



Mike Tipping
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THE MAINE SENATE
131st Legislature

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Senator Bailey, Representative Perry and esteemed members of the Committee on Health Coverage, Insurance and Financial Services:

My name is Mike Tipping. I represent Senate District 8 in Penobscot County. I'm proud to present LD 1395, An Act to Increase Transparency Regarding Certain Drug Pricing Programs.

The 340B Drug Pricing Program, established by the U.S. federal government in 1992, mandates that drug manufacturers supply outpatient drugs to eligible healthcare organizations, often referred to as "covered entities," at significantly reduced prices. The goal of the program is to help these organizations extend scarce federal resources, enabling them to serve more eligible patients and offer more comprehensive services. Entities benefiting from this program include health care providers that receive certain federal grants, such as federally qualified health centers (FQHCs), family planning clinics, and Ryan White HIV/AIDS program grantees, as well as certain types of hospitals that provide care to low-income, medically underserved individuals.

There is no doubt that the 340B program is an important program. It provides critical support to many health care providers and entities serving low-income and medically underserved populations. However, legitimate concerns have been raised about whether the program is operating as intended. Earlier this year, the Maine Prescription Drug Affordability Board released a report of recommendations to reduce prescription drug spending in Maine, which included a recommendation "that the Maine Legislature require greater transparency and accountability for the 340B program in Maine," which is exactly what this bill aims to do.¹

Outpatient drugs purchased by covered entities through the 340B program are usually discounted by 20-50%, with an average discount of 34% off the Average Manufacturer Price (AMP).² However, discounts can be much higher, and in many instances, providers can purchase drugs for as little as one penny through the 340B program. The 340B statute states that the intention of the program is to "stretch federal resources as far as possible reaching more eligible patients and providing more comprehensive services."

Some covered entities pass on 340B savings directly to their patients, while others may charge patients and third-party payers, such as private health plans, full price for 340B drugs. Covered entities can use profits generated through the program "to expand the number of patients served, increase the scope of services offered to low-income and other patients, invest in capital, cover

¹ Maine Prescription Drug Affordability Board. 2022 Prescription Drug Affordability Board Annual Report. <https://www.maine.gov/bhr/oeh/sites/maine.gov/bhr.oeh/files/inline-files/2022%20Prescription%20Drug%20Affordability%20Board%20Annual%20Report.pdf>

² U.S. Department of Health and Human Services, Office of Inspector General. (2015). Contract pharmacy arrangements in the 340B program (OEI-12-14-00030). <https://oig.hhs.gov/oei/reports/oei-12-14-00030.asp>

administrative costs, or for any other purpose,” since the federal 340B statute doesn’t dictate or limit how covered entities use 340B revenue.³

Some covered entities that are federal grantees have restrictions on how 340B revenue may be used, such as FQHCs, which must use funds for purposes consistent with their federal grant requirements. However, hospitals don’t have these requirements.

Since the 340B program was first implemented, it has expanded to include more types of providers and to allow providers to contract with a greater number of pharmacies to administer 340B drugs to patients. The Health Resources and Services Administration (HRSA), which administers the 340B program, estimates 340B sales make up more 7% of the overall U.S. drug market.⁴ In 2021, covered entities spent nearly \$44 billion on outpatient drugs under the 340B Program, of which more than 80% was spent by hospitals.⁵ As this program has expanded, concerns have been raised about how revenue is being used and whether it is working as intended

A 2019 report from the U.S. Government Accountability Office highlighted issues of insufficient oversight of aspects of the 340B program, as well as the lack of information in hospital contracts about how hospitals meet obligations to provide health care services to low-income individuals.⁶ A 2018 study published in the *New England Journal of Medicine* found there was no clear evidence that the 340B program had been associated with expanded care in hospitals or lower mortality among low-income patients.⁷

Without clear data, it is impossible to know how the 340B program is operating in Maine. Maine’s hospitals are a vital part of our communities and provide needed medical care and services to thousands of Maine people every day. However, requiring transparency is prudent and necessary to better understand how this program is operating in Maine. The information being requested is already required to be compiled in the case of a federal government audit and would not require a significant administrative burden.

This bill does not reduce hospitals’ access to 340B discounts or limit in any way how hospitals use 340B revenue. It only requires there be transparency so that we can better ensure this important program is operating as intended to benefit Maine people.

Thank you for your consideration and I’m happy to answer any questions.

³ Medicare Payment Advisory Commission. (2015). May 2015 Report to the Congress: Overview of the 340B Drug Pricing Program. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf

⁴ Congressional Research Service. (2022). Overview of the 340B Drug Discount Program. <https://crsreports.congress.gov/product/pdf/IF/IF12232>

⁵ Health Resources and Services Administration. (2022). 2021: 340B Covered Entity Purchases. <https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases>

⁶ U.S. Government Accountability Office. (2019). 340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements (GAO-20-108). <https://www.gao.gov/assets/gao-20-108.pdf>

⁷ Desai, S., & McWilliams, J. M. (2018). Consequences of the 340B Drug Pricing Program. *The New England Journal of Medicine*, Volume 378;6, pages 539-48. <https://doi.org/10.1056/NEJMsa1706475>