IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. XAVIER BECCERA, *et al.*, Defendants.	CASE NO.: 1:21-CV-00027-LPS

BRIEF IN SUPPORT OF
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

As this Court is aware from prior motions practice, the present dispute arose in mid-2020 when Plaintiff AstraZeneca Pharmaceuticals LP ("Astra") and several other large, global drug makers abruptly upended the twenty-five year operation of the 340B Program by restricting access to discounted drugs by safety-net healthcare providers that rely on neighborhood pharmacies. Specifically, the manufacturers announced that no longer will they offer (or offer without manufacturer-imposed, extra-statutory restrictions) access to discounted drugs for certain statutorily defined healthcare providers (called "covered entities") and their patients when the patients fill their prescriptions at outside "contract pharmacies." This policy has undoubtedly increased Astra's profits while dramatically curtailing much-needed funding for safety-net providers and forcing patients to pay more for medications or adjust their medication regimen.

After a thorough, months-long review of Astra's newly imposed contract-pharmacy restrictions, including assessment of thousands of complaints from safety-net providers, detailed analysis of real-world changes to Astra's discounted-sales volumes, review of correspondence from Astra and other manufacturers, and meetings with numerous stakeholders, the Health Resources and Services Administration ("HRSA") has determined that Astra is violating its obligation under Section 340B of the Public Health Service Act by overcharging covered entities for its drugs. That conclusion is based on sound statutory interpretation and voluminous evidence; this Court should reject Astra's challenge to HRSA's violation finding and allow HRSA's enforcement of the statute to proceed.

BACKGROUND

A comprehensive explanation of the 340B Program's statutory and regulatory background, and the concerted actions by six pharmaceutical manufacturers that led to the current litigation, are set forth in the U.S. Department of Health and Human Services' ("HHS") prior Motion to Dismiss or, in the Alternative, for Summary Judgment ("HHS First Mot.") 2-8, ECF No. 56. Included herein is information relevant to the new agency action, HRSA's May 17, 2021 violation letter issued to Astra

and challenged in Astra's second amended complaint (hereinafter "Compl."), ECF No. 86.[1]

Nearly four months before the since-withdrawn (and vacated) Advisory Opinion was issued, and shortly after Astra and its peers began announcing their novel restrictions on covered entities' access to 340B-discounted drugs, HRSA explicitly put Astra on notice that the agency was "considering whether" its "proposed [contract-pharmacy] policy constitutes a violation of section 340B and whether sanctions would apply," including, but "not limited to, civil monetary penalties pursuant to" 42 U.S.C. § 256b(d)(1)(B)(vi). *See* VLTR_6863. HRSA also expressly disavowed the manufacturers' assertion that their contract-pharmacy restrictions "did not give rise to an enforceable violation of the 340B statute," and warned that the newly imposed restrictions "would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," while "restrict[ing] access" for "underserved and vulnerable populations" during the global pandemic. *Id.* 7627. HRSA transparently explained that it "continues to examine" whether drug manufacturers' "actions amount to attempts to circumvent [the] statutory requirement by inappropriately restricting access to 340B drugs." *Id.* Unfazed by the warning and concerns expressed by HRSA, Astra and its peers proceeded to implement their new contract-pharmacy restrictions.

HRSA's comprehensive review of Astra's policy culminated in a new agency action in the form of a 340B-violation letter issued May 17, 2021, directly by HRSA. *Id.* 1, D. Espinosa Letter to O. Caprisecca ("Violation Letter"). That letter informed Astra that HRSA "has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* It relies on statutory text to determine that the requirement that Astra honor covered entities' purchases "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B

[1] Astra also appears to re-plead additional claims related to the Advisory Opinion previously set aside and vacated by this Court. This Court should decline to issue further relief on the Advisory Opinion, as Plaintiffs' claims challenging the Advisory Opinion have been mooted by the Court's vacatur of the Advisory Opinion. *See Ala. Power Co. v. EPA*, 40 F.3d 450, 456 (D.C. Cir. 1994) (declining to address additional claim because "decision to vacate the rule moots the issue"); *Nat'l Resources Def. Council v. EPA*, 489 F.3d 1250, 1262 (D.C. Cir. 2007) (dismissing as "moot" claim on vacated rule).

pricing on covered outpatient drugs purchased by covered entities." *Id.* HRSA's letter directs Astra to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy," and confirms that CMPs may be imposed. *Id.* 2. Although the letter instructs Astra to "provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price" by June 1, 2021, that date is *not* tied to the potential imposition of CMPs. *Id.* On the contrary, although "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in CMPs," HHS "will determine whether CMPs are warranted based on Astra's willingness to comply with its obligations under section 340B(a)(1)." *Id.* HHS has therefore made no determination as to whether sanctions are warranted at all but, should Astra continue to violate its 340B obligations, any such sanctions will not necessarily be limited to violations that occur after June 1. Importantly, the Violation Letter does not rest upon—or even reference—the General Counsel's now-withdrawn and vacated December 2020 legal advice (although the administrative record demonstrates that the agency considered that advice alongside other statutory interpretations, including the agency's previous guidances, VLTR_8048). Instead, the Violation Letter culminates the evaluative process Astra was aware of months before the Advisory Opinion issued.

The 8,000+-page administrative record demonstrates the thoroughness of HRSA's review and the voluminous evidence on which its conclusion is based. Alongside the statute and its legislative history, the agency's previous notices and guidances interpreting and administering the program, and several hundred pages of correspondence from manufacturers, covered entities, lawmakers, and other stakeholders, HRSA also gathered proof of the real-world implications of Astra's changes and the substantial harm to covered entities its restrictions have caused. The record contains *over six thousand pages* of complaints from covered entities. *Id.* 110–6,806. Although the entire volume of evidence of manufacturers' overcharges cannot adequately be summarized within the limitations of this brief, a few representative examples demonstrate the firm foundation of HRSA's Violation Letter. To start, Beverly Hospital's complaints alerted HRSA to the fact that "manufacturer(s) [are] deliberately refusing [the] 340B Pric[e]" and explained that the restrictions had forced it to pay "WAC [wholesale

acquisition cost] for [340B] [contract] pharmacy" orders—the highest commercial rate. *Id.* 1470–71; *see also id.* 1465–66. Those complaints included spreadsheets showing specific transactions where the 340B ceiling price[2] was denied and the hospital was subject to WAC prices on Astra's medications of up to §497.03 per unit; orders over two months totaled $156,563 in lost 340B savings. *Id.* 1468, 1474.

Strong Memorial Hospital, a safety-net healthcare provider, serves an area with "the third highest concentration of poverty in the U.S., with more than 50% of the city's children living in poverty," and "[n]early 40% of [the hospital's] patients … on Medicaid or law-income Medicare." *Id.* 6396. In April 2021, the hospital alerted HRSA that, since October 2020, it "had paid more than $2 million over the 340B ceiling price on covered outpatient drugs purchased from" Astra and other drug makers. *Id.* 6396. The hospital provided documentation of specific transactions in which Astra overcharged on 340B-eligible medications, forcing the safety-net provider to pay up to $565.37 per unit of medication. *Id.* 6404-05. And these orders represented only a fraction of "the lost opportunity and financial impact to the hospital"—which it had estimated to "exceed[] $10 million"—because the hospital's inability to purchase 340B drugs at the ceiling price not only resulted in paying higher prices for those drugs, but also deterred it from purchasing medications altogether. *Id.* 6396. The hospital explained to HRSA that "[t]he losses incurred due to manufacturer restrictions puts at risk [its] ability to maintain a robust charity care program and community services that [it is] able to provide." *Id.*

Arnot Ogden Medical Center also documented specific transactions with Astra that resulted in thousands of dollars of overcharges for the hospital. *Id.* 6229, 639-40. The safety-net provider, who "provid[es] care for a region with a poverty rate around 30%," explained to HRSA that it "has operated for years in the red," attributing its ability to "keep the doors open" to the help it receives from "the 340B program and largely the benefit from contract pharmacy relationships." *Id.* 6229. As a result of Astra's and other drug manufacturers' restrictions, the hospital estimated that it had "been charged [approximately] $360k over the 340B ceiling price on covered outpatient drugs." *Id.*

[2] The 340B ceiling price is statutorily protected, 42 U.S.C. § 256b(d)(1)(B)(iii), and thus is redacted in the administrative record, along with other figures that would allow a reader easily to calculate the ceiling price for any particular drug. Astra cannot dispute, however, that the ceiling price for medications referenced in this discussion are only a tiny fraction of the WAC price.

