L. 2021-161		Staff Attorney

OVERVIEW: S.L. 2021-161 requires pharmacy benefits managers (PBMs) to be licensed. It adds to the consumer protections in G.S. 58-56A-3, restricts PBMs from prohibiting pharmacies from taking certain actions, and establishes rules for claim overpayments and PBM networks. PBMs and health benefit plans are required to provide coverage for biosimilars and credit all amounts paid on behalf of insureds toward cost-sharing requirements for certain drugs. The act also increases the Commissioner's ability to take enforcement action against PBMs and creates a workgroup to study a single unified process to accredit specialty pharmacies.

The act became effective October 1, 2021, and applies to contracts entered into, renewed, or amended on or after that date.

BILL ANALYSIS:

Section 1.(a) recodifies G.S. 58-56A-10 as G.S. 58-56A-30.

Section 1.(b) makes several changes, including the addition of new sections, to Article 56A.

- **G.S. 58-56A-1. Definitions**, an existing section, adds new definitions for "340B contract pharmacy," "340B covered entity," "claim," "claims processing service," "maximum allowable cost list," "other prescription drug or device," "out-of-pocket costs," "pharmacist services," "pharmacy benefits manager affiliate," "pharmacy services administration organization." The existing definition of "health benefit plan" is be referenced to a different statute, but the State Health Plan would remain excluded from the definition.
- **G.S. 58-56A-2. Licensure**, a new section, prohibits PBMs from operating without a license. The initial application fee is $2,000, and annual renewal fees are $1,500. Applicants must provide corporate and financial documents to the Department of Insurance as part of the application process.
- **G.S. 58-56A-3. Consumer protections**, an existing section, is amended to extend its current consumer protection provisions. Under the new language, PBMs could not prohibit pharmacies from (i) charging a shipping and handling fee for mailed prescriptions, as long as the insured is notified about the fee, (ii) delivering appropriate health care information to insureds, (iii) discussing cost information and selling more affordable alternatives, and (iv) disclosing information to the Commissioner of Insurance. PBMs cannot collect a copay that was more than the total charges submitted to the PBM by the pharmacy. Amounts credited toward copays or out-of-pocket maximums must include any amounts paid on behalf of an insured, or on the insured's behalf if the drug does not have a generic equivalent or if the drug has been approved by the PBM or insurer.

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- **G.S. 58-56A-4 Pharmacy and pharmacist protections**, an existing section, is extensively amended to:
    - Prohibit PBMs from charging fees not on the remittance form or agreed to in advance by the pharmacy.
    - Allow pharmacists to refuse to fill prescriptions if they believed the prescription was not in the patient's best interest, or if there were a question about the validity of the prescription.
    - PBMs are prohibited from preventing pharmacies from dispensing any drug, including specialty drugs, from retaliating against pharmacies, and from engaging in a pattern of reimbursing independent pharmacies less that the National Drug Average Acquisition Cost.
    - Retroactive denials or reductions of paid claims are be prohibited in most circumstances.
    - PBMs retain the right to recover overpayments.
- **G.S. 58-56A-5. Maximum allowable cost price**, an existing section, is amended to prohibit PBMs from including dispensing fees in the maximum allowable cost price. PBMs must establish a procedure for pharmacies to appeal PBMs' reimbursement decisions.
- **G.S. 58-56A-15. Pharmacy benefits manager networks**, a new section, creates new rules for PBM networks.
    - All network pharmacies must be able to participate on the same terms, without benefit differentials.
    - Pharmacies that are members of pharmacy service administration organizations that enter into contracts with PBMs are entitled to receive a copy of the contract provisions applicable to the pharmacy.
    - Payments due a pharmacy must be paid even if the pharmacy is terminated from the network.
- **G.S. 58-56A-20. Pharmacy benefits manager affiliate disclosure; sharing of data**, a new section, prevents PBMs from sharing information in a manner that violated HIPAA.
- **G.S. 58-56A-21. Claims data provided to health benefit plans**, a new section, requires PBMs to provide claims and payment data to insurers.
- **G.S. 58-56A-25. Enforcement**, a new section, allows the Commissioner to examine the affairs of any PBM. The Commissioner could retain the professionals necessary to conduct the exam, and PBMs would bear the cost of the examinations. None of the information disclosed during the examination is a public record under Chapter 132. Violations of Article 56A are subject to penalties, including revocation of licensure.
- **G.S. 58-56A-30. Civil Penalties for violations; administrative procedure**, an existing section, is amended to allow the Commissioner to petition a court to compel a PBM to pay restitution to (i) pharmacies harmed by the PBM's violation of Article 56A or (ii) the Department of Insurance.
- **G.S. 58-56A-45. Rules**, a new section, gives the Commission the power to adopt rules necessary to implement the provisions of Article 56A.

- **G.S. 58-56A-50. Contracts with 340B covered entities**, a new section, prohibits contracts between PBMs and 340B entities and their contracted pharmacies from conditioning reimbursement, fees, chargebacks, or other adjustments on the entities' participation in the 340B drug discount program. PBMs are not allowed to discriminate against 304B entities or their contracted pharmacies in any way that interferes with the right of individuals to use in-network pharmacies of their choice. The pharmacy of choice provisions of G.S. 58-51-37 apply to PBMs with respect to 340B entities.

Sections 2, 3, and 4 of the act make conforming changes to G.S. 58-2-40 (the powers of the Commissioner of Insurance), G.S. 58-56-2 (third party administrator definitions), and G.S. 58-51-37 (pharmacy of choice provisions), respectively.

Section 5 of the act requires the Department of Insurance to convene a workgroup to study and recommend a single, unified process to accredit specialty pharmacies. The findings must be reported to the Joint Legislative Oversight Committee on Health and Human Services, the House Health Committee, and the Senate Health Care Committee by May 15, 2022.

EFFECTIVE DATE: The act became effective October 1, 2021, and applies to contracts entered into, renewed, or amended on or after that date.

BACKGROUND: The 340B drug discount program requires drug manufacturers to enter into a pricing agreement for certain drugs with the federal Department of Health and Human Resources in exchange for Medicaid and Medicare Part B covering those drugs. The agreements establish front end discounts on outpatient drugs purchased by healthcare providers listed in the federal statute.

**Amy Darden and Kristen Harris of the Legislative Analysis Division substantially contributed to this summary.*