PCMA

April 16th, 2025

The Honorable Donna Bailey
The Honorable Kristi Mathieson
Members, Committee on Health Coverage, Insurance and Financial Services
Cross Building, Room 220
100 State House Station
Augusta, ME 04333

**RE: LD 1018 An Act to Protect Health Care for Rural and Underserved Areas by Prohibiting Discrimination by Participants in a Federal Drug Discount Program; Opposed**

Chair Bailey, Chair Mathieson and Members of the Committee,

On behalf of the Pharmaceutical Care Management Association (PCMA), we wish to share opposition related to LD 1018. PCMA is the national association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for millions of Americans with health coverage provided through large and small employers, health plans, labor unions, state, and federal employee benefit plans, and government programs.

PBMs exist to make drug coverage more affordable by aggregating the buying power of millions of enrollees through their plan sponsor/payer clients. PBMs help consumers obtain lower prices for prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers and using lower-cost dispensing channels. Though employers, health plans, and public programs are not required to use PBMs, most choose to because PBMs help lower the costs of prescription drug coverage.

The federal 340B Drug Pricing Program was created in 1992 to extend significant discounts on covered outpatient drugs to eligible health care providers, known as "covered entities." The federal Health Resources and Services Administration ("HRSA"), part of the U.S. Department of Health and Human Services ("HHS"), oversees the 340 Program. The intent of the program is to enable these covered entities to serve the nation's most vulnerable patient populations. Because of an unintended profit motive built into the program, discussed below, 340B program sales in 2021 reached $93.6 billion.[1] This enormous growth has, in turn, spurred the Federal government to prioritize greater transparency in how covered entities use this profit to benefit the communities they serve.[2]

The 340B Program authorizes manufacturers to enter into a pharmaceutical pricing agreement ("PPA") with the HHS Secretary, under which the manufacturer agrees to provide front-end

[1] Martin, Rory, Ph.D., 340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect (April 2022), available at: (https://www.iqvia.com/locations/united-states/blogs/2022/04/340b-program-continues-to-grow-while-contract-pharmacy-restrictions-take-effect).

[2] Fiscal Year 2024 Budget in Brief, Department of Health and Human Services (March 2023), available at: (https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf).

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discounts on covered outpatient drugs purchased by covered entities. These discounts average 59% off the list price for drugs purchased at the 340B price, making the 340B program the second largest Federal prescription drug program.[3] A manufacturer that declines to enter into a PPA with the Secretary, forfeits reimbursement for their drugs under Medicaid and Medicare Part B. Current HRSA guidance permits 340B covered entities to dispense 340B covered outpatient drugs at their own in-house pharmacy, or at one or more contract pharmacies. In a typical case in which a covered outpatient drug is dispensed at a contract pharmacy, covered entities purchase a drug at about 70 percent (%) of the average wholesale ("AWP") and supply it to their contract pharmacy for dispensing. In turn, PBMs reimburse a contract pharmacy for 100 percent (%) of the drug's AWP. The result is the contract pharmacy pocketing the 30 percent (%) reimbursement difference as profit.

Recent studies show that covered entities can earn substantial profits on specialty drugs dispensed to patients via their own contract pharmacies arrangements.[4] For example, 340B hospitals often earn mark-ups of 380 percent (380%) over an oncology drug's acquisition cost. For some drugs, the mark-ups were ten times the acquisition costs.[5] What's more, commercial health plans generally paid hospitals almost twice the wholesale acquisition cost ("WAC") list price. Because of this inherent profit motive in the 340B program (and as recognized by Federal regulators) it is imperative that greater transparency is brought to bear on the 340B program and how profit from the program is being utilized to benefit patients. Requiring that 340B covered entities include modifiers on 340B claims – such that manufacturers and payers are able to determine when a particular claim Is benefitting from savings under the 340B program – is a commonsense, practical, and logical reform that ensure the 340B program is doing what it is intended to do: benefit patients.

As the state should be aware, the use of claims modifiers in the 340B program is neither novel nor unnecessary. For example, the Medicaid statute has long authorized the Secretary of HHS to require the use of claims modifier on 340B claims in order to protect against duplicate discounts in the program.[6] It seems unconscionable that the state would attempt to prohibit a practice that the Federal government has long endorsed as a way to bring transparency to a program in desperate need of reform. By prohibiting claims modifiers, LD 1018 would further shroud the significant profits of covered entities, denying the public of any way of ensuring the 340B program is benefiting the intended recipients of the program: low-income patients.

For these reasons, we respectfully request it be recognized that the savings generated by the federal 340B Program would not benefit patients ***without the use of claims modifiers***. Instead, the language LD 1018 would bolster the profits of covered entities and their contract pharmacies.

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[3] "340B Program at a Glance," Berkeley Research Group, available at https://media.thinkbrg.com/wp-content/uploads/2022/12/06082105/340B-Program-at-a-Glance-2022_clean.pdf.

[4] Aharon, Gal, Ph.D., Examining Hospital Price Transparency, Drug Profits, & the 340B Program (September 2021), available at: (http://communityoncology.org/hospital-304b-drug-profits-report/).

[5] "Examining 340B Hospital Price Transparency, Drug Profits, and Incentives," Community Oncology Alliance (September 2022), available at https://communityoncology.org/wp-content/uploads/2022/09/COA_340B_hospital_transparency_report_2_final.pdf.

[6] *See* 42 U.S.C. 1396r–8(a)(5). *See also* 42 U.S. Code § 256b(a)(5)(A).

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The language of Section 7706 of LD 1018 is both unclear and troublesome. Section 7706 appears to create a right of private action on behalf of 340B covered entities against PBMs and drug manufacturers. Such a private right of action would encourage frivolous litigation and interferes with provisions of the Affordable Care Act and its enacting regulations.

In 2010, as part of the Affordable Care Act, Congress added section 340B(d)(3) to the Public Health Service Act, which requires the Secretary of HHS to promulgate regulations establishing and implementing a binding Administrative Dispute Resolution (ADR) process for certain disputes arising under the 340B Program. On December 14, 2020, HHS issued a final rule implementing the ADR process, now codified at 42 CFR 10.20 through 10.24. Congress has thus set forth a careful and comprehensive statutory scheme for resolving disputes between manufacturers and covered entities – one that LD 1018 now seeks to disrupt. Independent private claims are inappropriate in the context of this comprehensive statutory and regulatory scheme. For this reason, Section 7706 and its private cause of action would face preemption challenges – both under ERISA and under 340B itself.

Moreover, the language of Section 7706 would encourage covered entity pharmacies (including those owned by large health systems) — who are market competitors of PBMs and health plans — to file frivolous lawsuits aimed at disrupting the business operations of payors and the normal contracting process between plans, PBMs, and pharmacies operating in Maine. The state would be placing its finger on the scale and distorting relationships between competing private stakeholders. It would be favoring one discrete special interest group to the detriment of PBMs as well as their insurer and plan sponsor clients. All of whom could face higher plan costs stemming from frequent and ruinous litigation. In turn, this state-imposed distortion would likely result in higher premiums or narrower benefits for beneficiaries in the state. It could also increase the cost of doing business for major employers in Maine who seek to offer drug benefits.

Thus, PCMA respectfully requests that the language of Section 7706 be removed from LD 1018.

In the interest of Maine patients and payers, it is for these problematic provisions noted above that we must respectfully oppose LD 1018.

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