No. 22-1676

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff–Appellee,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Delaware (No. 21-27)

JOINT APPENDIX
VOLUME 1 of 2 (Pages 1-53)

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IN THE UNITED STATES DISTRICT COURT
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NOTICE OF APPEAL

PLEASE TAKE NOTICE that all Defendants hereby appeal to the United States Court of Appeals for the Third Circuit from this Court's Order and Final Judgment, dated March 11, 2022, as well as all prior orders and decisions that merge into that Order and Final Judgment (including, but not limited to, the Court's Memorandum Opinion, ECF No. 112, and Order, ECF No. 113, dated February 16, 2022).

Dated: April 12, 2022

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. XAVIER BECERRA, DANIEL J. BARRY, DIANA ESPINOSA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and HEALTH RESOURCES AND SERVICES ADMINISTRATION, Defendants.	C.A. No. 21-27-LPS

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MEMORANDUM OPINION

June 16, 2021
Wilmington, Delaware

STARK, U.S. District Judge:

At the end of 2020, the general counsel of the U.S. Department of Health and Human Services ("HHS," "the agency," or "the government") issued an advisory opinion (the "Opinion") explaining the obligations of pharmaceutical manufacturers who participate in the federal 340B Program..[1] AstraZeneca Pharmaceuticals LP ("AstraZeneca" or "AZ") sued the government, asserting that the issuance of the Opinion violated the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-06. AstraZeneca now moves for summary judgment based on the administrative record ("AR"). The government cross-moves to dismiss or for summary judgment in its favor.

This case implicates numerous important issues of public policy, including access to health care, pharmaceutical companies' profit motives, and the wisdom (or not) of shifting some private profits to publicly funded health care facilities. The Court's role, however, is to set aside any personal views it may hold on these matters and to decide only the narrow questions properly before it: do the parties present a dispute over which the Court may exercise jurisdiction and, if so, is the position outlined in the Opinion compelled by the unambiguous text of the 340B statute? For the reasons explained below, the Court concludes that it has jurisdiction and that the Opinion's analysis is not the sole reasonable interpretation of the statute.

Accordingly, the Court will deny the government's motion to dismiss, except with respect to the one claim that AstraZeneca has abandoned. While AstraZeneca has shown that it is

[1] The "340B Program" takes its name from its codification at Section 340B of the Public Health Service Act, 42 U.S.C. § 256b.

entitled to at least some relief, the Court will provide the parties with an opportunity to offer further input on the precise relief to be awarded, the impact of the Court's conclusions on the cross-motions for summary judgment, and how (if at all) this case should now proceed.

BACKGROUND

About thirty years ago, Congress passed the Veterans Health Care Act ("VHCA"), Pub. L. No. 102-585, 106 Stat. 4943 (1992). One part of the VHCA was the establishment of the 340B Program. The Health Resources and Services Administration ("HRSA"), an agency within HHS, administers the 340B Program.

Under the 340B Program, certain hospitals and clinics ("covered entities") may purchase prescription drugs for their patients at or below maximum prices set by statute ("ceiling prices"). In general, covered entities are "public and not-for-profit hospitals that serve large numbers of patients with low income and/or living in rural areas." (D.I. 54 at 2; *see also* 42 U.S.C. § 256b(a)(4) (defining covered entities to include variety of organizations receiving federal funds, such as federally qualified health centers, sole community hospitals, and rural referral centers))

Congress created a powerful incentive to induce drug manufacturers' participation in the 340B Program: if drug manufacturers wish to receive reimbursements for their drugs under the Medicare Part B and Medicaid programs, the manufacturers must permit covered entities to buy those drugs at the 340B Program's discounted rates. *See* 42 U.S.C. § 1396r-8.

The 340B statute is not especially long nor detailed. The provisions most pertinent to the issues before the Court are reproduced below:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) ***purchased by a covered entity*** on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and ***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. § 256b(a)(1) (emphasis added). As discussed below, the government relies heavily on the first of these highlighted terms (the "purchased by" provision), while AstraZeneca emphasizes the latter (the "must offer" requirement). (*Compare, e.g.*, D.I. 56 at 23 & n.6 *with* D.I. 65 at 13; *see also* D.I. 43 at 3)

The dispute in this case relates to covered entities' use of third-party pharmacies, referred to by the parties (and the Court) as "contract pharmacies." Neither the "purchased by" provision nor the "must offer" requirement – nor any other part of the 340B statute – addresses whether a covered entity must have an in-house pharmacy for purchasing discounted drugs from manufacturers, or whether the covered entity may or must use an outside, third-party pharmacy to make purchases. The statute is silent on this matter.

According to the administrative record the government has put before the Court,[2] HRSA has issued two relevant guidance documents relating to covered entities' use of contract pharmacy services.

HRSA issued the first relevant guidance document in 1996. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996) ("1996 Guidance"). In the 1996 Guidance, HRSA acknowledged that "[t]he statute is silent as to permissible drug distribution systems." *Id.* at 43,549. At the time, "only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500)." *Id.* at 43,550. For covered entities that did not have in-house pharmacies, establishing them would likely have been prohibitively expensive. *See id.* Under the 1996 Guidance, each covered entity was permitted to contract with one (and only one) outside pharmacy to dispense 340B drugs. *Id.* at 43,555 ("Each covered entity [that] purchases its covered outpatients drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The ***limitation of one pharmacy contractor per entity*** does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, ***as long as only one site is used for the contracted services***.") (emphasis added).

HRSA issued the second relevant guidance document 14 years later. *See* Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010) ("2010 Guidance"). The 2010 Guidance was similar to the 1996 Guidance in

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[2] The parties agree that the government is solely responsible for preparing the administrative record and providing it to the Court (*see* D.I. 76 at 28, 105), as it has done. (*See generally* D.I. 40, 40-1, 40-2, 40-3, 40-4, 40-5, 40-6, 40-7) The parties further agree that the Court's decision must be based on the administrative record. (*See* D.I. 76 at 21-22, 38, 59)

many respects, but with at least one crucial difference: the 2010 Guidance allowed covered entities to use an unlimited number of contract pharmacies to dispense 340B drugs. *See id.* at 10,277 ("In addition to contracting with a single pharmacy for each clinical site, ***covered entities may pursue more complex arrangements that include multiple pharmacies*** . . . .") (emphasis added).[3]

Since the issuance of the 2010 Guidance, the number of contract pharmacies dispensing 340B drugs has increased dramatically. (*See* D.I. 43 at 4) (citing U.S. Gov't Accountability Off., *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (June 2018), https://www.gao.gov/assets/700/692697.pdf (noting increase from about 1,300 contract pharmacies in 2010 to about 20,000 contract pharmacies in 2017)) The five largest U.S. pharmacy chains – CVS, Walgreens, Walmart, Rite-Aid, and Kroger – constitute 60% of all contract pharmacies under the 340B Program. (*Id.*) Some drug manufacturers have suggested that the widespread use of contract pharmacies has increased pharmacies' profits without providing significant benefits for patients. (*See id.* at 4-5; *see also* D.I. 46 at 19-20)

Evidently in response to the proliferation of contract pharmacies, AstraZeneca announced in August 2020 that, effective October 1, 2020, it would begin limiting distribution of 340B drugs to: (i) covered entities with in-house pharmacies, as long as they do not use any contract pharmacy; and (ii) covered entities without in-house pharmacies, as long as they use only a

[3] The 2010 Guidance explicitly states that a covered entity having an in-house pharmacy may also use an unlimited number of contract pharmacies to "supplement" its services. 75 Fed. Reg. at 10,277.

single contract pharmacy. (*See* AR 1107; *see also id.* at 1075-78).[4] AstraZeneca asked HRSA to post a notice about AstraZeneca's policy change on HRSA's website. (*See id.* at 1110-11) HRSA declined that request. (*Id.*)

On December 30, 2020, in light of the policy change by AstraZeneca (and similar changes by other drug manufacturers), and in response to expressions of concern from other stakeholders, including covered entities and contract pharmacies (*see, e.g.*, *id.* at 1065-70, 1084-85, 1090-92), the HHS general counsel issued the Opinion (*see id.* at 1-8). The Opinion concluded: "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price – and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price – even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." (*Id.* at 8) The Opinion added that, "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." (*Id.* at 1) According to the Opinion, "manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies." (*Id.* at 8) Therefore, the view expressed in the Opinion is that all covered entities – and, implicitly, not just those lacking in-house pharmacies – may use contract pharmacy services without any limit on the number of contract pharmacies per covered entity.

