



What North Carolina FQHCs Need to Know About New State Protections Against PBM 340B Discrimination

On October 1, 2021, the Medication Cost Transparency Act ([Senate Bill 257-Session Law 2021-161](#), the “Act”) went into effect. In addition to establishing state oversight and licensure of **Pharmacy Benefit Managers (PBMs)**, the Act also creates new protections for federally qualified health centers (FQHCs), FQHC look-alikes, and other covered entities under the 340B Drug Discount Program. In general, the law prohibits many PBMs from discriminating against covered entities’ 340B in-house pharmacies and contract pharmacies through differential reimbursement, chargebacks, fees, adjustments, and network access. This memo provides an overview of the 340B provisions (N.C.G.S. § 58-56A-50) of the Act.

Frequently Asked Questions

Q1: How does the Act affect FQHCs’ 340B programs?

Among the law’s new standards for PBMs—which are now overseen, licensed, and regulated by the NC Department of Insurance (DOI)—is a requirement that they cannot discriminate against FQHCs based on their participation in the 340B drug discount program.

The law specifically prohibits PBMs from including certain discriminatory provisions in their pharmacy contracts, and it applies these protections to both FQHC-owned and -operated pharmacies (i.e. “in-house” pharmacies) and 340B contract pharmacies.

Under S.L. 2021-161, PBMs cannot discriminate against FQHCs based on their participation in 340B when it comes to:

1. Reimbursement rates, fees, chargebacks, and other adjustments
2. Contracting to be in-network with a PBM or gaining access to a preferred pharmacy network
3. Any other manner of discrimination that interferes with enrollee’s choice to use a 340B pharmacy.

Q2: When does the Act go into effect?

The law became effective October 1, 2021. However, it applies to any contracts entered into, renewed, or amended on or after that date between pharmacies and PBMs subject to the law (for more on which PBMs are subject to these requirements, see Q8 and Q9.).

Therefore, if an annual contract between an FQHC and a PBM renewed for a 12-month term in September 2021, the provisions of the Act would not apply to that contract until its annual renewal in September 2022 or if it were revised in the meantime.

Q3: To which 340B covered entities does this Act apply?

It extends 340B nondiscrimination protections to:

- FQHCs and FQHC look-alikes
- Ryan White HIV/AIDS program grantees
- Title X family planning clinics, tuberculosis clinics, and sexually transmitted disease clinics
- Critical access hospitals, rural referral centers, and sole community hospitals
- Urban Indian Health Organizations