Many other safety-net providers serving similarly disadvantaged and vulnerable populations echoed Strong's and Arnot's concerns regarding Astra's and other drug makers' restrictions on the covered entities' purchases of 340B-eligibile drugs, and further documented specific transactions reflecting overcharges by Astra. *See, e.g.*, *id.* 6280, 6237-38 (Highland Hospital: serving a population with 50% of children living in poverty), 6331, 6345, 6352-53 (Jones Memorial Hospital: serving "a rural area" with "among the poorest in New York"; "The 340B program and largely the benefit from contract pharmacy relationships are keeping the hospital's doors open."), 6360, 6388–89 (Noyes Memorial Hospital); *see also id.* 2592 (Gerald Champion Regional Medical Center: "[R]eport[ing] instances of overcharging by drug manufacturers," including Astra), 4446-47, 4452-53 (Nebraska Medicine: Providing HRSA with documentation of Astra products no longer offered at the 340B ceiling price through contract pharmacies), 5622 (UC Davis Medical Center: Explaining how its "adult and pediatric patients in Northern California" spread across *65,000* square mile area "rely on pharmacies closer to their homes" and how its contract pharmacies help its "patients to have access to medications"). Numerous providers also explained that they were forced to pay the wholesale acquisition cost for Astra's drugs that were no longer available at the 340B ceiling price. *See, e.g. id.* at 287 (Alcona Health), 1894 (CCHS Augusta), 2325 (Family Medical Center of Michigan), 2655 (HS Ohio), 4694 (North Country HealthCare, Inc.), 6586 (Maricopa County Special Health Care District).

Erie Family Health Center submitted a declaration explaining that Astra's policy is "unworkable." VLTR_7278. Erie serves over 80,000 patients per year at 12 locations around Chicago, predominantly low income and minority patients. *Id.* Even if Erie is able to designate one contract pharmacy under Astra's policy, certain of Erie's patients "would need to travel nearly three hours one-way on public transportation to arrive" at its singular contract pharmacy, for a total of six hours round trip, on a regular basis, to pick up important and life-saving medications. *Id.* 7281-82.

A critical-access hospital in Vermont explained that it is "highly dependent on the 340B program to support its mission of providing care to underserved populations. *Id.* at 4876. It expressed "concern[] that AstraZeneca's refusal to process 340B chargebacks for contract pharmacy arrangements will impose enormous financial burdens," particularly in light of the timing "in the midst

of the COVID-19 public health emergency . . . which has already stretched the finances and human resources of Porter Medical Center." *Id.*

The Truman Medical Center Lakewood explained it has been unable to purchase certain Astra drugs at the 340B ceiling price since Astra's policy went into effect. *Id.* at 5430. Astra's policy "impacts patient care in that it prevents TMC Lakewood's ability to perform its safety net mission by providing 340B pricing discounts directly to vulnerable patients in the communities where they live." *Id.*

HRSA also relied on evidence regarding the importance of outside, neighborhood pharmacies, even for covered entities that may also operate an in-house pharmacy. For instance, one federally funded health center in Georgia, which represents a sizeable, rural area and a "medically underserved population," submitted sworn testimony confirming that its in-house pharmacy can serve only 40% of its 25,000 patients. *Id.* 7255-56. That health center relies on 340B savings through its contract-pharmacy network to "provide its qualified patients medications such as insulin and epinephrine for as little as $4 to $7 a dose, or even at no cost at all." *Id.* The covered entity also explained that six of its eleven health centers do not operate an in-house pharmacy, and those that do are only open weekdays 8AM to 5PM, so neighborhood pharmacies are crucial because "available time during the traditional workday is a significant barrier for our patient population." *Id.* Aside from the benefit to patients, the covered entity explains that its contract pharmacies enable it to "generate additional revenue" through the spread between the 340B-discount price and the price paid by or on behalf of some patients, as Congress intended,[3] and that it "reinvest[s] all 340B savings and revenue in services that expand access" for patients and serve "vulnerable populations such as the homeless, migrant workers, people living in public housing, and low-income individuals and families."[4] *Id.*

[3] As previously explained, Congress designed the program to allow covered entities to generate revenue "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). Much of this revenue is generated through payments by private insurance. Uninsured patients often receive medications for free but also may be charged a small amount on a sliding-income scale, relative to their financial ability. This enables covered entities to reinvest in patient care and services.

[4] This covered entity also thoroughly rebutted manufacturers' portrayal of contract-pharmacy relationships as a boon for for-profit pharmacy chains, explaining that, although it pays a modest,

Copious sworn testimony further documents the harms caused by drug makers' unlawful 340B restrictions. A safety-net provider in Michigan evidenced its reliance on the 340B program; it serves a "*10,000-mile service area*" and thus relies extensively on retail pharmacies. *Id.* 7260-61. Through its contractual arrangements, it "purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped to" its pharmacy partners, under contracts specifying that "[t]he health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services to eligible … patients." *Id.* It passes on 340B discounts "directly to eligible patients who meet federal poverty guidelines," while using savings earned from other dispenses to pay for "essential health care services to its underserved rural community," including those not readily available in the rural Upper Peninsula, such as addiction treatment and OB/GYN care. *Id.* 7261–62. The covered entity detailed the impossibility of serving patients through just one pharmacy, along with the severe impacts on its services and budget that Astra's and its peers' restrictions have caused. *Id.* 7262–63. The administrative record contains numerous similar declarations detailing harms to covered entities. *E.g.*, *id.* 7270–75; 7277–83 (federally funded health center explaining that it does not operate an in-house pharmacy and instead pays for drugs to be shipped to a contract pharmacy where provider "maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the drugs and provide dispensing services"; savings generated are "100%" reinvested into patient care, including addiction treatment); 7295–98 (safety-net provider expects to lose $6 million from its $8 million budget due to 340B restrictions, and is preparing to lay off 35 employees as a result); 7300–06 (federally funded provider in Arizona documenting that patients would have to travel up to 180 miles *each way* to fill prescriptions at in-house pharmacies and that, as a result of lost revenue, entity is weighing services cuts); 7309–14 (confirming that "[u]ninsured patients get 100% of the savings at our partner (contract) pharmacies" and that, for other patients, "[a]ny net revenue we derive from the 340B Program also goes directly to our patients"); 7316–20; 7323–25; 7331–33; 7347–50.

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predetermined fee to the pharmacy for its services, "as required by HRSA, [it] does not and will never enter into an agreement with contract pharmacies where it does not retain the majority of the savings from the 340B discount" and that it recently "underwent a 340B HRSA Audit where there were no [non-compliance] findings." VLTR_7257.

During its evaluation HRSA also gathered relevant evidence through meetings with stakeholders impacted by Astra's and its peers' restrictions. For example, HRSA officials met with representatives of Avita Pharmacy, a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS clinics. *Id.* 7891-92. Avita relayed that, of its 270 covered-entity clients—98% of whom do not operate their own pharmacies—all were being denied 340B pricing and stand to lose millions of dollars in lost revenue. *Id.* Avita expressed concern that the changes "will lead to imminent harm to patients and possible site closures," and some health centers were forced to charge $300 for insulin that had been dispensed for as little as $0. *Id.* HRSA officials learned in another meeting that one pharmacy in West Virginia that dispenses on behalf of a covered entity "has already had 14 patients denied insulin based on these practices," which had only just gone into effect. *Id.* 7887. That same month, HRSA gathered evidence from tribal leaders detailing the harms befalling income-disadvantaged tribal members and underfunded rural health clinics as a result of manufacturers' restrictions, including that, for one tribe in California, "[p]atients are having to choose between buying food and buying medications" and "are ending up in the Emergency Room that costs a lot more money than medications cost." *Id.* 7894–97. Another tribe reported that its pharmacy bill has more than doubled, that it is "not financially feasible for the tribe to operate its own pharmacy" and that it had been forced to pay more than $3,400 for roughly 100 pills, which it described as "[un]sustainable costs." *Id.* 7894, 7898.