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[4] The Court cites the administrative record using the pagination provided in the bottom righthand corner. For example, "AR 1107" refers to the page marked "ADVOP_001107."

The Opinion asserts that its conclusions are compelled by the "plain meaning" of the 340B statute. (*Id.* at 2-3) Moreover, the Opinion declares that the government's interpretation of the statute has been consistent throughout the past 25 years. (*See id.* at 4-5)

Two weeks after HHS issued the Opinion, AstraZeneca sued the government in this Court. (D.I. 1).[5] AstraZeneca subsequently amended its complaint. (D.I. 13) ("Am. Compl.") The amended complaint contains four claims for declaratory and/or injunctive relief: (i) in promulgating and enforcing the Opinion, the government failed to observe notice-and-comment procedures, in violation of 5 U.S.C. § 706(2)(D); (ii) the Opinion exceeds the government's authority under the 340B statute, in violation of § 706(2)(A) & (C); (iii) the Opinion is arbitrary and capricious, in violation of § 706(2)(A); and (iv) in failing to post AstraZeneca's notice to covered entities on HRSA's website, the government exceeded its authority under the 340B statute and unlawfully withheld agency action, in violation of § 706(1). (Am. Compl. ¶¶ 141-65)

AstraZeneca moved for a preliminary injunction and sought to expedite the proceedings. (D.I. 14, 17) After negotiations with the government, the parties agreed to an accelerated briefing schedule for dispositive motions, and AstraZeneca dropped its motion for a preliminary injunction. (D.I. 23, 31)

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[5] Three other drug manufacturers brought similar suits against the government. *See Eli Lilly & Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind.) (filed Jan. 12, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J.) (filed Jan. 12, 2021); *Novo Nordisk Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J.) (filed Jan. 15, 2021). A trade association representing various brand-name pharmaceutical companies also sued HHS. *See Pharm. Research & Mfrs. of Am. v. Cochran*, No. 8:21-cv-99198-PWG (D. Md.) (filed Jan. 22, 2021).

On May 17, 2021, while briefing was ongoing, HRSA sent AstraZeneca a letter stating that AstraZeneca is "in direct violation of the 340B statute." (D.I. 66-1 at 1) ("Violation Letter") HRSA told AstraZeneca that it "must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements." (*Id.* at 2) The Violation Letter warned AstraZeneca that it faces civil monetary penalties if it does not comply with its statutory obligations. (*Id.*) HRSA initially requested a response from AstraZeneca by June 1, 2021 (*see id.*), though it subsequently extended that deadline to June 10 (*see* D.I. 77).

In response to the Violation Letter, AstraZeneca filed an emergency motion seeking an "administrative stay" and, in the alternative, expedition of the proceedings. (D.I. 66) The Court declined to enter an administrative stay but agreed to further expedite the already-expedited proceedings, moving up the motions hearing by about two weeks. (D.I. 71)

The Court has carefully considered the administrative record, the parties' briefing, and related materials. (*See generally* D.I. 40, 43, 56, 65, 74).[6] It has also considered the views of several *amici curiae*. (*See generally* D.I. 46, 54, 59, 72) The Court heard extensive oral argument by videoconference on May 27, 2021. (*See* D.I. 76) ("Tr.").[7]

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[6] The government's surreply brief is laden with unfair characterizations of AstraZeneca's positions. (*See, e.g.*, D.I. 74 at 1 (accusing AstraZeneca of making "blatant misstatements" and "spurious" contentions), *id.* at 4 ("preposterous," "nonsensical," "gallingly"), *id.* at 5 ("lengthy diatribe," "invective"), *id.* at 7 ("disingenuous," "bizarrely contends")) While these attacks have not affected the Court's decision, litigants should understand that this type of rhetoric is rarely justified and, more commonly, undermines confidence in the position of the party employing such language.

[7] During the hearing, the government lodged an objection to AstraZeneca's slide

LEGAL STANDARDS

I. Motion To Dismiss

"To survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true . . . .'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant . . . has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court is not obligated to accept "bald assertions" as true. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted). Nor is it obligated to credit "unsupported conclusions and unwarranted inferences." *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997).

II. Administrative Procedure Act

"[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). In that posture, "[t]he entire case on review is a question of law." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Accordingly, the "customary summary judgment standard" under Federal Rule of Civil Procedure 56 "does not apply." *Bintz v. Fed. Emergency Mgmt. Agency*, 413 F. Supp. 3d 349, 360 (D. Del. 2019) (citing *Am. Bioscience*, 269 F.3d at 1083). Rather, the APA provides the applicable standard for the reviewing court. *See*

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presentation for purportedly containing evidence outside the administrative record. (*See* Tr. 21-22) Because the Court's decision does not depend on any information that is contained only in the slide presentation, that objection is overruled.

id. According to the APA, the Court shall "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C) & (D).

DISCUSSION

I. The Court May Review The Opinion

The parties dispute whether the Opinion is final and reviewable, as well as whether AstraZeneca's challenge to the Opinion is timely. The Court concludes that the Opinion is final and reviewable and that AstraZeneca promptly challenged it.

A. The Opinion Is Materially Different From The 1996 And 2010 Guidance

The government's arguments regarding unreviewability and untimeliness largely rest on its repeated contention that the Opinion merely restates a position that the government has held throughout the entirety of the 340B Program. (*See. e.g.*, D.I. 56 at 1, 16, 18, 24, 28; D.I. 74 at 1-2, 6-8, 10) The Court rejects this contention.

Importantly, the Opinion's analysis is based (at least in part) on the "must offer" requirement. (*See* AR 2) ("[T]he core requirement of the 340B statute . . . is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities.") Congress did not codify the "must offer" requirement until March 23, 2010, ***after*** HRSA issued the 2010 Guidance on March 5. It was impossible, therefore, for either the 1996 or 2010 Guidance to have addressed the then-nonexistent provision. To the extent that the Opinion interprets manufacturers' obligations in accordance with the "must offer" requirement, it treads "new ground." *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004).

Furthermore, the focus of the Opinion is different from the focus of the 1996 and 2010 Guidance. Both guidance documents were directed toward covered entities, explaining how they could take full advantage of the 340B Program. *See, e.g.*, 1996 Guidance, 61 Fed. Reg. at 43,555 ("Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs are encouraged to sign and have in effect a contract pharmacy service agreement between the covered entity and the pharmacy."); 2010 Guidance, 75 Fed. Reg. at 10,277 ("This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate 'in-house' pharmacy services . . . ."). On the other hand, the Opinion is directed toward drug manufacturers. (*See, e.g.*, AR 1) ("[W]e conclude that . . . a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies . . . .")

AstraZeneca also persuasively argues that the mode of analysis in the Opinion is different from the mode of analysis employed in the 1996 and 2010 Guidance. (*See, e.g.*, D.I. 65 at 6-7) The 1996 Guidance acknowledged there were "many gaps" in the 340B statute. *See* 61 Fed. Reg. at 43,550..[8] The 2010 Guidance similarly recognized that HRSA sought to "create a working framework" to fill in statutory gaps. *See* 75 Fed. Reg. at 10,273. Neither guidance document cited specific provisions in the 340B statute. (*See* Tr. 71-72) That is, neither the

[8] The government tries to explain away the 1996 Guidance's reference to "gaps" by insisting that it was referring solely to the "approximately 11,500 eligible entities, 500 participating manufacturers, numerous wholesalers and many Federal Programs affected by this legislation," all of whom were "seeking guidance on how the Department intend[ed] to administer the 340B Program." (D.I. 56 at 27 n.9) (citing 61 Fed. Reg. at 43,550; internal quotation marks omitted) This explanation is unpersuasive. In context, HRSA was acknowledging a statutory "gap" as to the proper treatment of pharmacies.

