



OFFICE OF THE ATTORNEY GENERAL
CONNECTICUT

WILLIAM TONG
ATTORNEY GENERAL

July 28, 2023

By Email

The Honorable John Thune
The Honorable Debbie Stabenow
The Honorable Shelley Moore Capito
The Honorable Tammy Baldwin
The Honorable Jerry Moran
The Honorable Benjamin Cardin
United States Senate
Washington, D.C. 20510

Re: *Response to Request for Information to Strengthen the 340B Drug Pricing Program*

Dear Senators Thune, Stabenow, Moore Capito, Baldwin, Moran, and Cardin:

We, the undersigned State Attorneys General of Connecticut, Arizona, Colorado, Delaware, Hawaii, Illinois, Kansas, Maine, Maryland, Massachusetts, Minnesota, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Wisconsin, and the District of Columbia, write in response to your June 16, 2023 Request for Information (RFI) to 340B Drug Pricing Program (340B program) Stakeholders. We seek to offer input as to how Congress can meaningfully reform and strengthen the vitally important 340B program to ensure that essential safety-net providers—including community health centers, AIDS/HIV clinics, rural hospitals, disproportionate share hospitals, and non-profit critical access hospitals that serve low-income patients across the country—can continue to provide life-saving and affordable medicines, as well as a broad and comprehensive range of health-related services to low income, uninsured, and underserved patients in a manner and at a level consistent with Congress’s legislative purpose in creating the program.

As you are aware, Congress’s expressly stated purpose in enacting Section 340B of the Public Health Services Act program in 1992 through the passage of Public Law 102–585 (the Veterans Health Care Act of 1992) was to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹ Federal law establishes a strong connection between States, which administer and jointly finance their Medicaid programs for low-income

¹ H.R. Rept. No. 102-384 (II) at 12 (1992).

165 Capitol Avenue
Hartford, Connecticut 06106

An Affirmative Action/Equal Opportunity Employer

individuals, and 340B covered entities²—which are the safety-net health care organizations that provide essential health services to the underserved and financially vulnerable. Under the laws governing both the 340B program and Medicaid, drug manufacturers participating in Medicaid are required to sell outpatient drugs at discounted prices to 340B covered entities that care for many uninsured and low-income patients.³ As State Attorneys General charged with protecting the integrity of state Medicaid programs, as well as the health and welfare of the financially vulnerable patients served by 340B covered entities, we welcome the opportunity to respond to your request for information by highlighting areas of concern in terms of 340B program oversight and program integrity, along with key guiding principles that we believe should serve as the framework for strengthening this vital program.

The 340B program has grown significantly since the 1992 bipartisan Congress created it, both in terms of the number of covered entities eligible to participate and in the volume of drugs purchased through the program.⁴ Since 2020, we have become increasingly dismayed by the efforts of drug manufacturers—who *voluntarily* agreed to participate in the 340B program and state Medicaid programs—to thwart the purpose, public policy, program integrity and operation of the 340B program. Specifically, as of July 2023, no fewer than 24 drug manufacturers have imposed conditions on or have outright refused to offer covered drugs to 340B covered entities that utilize outside “contract” pharmacies. These outpatient pharmacies are a key mechanism for the delivery of life-saving drugs to eligible patients, including those who have limited access to transportation, live in remote or rural areas, or are confined to their homes and rely on mail-order pharmacies. These drug manufacturers’ actions are especially troubling to us considering that between July 2021 and July 2022 the price increases of more than 1,200 drugs exceeded the annual inflation rate, with an average annual rate of increase of 32%.⁵

As you know, the 340B Drug Pricing Program is administered and overseen by the Office of Pharmacy Affairs (OPA), located within the Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services (HHS). In December 2020, a coalition

² 42 U.S.C. § 256b(a)(4)-(5).

³ 42 U.S.C. §§ 1396r-8(a)(1), (a)(5).

⁴ U.S. House of Representatives, Committee on Energy & Commerce, Subcommittee on Oversight & Investigations, 115th Congress, email from the U.S. Dept. of HHS to Committee Staff (Dec. 21, 2017).