The administrative record also contains the result of an annual survey of 340B hospitals completed by 340B Health, a nonprofit trade organization for certain covered entities. *Id.* 7957–63. In the survey virtually all covered entities reported "feeling the impact of the refusal of some large drug companies to provide discounts on drugs dispensed by community pharmacies" while reporting that "cuts are likely" should these actions continue. *Id.* 7957. Respondents provided information on how they use 340B savings to provide more services for medically underserved and low-income patients. *Id.* 7958. Funding cuts caused by lost 340B savings were shown to "threaten a range of services for" hospitals, with the "most impact [to] oncology and diabetes services." *Id.* 7959. Fully one-third of covered-entity hospitals responding said that lost 340B savings could cause a hospital closure. *Id.* Rural

hospitals are at even greater risk, since fully three-fourths of such "hospitals rely on 340B savings to keep the doors open" and program cuts are most likely to harm general patient care and diabetes services. *Id.* 7960–61. Of particular note, survey respondents expressly tied financial concerns to six manufacturers' contract-pharmacy restrictions, which are impacting the resources of 97% of 340B hospitals—most of which expect to lose *more than fifteen percent* of their annual 340B savings as a result of contract-pharmacy restrictions—and "[n]early all 340B hospitals report they will have to cut programs and services if these restrictions become more widespread." *Id.* 7962.

Astra's overcharges are also reflected in aggregate statistics compiled at HRSA's request in an "attempt[] to quantify the loss of units sold and savings." *Id.* 7936–47. That analysis showed a decrease in 340B units sold *monthly* from 10.5 million prior to manufacturers' restrictions down to only 2.9 million in January 2021. *Id.* 7936 (Figure 1). "Annualized this equates to a reduction in 340B units sold of nearly 83 [million]." *Id.* The statistics include graphs showing the stark, immediate impacts of Astra's and its peers' refusal to honor 340B pricing. Figure 1 shows that, from August to October 2020, when Astra and three other manufacturers put in place their changes, 340B units sold took a nosedive from 9.6 million units to 5.1 million units sold monthly; WAC-priced units consequently rose sharply, from a negligible volume to 1 million units monthly.[5] *Id.* Figure 2 shows that covered entities' monthly 340B savings fell from $357 million in July 2020, just before restrictions were put in place, to $92 million in January 2021—representing annualized lost savings of $3.2 billion. *Id.* Figure 3 shows that, in January 2021, covered entities lost an estimated $234 million in that month *alone* and had lost an estimated $665 million in roughly four months of restrictions. *Id.* That analysis also shows the impact of Astra's specific changes, separated from other manufacturers; its restrictions caused 340B sales to decline in only a few months from roughly 2.72 million units to 0.53 million units—during that period, WAC-priced units sold by Astra saw a marked rise from approximately 0.01 to 0.53 million units in a *one-*

[5] As the analysis explains, VLTR_7936, WAC-priced units do not fully reflect the loss of 340B-priced sales and thus underrepresent the impact of manufacturers' changes. This is because some sales will be lost entirely and because covered entities' third-party administrators will shift 340B-priced sales to other purchasing accounts rather than pay the highly marked-up WAC price. For this reason, lost 340B sales is a better indicator of impact than increased WAC sales.

month stretch. *Id.* 7937. The analysis also quantifies the fiscal impact of Astra's changes. Monthly savings to covered entities dropped from $53.5 million just before it began overcharging safety-net providers to only about $7.2 million within two months. *Id.* 7939.

As even this truncated overview demonstrates, HRSA spent many months gathering a legion of evidence with which to analyze the legality of Astra's policy to "recognize one contract pharmacy arrangement per covered entity site in the event that the covered entity does not maintain its own, on-site pharmacy." *Id.* 7610. After evaluating Astra's policy and its real-world impact on the 340B program, alongside Astra's communications to the agency explaining its policy, *e.g.*, *id.* 7606-16, HRSA concluded that Astra is violating the 340B statute and issued its May 17, 2021 letter to that effect.

LEGAL STANDARD

In a case involving review of final agency action under the APA, the "customary summary judgment standard" under Rule 56 "does not apply." *Bintz v. FEMA*, 413 F. Supp. 3d 349, 360 (D. Del. 2019). Rather, "'[s]ummary judgment is the 'mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review.'" *Id.* (citation omitted). The party challenging agency action bears the burden of demonstrating a violation of the APA. *Washington v. Donley*, 802 F. Supp. 2d 539, 546 (D. Del. 2011).

ARGUMENT

I. HRSA CORRECTLY FOUND THAT ASTRA IS VIOLATING ITS STATUTORY OBLIGATION.

A. HRSA's interpretation fulfills Congressional purpose.

The question before this Court should properly be framed as whether HRSA correctly found that Astra's contract-pharmacy restrictions violate the statutory prohibition on overcharging covered entities. That question is not answered, as Astra suggests, by the fact that "Section 340B does not [explicitly] require manufacturers to *deliver* 340B-discounted drugs to contract pharmacies," Compl. ¶ 36 (emphasis added). The 340B statute is silent as to delivery location because Congress's intent was to provide access to discounted medications for safety-net providers, not to detail the logistics of how such transactions should be effectuated—and bedrock principles of statutory interpretation establish

that, even where Congress legislates in "starkly broad terms," *Bostock v. Clayton County*, 140 S. Ct. 1731, 1753 (2020), *remanded*, *Bostock v. Clayton Cnty. Bd. of Commissioners*, 819 F. App'x 891 (11th Cir. 2020), courts must use all the available tools of statutory interpretation to give effect to Congressional intent.

In reviewing HRSA's enforcement efforts, this Court must read the 340B statute "as a whole," *United States v. Atl. Research Corp.*, 551 U.S. 128, 135 (2007), and "must (as usual) interpret the relevant words not in a vacuum, but with reference to the statutory context, structure, history, and purpose." *Abramski v. United States*, 573 U.S. 169, 179 (2014) (citation omitted). "[I]t is a fundamental principle of statutory construction (and, indeed, of language itself) that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used." *Textron Lycoming Reciprocating Engine Div. Avco Corp. v. United Auto., Aerospace & Agric. Implement Workers of Am.*, 523 U.S. 653, 657 (1998) (citation omitted); *see also Regions Hosp. v. Shalala*, 522 U.S. 448, 460 n.5 (1998). Astra's reading of the statute improperly focuses on a single word—to the exclusion of necessary language found in the same statutory subsection—and fails to give effect to Congressional intent. As shown herein, HRSA correctly found that Astra's contract-pharmacy policy erects unlawful hurdles around covered entities' access and has resulted in overcharges in violation of the 340B statute.

The Violation Letter was issued only after HRSA—the entity that has administered the program for decades—"completed its review of [Astra's] policy that places restrictions on 340B pricing to covered entities," including "an analysis of the complaints HRSA has received from covered entities." VLTR_1. The determination "that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute," *id.*, relies directly on statutory text. *See id.* (citing "Section 340B(a)(1) of the Public Health Service (PHS) Act," 42 U.S.C. § 256b(a)(1)). The statute conditions Medicaid and Medicare Part B access on Astra's adherence to the 340B statutory scheme that Astra opted into by executing a Pharmaceutical Pricing Agreement ("PPA") requiring manufacturers to ensure that "the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a covered entity" does not exceed the statutory ceiling price. 42 U.S.C. § 256b(a)(1). It also specifies that "[e]ach such agreement shall require … that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is

made available to any other purchaser at any price." *Id.* As HRSA explained, that straightforward obligation "is not qualified, restricted, or dependent on how the covered entity chooses to distribute" the drugs it purchases to its patients, and no statutory provision authorizes a drug maker to place conditions on its fulfillment of that mandate. *See* VLTR_1. HRSA also reminded Astra that compliance with its PPA requires Astra to "ensure that the 340B ceiling price is available to all covered entities."

