

September 15, 2020

Stephen J. Ubl
President and Chief Executive Officer
Pharmaceutical Research and Manufacturers of America (PhRMA)
950 F Street, Northwest
Suite 300
Washington, DC 20004

Dear Mr. Ubl,

We write with deep concern over recent efforts by a number of your member pharmaceutical manufacturers that will threaten access to lifesaving, discounted drugs for low-income patients through the 340B Drug Pricing Program. In the midst of the COVID-19 pandemic, it is more important than ever that 340B covered entities, including Federally Qualified Health Centers (FQHCs), FQHC Look-Alikes, hospitals, including disproportionate share hospitals, rural hospitals, and children's hospitals, Ryan White HIV/AIDS clinics, and other safety net providers are able to serve the individuals who seek out their care. It is troubling that during a time of deep uncertainty involving access to health care, many of your member companies are taking retaliatory actions against FQHCs and other nonprofit health care providers that utilize legally permissible channels, such as contract pharmacies, to dispense 340B drugs. This coercive behavior is ultimately most harmful to patients and should be reversed.

As you know, the 340B Program requires drug manufacturers that receive reimbursements through Medicaid to provide drugs at a discount to eligible public and nonprofit health care organizations.¹ These health care providers then use 340B savings to provide discounted drugs to patients, especially those who are low-income or uninsured, and expand access to essential patient care.² In 1996, the Health Resources and Services Administration (HRSA), which oversees the 340B Program, released guidance indicating that the 340B statute allows 340B entities to contract with a pharmacy (known as a "contract pharmacy") to dispense 340B drugs.³ In 2010, HRSA released additional guidance specifying how covered 340B health

¹ 42 U.S.C. § 256b(a)(1).

² National Association of Community Health Centers, Inc., *Health Centers and the 340B Drug Discount Pricing Program: Increasing Access to Essential Medications and Services to Communities in Need [Fact Sheet]* (June 2014), http://www.nachc.org/wp-content/uploads/2016/02/340B_FS_2014.pdf

³ Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549 (Aug. 23, 1996).

care providers can use multiple contract pharmacies to support care for vulnerable populations, especially those in underserved areas.⁴

Despite the fact that the 340B statute requires manufacturers to sell drugs at 340B prices – including drugs dispensed through contract pharmacies, and the longstanding history of 340B covered entities providing access through the contract pharmacy model – multiple drug manufacturers have recently begun denying 340B pricing to covered entities for drugs dispensed through contract pharmacies. Such refusals to provide 340B pricing for use in contract pharmacies are likely a violation of the law. The 340B statute requires drug companies that participate in Medicaid to “offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any purchaser at any price”⁵ and HRSA’s 2010 guidance makes clear that “[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price.”⁶

Several drug manufacturers are also requiring 340B covered entities to submit claims data and threatening to deny 340B pricing for drugs dispensed through contract pharmacies if providers fail to provide the data. Rather than address program integrity, these requirements will make it easier for manufacturers to avoid voluntary rebates they have negotiated with third party payers while threatening patient privacy. If allowed to continue, this practice will result in discriminatory reimbursement practices against 340B covered entities. Unfortunately, this trend does not appear to be slowing: one report indicates that six more manufacturers will begin conditioning access to 340B drugs on excessive data requests.⁷

The reporting requirements are also not tied to 340B compliance obligations. For instance, the requirement by some drug manufacturers that 340B providers submit claims data on Medicaid managed care, Medicare Part D, and commercial insurance transactions to prevent duplicate discounts goes well beyond any alleged program integrity goals and statutory requirements, as the 340B statute only prohibits the duplication of 340B discounts and rebates from Medicaid fee-for-service (FFS) claims.⁸ These onerous requirements from the pharmaceutical industry’s 340B Program manufacturers are egregious oversteps that will limit the ability of 340B covered entities to provide affordable care, and ultimately, harm patients.

By improperly limiting access to 340B drugs, manufacturers will sever a lifeline to treatment for those who are overwhelmingly underserved, low-income, and vulnerable. HRSA has agreed, stating, “Manufacturers that refuse to honor contract pharmacy orders may be significantly limiting access to 340B discounted drugs for many underserved and vulnerable

⁴ Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

⁵ 42 U.S.C. 256b(a)(1).

⁶ 75 Fed. Reg. at 10278.

⁷ Tom Mirga, *BREAKING: Novartis the Latest to Seek 340B Contract Pharmacy Claims Data*, 340B Report (Aug. 18, 2020), <https://340breport.substack.com/p/breaking-novartis-the-latest-to-seek>

⁸ 42 U.S.C. § 256b(a)(5)(A).

populations. Many of these populations may reside in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions.”⁹

It is now more important than ever that 340B providers are able to flexibly provide treatment and care to the individuals they serve without undue burdens. However, the pharmaceutical industry’s recent actions are particularly troubling and detrimental to the goals of the 340B Program. Therefore, we request a response from PhRMA regarding steps being taken by the industry to end denials of 340B pricing for drugs dispensed through contract pharmacies and demands for contract pharmacy claims data no later than September 29, 2020. Patients, and the public and nonprofit health care providers that they rely on, depend on it.

Sincerely,

/s/ Richard Blumenthal
RICHARD BLUMENTHAL
United States Senate

/s/ Christopher S. Murphy
CHRISTOPHER S. MURPHY
United States Senate

/s/ Kirsten Gillibrand
KIRSTEN GILLIBRAND
United States Senate

/s/ Jeanne Shaheen
JEANNE SHAHEEN
United States Senate

/s/ Patrick Leahy
PATRICK LEAHY
United States Senate

/s/ Ron Wyden
RON WYDEN
United States Senate

/s/ Dianne Feinstein
DIANNE FEINSTEIN
United States Senate

/s/ Margaret Wood Hassan
MARGARET WOOD HASSAN
United States Senate

/s/ Tina Smith
TINA SMITH
United States Senate

/s/ Patty Murray
PATTY MURRAY
United States Senate

⁹ Michelle M. Stein, *HRSA Urges Pharma To Continue 340B Discounts At Contract Pharmacies* (Aug. 20, 2020), <https://insidehealthpolicy.com/daily-news/hrsa-urges-pharma-continue-340b-discounts-contract-pharmacies>

/s/ Amy Klobuchar
AMY KLOBUCHAR
United States Senate

/s/ Sheldon Whitehouse
SHELDON WHITEHOUSE
United States Senate

/s/ Bernard Sanders
BERNARD SANDERS
United States Senate

/s/ Sherrod Brown
SHERROD BROWN
United States Senate

/s/ Dick Durbin
RICHARD J. DURBIN
United States Senate

/s/ Mazie K. Hirono
MAZIE K. HIRONO
United States Senate

/s/ Tammy Duckworth
TAMMY DUCKWORTH
United States Senate

/s/ Jack Reed
JACK REED
United States Senate

/s/ Chris Van Hollen
CHRIS VAN HOLLEN
United States Senate

/s/ Cory A. Booker
CORY A. BOOKER
United States Senate

/s/ Jeffrey A. Merkley
JEFFREY A. MERKLEY
United States Senate

/s/ Robert Menendez
ROBERT MENENDEZ
United States Senate