LFC Requestor: ESQUIBEL, RubyAnn

2025 LEGISLATIVE SESSION
AGENCY BILL ANALYSIS

Section I: General

Chamber: House
Category: Bill
Number: 78
Type: Introduced

Date (of **THIS** analysis)**:** 01/23/2025
Sponsor(s): Elizabeth Thomson
Short Title: Prohibit Discrimination Against 340B Entities

Reviewing Agency: Agency 665 - Department of Health
Analysis Contact Person: Arya Lamb
Phone Number: 505-470-4141
e-Mail: arya.lamb@doh.nm.gov

Section II: Fiscal Impact

APPROPRIATION (dollars in thousands)

Appropriation Contained		Recurring or Nonrecurring	Fund Affected
FY 25	FY 26		
$0	$0.00	N/A	N/A

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY 25	FY 26	FY 27		
$0	$0	$0	N/A	N/A

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ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY 25	FY 26	FY 27	3 Year Total Cost	Recurring or Non-recurring	Fund Affected
Total	$	$	$	$		

Section III: Relationship to other legislation

Duplicates: None

Conflicts with: None

Companion to: None

Relates to: None

Duplicates/Relates to an Appropriation in the General Appropriation Act: None

Section IV: Narrative

1. BILL SUMMARY

a) Synopsis

HB 78 would prohibit a manufacturer, manufacturer's agent, or an affiliate of a manufacture from interfering in any way with the acquisition**,** or delivery**,** of a 340B drug to any contract pharmacy authorized to receive and dispense 340B drugs for their contracted covered entity unless prohibited by the US Department of Health and Human Services. HB 78 would prohibit the following manufacturer actions:

1. Deny, restrict, prohibit or interfere with the acquisition or delivery of a 340B drug to an authorized contract pharmacy
2. Interfere with a pharmacy contracted with a covered entity
3. Require a covered entity to submit claim or utilization data as a condition of allowing the acquisition or delivery of 340B drug unless required by federal law.

Is this an amendment or substitution? ☐ Yes ☒ No

Is there an emergency clause? ☐ Yes ☒ No

b) Significant Issues

The 340B program is a federal government program created by Congress in 1992 and administered by the Health and Resource Services Administration (HRSA). The program allows a limited list of safety net providers, including but not limited to disproportionate share hospitals, federally qualified health centers (FQHCS), family planning clinics, Ryan White programs (HIV), sexually transmitted disease clinics, tuberculosis, etc. that register with HRSA as a covered entity to receive medications at a discounted price. The intent of the program is to enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Manufacturers participate in Medicaid are required to agree to provide outpatient drugs to covered entities through the 340B program. Covered entities may choose to enter into contract pharmacy agreement(s) to assist in the administration of the

340B program. The covered entities have a due diligence to prevent duplicate discounts (prohibited duplicative discount through Medicaid and the 340B program) and ensure that only eligible patients are receiving 340B medications among other key program integrity pieces. HRSA and/or the manufacturer may conduct an audit of a covered entity or their contracted pharmacy to ensure program integrity. 340B Drug Pricing Program | HRSA

Beginning in 2020, multiple manufacturers have begun adding additional requirements for covered entities to utilize their contract pharmacy partner(s) to acquire 340B medications. These additional contract pharmacy restrictions include but are not limited to claims data submissions, designation of a single contract pharmacy, and geographic distance requirements from the entity's registered location. While manufacturers have utilized a wide range of measures the vast majority are utilizing a tool called 340B ESP, which manages the various manufacturer requirements, serves as a source for claims submissions and/or single contract pharmacy designation. Currently 36 manufacturers are utilizing 340B ESP. A list of current manufacturer contract pharmacy restrictions can be found at the following link: https://www.nachc.org/nachc-content/uploads/2023/11/crx-restrictions-2024-12-updated.pdf

Manufacturers claim that the broad requirements are part of their statutorily protected 340B program integrity audit process. However, HRSA has issued multiple enforcement letters to manufacturers. HRSA's position summarized in the letters:

1. Manufacturers under 340B Final Rule are not able to place conditions on fulfillment of 340B obligations.
2. Manufacturers are expected to provide the same opportunity for their medications to be available to 340B purchasers and non-340b purchasers.
3. HRSA has a clear mechanism, which manufacturers have the right to use to investigate duplicate discount/diversion concerns. 340B statute does not permit manufacturers to impose industry wide restrictions.