HRSA further explained that Astra's restrictions run afoul of its separate obligation "to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs" because Astra's restrictions prevent covered entities from accessing discounted drugs through the same wholesale channels where drugs are made available for full-price purchase. *Id.* HRSA cited existing regulations confirming that "a manufacturer's failure to provide 340B ceiling prices through" existing wholesale distribution agreements will result in CMPs. *Id.* (citing 340B Drug Pricing Program Ceiling Price & Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)). Existing regulations also define an "[i]nstance of overcharging" as "any order for a covered outpatient drug … which results in a covered entity paying more than the ceiling price … for that covered outpatient drug." 82 Fed. Reg. at 1230 (citing 42 C.F.R. § 10.11(b)(2)). In short, HRSA's analysis rests on the statute itself and duly promulgated regulations issued through an express grant of rulemaking authority (*not* on the now-withdrawn and vacated Advisory Opinion).

HRSA is correct in its statutory interpretation. Since 1992 the 340B statute has conditioned Medicaid coverage on compliance with "an agreement with each manufacturer of covered drugs under which the amount required to be paid … to the manufacturer for covered drugs … purchased by a covered entity … does not exceed" the statutory ceiling price. Veterans Health Care Act of 1992, Pub. L. No. 102-585, tit. VI, § 602(a), 106 Stat. 4943, 4967 (1992). Read "as a whole," *Atlantic Research Corporation*, 551 U.S. at 135, the core requirement of 42 U.S.C. § 256b(a)(1) plainly requires manufacturers to *sell* discounted drugs *to covered entities*.[6] In urging this Court to find that it can

[6] The fact that 42 U.S.C. § 256b(a)(1) is directed to the Secretary of HHS, requiring him to enter agreements obligating manufacturers to honor covered-entity purchases, *discussed* Op. 18, does not displace HRSA's finding because HRSA is acting (through delegation from the Secretary) to enforce

somehow fulfill its duty to honor "purchases by" covered entities while admitting that it now *denies* those very purchases (forcing covered entities instead to pay wholesale acquisition cost) based solely on delivery location or dispensing mechanism, Compl. ¶ 69, Astra asks this Court to consider a different phrase in a vacuum, divorced from statutory language *in the same subsection* and devoid of necessary context. The statute does not, as Astra portrays, only require it to *offer* drugs for purchase by covered entities, regardless whether the terms of its "offer" pose practical barriers restricting covered entities' access. *Contra, e.g.*, Compl. ¶ 31 (portraying "Section 340B's 'must-offer' requirement" as the full extent of manufacturers' obligation under 42 U.S.C. § 256b(a)(1)); *id.* ¶ 69 ("Section 340B's must-offer provision requires a manufacturer *solely* to 'offer' discounted drugs to a 'covered entity.' 42 U.S.C. § 256b(a)(1). Nothing in the statute supports that a manufacturer violates its obligation by declining to make discounts available for contract pharmacy sales.") (emphasis added).

The "offer" language in § 256b(a)(1), on which Astra exclusively relies, was added in 2010 to codify an *additional* requirement that manufacturers cannot discriminate by treating commercial purchases more favorably than 340B purchases. *See* ADVOP_394, Clarification of Non-Discrimination Policy, May 23, 2012. In other words, Congress clarified in 2010 that manufacturers cannot preference full-priced purchases over 340B purchases (a requirement HRSA had already set forth in guidance, as discussed *infra*). That amendment in no way changed the substance of Astra's preexisting obligation. Were the requirement to "offer each covered entity" discounted drugs the sum total of manufacturers' obligation, as Astra contends, Compl. ¶ 70, the inescapable conclusion would be that, from 1992 until 2010, the pharmaceutical industry sold deeply discounted drugs to covered entities on a purely voluntary basis (since the "offer" language did not yet exist). But of course that is not the case: From the statute's enactment, drug companies wishing to receive coverage for their products through certain government health-insurance programs have been required by both the statute and their PPAs to ensure that drugs "purchased by a covered entity" do not exceed the ceiling

against Astra the requirement in the statute and its PPA to provide discounts to safety-net providers. The Violation Letter is HRSA's effort to effectuate the command to the Secretary in § 256b(a)(1), and there is no question that the statute instructs the Secretary to ensure that covered entities are not charged more than the 340B ceiling price.

price. That obligation did not arise from the 2010 amendments and has not changed substantively (aside from the *additional* non-discrimination requirement) since the statute's enactment. Moreover, Astra fails to grapple with the fact that its restrictions *do* violate the "offer" provision's non-discrimination requirement by treating commercial purchases far more favorably than 340B purchases, as evidenced by the fact that Astra places no delivery-location or dispensing-mechanism restrictions on full-priced sales—only covered entities' purchases.

This Court should decline Astra's request to interpret the statutory text in isolation, without "exhaust[ing] [all of] the traditional tools of statutory construction to determine whether a congressional act admits of plain meaning." *See Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1287 (D.C. Cir. 2000). "In determining whether a statute is ambiguous …, [a court] must employ all the tools of statutory interpretation, including 'text, structure, purpose, and legislative history.'" *Loving v. IRS*, 742 F.3d 1013, 1016 (D.C. Cir. 2014) (citation omitted). As already explained above, the text, structure, and purpose of the 340B statute collectively demonstrate that Congress carefully crafted a comprehensive scheme designed to allow safety-net providers and patients to actually access discounted medications—*i.e.*, requiring manufacturers to honor the very purchases Astra now is denying. It matters not that Congress did not expressly address delivery location or expressly authorize outside-dispensing arrangements (upon which nearly all covered entities relied when Congress enacted the 340B statute). That type of hyper-technical reading does not comport with precedent; on the contrary, "[t]he mere possibility of clearer phrasing cannot defeat the most natural reading of a statute," *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012).

Astra asks this Court to construe the 340B statute in a manner that would run afoul of recent Supreme Court guidance. In *Bostock v. Clayton County*, 140 S. Ct. at 1737-38, the Court held "[t]he answer is clear" that Title VII's prohibition on discrimination "because of … sex" encompassed claims of sexual-orientation and transgender-status discrimination—despite the fact that nowhere is sexual orientation referenced in the text and notwithstanding that the drafters "might not have anticipated their work would lead to this particular result." The Court's approach is highly relevant for this case; indeed, Astra's focus on the fact that § 256b(a)(1) does not address delivery location or dispensing

mechanism, *e.g.*, Compl. ¶ 36, is directly analogous to the unsuccessful argument that, "[b]ecause homosexuality and transgender status can't be found on th[e] list" of statutorily "protected characteristics," "they are implicitly excluded from Title VII's reach." *Bostock*, 140 S. Ct. at 1746. Not so: the Court explained that there is no "such thing as a 'canon of donut holes,' in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception. Instead, when Congress chooses not to include any exceptions to a broad rule, *courts apply the broad rule*." *Id.* at 1747 (emphasis added). The Court further explained that, despite the absence of any language sweeping in sexual orientation or any reason to believe the drafters expressly intended that result, "no ambiguity exists about how Title VII's terms apply to the facts before us," since "the fact that a statute has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity; instead it simply demonstrates the breadth of a legislative command." *Id.* at 1749 (internal citations and alterations omitted). The Court also noted that Title VII "is written in starkly broad terms" and "has repeatedly produced unexpected applications." *Id.* at 1753.

