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 OPPOSITION TO
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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AstraZeneca Pharmaceuticals LP ("Astra") has tried and failed to call into question the validity of the Health Resources and Services Administration's ("HRSA") determination that Astra has violated its obligations under the 340B statute, 42 U.S.C. § 256b. In its motion for summary judgment, Astra offers no cogent response to the incontrovertible evidence demonstrating that it has unlawfully overcharged for 340B-eligible drugs and denied covered entities the ability to purchase discounted drugs to which they are statutorily entitled—clear-cut violations of § 256b(a)(1). Astra instead chiefly disputes HRSA's interpretation of the 340B statute, arguing that it has free rein under the 340B Program to impose burdensome restrictions on 340B purchases and that its statutory obligations do not require it to honor *any* such purchases made through a covered entity's contract-pharmacy arrangements. But Astra's arguments on this score misconstrue the statutory text and ignore the congressional purpose and history of the 340B statute—the hallmarks of statutory meaning that collectively demonstrate the correctness of HRSA's interpretation. And Astra's statutory theories further undermine its criticism that HRSA has acted arbitrarily and capriciously in finding Astra in violation of its statutory obligations, or that HRSA violated the procedural requirements of the Administrative Procedure Act ("APA"). None of Astra's claims are based on a permissible reading of the 340B statute, nor do they reflect an accurate portrayal of the agency's historical guidance or find support in the administrative record.

The Court should therefore enter summary judgment in favor of HHS on all of Astra's claims, and deny Astra's motion for summary judgment.

I. ASTRA HAS NOT CARRIED ITS BURDEN TO DEMONSTRATE THAT HRSA'S ENFORCEMENT OF THE STATUTE RESTS ON AN INCORRECT INTERPRETATION.

HRSA demonstrated in its opening brief, *see* Br. in Supp. of Defs.' Mot. for Summ. J., ("HRSA Mot.") 10-25, ECF No. 93, that, read "as a whole," *United States v. Atl. Research Corp.*, 551 U.S. 128, 135 (2007), 42 U.S.C. § 256b(a)(1) plainly requires drug manufacturers to sell discounted drugs to covered entities at no more than the ceiling price—and that Astra is violating this obligation by charging higher prices (and denying those purchases outright, in many instances) for all sales that fail

to comply with Astra's unilateral, non-statutory limitations. Astra's opening brief fails to confront the government's statutory interpretation head-on, instead pinning its argument to this Court's previous ruling on an altogether different agency action while ignoring copious evidence in the record. But as explained in HRSA's opening brief, this Court's previous ruling does not determine the legality of HRSA's Violation Letter, and Astra's reading of the statute conflicts with the statutory text, undermines Congress's purpose, and must be rejected.

First, Astra continues to misframe HRSA's interpretation as "want[ing] pharmaceutical manufacturers to deliver discounted 340B drugs to an unlimited number of contract pharmacies," Pl.'s Opening Br. in Supp. of Its 2d Mot. for Summ. J., ("Astra Mot.") 1, ECF No. 91. Not so. HRSA hasn't initiated enforcement action on the basis of a *delivery obligation*, but instead has found—after an extensive, months-long review and gathering voluminous evidence—that Astra is *overcharging* covered entities by demanding payment far above the ceiling price based solely on Astra's own disapproval of the "ship to" location on the *covered entities'* purchase order. *See* VLTR_1842 (invoice showing cost of $393 per unit of Astra medication Brilinta "*sold to*" St. Joseph Medical Center, a covered entity, but "*shipped to*" Franciscan Pharmacy Tacoma, a neighborhood pharmacy that dispenses for St. Joseph's).

Astra's focus on *delivery* (rather than the price paid for 340B purchases) attempts to obscure its lack of compliance with its actual statutory obligation. As explained in the government's opening brief, the 340B statute requires Astra to sell its drugs to covered entities at or below the ceiling price, and to treat covered entities' purchases as favorably as commercial purchases. HRSA has initiated enforcement action based on Astra's refusal to comply with *those* obligations, not some new shipping obligation. Tellingly, despite its protestations about covered entities' requests that drugs *purchased by the covered entities* be shipped to pharmacies capable of dispensing them to patients, *e.g.*, Astra Mot. 14, nowhere does Astra claim that it is not already shipping full-priced drugs to the very same pharmacies it now refuses to ship discounted drugs. Astra willingly ships its drugs to pharmacies when full, commercial prices are paid—it just newly is refusing to ship those same drugs to those same locations when they are ordered and paid for by covered entities at statutory discounts. HRSA has not read into the statute any novel delivery obligation, but instead has made clear that Astra risks losing access to

Medicaid and Medicare Part B if it continues to deny covered entities' purchases and/or to charge them inflated commercial prices.