Nine manufacturers have brought lawsuits challenging HRSAs enforcement actions. Four district courts have issued decisions, each on appeal before three circuit courts. The third and DC circuits have ruled in favor of the manufacturers allowing for contract pharmacy restrictions. The seventh circuit court decision is pending.

Multiple states have taken legislative action to protect 340B. The following link provides a summary: https://www.nachc.org/nachc-content/uploads/2024/01/05_03_24_nachc_state-level-340b-laws-and-legislation_tracker.pdf

Eight states (Arkansas, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Missouri, and West Virginia) have passed similar legislation to protect contract pharmacy arrangements. According to ASHP News Center, "legislation in Louisiana and Arkansas resulted in more than a dozen drug manufacturers lifting all contract pharmacy restrictions in those two states." According to the National Law Review, "This Week in

340B", there have been multiple legal challenges in states with laws that have passed. On December 9, 2024, the U.S. Supreme Court declined to review a U.S. Court of Appeals for the Eighth Circuit decision (223675P.pdf) upholding the Arkansas law protecting contract pharmacy arrangements.

Arkansas ACT 1103:

https://arkleg.state.ar.us/Home/FTPDocument?path=%2FACTS%2F2021R%2FPublic%2FACT1103.pdf

Eighth Circuit Court Decision:

223675P.pdf

Supreme Court Declines Challenge to Arkansas' 340B Contract Pharmacy Access Law

Supreme Court Declines to Hear PhRMA's Challenge to Arkansas' Landmark 340B Contract Pharmacy Access Law - 340B Report

2. PERFORMANCE IMPLICATIONS

- Does this bill impact the current delivery of NMDOH services or operations?

  ☒ Yes ☐ No

  NM Department of Health's Ryan White (HIV) and Sexually Transmitted Disease (STD) Programs utilize contract pharmacy agreements in order to provide 340B medications to clients.

- Is this proposal related to the NMDOH Strategic Plan? ☒ Yes ☐ No

  ☒ **Goal 1:** We expand equitable access to services for all New Mexicans

  ☐ **Goal 2:** We ensure safety in New Mexico healthcare environments

  ☒ **Goal 3:** We improve health status for all New Mexicans

  ☐ **Goal 4:** We support each other by promoting an environment of mutual respect, trust, open communication, and needed resources for staff to serve New Mexicans and to grow and reach their professional goals

  This proposal is related to Goal 1 "We expand equitable access to services for all New Mexicans" and Goal 3 "We improve health status for all New Mexicans" of NMDOH Strategic Plan.

  Contract pharmacy agreements enable NMDOH to most effectively administer its 340B program to ensure clients statewide have access to lifesaving medication. Additionally, the 340B contract pharmacy agreements generate significant revenue that allows NMDOH to fund additional safety-net services statewide.

According to the Health Resources and Services Administration (HRSA), the federal agency that oversees the 340B program, "the 340B program was created with the intent of the 340B Program is to enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" 340B Drug Pricing Program | HRSA

New Mexico Department of Health utilizes its 340B program and its contract pharmacies to stretch scarce federal resources and provider comprehensive services. Additionally, this bill supports other 340B providers in the community that provide services that ensure equitable access and improved health status such as FQHCs and some hospitals. This bill helps to protect the provision of those services and resources against increasing and potentially illegal actions by drug manufacturers.

3. FISCAL IMPLICATIONS

- If there is an appropriation, is it included in the Executive Budget Request?

  ☐ Yes ☐ No ☒ N/A

- If there is an appropriation, is it included in the LFC Budget Request?