Bostock demonstrates the flaws in Astra's approach. Just as the absence of express statutory text did not prevent sexual-orientation discrimination from falling within Title VII's broad sweep, the absence in § 256b(a)(1) of any express command to deliver to neighborhood pharmacies does not allow Astra to sidestep its obligations to honor "purchases by" covered entities at the ceiling price and to treat those sales on par with commercial purchases. True, the 340B statute creates "a broad rule," but that does not allow this Court to "create[] a tacit exception" that Congress omitted by limiting Astra's obligation to only purchases shipped to specific locations. *See Bostock*, 140 S. Ct. at 1747. No interpretive doctrine requires Congress to spell out the minutiae of every facet of every transaction encompassed within a program created through novel legislation. Stated differently, Congress is permitted to (and often does) legislate through broad commands or prohibitions, and the use of more-general language does not permit a regulated entity to take actions that contravene a statute's purpose simply because those actions were not expressly prohibited by the plain text. This intuitive principle is illustrated by the untenable results that would accrue should Astra's interpretation be credited. If Congress's failure to address delivery location indicated that manufacturers have *no* delivery or

shipping obligations—as Astra's contentions would suggest—then it would follow that Astra could entirely refuse to deliver 340B-discounted drugs and require each covered entity across the nation to physically pick up their purchased drugs from Astra's warehouses. Similarly, Astra's view of the meaning of Congressional silence would mean that, since the 340B statute is equally silent on payment method, Astra could require covered entities to pay only in pennies. Congress' failure to address drug quantities could similarly allow Astra to require high minimum-order requirements that rendered it infeasible for resource-strapped safety-net providers to purchase Astra's drugs. None of these results is permissible under the statute (nor is Astra's refusal to honor the ceiling price when covered entities direct drug shipments to neighborhood pharmacies) because Congress's intent in mandating maximum prices for covered entities is clear—and Congress was under no obligation to micromanage the details of those transactions in order to achieve its purpose of providing discounted drugs.

B. Astra's reading of the statute would render the statutory scheme ineffective.

Another canon of statutory interpretation, "the presumption against ineffectiveness," *United States v. Castleman*, 572 U.S. 157, 178 (2014) (Scalia, J., concurring), is violated by Astra's interpretation. That canon means "a textually permissible interpretation that furthers rather than obstructs [a statute's] purpose should be favored." *Tex. Workforce Comm'n v. U.S. Dep't of Educ.*, 973 F.3d 383, 389 (5th Cir. 2020) (citation omitted); *see also United States v. Hayes*, 555 U.S. 415, 426-27 (2009) (rejecting a construction of a statute that "would frustrate Congress' manifest purpose" and would have meant that the statute was "'a dead letter' in" many of its applications "from the very moment of its enactment"). Congress legislates against the backdrop of real-world facts and, in creating the program, surely knew both that (1) covered outpatient drugs can only be dispensed by licensed pharmacies, not any healthcare provider entitled to prescribe them, and (2) in 1992 when the statute was enacted, only 5% of covered entities had an in-house pharmacy, and reliance on outside pharmacies was commonplace. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Servs., 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). Had Congress intended to *exempt* covered entities from the usual business practice of the day (and require them to undertake the expense and effort to dispense medication in-house) surely it would have said so explicitly. On the contrary,

Congress's addition in 2010 of the non-discrimination requirement shows it intended covered entities to be treated on par with commercial purchasers, who plainly *are* permitted to serve patients through outside dispensers. The statute provides no reason to believe that Congress enacted a comprehensive legislative scheme to aid safety-net providers and vulnerable patients—but intentionally and implicitly structured it in such a way that only 5% of the providers statutorily eligible to participate would be able to access the program in practice. This Court already has confirmed that "HHS's current interpretation of the statute is permissible," Mem. Op. at 19, ECF No. 78, and thus should decline Astra's request to now interpret it in a manner that would render it toothless in practice.

Astra elides any substantive discussion of how, exactly, its policy can fulfill the statutory duty to charge covered entities no more than the ceiling price while *charging them WAC prices* based solely on delivery location. Instead Astra claims that, "under the prevailing contract pharmacy model," it "does not 'charge' covered entities at all." Compl. ¶ 147. This assertion is disproven by the administrative record, which shows that Astra's restrictions *have* forced covered entities to pay inflated commercial prices for Astra's products (because it is not, as Astra claims, contract pharmacies that make the purchases, *contra id.*). *E.g.*, VLTR_5952-58 (spreadsheet showing $8,956.70 in overcharges on Astra drugs shortly after policy went into effect); *id.* 6117, 6149-54 (covered entity providing "Spreadsheet of Astra[] overcharges … (totaling $43,032.60)"); *id.* 328 (covered entity paid $346 for single unit of Astra drug); *id.* 6585-86 (covered entity documenting specific Astra medications where 340B pricing denied); 6653-54 (covered entity "forced to pay WAC for [Astra's] products");

Astra also fails to confront the fact that its refusal to deliver its drugs to pharmacies capable of dispensing them on behalf of the covered-entity purchaser renders its "offer" to sell drugs meaningless in practice in many instances. These are prescription drugs, some of which are controlled substances—not everyday commodities that can be shipped to any address. Congress did not need to impose any explicit *delivery* obligation on manufacturers; it is self-evident that prescription drugs *cannot* be delivered to just any location. Just because a healthcare facility employs doctors able to prescribe medications does not mean it has the infrastructure, including state licensing, DEA registration, staff pharmacists, appropriate storage space to keep and safeguard medications, software to bill insurers,

etc., that would allow it to take delivery of, and dispense, pharmaceuticals. As has been explained, the majority of covered entities do not operate a licensed pharmacy or employ a pharmacist and thus are not entitled to handle their own dispensing or even to *take delivery* of Astra's medications. And even for those that do operate an in-house pharmacy, as explained *supra*, Background, covered entities often serve vulnerable populations over huge geographic areas with transportation and timing difficulties, making it impossible for all patients (tens of thousands per provider, in some cases) to fill their prescriptions each month on-site or in just one location. *E.g.*, VLTR_7260-61 (explaining that covered entity "provide[s] primary health care and related services *across a 10,000 square mile service area*" for population that "is significantly underserved, aging, and impoverished" and who rely on "local retail pharmacies" to obtain medications) (emphasis added). Were it as simple as Astra portrays for covered entities to accept its "offer" through direct, in-house dispensing, 340B sales would not have taken the nosedive evidenced in the analysis prepared for HRSA. *See supra,* Background.

These practical realities demonstrate that Astra's purported offer to ship its drugs to each provider's physical location often is meaningless in practice (and that Congress could not have intentionally created a scheme that, in reality, would be inaccessible to the majority of intended beneficiaries). If Astra were correct that it only had to *offer* drugs to covered entities, not also "to deliver 340B-discounted drugs" to a location where the covered entity can accept and use the drugs for its patients, Compl. ¶ 36, the statutory scheme would be ineffective in many instances. Clearly, in mandating that manufacturers provide discounted drugs to covered entities, Congress intended manufacturers to honor real-world, preexisting supply chains (including sales made through wholesale channels for delivery to pharmacies, which Astra now refuses), not to force safety-net providers to restructure their businesses entirely to allow for in-house drug dispensing *or* to require thousands of patients of the covered entity all to obtain their monthly refills at one designated location. Manufacturers like Astra have known for thirty years that they "may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program," Final Notice

Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994). Astra's restrictions thwart the intent of Congress by erecting barriers to covered entities' ability to access the program in practice.

C. Historical evidence supports HRSA's interpretation.

Legislative history supports HRSA's reading of manufacturers' statutory obligation, too: In 1992 Congress actually considered, but *removed from the statute*, a provision that would have mirrored Astra's explanation of the program's proper operation. The draft of what would become § 256b(a)(1) that first was considered by the Senate proposed to restrict 340B-discounted sales to drugs "purchased *and dispensed by*, or under a contract entered into *for on-site* pharmacy services with" a covered entity. *See* S. Rep. No. 102-259, at 1-2 (1992) (emphasis added). In other words, the bill as originally drafted would have restricted covered entities' purchases of 340B drugs to only those dispensed *directly by* the covered entity or *on-site* at the same location. Rather than codify that plain restriction on covered entities' choice of dispensing mechanism—indeed, precisely the constraint Astra urges this Court to read into the statute—Congress omitted it from the final bill and instead enacted a statute containing no requirement that 340B drugs be dispensed by a covered entity.