1996 Guidance nor the 2010 Guidance cites § 256b nor discusses its particular provisions. The Opinion, by contrast, is explicitly an exercise in statutory interpretation. (*See* AR 2) ("[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous.") (quoting *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004)) Statutory interpretation is a fundamentally different approach from programmatic gap-filling. (*See generally* Tr. 71) (government conceding that, in guidance documents, "the agency didn't engage in this sort of longer form of statutory interpretation that it did in the advisory opinion")

Based on the administrative record, the Court concludes that the 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.[9] Indeed, as noted above, the 1996 Guidance limited covered entities to using no more than a single contract pharmacy. *See* 61 Fed. Reg. at 43,555 (acknowledging "limitation of one pharmacy contractor per entity"). Strikingly, AstraZeneca's new policy, as announced in August 2020, would not have run afoul of the 1996 Guidance – yet it directly contradicts the Opinion.[10] This reality demonstrates that the

[9] During the hearing, the government insisted that HHS had articulated this position before 2020, but it could not cite anything in the administrative record to support this assertion. (*See* Tr. 72-73)

[10] The government now suggests that the 1996 Guidance was wrong in limiting covered entities to a single contract pharmacy. (*See* Tr. 67; *see also id.* at 94 (same for *amici*)) Regardless of whether the 1996 Guidance was correct, the important point is that the government's interpretation of the statute has not been consistent.

government's interpretation of manufacturers' obligations under the 340B Program has not remained constant but has, instead, evolved over time..[11]

The following table summarizes some of the key differences between the guidance documents and the Opinion:

Document	**Directed to:**	**Number of Contract Pharmacies Permitted**	**Mode of Analysis**	**Interprets "Must Offer" Requirement?**	**Does AZ's 2020 Policy Comply?**
1996 Guidance	Covered entities	One	Programmatic Gap Filling	No (did not exist)	Yes
2010 Guidance	Covered entities	Unlimited	Programmatic Gap Filling	No (did not exist)	No
2020 Opinion	Drug manufacturers	Unlimited	Statutory Interpretation	Yes	No

For at least the reasons already explained, and especially in combination, these differences establish that the government's position on drug manufacturers' obligations with respect to participation in the 340B Program has ***not*** remained constant but has, instead, materially shifted.

To be sure, since 1996, the government has maintained that the 340B statute broadly requires pharmaceutical manufacturers to provide discounts to covered entities. *See, e.g.*, 1996 Guidance, 61 Fed. Reg. at 43,549 ("It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price."); *id.* at

[11] As AstraZeneca points out, "the Opinion does not acknowledge (much less explain) a change in approach from prior agency guidance." (D.I. 65 at 1) The failure to accept this reality does not, of course, change the fact that the government's interpretation of the statutory obligations of drug manufacturers has actually changed. *See generally Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) ("[T]he agency must at least display awareness that it is changing position and show that there are good reasons for the new policy.") (internal quotation marks omitted).

43,555 ("Under section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price."); 2010 Guidance, 75 Fed. Reg. at 10,278 (similar). But the government's position overlooks that, throughout the past 25 years, the government has dramatically expanded how covered entities may purchase 340B drugs. The agency's interpretation of manufacturers' obligations with respect to covered entities necessarily shifts every time that HHS changes its guidance with respect to covered entities' rights. In this context, it is inaccurate to insist that manufacturers' duties have never changed, solely on the grounds that the government has always required manufacturers to accommodate all contract pharmacy arrangements that the government has permitted. Again, because the government has changed what covered entities ***may*** do, it has consequently changed what drug manufacturers ***must*** do.

B. The Opinion Constitutes Final Agency Action

There are two requirements for agency action to be final. First, "the action must mark the consummation of the agency's decisionmaking process." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal quotation marks omitted). That is, the action cannot be "merely tentative or interlocutory." *Id.* at 178. Second, "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* (internal quotation marks omitted). Both requirements are satisfied here.

The Opinion is the "consummation" of HHS's decisionmaking process. The Court agrees with AstraZeneca that the Opinion is not "tentative": it "was issued by the agency's General Counsel," "announces unqualified conclusions," and "anticipates no further

reconsideration of the issue." (D.I. 65 at 2) The government's only argument to the contrary, raised in a footnote, rests on the premise that the Opinion merely restates the position that HHS has held since 1996. (*See* D.I. 56 at 13 n.4) For the reasons explained above, that premise is faulty.

The Opinion also has legal consequences for AstraZeneca. It repeatedly states that pharmaceutical manufacturers are "obligated" and cannot "refuse" to provide 340B drugs to multiple pharmacies who contract with covered entities. (AR 1, 8) That language is mandatory and conveys at least the impression that HHS expects "immediate compliance." *Univ. of Med. & Dentistry of N.J. v. Corrigan*, 347 F.3d 57, 69 (3d Cir. 2003) (internal quotation marks omitted). The Opinion, then, is fairly characterized as "the agency's definitive position." *Id.* (internal quotation marks omitted). HHS has not offered only preliminary thoughts on the matter while launching a more thorough assessment; instead, it has offered its unequivocal answer to a legal question.

The availability of administrative dispute resolution ("ADR") proceedings does not render AstraZeneca's challenge to the Opinion unreviewable by this Court. ADR proceedings permit drug manufacturers to pursue claims against ***covered entities*** for alleged drug diversion and duplicate discounts. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,645 (Dec. 14, 2020) (the "ADR Rule"). ADR proceedings do not provide a venue for manufacturers to challenge ***agency*** action, as AstraZeneca does in this

litigation. If AstraZeneca (or another manufacturer) tries to raise the legal issue presented here in ADR proceedings, the result is preordained. (*See* D.I. 43 at 18-19).[12]

Accordingly, the Opinion is final and reviewable.

C. AstraZeneca's Challenge Is Not Time-Barred

The parties agree that, to be timely, this lawsuit must have been filed "within six years after the right of action first accrue[d]." 28 U.S.C. § 2401(a). The government contends that AstraZeneca waited too long to challenge the Opinion, even though AstraZeneca initiated this lawsuit only a couple of weeks after HHS issued the Opinion. (*See* D.I. 56 at 13-18) In the government's view, AstraZeneca's right of action accrued approximately 25 years ago with the issuance of the 1996 Guidance. (*Id.* at 14) This argument is unavailing. It is predicated, once again, on the false premise (*see supra* Section I.A) that the government's position has been consistent throughout the history of the 340B Program.

In arguing that AstraZeneca should have brought a version of this lawsuit 25 years ago, the government points to (i) a challenge by the trade association PhRMA to a precursor of the 1996 Guidance and (ii) a contemporaneous letter from the HRSA Administrator. (*See* D.I. 56 at 17-18) This evidence does not alter the Court's conclusions. AstraZeneca did not exist in its current form at the time of the PhRMA litigation (*see* Tr. 51), so the plaintiff before the Court

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[12] AstraZeneca also raises serious concerns about its inability to conduct effective audits of covered entities, which is a prerequisite for manufacturers to engage in the ADR process. *See* 42 U.S.C. § 256b(d)(3); ADR Rule, 85 Fed. Reg. at 80,645; *see also* D.I. 43 at 16; D.I. 65 at 19; Tr. 59-61. The administrative record contains no indication that the government ever grappled with these practical problems with the ADR process. *See generally Eli Lilly & Co. v. Cochran*, 2021 WL 981350, at *7-10, 12 (S.D. Ind. Mar. 16, 2021) (preliminarily enjoining government from enforcing ADR Rule against drug manufacturer given likelihood that ADR Rule is procedurally defective).

cannot fairly be faulted for not filing suit at that time. Moreover, the PhRMA litigation did not challenge the final 1996 Guidance, and it did not (and could not) challenge the Opinion. Once again, the fact that the government has not consistently taken the same position with respect to manufacturers' obligations under the statute defeats the government's suggestion that a challenge to an earlier iteration of its policy (in 1996) would also essentially be a challenge to the government's current policy (as expressed in the Opinion).

Hence, AstraZeneca's challenge is timely..[13] As the Court has jurisdiction to review the Opinion, it must deny the government's motion to dismiss.

II. The Opinion's Analysis Is Not The Only Permissible Interpretation Of The Statute

Turning to the merits of AstraZeneca's declaratory judgment claims, the Court concludes that there is more than one permissible interpretation of the 340B statute..[14] Because the Opinion wrongly determines that purportedly unambiguous statutory language mandates its conclusion regarding covered entities' permissible use of an unlimited number of contract pharmacies, the Opinion is legally flawed.

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[13] The government emphasizes that AstraZeneca and other pharmaceutical manufacturers have historically complied with the government's rules for the 340B Program. (*See, e.g.*, D.I. 56 at 17, 25) While that acquiescence may provide a basis for some skepticism regarding the motivation behind manufacturers' recent efforts to push back against the program, AstraZeneca has neither waived nor forfeited any rights to pursue its legal challenges.

[14] During the hearing, counsel for *amici* American Hospital Association and other organizations suggested a helpful way to characterize the two parties' positions: if AstraZeneca is right, then drug manufacturers participating in the 340B Program do not have to provide discounted pricing for ***any*** drugs delivered to contract pharmacies, while if the government is right, then those same manufacturers must give discounted pricing for ***all*** drugs prescribed by covered entities, including drugs delivered to an unlimited number of contract pharmacies or through any other system for obtaining drugs. (*See* Tr. 91) In the Court's view, the statute does not compel either interpretation, yet both are plausible.