⁵ Dep’t. of Health and Human Servs., Health Resources and Servs. Admin., Healthcare Systems Bureau, *Pharmaceutical Pricing Agreement*, OMB No. 0915-0327, § IV(c).

of State attorneys general⁶ wrote a letter to then-HHS Secretary Azar and then-HRSA Administrator Engels expressing concern that these drug manufacturers' refusal to provide critical drug discounts to covered entities that use contract pharmacies for dispensing and delivery of life-saving medicines to patients threatened to thwart the purpose and operation of the 340B program. Further, a coalition of twenty-five State attorneys general filed *amicus* briefs in cases before the United States Courts of Appeals for the Third Circuit and Seventh Circuit in support of HRSA's legal authority to prohibit drug manufacturers from limiting access to 340B program discounts on drugs purchased by covered entities that utilized outside contract pharmacies.

We share the concern in your June 16, 2023 letter that the 340B program may have outgrown its current statutory and regulatory regime in terms of HRSA's (1) authority to regulate, oversee and ensure the delivery of essential medications to underserved patients and communities, and (2) ability to regulate, oversee and ensure that the financial resources available to covered entities from 340B drug savings are used to provide a comprehensive safety-net to financially vulnerable and underserved patients. Certainly, a program of the level of importance and complexity of the 340B program requires a grant of appropriate regulatory authority and resources to HRSA and OPA.

These principles and recommendations are explained more fully below.

I. States are key stakeholders in the 340B program.

There is a clear connection and synergy between the States and the 340B program that makes States key stakeholders in the future of the program. States have a duty to protect the health and well-being of their residents. Congress also explicitly conditioned participation by drug manufacturers in Medicare and the Medicaid program—the jointly financed, state administered government insurance program for categorically needy individuals and families—on participation in the 340B program.⁷ Drug manufacturers are required to enter into Pharmaceutical Pricing Arrangements (PPAs) with HHS for drugs covered by the Medicaid program.⁸ These PPAs “require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if

⁶ That letter was signed by the State Attorneys General of California, Connecticut, Kansas, Nebraska, Colorado, Delaware, Hawaii, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Vermont, Virginia, Washington, Wisconsin, and the District of Columbia.

⁷ 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 1396r-8(a)(2018).

⁸ 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 1396r-8(a)(5).

such drug is made available to any other purchaser at any price.”⁹ States, through their Medicaid programs, and 340B covered entities work in partnership to provide access to affordable healthcare services across the continuum of care, of which affordable outpatient prescription drugs form a key component.

Participation in the 340B program allows covered entities to stretch scarce healthcare dollars,¹⁰ by allowing covered entities to offer drugs at a significant discount to their financially vulnerable patients and to provide other comprehensive services that are crucial in the effort to improve health outcomes but are often non-billable or beyond the reach of state Medicaid programs. The provision of these comprehensive health services, often preventative and targeted towards patients with complex or multifactorial health needs who are otherwise underserved, works to improve the health of our communities and keeps patients away from more costly courses of care like inpatient hospitalizations—all at no cost to taxpayers. Additionally, 340B covered entities¹¹ tend to disproportionately serve lower-income patients with higher morbidity and therefore constitute a key component of the “safety net” that keeps millions of Americans healthy.

II. Contract pharmacies are essential for the operation of the 340B program.

The 340B program has expanded significantly over the past decade. As of January 1, 2022, 13,661 covered entities and 39,485 associated sites are participating in the 340B program.¹² Beginning in 2020, an ever-increasing number of drug manufacturers—24 at the time of this writing—attempted to “self-police” the 340B program, without authority from, notice to or approval by HRSA, by placing conditions on and severely restricting covered entities’ ability to use outpatient retail community pharmacies¹³ and mail order pharmacies, commonly called “contract pharmacies,” to dispense medications to their patients. Drug manufacturers’ imposition of these barriers limiting access to life-

⁹ 42 U.S.C. § 256b(1). The ceiling price is defined as being “equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter.” 42 U.S.C. § 256b(a)(1)-(2).

¹⁰ H.R. Rep. No. 102-384, pt. 2, at 12 (Sept. 22, 1992).

¹¹ 340B Covered entities include Federally Qualified Health Centers, Ryan White HIV/AIDS Grantees, eligible Hospitals, and Specialized Clinics (Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Title X Family Planning Clinics, Sexually Transmitted Disease Clinics, and Tuberculosis Clinics).

¹² Health Res. and Servs. Admin., *Justification of Estimates for Appropriations Committees*, <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2023.pdf> (last visited July 27, 2023).