HRSA respectfully urges this Court to reconsider its assessment of the legislative history. Congress did not consider including this restriction when it "added the 'must offer' requirement to the statute in 2010," *contra* Mem. Op. at 21, but instead Congress considered restricting covered entities to in-house or on-site dispensing *when the statute was enacted in 1992*. Rather than "suggest[ing] that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies," *id.*, Congress's *removal* nearly three decades ago of any restriction on delivery site or dispensing mechanism can best be interpreted as evidence that it knew how to—but chose not to—restrict safety-net providers' access to the discount scheme. HRSA respectfully submits that "this Court may not narrow a provision's reach by inserting words Congress chose to omit," *Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020), and Congress's clear choice to omit from the final bill *any* requirement that 340B-priced drugs be dispensed in-house or on-site precludes an interpretation that would impose those restrictions now—particularly in light of the fact that covered entities have relied

on these mechanisms for decades.

HRSA's guidances bolster the interpretation set forth in the Violation Letter. In addition to the 1996 and 2010 guidances discussed in previous briefing (and addressed *infra*), additional historic evidence demonstrates that HRSA always has understood the statute (and, as evidenced by their past conduct, so have manufacturers) to prohibit drug makers from placing restrictive conditions on covered entities' access to 340B discounts. Nearly thirty years ago HRSA issued "final program guidelines," after notice and comment, confirming that manufacturers *may not* place conditions, even those which purport only to "require [covered] entity compliance" with the statute, before fulfilling 340B orders. Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,112-14 (May 13, 1994). In 1994 HRSA demonstrated the distinction between manufacturer requirements that *facilitate* access versus those that *restrict* access, explaining that manufacturers could "require the covered entities to sign a contract containing only the manufacturer's normal business policies (e.g., routine information necessary to set up and maintain an account) if this is a usual business practice of the manufacturers." *Id.* at 25,112. But—although the ministerial task of collecting "standard information" such as that needed "to set up … an account" is permissible—HRSA made clear that manufacturers could not deny 340B purchases by covered entities unless non-statutory demands are met. "Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* at 25,113. Indeed, "[a] manufacturer may not [even] condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," and drug companies are prohibited from conditioning 340B sales on covered entities "submitting information related to drug acquisition, purchase, and inventory systems." *Id.* at 25,113-14. HRSA may not have conceived in 1994 of the *precise* restrictions Astra now imposes, whereby it denies sales based on the delivery mechanism and commonplace dispensing mechanism employed by the covered entity, but the agency made plain that manufacturers cannot impose their own conditions generally on whether, and when, they will fulfill 340B orders.

Aside from manufacturer-imposed conditions, that early guidance also confirms that pharmaceutical companies may not restrict the *methods* by which covered entities obtain and dispense drugs. Contrary to Astra's insistence that its obligation to offer discounted drugs first was imposed through language added in the 2010 amendments, *in 1994* HRSA interpreted the statute to require that "manufacturers must offer covered outpatient drugs at or below the section 340B discount prices," and that, "[i]f the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue." *Id.* at 25,113. Furthermore, that guidance—in response to a comment urging the agency *not* to require manufacturers to honor contract-pharmacy sales—confirmed that use of contract pharmacies "is a customary business practice," that "[e]ntities often use purchasing agents or contract pharmacies," and that "[b]y placing such limitations on sales transactions," drug makers would "be discouraging entities from participating in the program." *Id.* at 25,111. In other words, since other commercial customers are freely able to purchase drugs through intermediaries and dispense to their patients through outside pharmacies, so too are 340B purchasers. *Id.* It also stated plainly that "[a] covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts." *Id.* at 25,113. In this early guidance HRSA made plain that manufacturers *may not* place limitations on sales to covered entities based on the dispensing mechanism or purchasing arrangement selected by the covered entity, particularly for a "customary business practice" such as the use of "purchasing agents or contract pharmacies." *Id.* at 25,111.

In addition to the 1994 guidance, both the 1996 and 2010 guidances interpreted the statute to require manufacturers to honor purchases by covered entities regardless how they dispense those drugs (importantly, both guidances were issued *before* Congress amended the statute to include the "offer" language). *See, e.g.*, 61 Fed. Reg. at 43,549 ("the statute directs the manufacturer to sell the drug at the discounted price" regardless whether "a covered entity us[es] contract pharmacy services [when it] requests to purchase a covered drug"). HRSA is mindful that this Court disagreed with its portrayal of these guidances, but respectfully contends that the relevant inquiry may have been too-narrowly framed as the question whether "the [Advisory] Opinion is the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple***

contract pharmacies," Mem. Op. at 12. HRSA's previous guidances had no reason to be so explicit regarding manufacturers' obligations vis-à-vis *multiple* neighborhood pharmacies because HRSA repeatedly was clear that manufacturers cannot refuse covered entities' sales based on dispensing mechanism or other manufacturer-imposed restrictions (and until mid-2020 manufacturers universally complied). More importantly, perhaps, HRSA's interpretation is not that drug makers must "provide" drugs to contract pharmacies, but that they must honor the ceiling price when selling to covered entities, whether the "ship to" location on the *covered entities'* invoice is the covered entities' own physical location or a neighborhood pharmacy capable of dispensing the drugs on its behalf.

Moreover, the previous briefing before this Court did not include the 1994 guidance discussed above, which interpreted the statute to require that "manufacturers *must offer* covered outpatient drugs at or below the section 340B discount prices" while confirming that use of contract pharmacies is a customary, common business practice, and that manufacturers are prohibited from placing limitations on such transactions. 59 Fed. Reg. at 25,113 (emphasis added). Regardless whether HRSA's allowance for the number of contract pharmacies *a covered entity may engage* has changed over time, each of these historic guidances consistently explained that, *e.g.*, "the statute directs the manufacturer to sell the drug at the discounted price" regardless whether "a covered entity us[es] contract pharmacy services [when it] requests to purchase a covered drug." 61 Fed. Reg. at 43,549. The agency had no cause to opine in this Court's precise formulation because the broader obligation to honor 340B purchases without manufacturer-imposed restrictions encompasses the more-explicit requirement to deliver drugs to a location where the covered entities' patients can actually access them.

And even though, as this Court noted, HRSA's guidance *for covered entities* changed between the 1996 and 2010 guidances, this does not evince a change in HRSA's interpretation of *manufacturers'* obligation. The statute contains multiple requirements—including distinct prohibitions on manufacturers (not to overcharge or discriminate against discounted purchases) versus covered entities (not to transfer discounted drugs or claim duplicate discounts). HRSA's 1996 guidance made clear that, while covered entities were initially restricted to reliance on one outside pharmacy, the agency "will be evaluating the feasibility of permitting these covered entities to contract with more

than one site and contractor," 61 Fed. Reg. at 43,555. HRSA respectfully contends that, properly viewed as the obligation to provide discounts to covered entities without non-statutory restrictions, its "interpretation of manufacturers' obligations" does not "shift[] every time that HHS changes its guidance with respect to covered entities' rights." Mem. Op. at 14. But even if this Court disagreed that the position has been consistent, HRSA's interpretation of the statute still would be the best interpretation for all the reasons set forth herein.

This Court's disagreement with the Advisory Opinion's conclusion that the statute is unambiguous does not provide reason to set aside HRSA's Violation Letter. As explained above, each of the tools of statutory construction strongly supports HRSA's interpretation as the most natural reading of the statute, and HRSA's finding is based on solid evidence and its decades of expertise administering the statute and thus is entitled to deference. HRSA's letter, however, does not purport to rest on unambiguous statutory text (nor do the arguments presented herein depend on any lack of ambiguity) so HRSA's rationale would not suffer from the same "flaw" this Court found with respect to the Advisory Opinion. To the extent this Court continues to find ambiguity in the 340B statute, it should afford deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Under *Skidmore*, informal interpretations such as this one "are entitled to respect … to the extent that they have the power to persuade." *Madison v. Res. For Hum. Dev., Inc.*, 233 F.3d 175, 186 (3d Cir. 2000) (internal quotation marks and citation omitted). Because HRSA's statutory interpretation is based on its "specialized experience" and the "broader … information available to [it]," evidences "thorough[]" consideration by the agency, contains "valid[]" reasoning, and is consistent with "earlier and later pronouncements," the interpretation has the "power to persuade," and should be accorded deference. *Sec. U.S. Dep't of Labor v. Am. Future Systs., Inc.*, 873 F.3d 420, 427 (3d Cir. 2017) (citations omitted)).