The statute is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs. Pharmacies are not mentioned anywhere in the statutory text – neither in § 256b(a)(1), which (as both parties agree) contains the relevant command, nor in § 256b(a)(4), which provides the definition of "covered entity." When a statute does not include even a single reference to the pertinent word (e.g., "pharmacy"), it is highly unlikely (if not impossible) that the statute conveys a single, clear, and unambiguous directive with respect to that word. Here, the absence of any reference to "pharmacies" is a strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies.

Instead of addressing pharmacies, the first part of the statute – the "purchased by" provision relied on by the government – is directed to the Secretary of HHS, requiring him to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . ***purchased by*** a covered entity . . . does not exceed" the ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added). This provision does not directly act on covered entities and, in any event, says nothing of the permissible role (if any) of contract pharmacies. The next sentence contains the "must offer" requirement, providing that each agreement between the Secretary and a manufacturer "***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.* (emphasis added). This provision, too, says nothing about the permissible role (if any) of contract pharmacies. Again, the statute is simply silent on this point.

The statute's total omission of contract pharmacies renders it ambiguous with respect to the central issue in this case.

Still, the Opinion asserts that the "***plain meaning***" of the statute "requires manufacturers to sell covered drugs to covered entities at or below the ceiling price, independent of whether the entity opts to use contract pharmacies to dispense the drugs." (AR 2) (emphasis added; capitalization modified) In particular, the government contends that the "purchased by" provision of § 256b(a)(1) imposes this obligation on manufacturers participating in the 340B Program. (*See, e.g.*, Tr. at 64-65) (arguing that "there is . . . no . . . plausible reading of 'purchased by' that would exclude drugs that are purchased by the covered entity but distributed by a contract pharmacy") This is unpersuasive. The "purchased by" language directly imposes an obligation on the Secretary (and only indirectly imposes obligations on manufacturers), and it refers to "covered outpatient drugs . . . purchased by a covered entity" without any reference to the amount of such drugs purchased or the model by which the drugs are distributed. That language simply cannot bear the weight that the government places on it. It is, instead, ambiguous on the points in dispute between the parties.

The Opinion goes on to add: "It is difficult to envision a less ambiguous phrase[,] and no amount of linguistic gymnastics can ordain otherwise." (AR 2; *see also id.* at 3 ("Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive.")) The Court disagrees. The government may now also disagree, for it acknowledged at the hearing that "Congress could have been more specific that . . . the drugs purchased by a covered entity had to be dispensed in an in-house pharmacy or had to be dispensed through a contract pharmacy or any number of . . . limited arrangements[,] but the fact is it was not specific . . . ." (Tr. 65; *see also*

1996 Guidance, 61 Fed. Reg. at 43,549 ("The statute is silent as to permissible drug distribution systems.")) In any event, it is not at all difficult to imagine a less ambiguous phrase that Congress could have included in § 256b(a)(1). Congress could have explicitly stated that drug manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies. Instead, Congress was silent on the issue, and the statute is ambiguous.

If the statute offers any clues on the issue, they militate against the view set out in the Opinion. The Opinion expressly relies on the assumption that contract pharmacies act as agents of covered entities. (*See* AR 6) (noting that "covered entity and contract pharmacy are not distinct, but function as principal-agent").[15] Neither the operative provision in § 256b(a)(1) nor the definition of "covered entity" in § 256b(a)(4) speaks about covered entities' agents – although other provisions in the 340B statute do speak about covered entities' affiliates. For example, § 256b(d)(3)(B)(vi) refers to "associations or organizations representing the interests of" covered entities. If Congress intended to include agents within the definition of "covered entity," it evidently knew how to do so. It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication.

Other statutory provisions also cut against HHS's position. For example, another part of the VHCA (which established the 340B Program) refers specifically to "drugs procured by an agency of the Federal Government" that are "received[,] stored, and delivered" by "a commercial

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[15] During the hearing, the government argued that agency relationships between covered entities and contract pharmacies are merely exemplary. (Tr. 34-35) The Court cannot square that contention with the text of the Opinion, which states that it applies "***to the extent*** contract pharmacies are acting as agents of a covered entity." (AR 1) (emphasis added)

entity ***operating under contract*** with such agency." 38 U.S.C. § 8126(h)(3) (emphasis added). Likewise, a provision in a different health care statute explicitly covers "a person authorized to act as a purchasing ***agent*** for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(C) (emphasis added). Congress knows how to write statutes that cover agents and contractors, but it did not do so in the 340B statute.

The legislative history is of no greater assistance to the government. When Congress added the "must offer" requirement to the statute in 2010, it specifically contemplated including language referring to drugs "purchased and dispensed by, or ***under a contract entered into for on-site pharmacy services*** with" covered entities. *See* S. Rep. No. 102-259 at 2 (1992) (emphasis added). Congress chose not to include pharmacy services in the version of the bill that it ultimately passed. That omission suggests that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies..[16]

Both parties agree that only Congress may add requirements to the 340B statute. (*See* Tr. 22, 36, 41-42) Yet both parties' interpretations of the statute effectively, and impermissibly, add requirements to it. Under the government's interpretation, pharmaceutical manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies. Under AstraZeneca's interpretation, covered entities are required to purchase their 340B drugs through

[16] The House Report on the 340B Program states: "Drug discounts enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II) at 12 (1992). While that general goal informs the Court's reading of the statute, it does not transform ambiguous statutory language into an unambiguous congressional command.

in-house pharmacies..[17] Neither requirement is contained in the statute, nor (therefore) compelled by it..[18] Thus, on the parties' own views, the Court is not permitted to read either of these requirements into the statute.

In the Court's view, given the ambiguous statutory language, HHS could reasonably choose to opine that manufacturers are not required to deliver 340B drugs to an unlimited number of contract pharmacies when the covered entities themselves never possess the drugs. The Secretary might be motivated to interpret the statute in that manner to deter waste and fraud. (*See generally* D.I. 43 at 5) ("The promise of outsized profits, combined with lax federal oversight, has created a perfect storm for abuse.").[19] Of course, the statutory language does not compel this view, just as it does not compel the view articulated in the Opinion. The point is, once more, that Congress simply has not spoken on the issue.

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[17] Even though AstraZeneca's new policy permits each covered entity that lacks an in-house pharmacy to use a single contract pharmacy, AstraZeneca contends that its agreement to work with any contract pharmacies is voluntary. (*See, e.g.*, Tr. 57-58) Under AstraZeneca's interpretation of the statute, a drug manufacturer participating in the 340B Program is only required to sell covered drugs directly to covered entities.

[18] In reaching this conclusion, the Court necessarily rejects AstraZeneca's "first line position" that the Opinion is "objectively wrong" and "contrary" to the plain language of the 340B statute. (Tr. 43; *see also* D.I. 65 at 12)

[19] Under the now-prevalent "replenishment model," pharmaceutical manufacturers ship prescription drugs to pharmacies for dispensing to all patients. At the time of dispensing, the pharmacies do not know whether the prescriptions were written by medical providers at covered entities and qualify for 340B discounts. After 340B eligibility is later determined (typically using an algorithm), the manufacturers process chargebacks to account for the 340B drugs' discounted prices. The covered entities never physically possess the drugs. (*See* D.I. 65 at 11; D.I. 46 at 12-14; *see also* AR 6 n.6 (extending Opinion's reasoning to replenishment model))

If the Opinion had endorsed AstraZeneca's view of its obligations under the 340B statute, it is possible that covered entities would have brought their own suit against HHS to challenge that interpretation. In that hypothetical case, the outcome would have been the same as the one reached here, because the statutory language does not speak to covered entities' use of contract pharmacies. The text no more compels AstraZeneca's interpretation than the government's alternative interpretation.

While HHS's current interpretation of the statute is permissible, the Opinion is based on the "unjustified assumption" that Congress imposed this interpretation as a statutory requirement. *See Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021). "[D]eference to an agency's interpretation of a statute is not appropriate when the agency wrongly believes that interpretation is compelled by Congress." *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (internal quotation marks omitted). Thus, AstraZeneca is entitled to some relief. *See, e.g.*, *Am. Lung Ass'n*, 985 F.3d at 944 (vacating regulation and remanding for further consideration). Before determining the precise relief to be granted – be it setting aside the Opinion, vacating it with respect to AstraZeneca, remanding to HHS, and/or something else – the Court will benefit from obtaining the parties' views on what is most appropriate given the Court's conclusions.