¹³ The term “retail community pharmacy” means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and dispenses medication to the public at retail prices. 42 U.S.C. § 1396r-8(k)(10).

saving and life-sustaining medications upon which 340B patients rely is potentially unlawful and certainly runs afoul of Congress’s legislative purpose for the 340B program. Any effort at legislative reform by Congress of the 340B program must prioritize codifying the use of contract pharmacies by 340B covered entities and granting HRSA express and sole authority to regulate the use of 340B contract pharmacies to ensure that the 340B program operates in a manner consistent with its expressly stated original legislative intent in establishing the program.

Outpatient contract pharmacies long have been a critical link to the effective operation of the 340B program and are a key component of the 340B program’s ongoing success in fulfilling its dual mission of providing drugs at discounted prices to financially vulnerable patients and stretching covered entities’ scarce federal resources to provide the broadest possible range of comprehensive health services. When the 340B program was created in 1992, only a few covered entities had in-house pharmacies, which limited the reach of and patient access to the program. In 1996, HRSA issued guidance allowing covered entities to use a contract pharmacy for purposes of the 340B program¹⁴ and acknowledged that contract pharmacies “facilitate [340B] program participation for those eligible covered entities who do not have access to appropriate in-house pharmacy services.”¹⁵ In 2010, HRSA issued updated guidance allowing covered entities to use multiple contract pharmacies so that financially vulnerable patients who lived great distances from the clinics, community health centers, and critical access and rural hospitals could obtain their necessary and life-sustaining medications with greater ease and less worry.¹⁶

Contract pharmacies enable federally qualified health centers (FQHCs), other community health centers, clinics, and public hospitals to carry out their critical role as covered entities by increasing patient access to the benefits of the 340B program by allowing their patients to obtain medications at accessible and convenient locations. Additionally, the option to use contract pharmacies allows smaller, but critically important, covered entities such as community health centers and clinics to participate in the 340B program even if they are unable to offer in-house pharmacy services, or if they want to supplement in-house pharmacy services to a broad set of underserved patients across a wide geographic area.

Drug manufacturers’ justifications for imposing restrictions on contract pharmacy use—namely, that the use of contract pharmacies results in duplicate discounting (where covered entities receive a 340B drug price on drugs subject to the Medicaid rebate) and drug diversion (where covered

¹⁴ 61 Fed. Reg. 43,549 (Aug 23, 1996).

¹⁵ 61 Fed. Reg. 43,555 (Aug. 23, 1996).

¹⁶ 75 Fed. Reg. 10,272 (Mar. 5, 2010).

entities sell covered 340B outpatient drugs to non-patients)—are based on exaggerated concerns that are neither supported by the text of the 340B statute nor relevant public guidance issued by HRSA. First, the 340B statute already bans both duplicate discounting¹⁷ and diversion.¹⁸ Covered entities can be fined¹⁹ or removed²⁰ from the 340B program for violations of either of these requirements. Further, HRSA also requires covered entities to be responsible for ensuring compliance of their contract pharmacy arrangement(s) with all 340B program requirements. In addition, contract pharmacies are required to carve-out Medicaid patients (*i.e.*, not use 340B drugs for Medicaid patients), unless the covered entity has an arrangement in place with the state Medicaid agency to prevent duplicate discounts. The covered entity must report such arrangements to HRSA.

Simply put, drug manufacturers’ unilaterally imposed conditions have created enormous barriers to the purchase of common, yet life-saving and life sustaining drugs, and drug manufacturers’ purported policy reasons for imposing these restrictions—diversion and duplicate discounts—are not a credible basis for engaging in this type of “self-help” to the detriment of 340B covered entities and their patients. Instead of streamlining the operation of the 340B program, drug manufacturers have changed their requirements and conditions relating to the use of contract pharmacies with limited or no notice to covered entities, which are expected to immediately comply, regardless of the resulting administrative burdens.