D. Additional considerations support HRSA's finding.

HRSA fully agrees with the Court that "Congress [did not] enumerate[] 15 types of covered entities with a high degree of precision and intend[] to include contract pharmacies as a 16th option by implication." Mem. Op. at 20. HRSA has never included contract pharmacies as a type of covered entity or allowed pharmacies to participate in 340B. But—just as commercial purchasers are able to

rely on real-world dispensing models, including outside pharmacies and specialty mail-order pharmacies, and just as the overwhelming majority of covered entities relied on outside pharmacies at the program's inception—covered entities today are permitted to utilize outside pharmacies to dispense medications *the covered entities have purchased* without including those pharmacies as another "type" of covered entity. As HRSA explained decades ago, "the use of contract services is only providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing. The mechanism does not in any way extend this pricing to entities which do not meet program eligibility." 61 Fed. Reg. at 43,550.

Nor does the model run afoul of Congress's prohibition on unlawful transfer of discounted drugs: The proper understanding of that provision has been clear since 1994, when HRSA issued "guidelines regarding drug diversion," explaining that "[c]overed entities are required not to resell or otherwise transfer outpatient drugs purchased at the statutory discount to an individual who is not a patient of the entity" and that "[t]here are several common situations in which this might occur." 59 Fed. Reg. at 25,112-13. That guidance went on to explain that covered entities must "develop and institute adequate safeguards" to ensure that discounted drugs are dispensed only to eligible patients, that covered entities must use 340B drugs only in outpatient settings (not for inpatient services), and that a larger provider which contains both a covered entity and non-eligible entity must "maintain separate dispensing records for the eligible entity." *Id.* These situations have in common that they all would involve dispensing and use of 340B-discounted drugs for either ineligible patients, services, or settings—but they certainly would not encompass instances where a licensed pharmacist dispenses outpatient drugs to an eligible patient on behalf of an eligible covered entity. There is no unlawful transfer of discounted drugs when a covered entity purchases drugs for dispensing at outside pharmacies, because pharmacies only are facilitating the exchange of tightly controlled *prescription drugs* on behalf of admittedly eligible patients of admittedly eligible prescribers.

Astra's attempt to pre-litigate whether its overcharges constitute "knowing and intentional" violations sufficient to support sanctions should be rejected. As an initial matter, HRSA has made clear that Astra's overcharges *may* lead to sanctions, but has not yet imposed any penalties, so any

dispute over yet-to-be-determined penalties is unripe. Astra's theory, however, is meritless. Astra points to HHS's Civil Monetary Penalty Rule, which states that an overcharge does not occur if "a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible *at the time of purchase*." *See* Compl. ¶ 148. But as the penalty rule makes clear—and contrary to Astra's portrayal—the relevant "time of purchase" is *the covered entity's purchase of Astra's drugs*, not the later dispensing to an eligible patient of an eligible provider. After all, the statute plainly limits the price Astra may charge covered entities, not the price patients pay when they receive the drugs. HRSA has gathered voluminous evidence of Astra refusing 340B pricing *to covered entities themselves*. Astra's policy thus violates the will of Congress because, when Astra refuses to honor purchase requests placed by a covered entity based solely on the "ship to" location specified on an invoice, it forces the covered entity either to pay commercial pricing or forego the needed medication altogether. *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57,234 (Sept. 20, 2010) (evidence of overcharge may include "cases where refusal to sell at the 340B price has led to the purchase of the covered outpatient drug outside of the 340B Program"); 59 Fed. Reg. at 25,113 ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.").

It is certainly the case that the 340B statute does not allow contract pharmacies to participate in or become beneficiaries of the 340B Program, and that Astra has no obligation to sell discounted drugs to *any* pharmacies. But the statute conditions Medicaid and Medicare Part B access on Astra's agreement to provide its discounted drugs to covered entities, and does not authorize Astra to place barriers that make those purchases inaccessible in practice. HRSA's review of the evidence has demonstrated that Astra is denying 340B sales *to covered entities* when those providers dispense drugs through neighborhood pharmacies. Astra remains vulnerable to monetary sanctions and expulsion from Medicaid and Medicare Part B for each day it continues to deny 340B pricing to covered entities.

II. HRSA'S VIOLATION LETTER IS NEITHER ARBITARY NOR CAPRICIOUS.

HRSA reasonably explained its conclusion that Astra is violating its statutory obligation in the

Violation Letter, and properly grounded its determination in the 340B statute's text. "The APA's arbitrary-and-capricious standard requires that agency action be [only] reasonable and reasonably explained." *FCC v. Prometheus Radio Proj.*, 141 S. Ct. 1150, 1158 (2021). Judicial review is "deferential, and a court may not substitute its own policy judgment for that of the agency." *Id.* (citation omitted). A court "should 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 513–14 (2009) (citation omitted).

Astra first argues that the Violation Letter is arbitrary and capricious because HRSA did not give adequate consideration to 340B's text. Compl. ¶ 191. As explained *supra*, however, HRSA's interpretation is not only consistent with the text of the statute, but is also the best reading in light of congressional intent. It thus satisfies the APA's deferential review standard.

Next, Astra argues that the Violation Letter represents a shift in position from prior guidances, and is thus not adequately explained. Compl. ¶ 192. Although the Court previously concluded that "the government's position on drug manufacturers' obligations with respect to participation in the 340B Program" has "materially shifted," Mem. Op. at 13, Defendants respectfully ask the Court to reconsider its conclusion in light of the discussion in this brief, and submit that HRSA's guidance makes clear that its view of manufacturers' obligations has not changed in more than twenty-five years—manufacturers are obligated to honor covered entities' arrangements with contract pharmacies and may not impose extra-statutory obligations or conditions on fulfillment of their drug purchases.

In 1994, HRSA issued "final program guidelines," after notice and comment, confirming that manufacturers *may not* place conditions, even those which purport only to "require [covered] entity compliance" with the statute, before fulfilling 340B orders. 59 Fed. Reg. at 25,112–14. Aside from manufacturer-imposed conditions, that early guidance also confirms that drug makers may not restrict the *methods* by which covered entities obtain and dispense drugs. Furthermore, that guidance—in response to a comment urging the agency *not* to require manufacturers to honor contract-pharmacy sales—confirmed that use of contract pharmacies "is a customary business practice," that "[e]ntities often use purchasing agents or contract pharmacies," and that "[b]y placing such limitations on sales transactions," drug makers would "be discouraging entities from participating in the program." *Id.* at

25,111. It also stated plainly that "[a] covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts." *Id.* at 25,113.

In 1996, HHS issued further guidance, concluding that the 340B statute does not allow drug makers to refuse discounted-drug purchases by covered entities that rely on contract pharmacies. 61 Fed. Reg. at 43,549 (confirming if the "entity directs the drug shipment to its contract pharmacy," that in no way "exempts the manufacturer from statutory compliance"). There is nothing voluntary in that interpretation of the statute; on the contrary, the only voluntary aspect of the 1996 Guidance was the choice of covered entities whether to use contract-pharmacy arrangements, given that covered entities remain liable to prevent duplicate discounting and diversion regardless of the dispensing mechanism chosen for covered drugs. *See id.* at 43,549-50.

In 2010, HHS again set forth its statutory interpretation: "Under 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." 75 Fed. Reg. at 10,278. That mandatory language reiterated the agency's decision on what the 340B *statute* requires—not a new position or obligation created by the agency. Consistently, the Violation Letter concluded that: "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor [covered entities'] purchases regardless of the dispensing mechanism." VLTR_5.