III. AstraZeneca Has Abandoned Its Fourth Claim For Relief

AstraZeneca originally asked the Court to direct the government to post AstraZeneca's notice to covered entities on HRSA's website. (Am. Compl. at 55) In the government's view, the Court lacks jurisdiction to compel such agency action because it is not required by statute. (D.I. 56 at 30) (citing *Massie v. U.S. Dep't of Hous. & Urb. Dev.*, 620 F.3d 340, 347 (3d Cir.

2010)) AstraZeneca's briefs do not address this claim, and the Court understands that AstraZeneca no longer intends to pursue it. (Tr. 58) Accordingly, the Court will dismiss AstraZeneca's fourth claim.

CONCLUSION

The Court concludes by stressing what it is ***not*** deciding today. The government, *amici*, and others have warned that repudiating the government's interpretation of the 340B statute may make it more difficult for covered entities to serve uninsured or underinsured patients, many of whom live in low-income or rural communities. (*See, e.g.*, AR 3-4; D.I. 59 at 8-19) These concerns are amplified by the fact that the world is still recovering from the worst pandemic in a century. The Court does not take these concerns lightly and hopes that the fears prove unfounded.[20] Congress may very well want pharmaceutical manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies as a condition for manufacturers' participation in the Medicare Part B and Medicaid programs. But that kind of policymaking is for Congress, not this Court. The only issue before the Court is whether Congress has spoken clearly and unambiguously on this arrangement. It has not.

Therefore, and for all the reasons explained above, the Court will deny the government's motion to dismiss, except with respect to AstraZeneca's abandoned fourth claim for relief. To

[20] The government's suggestion that the Court's ruling may entirely eviscerate the benefits of the 340B Program is not convincing. As far as the record reveals, permitting drug manufacturers to implement policies like the one AstraZeneca intends to follow would likely result in benefits to covered entities roughly equal to the benefits that they derived from the program between 1996 and 2010. The government admitted at the hearing that nothing in the record would support a contrary conclusion. (*See* Tr. 83) Whether "turning back the clock" in this manner is good or bad policy is not a matter for this Court to decide.

the extent that the government's motion seeks summary judgment, that portion of the motion remains pending. AstraZeneca's motion for summary judgment also remains pending until the Court receives further input from the parties. Thereafter, the Court will determine the precise relief to be awarded to AstraZeneca.

An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. XAVIER BECERRA, DANIEL J. BARRY, DIANA ESPINOSA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and HEALTH RESOURCES AND SERVICES ADMINISTRATION, Defendants.	C.A. No. 21-27-LPS

MEMORANDUM ORDER

WHEREAS, in a memorandum opinion dated June 16, 2021, the Court held that AstraZeneca is "entitled to at least some relief" in this case (D.I. 78 at 1-2);

WHEREAS, in a corresponding order also dated June 16, 2021, the Court denied Defendants' motion to dismiss (D.I. 55) with respect to the first three claims of AstraZeneca's amended complaint and granted the motion solely with respect to the fourth claim, which AstraZeneca had withdrawn (*see* D.I. 79);

WHEREAS, the Court directed the parties to meet and confer regarding: (i) the precise relief to be granted to AstraZeneca given the Court's analysis, (ii) what additional order the Court should enter, and (iii) the next steps in this case (*see id.*);

WHEREAS, on June 21, 2021, the parties submitted a joint status report outlining their positions on those issues (D.I. 82), which the Court has carefully considered;

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. It is **DECLARED** that HHS's withdrawal of the Opinion (*see* D.I. 81) does not moot this litigation. "It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice unless it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't of Health & Human Resources*, 532 U.S. 598, 609 (2001) (internal quotation marks omitted); *see also Solar Turbines Inc. v. Seif*, 879 F.2d 1073, 1078-79 (3d Cir. 1989) (holding case not moot despite agency's withdrawal of administrative order because agency "ha[d] not altered its position on the merits"). Here, although HHS withdrew the Opinion, HHS has made it clear that its position on the 340B statute has not changed. (*See* D.I. 81-1 ("[HHS's general counsel] notes that its withdrawal of the Opinion does not impact the ongoing efforts of the Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers . . . ."); *see also* D.I. 82 at 4 ("HRSA intends to continue enforcement proceedings against AstraZeneca pursuant to the 340B statute.")) Because HHS and its sub-agency, HRSA, intend to act in accordance with the withdrawn Opinion, this litigation is not moot. *See Solar Turbines*, 879 F.2d at 1079.[1]

2. With respect to the third claim of the amended complaint, AstraZeneca's motion for summary judgment (D.I. 42) is **GRANTED**, and the government's motion for summary

[1] The government cites only one case in support of its argument that this litigation is now moot. (*See* D.I. 82 at 4) (citing *Marcavage v. Nat'l Park Serv.*, 666 F.3d 856, 861-62 (3d Cir. 2012)) In *Marcavage*, the Third Circuit determined that the alleged constitutional violations were unlikely to recur because the agency had amended the challenged regulations ***before*** the litigation. This case is different: HHS withdrew the Opinion only ***after*** the Court issued its memorandum opinion, and, as described above, HHS has indicated that its position on the 340B statute has not actually changed.

judgment (D.I. 55) is **DENIED**. Because the Court has concluded that AstraZeneca's claims are not moot, and given the Court's conclusions in the Opinion, the government agrees that this relief is proper. (*See* D.I. 82 at 6)

3. With respect to the first and second claims of the amended complaint, AstraZeneca's motion for summary judgment (D.I. 42) and the government's motion for summary judgment (D.I. 55) are **DENIED WITHOUT PREJUDICE**.

4. The Opinion issued by the general counsel of HHS on December 30, 2020, is **SET ASIDE** and **VACATED**.

The Court has considered the parties' other proposals (*see* D.I. 82 at 5-6), but it has determined that the relief granted in this Order is appropriate given the Court's conclusions in the June 16, 2021 Memorandum Opinion.

IT IS FURTHER ORDRED that the parties are directed to meet and confer regarding how this case will now proceed. No later than **July 6, 2021**, the parties shall submit a joint status report outlining their proposed schedule for: (i) AstraZeneca's filing of its second amended complaint, (ii) the government's filing of the administrative record regarding the Violation Letter, and (iii) both parties' filing and briefing of any forthcoming motions to dismiss, motions for summary judgment, or any other motions. Any proposed briefing schedule should take care to limit the number of requested pages to the minimum truly needed, and it should provide each party with at least one opportunity to respond in writing to the other party's arguments.

June 30, 2021
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. XAVIER BECERRA, DANIEL J. BARRY, DIANA ESPINOSA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and HEALTH RESOURCES AND SERVICES ADMINISTRATION, Defendants.	C.A. No. 21-27-LPS

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MEMORANDUM OPINION

February 16, 2022
Wilmington, Delaware

STARK, U.S. District Judge:

On May 17, 2021, the Acting Administrator of the Health Resources and Services Administration ("HRSA") within the U.S. Department of Health and Human Services ("HHS") sent a letter to AstraZeneca Pharmaceuticals LP ("AstraZeneca" or "AZ"). In the letter, HRSA notified AstraZeneca of HRSA's conclusion that AstraZeneca has violated its obligations under the federal 340B Program. In this Court, AstraZeneca challenges this "Violation Letter," arguing that the agency did not comply with the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-06. AstraZeneca and the government have both moved for summary judgment on the administrative record.

As the Court previously acknowledged (*see* D.I. 78 at 1), this case implicates a number of important issues of public policy, including funding for healthcare facilities across the country and access to care – especially for low-income individuals – at those facilities. As before, the Court must set aside any personal views it may have on these matters and decide only the narrow question properly before it, which is now: did HRSA comply with the APA when it issued the Violation Letter? For the reasons explained below, the Court concludes that HRSA did not.

Accordingly, the Court will vacate and set aside the Violation Letter and remand to the agency for further consideration in light of the Court's opinion. The Court will also solicit the parties' views on the impact of the Court's conclusions on the claims for relief in AstraZeneca's second amended complaint and whether (and, if so, how) this case should now proceed.