The results of a recently released study of 340B urban and rural hospitals, Ascension Hospitals located in Kansas, confirm and highlight the important role that outside contract pharmacies play in ensuring that patients of 340B covered entities have access to life-saving medications.²¹ The study sought to measure the impact of reduced-cost medications for chronic obstructive pulmonary disease (COPD) through 340B Prescription Assistance Programs (PAPs) on “all-cause hospitalizations” and emergency department visits. As part of their review, the study authors set out to determine whether and how much patients of the Ascension hospitals—all of which were eligible 340B covered entities—benefitted when these 340B hospitals passed along their 340B cost savings on common, high-cost inhalers for chronic obstructive pulmonary disease (COPD). The authors noted that the Ascension rural hospital included in the study “relied on a *contract pharmacy* as the mechanism to provide free and discounted medications to eligible patients.” (Emphasis added.) After reviewing

¹⁷ 42 U.S.C. § 256b(a)(5)(A)(i).

¹⁸ 42 U.S.C. § 256b(a)(5)(B).

¹⁹ 42 U.S.C. § 256b(d)(1)(B)(vi).

²⁰ 42 U.S.C. § 256b(d)(2)(B)(v)(I)-(II).

²¹ Leah M. Taliaferro et al., *Evaluation of 340B prescription assistance program on healthcare use in chronic obstructive pulmonary disease*, Explor. Res. Clin. Soc. Pharm, <https://pubmed.ncbi.nlm.nih.gov/37404594> (2023).

and comparing the discounted out-of-pocket costs of inhalers prescribed and dispensed to 115 eligible Ascension 340B PAP patients who either used hospital-owned outpatient pharmacies or a 340B contract pharmacy, the study authors found that the 340B PAP discount cut the out-of-pocket cost for the Ascension patients without insurance from about \$350 a month to about \$15 for a three-month supply, and that the 115 patients saved about \$178,000 combined in out-of-pocket costs during the study period. In addition, the study authors found that Ascension's 340B PAP also significantly reduced hospitalizations and emergency department visits for the same 115 patients for all causes, and that there was an estimated \$1,012.82 mean cost avoidance per patient due to reduction in healthcare utilization. The authors concluded that their "study suggested that access to reduced-cost medications through the federal 340B Drug Pricing Program was associated with a significant reduction in hospitalizations and emergency department visits for patients with COPD, decreasing patients' utilization of healthcare resources." The patient cost savings through improved access to life-saving inhalers at a significantly discounted rate, along with the reduced health expenditures based on the decrease in 340B PAP patients' utilization in the study of healthcare resources, simply would not have been possible had the Ascension hospitals that were the subject of the study as 340B covered entities administering the 340B PAP been blocked from being able to pass on their 340B discount to reduce the high cost of inhalers through the use of outside contract pharmacies.

Certainly, Congress in creating the 340B program, did not intend for drug manufacturers to undermine HRSA's authority over the 340B program by imposing one-sided, self-styled, byzantine, and complicated rules and conditions on covered entities who use contract pharmacies to dispense and deliver drugs to their patients. Congress therefore should grant HRSA the express and sole regulatory authority to promulgate regulations, after notice and public comment by all 340B stakeholders, relating to the use of contract pharmacies as an essential mechanism for the dispensing of 340B drugs, to ensure that the 340B program is properly managed and administered by HRSA, rather than arbitrarily in a manner that favors only drug manufacturers.

III. Congress should reaffirm its historically strong support of the 340B program and give HRSA the resources and tools it needs to effectively monitor and oversee the program.

It is undisputable that the 340B program has grown vastly in the years since Congress first created it: Unfortunately, the statutory grant of authority and appropriation to HRSA to administer the program has not kept pace in important ways. The uncertainties in the 340B program have created distractions for both HRSA and for covered entities, and Congress needs to reaffirm its longstanding, bipartisan support of the 340B program by granting HRSA the authority to promulgate regulations and engage in rulemaking relating to the use of contract pharmacies, program transparency and integrity, and affirmative civil enforcement tools against noncompliant actors. In reforming the 340B program, Congress should ensure that savings derived from discount programs are directed to fulfilling the mission of the 340B program—namely, to enable 340B covered entities "to obtain lower

prices on the drugs that they provide to their patients,” thereby “reaching more eligible patients and providing more comprehensive services.”

A key component missing in HRSA’s current ability to regulate the 340B program is program transparency. Although some requirements currently exist with respect to how covered entities use the savings derived from the 340B program, they vary depending upon the type of 340B covered entity. Congress should grant HRSA clear statutory authority to leverage and harmonize the existing reporting infrastructure between and among disparate 340B covered entities such as hospitals, FQHCs, and community health centers to create a uniform reporting system housed within OPA that is publicly accessible. In addition, Congress should mandate that 340B covered entities of all types report, at a minimum, the aggregated acquisition cost for prescription drugs obtained under the 340B program (both total cost and net of rebates), the aggregated payment amount received for drugs obtained under the 340B program and dispensed to patients, and the aggregated payment made to contract pharmacies to dispense drugs obtained under the 340B program.

