STATEMENT

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In Opposition to ME LD 1018 (Bailey)
4-15-2025

Position: The Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully opposes four provisions of LD 1018: §7702(7), §7703, §7704(2)(E), and §7704(4).

It is important for policymakers to ensure the 340B program truly benefits the safety net that serves our underserved communities in Maine and throughout the country. Unfortunately, over the three decades after it was originally created, the 340B program has deviated from its original mission to now benefit entities such as large, tax-exempt hospital systems, 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. State actions such as those proposed in several sections of LD 1018 will only serve to exacerbate issues with the current program.

§7702(7) and §7703 require pharmaceutical manufacturers to ship drugs to all contract pharmacies for 340B providers, and by extension, offer 340B pricing at these locations. These provisions enshrine the concept of contract pharmacies, which are not defined in federal law or regulation, and there is little evidence to suggest that patients have benefited from contract pharmacy growth.

Congress created the 340B drug discount program in 1992 to help vulnerable and uninsured patients access prescription medicines at safety-net facilities. Through the program, biopharmaceutical manufacturers provided $66.3 billion in medicines at significantly reduced prices in 2023 to qualifying safety-net hospitals and certain clinics ("covered entities"),[i] but patients are often not benefitting. Today, large hospital systems, chain pharmacies, and pharmacy benefit managers (PBMs) are generating massive profits from the 340B program even though its intended beneficiaries were true safety-net hospitals and clinics and the low-income and vulnerable patients they treat.

A lack of transparency and oversight has led to abuse of the 340B program.

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. There is no requirement that a contract pharmacy pass along the reduced price of a medicine to a patient. The arrangement between a covered entity and contract pharmacy is confidential, but according to available information, contract pharmacies retained 9% of the $64 billion in 340B profits generated in 2023—for a total of $5.76 billion.[ii] Between 2013-2023, the share of 340B margin retained by contract pharmacies tripled.[iii] The average profit margin for non-340B medicines dispensed through non-340B pharmacies is 3-4%, while 340B medicines dispensed through contract pharmacies is 72%.[iv]

Since 2010, the number of contracts with pharmacies has grown by more than 12,000%, and between 2013 and 2024, over 200,000 contract pharmacy agreements were established.[v] Because the program has no transparency or guardrails on how hospitals and clinics use 340B profits, the money often is not going to

help low-income and uninsured patients access medicines. An analysis of contract pharmacy claims for brand medicines only found evidence that patients were directly receiving a discount for 1.4% of prescriptions eligible for 340B.[vi]

A traditional retail pharmacy contracted with a covered entity is, on average, 46 miles away from the covered entity.[vii] Additional studies have found that 65% of the roughly 3,000 hospitals that participate in the 340B program are not located in medically underserved areas,[viii] and in Maine, just 53% are in rural areas, despite 69% of zip codes in the state being considered rural. Research has also found that more than 77% of 340B hospitals provide less charity care than the national average for all hospitals, and they often spend less on charity care and community investment than the estimated value of their tax breaks as nonprofits.[ix] In fact, 100% of 340B hospitals in Maine are below the national average for charity care levels.[x]

Despite some proponents' claims, the potential for a pharmacy to contract with a covered entity does not impact a patient's ability to access their medicines. A pharmacy's status as a "contract pharmacy" has no impact on whether or not a patient can pick up their prescriptions.

The 340B program has become a hidden tax on employers and their workers, including in Maine.

Marking up the costs of 340B medicines for employer-sponsored commercial plans and patients with private insurance generates significant revenue for 340B hospitals. 340B hospitals collect 7 times as much as independent physician offices for the sale of medicines administered to commercially insured patients[xi] and average spending per patient in the commercial market on outpatient medicines was more than 2.5 times higher at 340B hospitals than non-340B hospitals.[xii]

The current design of the program directly increases costs for employers by an estimated 4.2%, or $5.2 billion, [xiii] due to foregone rebates from manufacturers (which reduce the price of medicine), and indirectly increases employer costs by incentivizing provider consolidation and use of higher cost medicines.[xiv] Employers in Maine pay an estimated $54.3 million more in health care costs due to foregone rebates as a result of the 340B program.[xv] This leads to a $2 million reduction in state and local tax revenue.[xvi]

With no obligation to invest profits from 340B markups at satellite facilities into underserved communities, 340B hospitals frequently purchase independent physician offices so they can then buy more medicines and increase their 340B profits.[xvii] Further, incentives in the 340B program increase the use of higher-cost medicines as hospitals participating in 340B generally obtain substantially larger profits from more expensive medicines.[xviii,xix]

The 340B program has fiscal implications for state employees and ultimately taxpayers. Contract pharmacy mandates like §7702(7) and §7703 increase that fiscal impact.

In an unprecedented report examining 340B hospital practices in its state, the North Carolina State Treasurer found North Carolina 340B hospitals charged state employees massive markups for oncology medicines. According to the report, North Carolina 340B hospitals charged state employees, on average, a price markup of 5.4 times the hospitals' discounted 340B acquisition cost for outpatient infused cancer medicines. This resulted in billing the North Carolina State Health Plan for Teachers and State Employees a price markup on cancer medicines that was 84.8% higher than North Carolina hospitals outside of the 340B program.[xx]

Proposed contract pharmacy legislation in Maine is estimated to increase health care costs for employers and state and local government by $23 million due to additional foregone rebates.[xxi]

§7702(7) and §7703 will line the pockets of PBMs, pharmacy chains, and large hospital systems.