In its prior opinion, this Court determined that HRSA had not previously "concluded that drug manufacturers are required by statute to provide 340B drugs to multiple contract pharmacies." Mem. Op. at 12 (emphasis removed). But Defendants respectfully submit this is not the relevant inquiry. HRSA had no reason to be so explicit regarding manufacturers' obligations vis-à-vis *multiple* neighborhood pharmacies because HRSA repeatedly was clear that manufacturers cannot refuse covered entities' purchases based on dispensing mechanism or other manufacturer-imposed restrictions (and until mid-2020 manufacturers universally complied). Plus, HRSA's stance is not that drug makers must "provide" drugs to contract pharmacies, but that they must honor the ceiling price when selling to covered entities, regardless of the "ship to" location on the *covered entities'* invoice.

Whether HRSA's allowance for the number of contract pharmacies *a covered entity may engage* has changed over time, each of these guidances consistently explained that "the statute directs the manufacturer to sell the drug at the discounted price" regardless whether "a covered entity us[es] contract pharmacy services [when it] requests to purchase a covered drug." 61 Fed. Reg. at 43,549. The broader obligation to honor 340B purchases without manufacturer-imposed restrictions encompasses the more-explicit discussion of the number of contract-pharmacy arrangements. HRSA respectfully contends that, properly viewed as the obligation to provide discounts to covered entities without non-statutory restrictions, its "interpretation of manufacturers' obligations" does not "shift[] every time that HHS changes its guidance with respect to covered entities' rights." Mem. Op. at 14.

Because there has been no "change in position over time" for HRSA to explain, the Violation Letter is not rendered arbitrary and capricious by failure to do so.

III. HRSA'S VIOLATION LETTER IS PROCEDURALLY COMPLIANT WITH THE APA.

Astra claims that HRSA's Violation Letter should be set aside for failing to comply with the APA's notice-and-comment procedures set forth in 5 U.S.C. § 553(b)(3)(A). Compl. ¶¶ 175–80. This procedural objection is built on the same flawed assertion that Astra leveled at the Advisory Opinion: That the Violation Letter "creates rights" and "imposes [new] obligations" with which Astra must either comply or face potential penalties, turning the letter into a "legislative rule" that can only be issued by notice-and-comment rulemaking. *See* Compl. ¶ 179; *see also SBC Inc. v. FCC*, 414 F.3d 486, 497 (3d Cir. 2005) ("Legislative rules are subject to the notice and comment requirements of the APA because they … 'create new law, rights, or duties" for regulated parties. (citation omitted)). But as with the Advisory Opinion, *see* HHS First Mot. at 19–21, HRSA's letter imposes no new obligations on Astra. The Violation Letter merely enforces a *pre-existing* obligation sounding in the 340B statute itself, *see supra* § I, and is thus an interpretive rule exempt from the APA's notice-and-comment requirement.[7] *See Penn. Dep't of Hum. Servs. v. United States*, 897 F.3d 497, 505 (3d Cir. 2018) ("Interpretive rules …

[7] Were agencies like HRSA required to undergo notice-and-comment rulemaking "to promulgate every regulatory or statutory interpretation arrived at in the course of adjudicating specific cases," they "would be condemned to inactivity." *Orengo Caraballo v. Reich*, 11 F.3d 186, 195 (D.C. Cir. 1993).

simply state what the administrative agency thinks [a] statute means, and only remind affected parties of existing duties." (cleaned up)); *see also Dismas Charities, Inc. v. U.S. Dep't of Justice*, 401 F.3d 666, 682 (6th Cir. 2005) ("[A] pure legal determination of what the applicable law already is does not require notice and comment under APA § 553(b).").

That HRSA's Violation Letter is properly viewed as an interpretive rule is demonstrated by the court's analysis in *Metropolitan School District of Wayne Township v. Davila* (*Davila*), 969 F.2d 485 (7th Cir. 1992). There, the court considered whether a letter (issued by a sub-agency of the Department of Education) interpreting Part B of the Individuals with Disabilities Education Act ("IDEA-B") to require that school districts provide educational services to expelled disabled children "or face potential sanctions" was a legislative rule subject to the APA's notice-and-comment requirement. *Id.* at 487–89. The court found the letter to be a "paradigmatic case of an interpretive rule," because it "relie[d] upon the language of the statute and its legislative history" to "simply state[] what" the agency "thinks the IDEA-B requires." *Id.* at 492.

The court in *Davila* addressed two procedural arguments virtually identical to those that have been asserted by Astra in this litigation. *First*, the court rejected the notion "that a binding rule is necessarily a legislative one," *id.* at 493; *contra* ECF No. 43 at 24 (arguing that "mandatory language" and "a binding intent" alone evinces a legislative rule), asking rhetorically: "Could an agency [seriously] announce, 'We think Congress intended this when it enacted this statute, but you don't have to do it.'?" *Davila*, 969 F.2d at 493. "All rules which interpret the underlying statute must be binding … on the regulated parties," the court reasoned, "in the sense that they set … the legal minima of behavioral standards" in light of "what the agency believes is congressional intent." *Id.* (citation omitted); *accord Alcaraz v. Block*, 746 F.2d 593, 614 (9th Cir. 1984). But legislative rules are distinct from interpretive rules because they "are as binding upon *courts* as congressional enactments." *Davila*, 969 F.2d at 490 (emphasis added); *accord Buczynski v. Gen. Motors Corp.*, 616 F.2d 1238, 1242 (3d Cir. 1980); *Splane v. West*, 216 F.3d 1058, 1064 (Fed. Cir. 2000). *Second*, the court explained that a rule "is not *ipso facto* legislative" simply because it "affect[s] rights and obligations." *Davila*, 969 F.2d at 493 (citation omitted); *contra* ECF No. 43 at 24 (arguing that a rule must be legislative if it has "a real-world effect").

As the court put it: "Penalizing the agency for explaining what was for the plaintiffs bad news about [the meaning of a statute], by labeling the explanation 'substantive,' would be like killing the messenger." *Davila*, 969 F.2d at 493 (alteration adopted) (quoting *Alcaraz*, 746 F.2d at 614). Although the letter at issue in *Davila* announced "binding" obligations that had substantial impacts on regulated parties, the court found that the letter "simply explained what the statute already requires" and was thus exempt from the APA's notice-and-comment requirement. *Id.* at 493.

So too here. HRSA's Violation Letter simply alerts Astra that it is acting in contravention of "what the [340B] statute already requires"—namely, that Astra sell 340B-discounted drugs to covered entities regardless of how those drugs will be dispensed to patients. *See id.* This statutory obligation is "fully operative without" the Violation Letter, *see Applachian States Low-Level Radioactive Waste Comm'n v. O'Leary*, 93 F.3d 103, 113 (3d Cir. 1996), and Astra "must comply with [it] regardless of how" HRSA chooses to enforce it, *see Chao v. Rothermel*, 327 F.3d 223, 227 (3d Cir. 2003). And it matters not whether the Court finds that HRSA's interpretation is clearly delineated in the text of the statute, as a rule "would hardly be interpretive" if it "only paraphrase[d] statutory or regulatory language." *Orengo Caraballo*, 11 F.3d at 195. Rather, an interpretive rule "may supply crisper and more detailed lines than the authority being interpreted without losing its exemption from notice and comment requirements under § 553." *Id.* (cleaned up). That is precisely what HRSA's Violation Letter has done here. By drawing the challenged obligation directly from "the language of … specific statutory provisions" and the 340B statute's purpose and legislative history, the letter "merely explicat[es] Congress' desires." *Davila*, 969 F.2d at 490, 492 (cleaned up). It is thus *Congress* that has spoken with "the force and effect of law" to "bind[]" Astra to this statutory requirement, not HRSA. *See id.* at 490, 493; *see also Alcaraz*, 746 F.2d at 614 ("The [legal] requirement here was made 'binding'—in the sense of being given primary legal effect—by Congress, not by the Secretary ….). The Violation Letter is therefore an interpretive rule that is exempt from the APA's notice-and-comment requirement.

CONCLUSION

For these reasons, Defendants ask the Court to grant summary judgment for HHS.

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