From: Cara J. Sammartino, PhD MSPH 4/10/2025

Memo: Defending Affordable Prescription Drug Costs Act H 5634 /S 114

M

Madam Chairman and Members of the House Health & Human Services Committee:

My name is Cara Sammartino. I apologize I am out of the country hence unable to testify in person. As background I am a RI native, a life long resident of Saunderstown. I am a Brown University graduate with a PhD in Health Services, Research, Policy & Practice. I currently serve as Department Chair Johnson & Wales University, Department of Health Services. My CV is attached.

I am submitting testimony based on my education and professional experience not only in health care policy, but in 340b auditing. From 2012 - present I have been an Analytic Consultant for Demers & Associates, which provides 340b Pharmacy Analytic Support, working with numerous states across the country.

Early in my career I had the privilege of interning with Dr. Marie Ganim, former RI Health Insurance Commissioner and long time Director of Senate Policy. I have had the honor of working within the RI state government at the Executive Office of Human Services and as a reporting analyst for Blue Cross Blue Shield of RI.

I want to share with you my insights and recommendations on the proposed legislation and their impact on the most vulnerable patients in RI as well as the impacts on the 2026 state budget. I am happy to follow up with the committee upon my return.

In light of the Federal Medicaid and HHS uncertainties, the existing RI 2026 Budget shortfalls, and to protect the vulnerable 340b patient population the program is intended to help, I believe the following would achieve the objectives.

- Sub A the existing legislation to mandate an audit of 340b entities. The audit findings would report back to the legislature and a Task Force made up of 340b entities by 1/1/26.
- This would maintain the status quo for existing entities while collecting the necessary
- Data to assure the existing programs are serving the intended patients.
- Although there may be potential "pushback" that an audit would be overly burdensome, that is not the case. There are numerous resources to do so quickly, efficiently and cost effectively.

- **The 340b challenges are legal compliance of the Federal program on the part of the entities. It is not an issue on the pharmacy level, although a vital component, they are dispensing the drugs to the patients.**
-

Executive Summary:

The overall premise of **H 5634/S 114** is to protect 340b entities from potentially discriminatory reimbursement practices by insurers and pharmacy benefit managers. Protection of 340b entities is important; however, it should not come at the expense of the medication manufacturers who are providing charitable contributions in the form of reduced prices through the 340b discount. These bills seek to remove additional compliance and oversight of entities who participate in the 340b program.

Traditional 340b entities are federally qualified health centers (FQHCs), hospitals, and other safety-net providers. There are other factors impacting health center revenue and 340b should not be the only focus. Additional concern should be focused on reimbursement rates from public and private payers. 340b should not be used to address the shortfall in revenue due to reduced reimbursement rates to health centers and hospitals. According to HRSA, there are currently 151 active 340b entities in the state of Rhode Island.[1]

If passed, these bills **impose** restrictions or interfere with how pharmacies acquire or dispense 340b drugs. The bill shifts power away from pharmaceutical companies and ensures access to discounted medications for safety-net providers, but without an audit requirement the manufacturers are unaware of distribution of dispensation across patients payers.

It must be remembered that the original intent of the program was to provide drugs to 340b entities who serve high numbers of Medicaid and/or un/underserved patients. IF an entity is purchasing 50% of drugs through 340b discounts, but dispensing a majority of those to Medicare or commercially covered patients, then the original intent of the program is lost. The 340b program has grown over 120% over five years with discounted purchases making up $66.3 billion in total costs. This is a LEGAL issue and a much larger healthcare systems issue.

One issue to be aware of is that removal of audit raises potential compliance issues around duplicate discounts, meaning that **entities can only receive either the Medicaid or 340b rebate discount.**[2] To prevent duplicate discounts the covered entities must decide whether they will use 340b drugs for Medicaid FFS patients (carve-in). If they choose to carve in, they must ensure that all Medicaid and National Provider Identifier (NPI) numbers used to bill Medicaid for 340b drugs are listed on the Medicaid Exclusion File (MEF). Compliance audits allow for this duplication to be flagged and regulated. Additionally, while these bills aim to ensure access to discounted medications for safety-net providers, studies have shown that expansion of the 340B program through contract

pharmacy arrangements are not benefiting patients at 340B entities - instead benefiting larger hospitals and for-profit pharmacies.