BACKGROUND[1]

In August 2020, AstraZeneca announced that, effective October 1 of that same year, it would limit 340B pricing for covered outpatient drugs to drugs delivered to: (i) each covered entity's in-house pharmacy; or (ii) a single contract pharmacy chosen by each covered entity, provided that the covered entity does not have an in-house pharmacy. (*See* AR 7608-11)[2]

In response to AstraZeneca's policy change, as well as similar policy changes by other drug manufacturers and complaints from covered entities, on December 30, 2020 the general counsel of HHS issued "Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program." (AR 8048-55) ("Opinion") In the Opinion, HHS mandated that drug manufacturers facilitate sales of 340B drugs regardless of how covered entities distribute those drugs, writing: "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." (*Id.* at 8048) In particular, HHS took the view that all covered entities may use an unlimited number of contract pharmacies for dispensing 340B drugs. (*See id.* at 8055)

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[1] In a prior memorandum opinion, the Court provided general background information regarding the 340B Program. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 50-53 (D. Del. 2021). The Court incorporates that background information by reference.

[2] As is typical in APA cases, the government was solely responsible for assembling and providing the administrative record ("AR"). Given the size of this administrative record, the Court permitted the government to file it manually. (*See* D.I. 88, 88-1, 89) The Court cites the administrative record using the pagination provided in the bottom righthand corner of each page. For example, "AR 7608" refers to the page marked "VLTR_007608."

According to the Opinion, these conclusions were mandated by the plain and unambiguous language of the statute establishing the 340B Program. (*See id.* at 8049-50)

Shortly after HHS issued the Opinion, AstraZeneca filed suit in this Court. (D.I. 1)[3] AstraZeneca then moved for summary judgment. (D.I. 42) In response, the government filed a combined motion to dismiss and cross-motion for summary judgment. (D.I. 55) After expedited proceedings, the Court issued a memorandum opinion regarding HHS's Opinion and the 340B statute. First, the Court explained how the Opinion differed in material ways from two guidance documents HRSA had issued in 1996 and 2010. *See AstraZeneca*, 543 F. Supp. 3d at 54-57. Next, the Court held that the Opinion constituted final and reviewable agency action. *See id.* at 57-58. For related reasons, the Court also held that AstraZeneca's challenge to the Opinion was timely. *See id.* at 58. Accordingly, the Court denied the government's motion to dismiss, except with respect to one claim for relief AstraZeneca had abandoned. *See id.* at 58, 62.

On the merits of AstraZeneca's claims, the Court concluded that the interpretation of the 340B statute in the Opinion was not compelled by the unambiguous text of the statute, as HHS had reasoned. *See id.* at 58-62. Rather, the 340B statute is "silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *Id.* at 59.

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[3] Other drug manufacturers filed similar suits in other district courts. *See Eli Lilly & Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind.); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J.); *Novo Nordisk Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J.); *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-14979-DLF (D.D.C.); *United Therapeutics Corp. v. Espinosa*, No. 21-cv-1686-DLF (D.D.C.). A trade association representing multiple drug manufacturers, including AstraZeneca, brought another own suit against the government. *See Pharm. Research & Mfrs. of Am. v. Cochran*, No. 8:21-cv-99198-PWG (D. Md.).

Analyzing the text and structure of the 340B statute and similar statutory provisions, the Court explained that textual clues do not support the government's reading of the 340B statute. *See id.* at 60. Moreover, the legislative history cuts against the government's position because Congress specifically did not enact statutory language referring to contract pharmacies. *See id.* at 60-61. Ultimately, the Court concluded that both sides' interpretations are permissible readings of the 340B statute but that neither interpretation is compelled by the plain text of the statute. *See id.* at 61.

Because the Opinion was based on an "'unjustified assumption'" about the statute, AstraZeneca was entitled to relief. *Id.* at 61-62 (quoting *Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021)). Before disposing of the cross-motions for summary judgment, the Court opted to provide the parties with an opportunity to submit additional views. *See id.* at 62.

Two days later, and before the Court was able to grant AstraZeneca appropriate relief, the acting general counsel of HHS withdrew the Opinion. (D.I. 81-1) In a joint status report filed shortly thereafter, the government argued that the withdrawal of the Opinion mooted AstraZeneca's claims. (D.I. 82) The Court disagreed, observing that the record demonstrated the government's intent to "act in accordance with the withdrawn Opinion." (D.I. 83 at 2) In light of the parties' additional views, the Court granted AstraZeneca's summary judgment motion with respect to one of its claims – that the Opinion was arbitrary and capricious – and denied the corresponding portion of the government's motion. (*See id.* at 2-3) The Court denied without prejudice AstraZeneca's summary judgment motion with respect to the remaining claims and the

corresponding portions of the government's cross-motion for summary judgment. (*See id.* at 3) The Court also vacated and set aside the Opinion. (*See id.*)[4]

In the meantime, while the parties were briefing the issues regarding the Opinion, HRSA sent AstraZeneca the Violation Letter. (AR 1-2) In it, HRSA states that, after a review of AstraZeneca's new policy regarding 340B drugs and "an analysis of the complaints HRSA has received from covered entities, HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute." (AR 1) The Violation Letter points specifically to the statute's "shall offer" requirement, which provides that drug manufacturers "'shall . . . 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.*) (quoting 42 U.S.C. § 256b(a)(1)) According to HRSA, "[n]othing in the 340B statute grants a [drug] manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." (*Id.*)

The Violation Letter goes on to state that the agency's interpretation of the 340B statute has been consistent for over 25 years: "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor . . .

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[4] After the Court vacated and set aside the Opinion, another district court endorsed this Court's reasoning and similarly concluded that the Opinion was arbitrary and capricious. *See Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, 2021 WL 5039566, at *14 (S.D. Ind. Oct. 29, 2021). In light of this Court's decision and the *Eli Lilly* decision, a third district court determined that another drug manufacturer's claims regarding the Opinion were moot. *See Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, --- F. Supp. 3d. ---, 2021 WL 5150464, at *55 (D.N.J. Nov. 5, 2021).

purchases [of 340B drugs] regardless of the dispensing mechanism." (*Id.*) The Violation Letter instructs AstraZeneca that it "must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements." (*Id.* at 2) In the next sentence, the agency tells AstraZeneca it "must comply with its 340B statutory obligations" and "refund all covered entities for overcharges that have resulted from AstraZeneca's policy." (*Id.*) Otherwise, the Violation Letter warns, AstraZeneca may face civil monetary penalties of up to $5,883 per overcharge. (*Id.* at 2 & n.3) Ultimately, a decision on whether to impose civil monetary penalties will be made by HHS's Office of the Inspector General. (*See* D.I. 100-1 Ex. A)

After the Court vacated and set aside the Opinion, AstraZeneca filed a second amended complaint. (D.I. 86) ("2d Am. Compl.") The revised pleading includes the first three claims from the previous version of the complaint, on which the Court has already ruled. (*Id.* ¶¶ 152-73) It also adds three new claims regarding the Violation Letter:

- In its fourth claim, AstraZeneca seeks declaratory/injunctive relief that, in issuing and enforcing the Violation Letter, Defendants failed to observe notice-and-comment procedures, in violation of 5 U.S.C. § 706(2)(D). (2d Am. Compl. ¶¶ 174-80)

- In its fifth claim, AstraZeneca seeks declaratory/injunctive relief that the Violation Letter exceeds Defendants' statutory authority under 42 U.S.C. § 256(b), in violation of 5 U.S.C. § 706(2)(A), (C). (2d Am. Compl. ¶¶ 181-86)

- In its sixth claim, AstraZeneca seeks declaratory/injunctive relief that the Violation Letter is arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A). (2d Am. Compl. ¶¶ 187-93)

The parties agreed on a schedule for the filing of the administrative record and briefing on AstraZeneca's new claims regarding the Violation Letter, which the Court approved. (D.I. 84, 85)

The Court has carefully considered the administrative record and the briefing, as well as various letters, a notice of supplemental authority, and multiple joint status reports submitted by the parties. (*See generally* D.I. 88-1, 91, 93, 94, 95, 100, 102, 104, 106, 107, 108, 110, 111) The Court heard oral argument by videoconference on October 18, 2021. (*See* D.I. 103) ("Tr.")

LEGAL STANDARDS

"[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). In that posture, "[t]he entire case on review is a question of law." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Accordingly, the "customary summary judgment standard" under Federal Rule of Civil Procedure 56 "does not apply." *Bintz v. Fed. Emergency Mgmt. Agency*, 413 F. Supp. 3d 349, 360 (D. Del. 2019) (citing *Am. Bioscience*, 269 F.3d at 1083). Rather, the APA provides the applicable standard for the reviewing court. *See id.* According to the APA, the Court shall "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C) & (D).

