STATEMENT

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In Opposition to House Bill 7879 (Representative Brien)
3-19-2024

Position: The Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully opposes four provisions of House Bill 7879 (HB 7879), Sections 519.32-2(2), 5-19.3-3(2)(v), 5-19.3-3(4), and 5-19.3-5.

Sections 5-19.3-3(2)(v) and 5-19.3-3(4) prohibit the use of 340B "claims modifiers" for 340B drugs or any other billing or reporting requirements to identify 340B claims, which has the potential to undermine program integrity by further increasing the risk of duplicate discounts (when a Medicaid rebate and 340B discount are applied to the same unit of covered outpatient drug) and diversion within the 340B program.

A 340B claims modifier is an electronic "tag" used in electronic transactions between PBMs and pharmacies. This can be done in real-time when a pharmacy sends claims information to a PBM, occurring within seconds. Claims modifiers are cited as a best practice for identifying 340B claims by the Centers for Medicare & Medicaid Services ("CMS").[1] Data exchange has always been essential to effective functioning of the 340B program, ensuring that participating organizations comply with statutory prohibitions against diversion and Medicaid duplicate discounts. With the rise of health information technology, data exchanges have become more seamless for pharmacy providers and occur within the usual course of processing a prescription claim.

Claims modifiers provide data that, along with other information, can help identify cases of diversion, which occur when a covered entity dispenses 340B discounted drugs to anyone other than an eligible patient. "Tagging" 340B claims with a unique identifier and sharing this information throughout the dispensing supply chain helps to ensure program alignment and transparency from end to end and is the first step to ensuring patients can benefit in the way the program is intended. Further, without proper identification of 340B claims, Rhode Island's Medicaid program would potentially lose out on rebates to which it is legally entitled.

In 2023, CMS will continue requiring hospitals participating in the 340B program to use claims modifiers, which enable the Agency to "track the utilization of 340B acquired drugs and biologicals…"[2] Hospitals have had several years of experience with 340B claims modifiers,

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1 Centers for Medicaid and Medicare Services. CMCS Informational Bulletin. Best Practices for Avoiding 340B Duplicate Discounts in Medicaid. January 2020.
2 87 Fed. Reg. 71974

which were first utilized in 2018. CMS has underscored that continued use of these modifiers in 2023 would not impose additional burden on hospitals.

Sections 5-19.3-2(2) and 5-19.3-5 require manufacturers to ship drugs to all contract pharmacies for 340B providers, and by extension, offer 340B pricing at these locations, thereby attempting to add a state requirement to the federal statute. Issues related to the contract pharmacy policy are currently being litigated in multiple lawsuits across the country.

The term "contract pharmacy" does not appear anywhere in the federal 340B statute and was created by the Health Resources and Services Administration (HRSA), which administers the 340B program, solely through guidance, which does not have the force and effect of law.

Because there is ongoing litigation across the country about HRSA's 340B contract pharmacy policy, Rhode Island should allow the federal courts to address and resolve the relevant issues before considering any legislative action. If the courts hold that the federal 340B law does not authorize a requirement that manufacturers ship drugs to contract pharmacies, that would raise additional constitutional concerns about state legislation related to that issue. In fact, in late January 2023, the U.S. Court of Appeals for the Third Circuit held that "[s]ection 340B [of the federal statute] does not require delivery to an unlimited number of contract pharmacies" and "Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies."

It is important for policymakers to ensure the 340B program truly benefits the safety net that serves our underserved communities in Rhode Island and throughout the country. Unfortunately, over the three decades after it was originally created, the 340B program has deviated from its original mission to instead benefit entities such as hospitals, for-profit pharmacies, and other middlemen, leaving behind the patients that the program is meant to serve and threatening the sustainability of the program for true safety-net entities that provide much needed care to vulnerable communities.

In 1992, when the 340B program was established by federal law, it was meant to help safety-net entities access affordable drugs to treat their low-income and uninsured patients. Due to weak oversight, the 340B program has expanded in a way that has allowed covered entities to divert, to the benefit of the entities' bottom-line, money intended to help patients get better care and afford their medicines. As a result, the 340B program has changed and grown dramatically since its establishment, while charity care at 340B hospitals has declined below national averages.[3]

There is little evidence to suggest that patients have benefited from contract pharmacy growth. Many contract pharmacies may often charge a patient a drug's full retail price because they are not required to share any of the discount with those in need.[4] Big-box retailers such as Walgreens, CVS Health, and Walmart are major participants in the 340B program through contract pharmacy arrangements. In fact, the five largest for-profit pharmacy chains comprise 60

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3 AIR340B Coalition, "Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program," November 2019, https://340breform.org/wp-content/uploads/2019/11/AIR340_LeftBehind-v6.pdf.

4 Conti, Rena M., and Peter B. Bach. "Cost consequences of the 340B drug discount program." *Jama* 309.19 (2013): 1995-1996.

percent of 340B contract pharmacies, but only 35 percent of all pharmacies nationwide.[5] 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines in 2018, which represents more than 25% of pharmacies' and providers' total profits from dispensing or administering brand medicines.[6]

In addition to exacerbating existing problems with the 340B program, Sections 519.32-2(2) and 5-19.3-5 would impose a significant financial obligation on manufacturers, which could disincentivize participation in the 340B program and impact the Medicaid program.

PhRMA respectfully opposes the provisions outlined above and appreciates your consideration prior to advancing HB 7879.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone.

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5 Government Accountability Office, *"Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,"* GAO-18-480, June 2018.

6 Berkeley Research Group. For-Profit Pharmacy Participation in the 340B Program. October 2020.