

IN SUPPORT OF:

HB1056 – State Board of Pharmacy – Prohibition Against 340B Drug Distribution

House Government Operations Committee Hearing: 2/29/2024 at 1:00 PM

EPIC Pharmacies, Inc. <u>SUPPORTS HB1056 – State Board of Pharmacy – Prohibition Against</u> 340B Drug Distribution.

<u>340B Program Brief Description (skip the next 4 paragraphs if already discussed by other proponents):</u>

The 340B prescription pricing program was a compact developed in 1992 between drug manufacturers and the government. In return for gaining access to the largest payer program in the country, Medicaid, manufacturers had to offer very steep discounts to defined safety-net providers also known as covered entities.

The covered entities use access to these highly discounted medicines for two main reasons:

- To directly reduce the price for outpatient medications for the populations they serve.
- To generate income for the covered entity to allow that entity to stretch limited federal resources, expand health services for patients, and to expand the number of patients that they serve.

The covered entities are non-profit entities that provide desperately needed health care services for the neediest patents in our communities. They include Federally Qualified Health Centers (FQHC) that treat unhoused patients, Ryan White programs that treat HIV positive patients, some hospitals, and other safety net providers.

Covered Entities have often focused on other areas of healthcare and services besides becoming pharmacy operators and will often engage in a contractual relationship with a retail pharmacies to provide the prescription counseling, dispensing, and inventory services for their clients and patients.

Mt. Vernon Pharmacy provides contract pharmacy services to four covered entities (2 FQHCs, and 2 Ryan White programs). The longest and still ongoing relationship with Health Care for the Homeless started in 1999 and is still ongoing after 24 years.

Common Questions and Answers:

<u>-Why is this legislation necessary?</u> In 2020, Eli Lilly, today the most valuable drug manufacturer in the world, enacted restrictions, and limitations on the ability of covered entities to acquire these highly discounted medications. Astra Zeneca, Novo Nordisk, and Sanofi soon joined Lilly. It's curious how many of the initial manufacturers were all insulin makers. The limitations often restrict covered entities to utilize only one contract pharmacy, they sometimes mandate that the covered entity provide dispensing

2/29/2024

data to the manufacturer or an agent of the manufacturer, and sometime even try to restrict the sale of the discounted inventory to uninsured patients only. These restrictions directly and adversely affect the revenue of covered entities and their ability to provide safety net services that their patients rely on. Because the government was slow to respond, other manufacturers piled on; to date there are thirty-one manufacturers that are restricting access to 340B medications to covered entities in one form or another. For a link to all of the manufacturer restrictions and manufacturer letters go to: https://www.amerisourcebergen.com/provider-solutions/340b-advisory-services/340b-manufacturer-updates

<u>-Why are the manufacturers placing restrictions on the program?</u> The manufacturers argue that these discounted medications are being diverted to patients that are not patients of the covered entity, and/or the manufacturer is being double hit by both providing the medication at a deep discount on the front end as well as paying large rebates on the back end. The reality is much easier to understand. The manufacturers would much prefer to make large profits on these meds by selling them at high prices rather than the discounted 340B prices that they are obligated to provide. Barriers to 340B access directly profit manufacturers and directly harm covered entities.

-Didn't the government place rules and regulations on the 340B program to maintain the integrity

of the program? Yes. There are two main rules that govern the program:

- 1. The patient must be a patient of the covered entity.
- 2. The prescription claim must not be paid for by the Medicaid Fee for Service Program, because that program legislatively is entitled to the largest rebate that a manufacturer may provide. I.E. No double dip on Medicaid Fee for Service!

-Can 340B inventory be used on insured prescription claims? Yes. The only restriction is that this inventory cannot be used for Medicaid Fee for Service patients. The inventory can be used for uninsured, MCO, Commercially Insured, and Medicare Part D claims.

-Aren't MCO claims a form of Medicaid. Don't manufacturers need to demand dispensing data to prevent duplicate Medicaid discounts? The Maryland Department of Health mandates that any MCO claim that utilizes 340B inventory must have an electronic claim identifier on the claim to identify that 340B inventory was used and prevent the department of health from asking the manufacturer for back-end rebates. In short, the Maryland Department of Health already had a fix for manufacturer concerns going back to 11/1/2014.

-I guess the manufacturers had no recourse but to restrict access to 340B medications and place these barriers? Since the start of the program both covered entities and contract pharmacies have been subject to audits by both HRSA and drug manufacturers. On the few manufacturer-initiated audits that have occurred, there were very few instances found of 340B product diversion or misuse, however it is quite a bit more economical for manufacturers to simply restrict legitimate access than to perform audits.

-Why not wait for these issues to work their way through the federal courts? It's already going on four years with no federal court final resolution in site. Covered entities are losing their ability to serve our neediest citizens. Our community simply cannot afford to wait.

-Isn't this a federal manner. Even if this bill passes will the manufacturers abide by it? The only states where manufacturers are abiding by their original 340B obligations are Arkansas and Louisiana because those states had the foresight to enact these covered entity protections against the drug manufacturers.

-Does this really affect patient access? After all, don't the manufacturers allow the covered entity to designate a single contract pharmacy to receive 340B inventory? In my personal instance, one of my

2/29/2024

pharmacies has a robust delivery practice. The other location which is located at the covered entity building does not. Some of those patients are homebound and have difficulty traveling. When we use the pharmacy location that has delivery service, we cannot use some 340B inventory from the delivery location pharmacy because some manufacturers only allow us to utilize 340B inventory at the other designated location. Or to be more precise, Insulins and GLP-1s from Eli Lilly, Novo Nordisk, and Sanofi Aventis among other meds that are delivered to patients do not generate 340B revenue for my covered entity.

For other entities and contract pharmacy relationships, sometimes the patient lives quite a distance from the one designated pharmacy, so the entity might contract with some chain pharmacies to service those distant patients.

That lost revenue will result in less services to the patients that need those services most. And obviously the covered entities will make larger revenue requests from the State of Maryland to make up for the revenue shortfall.

EPIC Pharmacies are local businesses that serve communities that might not have the economic footprint that a larger chain pharmacy demands. We support legislation that supports local safety net providers and the patients and communities that both we and they serve.

EPIC Pharmacies thanks the sponsors, Delegates Guzzone, Bagnall, Hill, Kaiser, Lewis, Holland and Woods, and respectfully requests the Committee's **FAVORABLE SUPPORT FOR HB1056.**

Should the Committee require any additional information, please contact me or Caitlin McDonough, caitlin.mcdonough@mdlobbyist.com or 410-366-1500.

Respectfully,

Stephen Wiene, Phennecial

Steve Wienner, RPh EPIC Legislative Committee Mt. Vernon Pharmacy and Mt. Vernon Pharmacy at Fallsway <u>mtvernonpharmacy@gmail.com</u> – 410-207-3052