Rather than confront this fact head-on, Astra presents a red herring: "[T]he contract pharmacy distribution model that some covered entities use is unique to the 340B context. The administrative record fails to identify any non-340B entities that purchase drugs from AstraZeneca through contract pharmacies, and Astra Zeneca is aware of none." Astra Mot. 14. That portrayal lacks necessary context; there is nothing "unique" about healthcare providers relying on outside-dispensing models to serve their patients—in fact, as has repeatedly been discussed in previous briefing (and made clear in HRSA's 1994 guidance), the overwhelming majority of covered entities relied on outside pharmacies *when the statute was enacted*. And other, non-340B healthcare providers rely on such logistics today. The "contract" part in the contract-pharmacy model is distinct in that it effectuates Congress's command that covered entities comply with the prohibitions on duplicate discounting and diversion. In other words, the contracts contain provisions, such as inventory and auditing procedures, that allow *covered entities* to ensure that their purchases of drugs dispensed through outside pharmacies meet the covered entities' own statutory requirements. There is no need for such a contract in the commercial world, because those prohibitions do not exist. But that does not mean *the dispensing model* is "unique" to 340B in the manner Astra contends. Relatedly, Astra is wrong in stating that its "'offer' is the same to all entities" and that it "makes its products available to other customers" in the same manner as it "make[s] its medicines available to covered entities at the discounted price." *Id.* This is evidenced by the fact that Astra places *no* delivery-site or dispensing-mechanism restrictions on full-priced purchases. Just as commercial purchases are free to indicate any (lawful) delivery site on the "ship to" section of their own invoices, so too covered entities—when making their own purchases of Astra drugs—are entitled to indicate a "ship to" location other than their own, in-house pharmacy.

Aside from its inapposite portrayal of HRSA's interpretation of manufacturers' statutory obligation, Astra largely ignores copious evidence in the administrative record showing *both* that it is charging covered entities prices far above the ceiling price *and* denying covered entities' access to discounted drugs altogether. *See, e.g.*, VLTR_5952-58 (spreadsheet showing $8,956.70 in overcharges

on Astra drugs); *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.* 6229-40 (documenting specific transactions with Astra resulting in thousands of dollars in overcharges); *id.* 6404-05 (evidence of specific Astra overcharges of up to $565 per unit); *id.* 6585-86 (documenting denial of 340B pricing for purchase by covered entity). Astra mainly dismisses these complaints as containing many "boilerplate complaint forms submitted to HRSA by covered entities" and speculates that they may "have been compiled in anticipation of litigation." Astra Mot. 7. This is unavailing; the fact that many covered entities chose to report overcharges to HRSA through the system set up to receive such information (thus creating numerous similar *forms* in which covered entities filled in their own complaint) in no way detracts from the substance of those complaints. Nor should it be remotely surprising if, as Astra surmises, covered entities compiled their evidence "in anticipation of litigation" after the enormous changes wrought by Astra and its peers' restrictions. Astra similarly derides as a purported admission the fact that one covered entity acknowledged receiving help in filing a report from the National Association of Community Health Centers and from the 340B prime vendor, *id.* 7-8. But the fact that a resource-strapped safety-net provider was "show[n] [] how to report when 340B drugs are unavailable at the ceiling price" has nothing whatsoever to do with the accuracy of that information. Astra attempts death by a thousand cuts, criticizing the legion of evidence in the administrative record as overly duplicative, for having included among the list of affected medications "oncology or specialty medicines to which [the] new policy does *not* apply," for having failed to recognize that Astra "divested its rights to" one particular drug a few months earlier, and because many of the covered entities complaining to HRSA of overcharges "may be eligible to" designate one contract pharmacy under Astra's policy. *Id.* 8 & n.3. But each of these points is irrelevant and—most importantly—Astra lodges these criticisms *largely without denying the veracity of the information submitted by*

covered entities. At bottom, the administrative record provides copious evidence undergirding HRSA's finding that Astra is overcharging covered entities, and Astra offers no cogent response.[1]