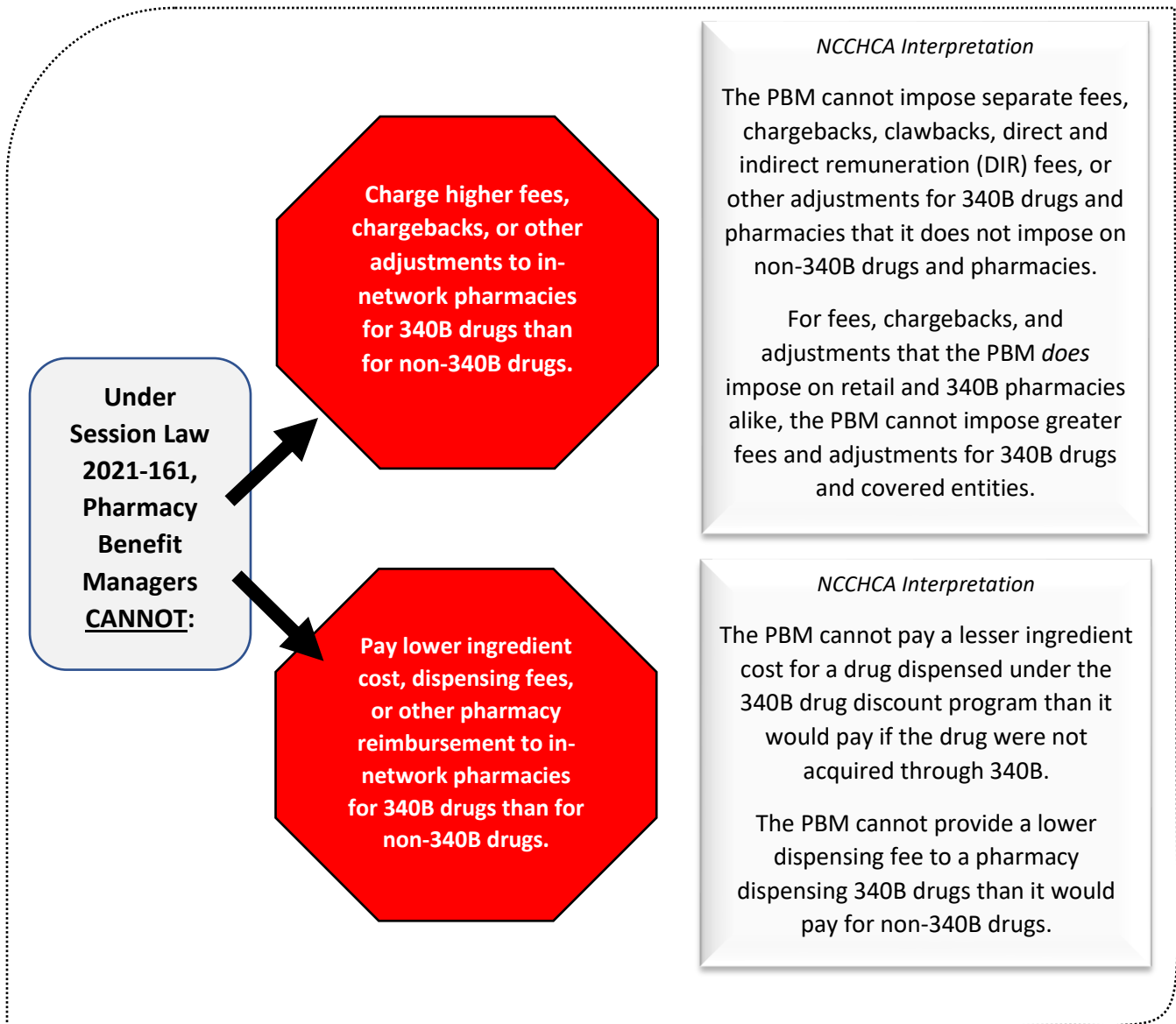
However, the Act’s protections do not apply to some safety net hospitals—such as Disproportionate Share Hospitals, children’s hospitals, free-standing cancer hospitals, and hemophilia treatment centers—or to other 340B covered entity types which do not currently operate in North Carolina.

Q4: How does the law protect FQHCs financially from 340B discrimination by PBMs?

The legislative language holds that a PBM contract with 340B covered entity pharmacies and 340B contract pharmacies shall not:

- “...**adjust 340B drug reimbursement rates** based on whether a pharmacy dispenses drugs under the 340B drug discount program.”
- “**Assess any additional, or vary the amount of any, fees, chargebacks, or other adjustments** on the basis of a drug being dispensed under the 340B drug discount program or a pharmacy's status as a 340B covered entity or a 340B contract pharmacy.”

Here is how North Carolina Community Health Center Association (NCCHCA interprets these protections in practice:



Q5: What other protections against 340B discrimination does the Act provide?

Contracting and Network Access: In addition to protecting against discriminatory reimbursement, fees, chargebacks, and other adjustments, the law prohibits PBMs from preventing 340B pharmacies from participating in pharmacy provider

Last Update: December 6, 2021

networks on similar terms to non-340B pharmacies. Specifically, the legislative language holds that a PBM contract with a 340B pharmacy shall not:

- “Restrict access to a pharmacy network...based on whether a pharmacy dispenses drugs under the 340B drug discount program.”

The law also clarifies that the existing North Carolina Pharmacy of Choice law (N.C.G.S. § 58-51-37) applies to 340B covered entities and contract pharmacies. This existing law provides similar protections against unfair exclusions from a pharmacy network, from pharmacy benefit and cost-sharing differentials, and other types of interference with enrollee’s choice of in-network pharmacy.

Enrollee Choice: The legislation also includes additional broad 340B nondiscrimination requirements for PBMs. PBMs are prohibited from discriminating against a 340B covered entity or 340B contract pharmacy in a way that “prevents or interferes with an enrollee’s choice to receive a prescription drug” from that pharmacy.

Q6: What do I do if I think being discriminated against?