DISCUSSION

I. The Violation Letter Is Based On Essentially The Same Interpretation Of The 340B Statute As The Vacated Opinion

AstraZeneca principally argues that the Violation Letter is "based on the same 'legally flawed' reading" of the 340B statute that plagued the Opinion. (D.I. 91 at 9 (capitalization modified); *see also* Tr. at 6) The Court agrees.

A comparison of the Violation Letter and the Opinion reveals multiple parallels between the documents:

- Both the Violation Letter and the Opinion emphasize the "shall offer" language in 42 U.S.C. § 256b(a)(1), i.e., Section 340B(a)(1).
  (*Compare* AR 1 ("Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers 'shall . . . 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.'") *with* AR 8049 ("[T]he core requirement of the 340B statute . . . is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities."))

- Both the Violation Letter and the Opinion state that the 340B statute establishes an unqualified requirement.
  (*Compare* AR 1 ("This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs.") *with* AR 8049 ("This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs."))

- Both the Violation Letter and the Opinion suggest that a drug manufacturer's refusal to facilitate sales of covered outpatient drugs for dispensing by an unlimited number of contract pharmacies directly contravenes the 340B statute.
  (*Compare* AR 1 ("HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute.") *with* AR 8049 ("The plain meaning of Section 340B requires manufacturers to sell covered drugs to covered entities at or below the ceiling price, independent of whether the entity opts to use contract pharmacies to dispense the drugs.") (capitalization modified))

- Both the Violation Letter and the Opinion underscore that drug manufacturers may not place conditions on their offers of 340B drugs. (*Compare* AR 1 ("Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities.") *with* AR 8052 ("'[M]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity.'") (quoting 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017)))

- Both the Violation Letter and the Opinion insist that HRSA's interpretation of the 340B statute has remained constant. (*Compare* AR 1 ("HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.") *with* AR 8051 ("The Department's longstanding interpretation of the statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used.") (citing Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996) ("1996 Guidance"); Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010) ("2010 Guidance")))

One difference between the documents is that the Opinion leans heavily on the "purchased by" language in 42 U.S.C. § 256b(a)(1), whereas the Violation Letter focuses exclusively on the "shall offer" requirement, which is also in § 256b(a)(1). (*Compare* AR 8049-50 *with* AR 1)[5] That difference is not particularly relevant here because both documents still

[5] The government argues that the Violation Letter does not rely exclusively, or perhaps even at all, on the "shall offer" requirement. (Tr. at 43) In the government's view, the Violation Letter relies additionally on the statute's "purchased by" language, reasoning "these commands are found in the same statutory subsection, and the Violation Letter repeatedly discusses the '340B statute' throughout its text." (D.I. 94 at 6) That argument is unpersuasive. The paragraph of the Violation Letter that quotes the "shall offer" requirement goes on to discuss

insist that drug manufacturers' obligations with respect to contract pharmacies flow directly from the text of § 256b(a)(1). Indeed, the government admits that the Violation Letter "relies directly on statutory text." (D.I. 93 at 11)

It is not surprising that the Violation Letter takes essentially the same legal position as the one espoused in the Opinion. The Opinion was issued by HHS' general counsel, who "[s]upervises all legal activities of the Department and its operating agencies," such as HRSA. Statement of Organization, Functions, and Delegations of Authority, 86 Fed. Reg. 6349, 6351 (Jan. 21, 2021). When HRSA sent AstraZeneca the Violation Letter, the Opinion was still in effect.[6] Accordingly, HRSA, when it sent AstraZeneca the Violation Letter, was bound to follow the Opinion. Moreover, as even the government acknowledges, the Opinion is in the administrative record supporting the Violation Letter precisely because HRSA relied on it in issuing the Violation Letter. (*See* D.I. 93 at 3) ("[T]he administrative record demonstrates that the agency considered that advice [in the Opinion] alongside other statutory interpretations . . . .")

Because the Violation Letter advances essentially the same statutory interpretation as the one contained in the Opinion, the Court's previous analysis of the 340B statute applies here with equal force. *See generally AstraZeneca*, 543 F. Supp. 3d at 58-62; *see also* D.I. 93 at 25-26 (government acknowledging that, in Violation Letter, agency "grounded its determination in the

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drug manufacturers' obligations with respect to that specific requirement. (*See* AR 1) The Violation Letter says nothing about the "purchased by" language.

[6] This Court did not vacate and set aside the Opinion until the end of the following month. (*See* D.I. 83 at 3)

340B statute's text"); Tr. at 48 (government acknowledging that "agencies can't base an enforcement action [on] guidance," but must "base an enforcement action on the statute").[7] The Court will not repeat all that analysis here but will, instead, highlight some of the key points.

Most importantly, the text of 42 U.S.C. § 256b(a) never mentions pharmacies, which is a "strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies." *AstraZeneca*, 543 F. Supp. 3d at 59. That omission is notable because another provision in § 256b explicitly refers to certain affiliates of covered entities. *See id.* at 60. It is difficult to imagine that "Congress enumerated 15 types of covered entities with a high degree of precision" and then intended to impliedly sweep in sales implicating contract pharmacies. *Id.*

Moreover, the "legislative history is of no greater assistance to the government." *Id.* In 1996, Congress considered but ultimately rejected language referring to drugs "purchased and dispensed by, or under a contract entered into for on-site pharmacy services with" covered entities. *See* S. Rep. No. 102-259 at 2 (1992).[8] The exclusion of that language indicates that

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[7] In the latest round of briefing, the government offers additional arguments in favor of its preferred statutory interpretation. (*E.g.*, D.I. 93 at 13 (explaining history of "shall offer" requirement); *id.* at 14-15 (discussing *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020)) The government does not convincingly explain why it did not make its additional arguments earlier in this case. The Court has not been persuaded that it should reconsider its interpretation of the 340B statute. *See generally ACLU v. Mukasey*, 534 F.3d 181, 187 (3d Cir. 2008) ("Under the law-of-the-case doctrine, 'when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.'") (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988)).

[8] The government seizes on a typographical error in the Court's previous memorandum opinion, where the Court mistakenly referred to congressional action occurring in 2010, even though the Court correctly cited the pertinent Senate Report with the correct date: 1992. (D.I.

Congress did not clearly intend for drug manufacturers to be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies. *See AstraZeneca*, 543 F. Supp. 3d at 60-61.[9]

Because the Violation Letter rests on essentially the same flawed statutory interpretation that the Court already rejected, the Violation Letter cannot stand. *See generally Am. Lung Ass'n*, 985 F.3d at 944; *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) ("[D]eference to an agency's interpretation of a statute is not appropriate when the agency wrongly believes that interpretation is compelled by Congress.") (internal quotation marks omitted). It does not matter that the Violation Letter does not describe the statute as "unambiguous" because the Violation Letter still evinces an understanding that its conclusion is driven by a clear statutory command with respect to drug manufacturers' obligations. (*See* Tr. at 21) Accordingly, the Court will vacate and set aside the Violation Letter, just as it vacated and set aside the Opinion.

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93 at 19; Tr. at 57; *see also AstraZeneca*, 543 F. Supp. 3d at 60) That error does not provide a basis for "this Court to reconsider its assessment of the legislative history." (D.I. 93 at 19) Without the error, the Court's analysis still would have been the same.

[9] The government maintains that the legislative history contradicts the Court's interpretation. According to the government, Congress' omission of the reference to drugs "dispensed by" pharmacies located "on-site" was intended to remove a restriction on possible dispensing mechanisms for covered entities. (D.I. 93 at 19) The Court agrees with AstraZeneca that the government's reading focuses too much on selected words in the omitted phrase rather than on the omission of the entire phrase. As AstraZeneca explains, "once Congress had dropped the (far longer and more specific) contract pharmacy language – thereby limiting 340B discounts to sales made to covered entities themselves – there was no need to specify that the covered entity who 'purchased' the drug also 'dispensed' it." (D.I. 95 at 7; *see also* Tr. at 19-20)

II. The Violation Letter Rests On The Faulty Assumption That HRSA's Position Has Not Shifted Over Time

The Violation Letter states that "HRSA has made plain, ***consistently since the issuance of its 1996 contract pharmacy guidance***, that the 340B statute requires manufacturers to honor . . . purchases [of covered outpatient drugs] regardless of the dispensing mechanism." (AR 1) (emphasis added) The Court's previous memorandum opinion explained, however, that the agency's position has not been consistent over the past 25 years. *See generally AstraZeneca*, 543 F. Supp. 3d at 54-57. Again, the Court need not rehash that entire discussion here, though a few points are worth emphasizing.