Astra otherwise pins its argument on this Court's previous opinion concerning the now-withdrawn and vacated Advisory Opinion. Astra Mot. 9-15. This Court's previous opinion does not control for numerous reasons—most obvious among them being that neither HRSA's Violation Letter nor the administrative record underlying it were then before the Court. More substantively, HRSA's determination was specific to Astra's restrictions (not a pronouncement of general interpretation); it was based on HRSA's expertise administering the program for decades; and it relied on months of study and thousands of pages of evidence gathered by the agency. Moreover, contrary to Astra's insistence, *e.g.*, *id.* 11, the Violation Letter does not repeat the same "flaw" this Court found with respect to the Advisory Opinion because it does not purport to rely on unambiguous statutory text. True, HRSA found that Astra's policy is directly violating its statutory obligation. But that is because HRSA found that Astra is overcharging covered entities and wrongly denying *sales to covered entities*. Were Astra correct that "[t]he May 17 letter 'wrongly determines that purportedly unambiguous statutory language mandates its conclusion,'" *id.* 11 (quoting D.I. 78 at 17), there would be no need for HRSA officials to have spent months considering the impact of Astra's restrictions and compiling an 8,000+ page administrative record. Clearly, HRSA's careful analysis and evidence-gathering would be unnecessary had its conclusion been *mandated* from unambiguous statutory text. Moreover, this Court explicitly found that the agency's interpretation of the statute is "permissible," Mem. Op. 23, ECF No. 78, and should now uphold HRSA's determination as the best interpretation of congressional intent.

Astra's contention that the Violation Letter does not rest on the "purchased by" language in the statute is inaccurate. *See, e.g.*, Astra Mot. 6; *see also id.* 11 (claiming "letter relies" on "must-offer

[1] Astra's focus on purchases by contract pharmacies, rather than covered entities, is a distraction. *See* Astra Mot. 24 (arguing that "there can be no 'overcharge' … when drugs are purchased by a contract pharmacy at normal market prices rather than 340B prices"). As has repeatedly been explained, HRSA is not requiring Astra to sell any drugs to any pharmacies. As the record demonstrates, *it is covered entities* that place orders for, purchase, and pay for the 340B-discounted drugs at issue.

provision"). Astra bases this charge on the fact that the letter *quotes* the offer phrase, not the purchase phrase. But, once again, these commands are found in the same statutory subsection, and the Violation Letter repeatedly discusses "the 340B statute" throughout its text. There is no obligation for the agency to parse each relevant phrase individually because it plainly states that Astra's "actions have resulted in overcharges in direct violation of the 340B statute"—not only the "offer" phrase. *Id.* 16. Moreover, the letter discusses extensively the PPA that Astra is violating, and Astra's PPA expressly incorporates its obligation to honor "purchases by" covered entities. The Violation Letter plainly shows that Astra is both overcharging for purchases by covered entities (where WAC prices are paid) *and* discriminating against covered entities (by denying sales altogether), and Astra's claim that the agency relied on only one piece of the broader statutory subsection is incorrect.

Astra contends that the Violation Letter is legally flawed because it "rests on the same erroneous assertion of interpretive consistency," Astra Mot. 1.[2] In its opening brief the government urged this Court to reconsider its view of the legislative history and previous guidances, HHS Mot. 21-23, explaining that the previous briefing in this litigation did not include the 1994 guidance in which HRSA expressly forbid manufacturers from imposing restrictive conditions on covered entities' purchases and that the 1996 and 2010 guidances may have *advised* covered entities differently, but were consistent in explaining that the statute directs manufacturers to fulfill orders regardless whether the delivery location is an outside pharmacy. But even were this Court to find that HRSA's letter differs materially from its previous positions (a determination that HRSA respectfully contends would be