The state needs to mandate an audit requirement. Although in theory there is a Federal/HRSA audit process, in reality **HRSA is NOT doing the audits. 340b entities are doing audits in-house OR hiring contractors to do them**. They have to send compliance reports to HRSA, but the original language of the law is vague in terms of what is required. The entities just have to demonstrate they are not filling for ineligible patients. The patients do not have to be uninsured or on Medicaid. Eligible patients of 340b entities can have any type of insurance coverage, and just have to visit the entity and establish a relationship with a provider. HRSA gets the reports from the entities, they DO NOT do the audits themselves. The audits can be shared with the manufacturer as pharmacy claims include manufacturer as part of the extract. A manufacturer should see what types of patients are receiving their medications.

[1]National Association of Community Health Centers, available at: https://www.nachc.org/wp-content/uploads/2024/02/StateFactSheet_RI_2022UDS_Feb2024.pdf (accessed on 3/31/2025)
[2]Available at https:www.macpac.gov (accessed on 3/31/2025)

Economic Impact on Rhode Island

H 5634 and S 114 are unlikely to have a negative impact on the RI economy if they are not passed. Without 340b, entities can continue providing health care services without any changes to medication purchasing agreements. Community health centers employ over 3,400 individuals in the state of RI and in 2021 saw 202,716 patients. Entities rely on drug savings and fair reimbursement to fund patient services, such as providing care for un/underinsured populations. In the state of RI, ~75% of CHC patients are uninsured, have Medicare, have Medicaid, or are dually enrolled. This bill prohibits PBMs and insurers from reimbursing 340b entities at lower rates allowing for increased marginal revenue to be reinvested into patient care and other community health programs. Having increased operating revenue allows for health centers and other 340b entities to have increases in job retention and growth across all healthcare services.

By mandating non-discriminatory reimbursement, as S-0114 and H 5634 recommends, insurers and PBMs could potentially pass higher costs to employer or private plans through premium increases; however this is dependent on how much PBMs were previously reducing reimbursement for 340b drugs.

Finally, these bills prevent insurers and PBMs from excluding 340b entities from networks, ensuring that community pharmacies, including independent and hospital-owned continue to participate in the prescription drug program and allows for improved access to medications.

Impact to Rhode Island Health Centers

These bills ensure that PBMs cannot apply lower reimbursement rates to 340b drugs, preventing revenue cuts that would otherwise force health centers to scale back services. 340b entities currently purchase medications at steep discounts with the assumption that these medications are being dispensed to patients who are uninsured or cannot afford their medications; however, there is little oversight in ensuring that discounted drugs are being provided to those patients. Many RI health centers use the revenue generated from 340b reimbursement to fund behavioral health, dental, specialty, and other types of care.

The original intent of the law was not for 340b to be a revenue generator for entities, but a mechanism in which medications could be purchased and distributed to patients in need.

These bills also prohibit audits, claim resubmissions, and billing modifiers, which could lead to 340b entities submitting for duplicate discounts.

Regulatory compliance to 340b needs to start with a baseline audit of all medications purchased with the 340b discount and then look at the distribution of dispensation of those 340b medications across patient insurance type. This will allow for manufacturers to see if these discounted drugs designated for charitable care are being
dispensed to those patients or if they are being dispensed to Medicare or private pay patients and reimbursed at much higher rates.

Manufacturer Concerns

The largest opposition for these bills is likely from the pharmaceutical industry. Pharmaceutical manufacturers already provide prescription drugs at extreme discount to 340b entities. These bills could limit their ability to negotiate reimbursement terms with insurers and PBMs leading to increased costs for manufacturers. Increased overall manufacturing costs eventually get passed down to consumers. Without being able to negotiate terms, manufacturers will adjust drug pricing strategies.

There is an argument that 340b savings do not always directly benefit patients, but only contribute to increased revenue for hospitals and health centers. **One recommendation is for 340b entities to provide annual updates about drugs dispensed, revenue generation, and an overview of patient services provided because of the 340b revenue**.

One major concern of these bills with manufacturers is that these bills prohibit PBMs from requiring 340b claims to be flagged, making it harder for pharmaceutical companies to track how much of their inventory is sold at 340b prices and how much is sold to payers with higher reimbursement rates. **Increasing transparency through use of quarterly audits could alleviate**

this tension from the pharmaceutical companies. Data for the audits can come from contract pharmacies and 340b entities including data elements such as eligible patients, eligible providers, and prescription information.

Other recommendations to reduce opposition:

The Connecticut law and process is ideal and easily replicated. Public Act 23-171 Substitute House Bill 6669.

- Mandatory reporting by 340b entities showing how savings are used for patient care. • Caps or limitations on contract pharmacy arrangements to prevent program expansion beyond original intent of serving low-income patients.
- Allowing manufacturers to set conditions with 340b pricing through limited distribution models or be involved in negotiating reimbursement rates.

Respectfully submitted:
Cara Sammartino , PhD MSPH
(401) 932-2118