Many contract pharmacies charge a patient based on a drug's full retail price because they are not required to share any of the discount with those in need.[xxii] Big-box retailers such as Walgreens, CVS Health, and Walmart are major participants in the 340B program through contract pharmacy arrangements. Because of vertical integration in the supply chain, PBMs now own the vast majority of pharmacies, meaning they also make a profit from contract pharmacy arrangements. In fact, the five largest for-profit pharmacy chains comprise 60% of 340B contract pharmacies, but only 35% of all pharmacies nationwide.[xxiii] 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.[xxiv]

In 2023, the Minnesota Legislature passed legislation[xxv] that requires the Minnesota Department of Health (MDH) to collect and aggregate data from Minnesota providers that participate in the federal 340B program. The Minnesota 340B report provides further evidence that for-profit middlemen are profiting from the 340B program. Payments to contract pharmacies and third-party administrators (TPAs) were over $120 million, representing approximately $16 of every $100 of gross 340B revenue generated paid to external parties. In fact, 10% of safety-net federal grantees reported a negative net 340B revenue due to payments made to middlemen. The top 10% of critical access hospitals and disease-specific grantees with the highest external operational costs lost at least half their gross 340B revenue to TPAs and contract pharmacies.[xxvi]

The Minnesota 340B report also sheds light on the massive profits 340B hospitals retain from the 340B program. Minnesota providers participating in the 340B program earned a collective net[xxvii] 340B revenue of at least $630 million for the 2023 calendar year. Based on national data, MDH believes this figure may represent as little as half to one-third of the actual total 340B revenue for Minnesota providers due to lack of reporting from the covered entities for office administered drugs.[xxviii] Most entities did not report data for office administered drugs, which are estimated to account for 80% of all 340B drug spending.[xxix] The state's largest 340B hospitals benefitted most from the 340B program, accounting for 13% of reporting entities but representing 80%—more than $500 million—of net 340B revenue.[xxx]

The 340B program is a comprehensive federal program that is governed exclusively by federal law.

States do not have the authority to create new requirements that are not in the federal statute or that conflict with the statute. Whether manufacturers can be required to ship drugs to contract pharmacies for 340B providers is currently being litigated in multiple federal courts across the country. Maine should allow the federal courts to address and resolve the relevant issues before considering any legislative action.

§7704(2)(E) and §7704(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 diversion within the 340B program.

A 340B claims modifier is an electronic "tag" used in electronic transactions between pharmacy benefit managers (PBM) 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").[xxxi] 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.

CMS requires hospitals participating in the 340B program to use claims modifiers, which enable the Agency to "track the utilization of 340B acquired drugs and biologicals..."[xxxii] Hospitals have had several years of experience with 340B claims modifiers, which were first utilized in 2018. CMS has underscored that use of these modifiers would not impose additional burden on hospitals.

For the above-stated reasons, PhRMA respectfully opposes §7702(7), §7703, §7704(2)(E), and §7704(4) of LD 1018 and urges Maine legislators to strike these sections from the bill.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

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[i] HRSA, "2023 Covered Entity 340B Purchases," Oct. 2024. https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases

[ii] 340B Industry Roundtable, "For-Profit Pharmacy Participation in the 340B Program: 2025 Update," Jan. 2025. https://roundtable.thinkmosaic.com/links/for_profit_phcy_340b_2025_update

[iii] Berkeley Research Group, "The Pharmaceutical Supply Chain: 2013-2023," Jan. 2025. https://www.thinkbrg.com/insights/publications/the-pharmaceutical-supply-chain-2013-2023/

[iv] *Ibid.*

[v] *Ibid.*

[vi] IQVIA. "Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies." Oct. 10, 2022. Access: https://www.iqvia.com/locations/united-states/library/fact-sheets/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.

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[viii] Alliance for Integrity & Reform. "340B – A Missed Opportunity to Address Those That Are Medically Underserved." 2023 Update. Access: https://340breform.org/wp-content/uploads/2023/07/340B_MUA_July23-4.pdf.

[ix] BRG Analysis of HRSA OPAIS Database and Medicare Cost Reports. Q1, 2024.

[x] BRG Analysis of HRSA OPAIS Database and Medicare Cost Reports. Oct. 2023.

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[xiv] Sun C, Zeng S, Martin R. "The Cost of the 340B Program Part 2: 340B Revenue Sharing." *IQVIA*, March 2024. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/the-cost-of-the-340b-program-part-2-340b-revenue-sharing.pdf

[xv] IQVIA, "The Cost of 340B to States," Feb. 2025. https://www.iqvia.com/locations/united-states/library/white-papers/the-cost-of-the-340b-program-to-states

[xvi] Magnolia Market Access, "How The 340B Program Impacts Federal & State Tax Liability," Jan.2025. https://www.magnoliamarketaccess.com/insight/how-the-340b-program-impacts-federal-state-tax-liability/

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

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

[xxv] 2023 Minnesota Statutes, Section 62J.312

[xxvi] Minnesota Department of Public Health, "340B Covered Entity Report," Nov. 25, 2024. https://www.health.state.mn.us/data/340b/docs/2024report.pdf

[xxvii] MDH defines "net" as the difference between the payments received for discounted drugs ($1.5 billion), and the cost of acquiring those drugs ($734 million) plus payments to external administrators ($120 million). (see p.7)

[xxviii] The Minnesota Legislature amended the transparency law in 2024 to explicitly require covered entities to report data for office-administered drugs. See 2024 Minnesota Statutes, Section 62J.461

[xxix] Spending in the 340B Drug Pricing Program, 2010 to 2021 (https://www.cbo.gov/system/files/2024-06/60339-340B-DrugPricing-Program.pdf)

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[xxxii] 87 Fed. Reg. 71974.