  ☐ Yes ☐ No ☒ N/A

- Does this bill have a fiscal impact on NMDOH? ☒ Yes ☐ No

NMDOH currently generates $7.1 million dollars annually of revenue which are utilized to provide safety net services related to family planning and HIV, STD, and TB prevention and care. This bill would aide in protecting against manufacturers that are not fulfilling their obligations within the 340B program by setting overly burdensome and increasingly aggressive and potentially illegal requirements for covered entities.

NMDOH is at risk of losing this revenue source if 340b contract pharmacy agreements are not protected. Funding deficits would either result in the discontinuation of some services or require future appropriations to offset the lost revenue.

4. ADMINISTRATIVE IMPLICATIONS

Will this bill have an administrative impact on NMDOH? ☐ Yes ☒ No

5. DUPLICATION, CONFLICT, COMPANIONSHIP OR RELATIONSHIP

None

6. TECHNICAL ISSUES

Are there technical issues with the bill? ☐ Yes ☒ No

7. LEGAL/REGULATORY ISSUES (OTHER SUBSTANTIVE ISSUES)

- Will administrative rules need to be updated or new rules written? ☐ Yes ☒ No
- Have there been changes in federal/state/local laws and regulations that make this legislation necessary (or unnecessary)? ☒ Yes ☐ No

According to a public statement from HRSA on 340B Report, "HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute. Without comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the

interdependent aspects of the 340B Program." https://340breport.com/hrsa-says-its-340b-contract-pharmacy/

HRSA has issued multiple enforcement letters to manufacturers regarding contract pharmacy restrictions. HRSA's position summarized in the letters:

1. Manufacturers under 340B Final Rule are not able to place conditions on fulfillment of 340B obligations
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Nine manufacturers have brought lawsuits challenging HRSAs enforcement actions. Four district courts have issued decisions, each on appeal before three circuit courts. The third and DC circuits have ruled in favor of the manufacturers allowing for contract pharmacy restrictions. The seventh circuit court decision is pending.

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- Does this bill conflict with federal grant requirements or associated regulations?
  ☐ Yes ☒ No
- Are there any legal problems or conflicts with existing laws, regulations, policies, or programs? ☐ Yes ☒ No

8. DISPARITIES ISSUES

- Unhoused, marginalized health conditions, and low-income individuals would be impacted if the bill did not pass. The 340B program was created to help covered entities stretch scarce resources for the provision of safety net services. Changes increasing the burden and accessibility of the 340B program through contract pharmacy partners would negatively impact the provision of NMDOH, hospital, and FQHC safety-net services statewide.

9. HEALTH IMPACT(S)

- The 340B program was created to help covered entities stretch scarce resources for the provision of safety net services. Changes increasing the burden and accessibility of the 340B program through contract pharmacy partners would negatively impact the provision of NMDOH, hospital, and FQHC safety-net services statewide. Within the Department of Health, the programs most impacted would be the Ryan White (HIV) program and Sexually Transmitted Disease Program. The health impacts would be wide ranging from reduced ability to provide HIV treatment to uninsured individuals, provide HIV Pre-Exposure Prophylaxis (PrEP), Hepatitis C treatment, and a variety of STD prevention and treatment initiatives that are funded through revenue. New Mexico needs every resource at its disposal to improve its sexually transmitted infection rates. The state is currently ranked by the CDC as 2nd in the country for primary & secondary syphilis rates as well as congenital syphilis rates. Tables from STI Surveillance, 2023 | STI Statistics | CDC

10. ALTERNATIVES

None.

11. WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL?

If HB78 is not enacted, 340B eligible covered entities that utilize contract pharmacies will need to submit claims or utilization data to procure 340B drugs as per the respective, manufacturer's policy, or purchase at actual wholesale price. This impact to covered entities will be restrictive contract pharmacy limitations, additional onerous reporting burden, additional administrative costs associated with 340B program, and reduced ability to stretch scarce resources to provide safety-net services.

12. AMENDMENTS

It is recommended to review Arkansas law as it has been upheld in appeals court. (https://arkleg.state.ar.us/Home/FTPDocument?path=%2FACTS%2F2021R%2FPublic%2FACT1103.pdf).