[2] Most inscrutable is Astra's near-complete reliance on this Court's prior opinion while insisting that "Section 340B at most is silent on the question" whether manufacturers can deny sales based on delivery location, "not ambiguous." Astra Mot. 13 n.5. Astra's contention that "Section 340B as written unambiguously permits AstraZeneca's contract pharmacy policy" is irreconcilable with this Court's ruling on the Advisory Opinion. It also is facially incorrect; the statute contains *no* textual support whatsoever for Astra's denial of 340B pricing for covered entities' purchases based solely on delivery location. And, as previously explained, "Congress's failure to speak directly to a specific case that falls within a more general statutory rule" does not "create[] a tacit exception," and "the fact that a statute has been applied in situations not *expressly* anticipated by Congress does not demonstrate ambiguity," but rather "the breadth of a legislative command." *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1749 (alterations omitted and emphasis added). As Astra itself acknowledges, "the failure of Congress to use 'Thou Shalt Not' language doesn't create a statutory ambiguity." Astra Mot. 19 (citing *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 566 (D.C. Cir. 2004)).

difficult, at best, to square with the 1994 guidance), that would not provide ground to vacate HRSA's Violation Letter. As explained in the government's opening brief, HRSA's enforcement action is based on its interpretation of what the statute requires vis-à-vis Astra's current actions, not its interpretation of its own previous guidances.

Finally, Astra's attempt to pre-litigate its amenability to sanctions should be rejected. As explained in the government's opening brief, HRSA Mot. 24-25, this question is unripe before HHS, as regulator, makes a determination as to whether sanctions are warranted. For that reason, the government omits here substantive discussion as to whether Astra's overcharges are knowing and intentional (but certainly does not concede the issue). For present purposes it suffices to point out that Astra's contention that "covered entities are not charged any price under" its contract-pharmacy policy "when contract pharmacy sales are made outside the policy," Astra Mot. 24, is incorrect. As documented above, covered entities *are* overpaying, but more importantly, HRSA has made clear that evidence of overcharges 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." *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57,234 (Sept. 20, 2010); *see also* 42 C.F.R. § 10.21(c)(1) (ADR process permits "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price[.]"); 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,226 (Jan. 5, 2017) (When a manufacturer's documented refusal to sell or make drugs available at the 340B ceiling price results in the covered entity purchasing at the non-340B price, a manufacturer's sale at the non-340B price could be considered an instance of overcharging.").

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

Astra's attempt to undermine HRSA's Violation Letter by arguing that it is arbitrary and capricious is unpersuasive. First, Astra repeats its argument that the Violation Letter "is based on the

unjustified assumption that Congress imposed the agency's interpretation as a statutory requirement." Astra Mot. 20-21. But, as explained above, *supra* page 5, HRSA's determination was not a general pronouncement of statutory requirements. The fact that this conclusion was consistent with HRSA's reading of the statute does not render the Violation Letter arbitrary and capricious.

Next, Astra argues that the Violation Letter is arbitrary and capricious because HRSA does not acknowledge a change in position over time. This argument is unconvincing because, properly viewed as the obligation to provide discounts to covered entities without non-statutory restrictions, HRSA respectfully contends that its "interpretation of manufacturers' obligations" does not "shift[] every time that HHS changes its guidance with respect to covered entities' rights." Mem. Op. 14.

Finally, Astra argues that the Violation Letter is unlawful because, under the predominant replenishment model, there can be no overcharge, as there is "no sale at all to the covered entity." Astra Mot. 23. This statement, unsupported by any evidence, is incorrect. And, contrary to Astra's claim, the administrative record does contain "evidence regarding the replenishment model." *Id.* 23 n.6. Generally speaking, under the replenishment model, a covered-entity patient who is 340B eligible fills a prescription at a neighborhood pharmacy and, after the pharmacy dispenses the prescription out of its general inventory, its inventory is "replenished" with a drug that the covered entity has purchased at the 340B price. *See, e.g.,* VLTR_7323 (declaration of covered entity CEO explaining that "contract pharmacy partners use their own inventory for 340B eligible fills, and third-party administrators tally 340B accumulations and automatically trigger drug orders from the appropriate wholesaler to replenish their inventory whenever a full package size of a particular drug has been used"); *Id.* 7257 (same).