1. **Notify the North Carolina Community Health Center Association (NCCHCA).** [Use this online form](#) to notify us.

2. **Attempt to resolve the complaint directly with the PBM or insurer.**

Keep copies of all communications and evidence of suspected 340B discrimination by the PBM.

3. **File a complaint with the Department of Insurance.**

In addition to notifying the NCCHCA, FQHCs and other covered entities under the Act who suspect discriminatory treatment by PBMs are encouraged to [file a complaint through the North Carolina Department of Insurance](#) against the PBM and underlying health plan.

- a. Call the Consumer Services Division at 855-408-1212 prior to submitting a written complaint.
- b. File a complaint using either the [online complaint form](#) or [downloading and mailing a paper complaint form](#).

Q7: How would I know that I’m being discriminated against by a PBM?

In the most egregious cases of 340B discrimination, a PBM contract or attachment may include separate fee schedules for 340B pharmacies and non-340B pharmacies, which makes very clear that prohibited conduct has taken place.

However, in other cases, when reviewing their PBM contracts, FQHCs may not immediately be able to determine whether they are being reimbursed less or otherwise discriminated against solely due to their participation in the 340B drug discount program.

FQHCs who experience patterns of PBM conduct that invite suspicion should notify NCCHCA and consider filing a complaint with the Department of Insurance to investigate the matter.

Q8: Does the Act apply to all PBMs across different types of health insurance?

The Act applies 340B nondiscrimination requirements to PBMs of most private health insurance plans in the state, including:

- Qualified Health Plans sold on the Health Insurance Marketplace, also known as ACA plans or HealthCare.gov plans
- Other ACA-compliant individual health insurance plans

- Employer sponsored insurance plans, including fully insured small group and large group plans, as well as self-insured ERISA plans and Multiple Employer Welfare Arrangements

The Act's 340B nondiscrimination requirements do not apply to several common types of health plans or their PBMs (see Q9 for more information).

Q9: Which PBMs and/or third-party payors are exempt from the Act's 340B requirements?

Medicare

- State law cannot regulate the pharmacy benefits of Medicare plans (including Medicare Part D and Medicare Advantage).
- An act of the U.S. Congress would be required to prohibit 340B discriminatory contracting by these plans such as the pending bipartisan PROTECT 340B Act (H.R. 4390).

Medicaid

- This legislation does not regulate either Medicaid Direct or Medicaid Prepaid Health Plans (PHPs) under Managed Care.
- However, under current rules for Managed Care, PHPs are required to reimburse 340B drugs at actual acquisition cost and the state fee-for-service minimum dispensing fee.

State Health Plan

- The Act does not apply to the North Carolina State Health Plan, which covers over 700,000 teachers, state employees, retirees, and their dependents.

Other Commercial Plans

- Health insurers that manage their own pharmacy benefits without a PBM may not be subject to the law.
- Certain products not considered health insurance under federal law, such as short-term limited duration insurance and Health Care Sharing Ministries, may not be subject to the law.

Q10: Are the 340B protections actually enforceable?

Yes! There are several avenues under the Act through which protections may be enforced.

- Any PBM contract provision that violates the 340B nondiscrimination protections of the law is rendered "unenforceable" under the Act, which in practice should require the PBM to renegotiate new, nondiscriminatory terms with a 340B pharmacy.

The Act also creates other mechanisms by which PBMs violating the law can be held accountable:

- The Commissioner of Insurance may make examinations of any PBM to ensure compliance with the law. The findings of those examinations are not made public, but if the Commissioner determines the PBM's violations of the law are frequent enough to constitute general business practice, the commissioner
 - may impose monetary penalties on the PBM.
 - may revoke or refuse to renew the license of any PBM in violation of this law.
- The Commissioner may also petition the Superior Court of Wake County to order a PBM in violation of the law to make restitution to a harmed pharmacist such that they are made whole for any violations suffered.
- PBMs may also be ordered to make restitution to the Department of Insurance for costs incurred associated with the investigation of the PBM.
- The Commissioner of Insurance shall also report violations of the law by PBMs to the North Carolina Attorney General, and "may institute civil actions or criminal prosecutions either by the Attorney General or another attorney whom the Attorney General may select for any violation of the provisions" of this law.