HRSA can and does already conduct audits of covered entities to ensure compliance with program requirements. Since FY 2012, HRSA has completed 1,720 audits of covered entities, which included a review of 23,278 offsite outpatient facilities and 40,811 contract pharmacies.²² Findings of noncompliance can result in sanctions, up to and including removal from program participation. Drug manufacturers can also seek audits of covered entities by HRSA at their own expense, and as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity. However, HHS and HRSA currently lack rulemaking authority under the 340B Statute. We strongly recommend that Congress clarify the 340B program enabling statute,²³ including the scope of HRSA’s authority to promulgate regulations, to “catch up” with the progression and expansion of this critically important program. We also advise Congress to provide better enforcement tools and appropriate significantly greater financial resources to HRSA and OPA so that they can more effectively oversee the 340B program. HRSA’s budget should be increased so that additional staff and resources can be deployed for this important program. President Biden’s FY 2023 Budget requests an additional \$7 million and six additional FTEs to strengthen program integrity and to support additional oversight and operational improvements, including the implementation of a comprehensive Administrative Dispute Resolution (ADR) process.²⁴ These steps will ensure, as was Congress’s intent, that it is HRSA who is empowered to police abuse of the program, not drug manufacturers.

²² Health Res. and Servs. Admin., *Justification of Estimates for Appropriations Committees*, <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2023.pdf> (last visited July 27, 2023).

²³ 42 U.S.C. § 256b, as amended.

²⁴ 42 U.S.C. § 256b(d)(3).

* * * * *

The undersigned State Attorneys General appreciate this opportunity to provide meaningful input on the important 340B program and look forward to engaging, either formally or informally, with Senators in the bipartisan 340B Working Group regarding the content of this letter. Congress must take action to clarify and strengthen the 340B program, by adding accountability and transparency, reducing ambiguity and confusion, and allowing covered entities to go back to what they do best—treating and caring for patients.


Very truly yours,



WILLIAM TONG
Attorney General of Connecticut



KRIS MAYES
Attorney General of Arizona



PHILIP J. WEISER
Attorney General of Colorado



KATHLEEN JENNINGS
Attorney General of Delaware



ANNE E. LOPEZ
Attorney General of Hawaii



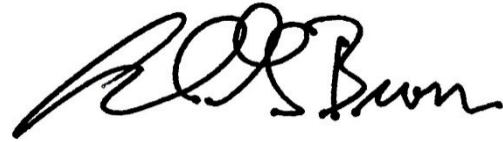
KWAME RAOUL
Attorney General of Illinois



KRIS W. KOBACH
Attorney General of Kansas



AARON M. FREY
Attorney General of Maine



ANTHONY G. BROWN
Attorney General of Maryland



ANDREA JOY CAMPBELL
Attorney General of Massachusetts




KEITH ELLISON
Attorney General of Minnesota



MIKE HILGERS
Attorney General of Nebraska



AARON D. FORD
Attorney General of Nevada



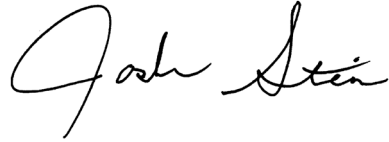
MATTHEW J. PLATKIN
Attorney General of New Jersey



RAUL TORREZ
Attorney General of New Mexico



LETTITIA A. JAMES
Attorney General of New York



JOSH STEIN
Attorney General of North Carolina



ELLEN F. ROSENBLUM
Attorney General of Oregon



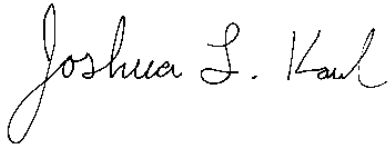
MICHELLE A. HENRY
Attorney General of Pennsylvania



PETER F. NERONHA
Attorney General of Rhode Island



CHARITY R. CLARK
Attorney General of Vermont



JOSHUA L. KAUL
Attorney General of Wisconsin



BRIAN L. SCHWALB
Attorney General of the District of Columbia