The model works in three main steps. First, a contract pharmacy dispenses a drug to a patient, and 340B-tailored software programs determine whether the patient was eligible for 340B product. *See, e.g., id.* 7261. Second, the software will notify the covered entity that it may place a replenishment order for drugs when enough dispenses have accumulated to reach a pre-set package size. *See, e.g., id.* 7317 (covered entity CEO explaining "virtual inventory" system where "[e]ach contract pharmacy dispenses covered prescriptions to our patients, and when enough medication is dispensed … [the

covered entity] places an order via our 340B wholesaler to replenish the contract pharmacies' stock"). Importantly, the replenishment order is placed on a covered entity's 340B account and the covered entity is billed for that order. *See, e.g., id.* 7323 ("The cost of the 340B purchases are billed to [the covered entity] and the drugs are shipped to the contract pharmacies."). Finally, the "replenished" drug is shipped to the contract pharmacy, where it becomes neutral inventory and may be dispensed to any subsequent patient. *See, e.g. id.* 7279 (covered entity CEO explaining that some contract pharmacies "dispense a retail pharmacy product to patients" and then are "replenished" with a covered entity-purchased "340B drug for that dispense"). Under this replenishment model, covered entities generally maintain title to the drugs at least until they reach neutral inventory, but contract pharmacies continue to handle "storage, distribution, and patient-related information." *Id.* 7296; *see also, e.g., id.* 7279, 7261.

At no point during this process are the 340B drugs "purchased by" the contract pharmacy. The drugs are simply delivered to contract pharmacies after being purchased by covered entities to replenish the pharmacy's stock of drugs that were distributed to 340B-eligible patients. Thus, contrary to Astra's argument, the replenishment model does not foreclose HRSA's determination that Astra's policy resulted in overcharges to covered entities. *See* Astra Mot. 22-24. As explained above, the manufacturer or wholesaler is still *charging the covered entity* for the price of the 340B-eligible drug under the replenishment model. Since the commercial price charged often is much higher than the 340B ceiling price, this provides a reasonable basis for HRSA's conclusion that Astra is overcharging covered entities in violation of the 340B statute. Moreover, even if Astra's contention that no covered entity was "charged" for 340B-eligible drugs was always true, Astra would still be overcharging covered entities by not allowing covered entities to reap the benefits of the 340B statute at all. *See* 75 Fed. Reg. at 57234 (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"); 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) ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective."). And, as identified above, as well

as in HHS's opening brief, Astra has in fact overcharged numerous covered entities, providing a reasonable basis for HRSA's conclusions. HRSA Mot. 3-6, 9-10.

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

Although the line between a legislative and interpretive rule can be difficult to discern at times, in this case, the criteria that courts evaluate to distinguish between these two types of rules—including the criteria relied on by Astra—all point towards the same conclusion: HRSA's Violation Letter is an interpretive rule that merely interprets and enforces Astra's *pre-existing* obligation under § 256b(a)(1). *See, e.g.*, *Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1110 (D.C. Cir. 1993) ("[A]n interpretation that spells out the scope of a[] … regulated entity's pre-existing duty … [is an] interpretive [rule]."). Astra misapplies the relevant criteria and thus offers no persuasive reason to find the Violation Letter to be an "[u]nauthorized" legislative rule. *See* Astra Mot. 15.

First, Astra contends (as expected, *see* HRSA Mot. 29) that the Violation Letter is a "quintessential legislative rule[]" simply because it draws a "conclusion[]" as to the scope of drug manufacturers' obligations under the 340B statute, and therefore "uses mandatory language making clear that the agency expects immediate compliance." *Id.* 16 (internal quotation marks and citation omitted). Astra's argument begs the question, however: Could HRSA—the agency tasked by Congress with enforcing the 340B Program's requirements—seriously have announced in the Violation Letter: "'We think Congress intended this when it enacted [the 340B] statute, but you[, Astra,] don't have to do it.'?" *See Metro. Sch. Dist. of Wayne Twp. v. Davila* (*Davila*), 969 F.2d 485, 493 (7th Cir. 1992) (citation omitted). Of course not. As already explained, *see* HRSA Mot. 29, every rule that interprets the meaning of a *statutory* obligation *must* convey the message that compliance with that obligation has been mandated by Congress. *See Davila*, 969 F.2d at 493; *accord Alcaraz v. Block*, 746 F.2d 593, 614 (9th Cir. 1984); *Warder v. Shalala*, 149 F.3d 73, 82–83 (1st Cir. 1998).

Second, Astra suggests there is no "adequate legislative basis" for HRSA's Violation Letter. Astra Mot. 16. But again, Congress itself provided the legislative predicate for HRSA's enforcement action in § 256b(a)(1), which requires Astra to sell 340B-eligible drugs to covered entities regardless

of the mechanism by which those drugs are dispensed to patients. And where, as here, "a statute or legislative rule has created a legal basis for enforcement," an agency may rely on its interpretation of the statute "in the process of enforcement" without having to channel that interpretation through the APA's notice-and-comment procedures.[3] *See Am. Mining Congress*, 995 F.2d at 1111–12; *accord Truckers United for Safety v. Fed. Highway Admin.*, 139 F.3d 934, 939 (D.C. Cir. 1998) (finding that, because a pre-exiting regulatory duty provided an adequate legislative basis for the agency to take enforcement action, an agency's rule that "elaborate[d] upon that duty" was merely interpretive); *Erringer v. Thompson*, 371 F.3d 625, 630–31 (9th Cir. 2004) (finding that a statute had provided "an overarching duty" upon which an agency could rest its enforcement action, and thus an agency's rule defining the scope of that duty was merely interpretive).

Lastly, Astra argues that the Violation Letter must be a legislative rule because the 340B statute does not explicitly address use of contract-pharmacy arrangements, and thus HRSA must have engaged in "*legislative* … rulemaking" to "[f]ill" that "statutory silence." Astra Mot. 16–17. But an agency need not engage in legislative rulemaking to simply explicate the implicit requirements of a statute. *See Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1088 (D.C. Cir. 1996) (explaining that Congress may "clearly require[] a particular outcome" even though it does so "implicitly"). Indeed, under Astra's reasoning, "no rule could pass as an interpretation … unless it were confined to parroting" statutory text. *See Am. Mining Congress*, 995 F.2d at 1112. But a rule is not legislative "merely because it supplies crisper and more detailed lines than the authority being interpreted." *Id.* Moreover, HRSA never "purport[ed] to act legislatively" based on congressionally delegated legislative authority—nor did it have to—when it interpreted the meaning of § 256b(a)(1) in the Violation Letter. *See Am Mining Congress*, 995 F.2d at 1112; *see also Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1308 (D.C. Cir. 1991) ("[T]he proper focus in determining whether an agency's act is legislative is the source of the agency's action, not the implications of that action: If the rule is based on specific statutory provisions, it is an interpretative rule."); *Erringer*, 371 F.3d at 631–32 (finding "no reason to doubt that" a rule simply

[3] That remains true "even if" the agency's interpretation "widens" the legislative basis for enforcement. *See Am. Mining Congress*, 995 F.2d at 1110.

interpreted a vague statutory mandate where there was "no indication of an explicit invocation of legislative authority" by the agency); *Louisiana v. Slazar*, 170 F. Supp. 3d 75, 90 (D.D.C. 2016) ("The defendants[] … did not explicitly invoke their general rulemaking authority in developing their revised methodology …. Their new approach did nothing more than interpret a statutory term, which is the quintessential example of an interpretive rule." (cleaned up)).[4]

CONCLUSION

Because each of Astra's claims fails, the Court should grant summary judgment in favor of Defendants and deny Astra's motion for summary judgment.

Dated: August 6, 2021

Respectfully submitted,

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[4] Because "it is clear that [HRSA] has the authority to advise the public of its interpretation of the [340B] statute," *Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 138 F. Supp. 3d 31, 38 (D.D.C. 2015), and the "inherent authority to issue interpretive rules" (like the Violation Letter) in carrying out its enforcement and administration of the 340B statute, *see Davila*, 969 F.2d at 490 (citation omitted); *accord Vanguard Interstate Tours, Inc. v. ICC*, 735 F.2d 591, 596 n.5 (D.C. Cir. 1984), Astra's contention "that HRSA lacks statutory authority to engage in substantive rulemaking" is irrelevant, *see* Astra Mot. 17–20.