To start, the Violation Letter focuses on the "shall offer" requirement (*see* AR 1), which Congress did not add to the 340B statute until 2010. Because the 1996 and 2010 Guidance documents were issued before the "shall offer" requirement was enacted, the Violation Letter treads at least some "new ground." *See Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004). Additionally, the 1996 and 2010 Guidance documents were directed to covered entities, *see AstraZeneca*, 543 F. Supp. 3d at 55, whereas the Violation Letter is directed to a specific drug manufacturer.[10] Moreover, the 1996 and 2010 Guidance documents attempted to fill statutory gaps, *see id.*, but the Violation Letter seeks to enforce a requirement allegedly contained in the statute. Notably, AstraZeneca's new policy regarding 340B drugs would have ***complied*** with the parameters set out in the 1996 Guidance, *see id.* at 56, while the Violation

[10] HRSA issued additional violation letters to other drug manufacturers. (*See* AR 3-12) Those letters were substantially the same as the letter addressed to AstraZeneca.

Letter determines that AstraZeneca's new policy does ***not*** comport with the agency's current understanding of the 340B statute.[11]

To summarize, the Court provides the following updated table of differences among all the relevant documents:

Document	**Directed to:**	**Number of Contract Pharmacies Permitted**	**Mode of Analysis**	**Based on "Shall Offer" Requirement?**	**Does AZ's 2020 Policy Comply?**
1996 Guidance	Covered entities	One	Programmatic Gap Filling	No (did not exist)	Yes
2010 Guidance	Covered entities	Unlimited	Programmatic Gap Filling	No (did not exist)	No
2020 Opinion	Drug manufacturers	Unlimited	Statutory Interpretation	Yes (in part)	No
2021 Violation Letter	AstraZeneca	Unlimited	Enforcement	Yes	No

As this Court has explained, the Opinion was "the first document in which HHS explicitly concluded that drug manufacturers are required by statute to provide 340B drugs to multiple contract pharmacies." *Id.* at 55-56 (emphasis omitted). Now that the Opinion has been vacated and set aside, the Violation Letter (and the similar letters sent to other drug manufacturers) are the only documents concluding that the 340B statute requires drug manufacturers to facilitate sales of covered outpatient drugs for dispensing by an unlimited number of contract pharmacies.

[11] Another district court that considered the 1996 and 2010 Guidance documents agreed with this Court that the agency's "position has in fact shifted over time." *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *8 (D.D.C. Nov. 5, 2021). Yet another district court agreed that the agency has changed its views but also concluded that the agency sufficiently explained its changes. *See Sanofi-Aventis*, 2021 WL 5150464, at *50-53. This Court respectfully disagrees with that conclusion.

Despite the logical application of the reasoning in the Court's previous memorandum opinion to the Violation Letter, the government maintains that the Violation Letter is consistent with the view the agency has held all along. It states, for example, "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." (D.I. 94 at 8) (internal quotation marks and brackets omitted) That contention directly contradicts the Court's previous memorandum opinion. *See AstraZeneca*, 453 F. Supp. 3d at 57.[12] So the government asks the Court to "reconsider its conclusion" in light of the latest round of briefing (D.I. 93 at 26), but the Court has been provided no meritorious basis to do so. *See* D. Del. LR 7.1.5 (noting that motions for reconsideration should be granted "sparingly"); *see also Smith v. Meyers*, 2009 WL 5195928, at *1 (D. Del. Dec. 30, 2009) ("A motion for reconsideration is not properly grounded on a request that a court rethink a decision already made.").

Notably, the government points to a guidance document that was not cited during the previous round of briefing on the parties' earlier motions. *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110 (May 13, 1994) ("1994 Guidance"); *see also* D.I. 93 at 22 (government acknowledging that "the previous

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[12] As the Court previously explained:

> In this context, it is inaccurate to insist that manufacturers' duties have never changed, solely on the grounds that the government has always required manufacturers to accommodate all contract pharmacy arrangements that the government has permitted. Again, because the government has changed what covered entities ***may*** do, it has consequently changed what drug manufacturers ***must*** do.

AstraZeneca, 543 F. Supp. 3d at 57.

briefing before this Court did not include the 1994 guidance"). In that document, HRSA announced "final program guidelines regarding eligible covered entities." *Id.* at 25,110. The agency noted in the 1994 Guidance that "issues deal[ing] with manufacturer guidelines" were "beyond the scope" of that document. *Id.* In explaining the covered entity guidelines, the 1994 Guidance refers to a comment in which a stakeholder asked the agency not to require manufacturers "to sell directly to . . . a contract pharmacy," but only to "covered entities and their wholesalers." *Id.* at 25,111. HRSA rejected that proposal because covered entities "often use . . . contract pharmacies," and the agency did not want covered entities to be discouraged from participating in the 340B Program. *See id.*

The Court agrees with AstraZeneca that the government's reliance on the 1994 Guidance is faulty in a few ways. (*See* D.I. 95 at 10) First, the Violation Letter says that HRSA's position has been "consistent[] since the issuance of its ***1996*** contract pharmacy guidance" (AR 1) (emphasis added), a statement which plainly does not encompass the 1994 Guidance. It is a fundamental principle of administrative law that "a reviewing court . . . must judge the propriety of [agency] action solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947); *see also* Tr. at 52. Courts do not accept counsel's "*post hoc* rationalizations." *Burlington Truck Lines, Inc. v. United States,* 371 U.S. 156, 168 (1962). Second, and consistent with the Court's analysis above, the government previously told the Court expressly that the ***1996 Guidance*** was the first relevant guidance document. (D.I. 76 at 65-66)[13] Thus, the Court should not even consider the 1994 Guidance.

[13] While the government made this statement in connection with the Court's review of

In any event, the 1994 Guidance does not save the government, as it is inconsistent regarding its implications for drug manufacturers. On one hand, it suggests that drug manufacturers should be required to facilitate sales of 340B drugs dispensed by contract pharmacies. *See* 1996 Guidance, 59 Fed. Reg. at 25,111. On the other hand, it acknowledges that it is not providing any guidelines for manufacturers. *Id.* at 25,110 (explaining that "manufacturer guidelines" are "beyond the scope of this notice"). The Court hesitates to read too much into a single paragraph on drug manufacturers' duties with respect to contract pharmacies when the whole document was never intended to impose any duties on drug manufacturers.

Another reason for hesitancy in according any weight to the 1994 Guidance is that it (somewhat confusingly) refers to sales from drug manufacturers "***to*** intermediaries," such as contract pharmacies. *Id.* at 25,111 (emphasis added). In the instant litigation, however, the government acknowledges that drug manufacturers are not required to sell covered drugs ***to*** pharmacies but, instead, insists that manufacturers must facilitate arrangements in which sales are made ***to*** covered entities ***through*** contract pharmacies. (*See* D.I. 93 at 23-25; D.I. 94 at 5 n.1) That is, on the government's current view, drug manufacturers sell to covered entities – and not to contract pharmacies – even when covered entities never physically possess the covered outpatient drugs. The 1994 Guidance appears to have assumed the materially different view that manufacturers would sell covered drugs directly "to intermediaries," including pharmacies.

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the Opinion, it is fair to conclude that the government's statement also applies to the Court's review of the Violation Letter. (*See* D.I. 76 at 65-66) (Court asking if 1996 Guidance was "first relevant guidance" in context of authorization for covered entities to work with contract pharmacies)

The 1994 Guidance is even more confusing when considered alongside the 1996 and 2010 Guidance documents. If the 1994 Guidance is read as having approved arrangements involving multiple contract pharmacies, then the government would have to explain how and why it took a narrower view in the 1996 Guidance, when it limited covered entities to using only a ***single*** contract pharmacy. Later, in 2010, it similarly would have to explain how and why it was returning to a broader view. The administrative record does not reveal any credible explanation, and the government has not offered one in the arguments before this Court.

The Violation Letter's failure to acknowledge that the agency's position has shifted over time provides an independent basis for the Court to award AstraZeneca relief. *See generally Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) ("[T]he agency must at least display awareness that it is changing position and show that there are good reasons for the new policy.") (internal quotation marks omitted); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books."). Accordingly, the Court will vacate and set aside the Violation Letter.[14]

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[14] All district courts that have considered similar violation letters addressed to other drug manufacturers have at least partially vacated and/or set aside those letters, although they have done so for different reasons. *See Eli Lilly*, 2021 WL 5039566, at *22-25 (holding that violation letter was arbitrary and capricious because HRSA failed to explain its "change in position regarding its authority to enforce potential violations of the 340B statute connected to contract pharmacy arrangements"); *Sanofi-Aventis*, 2021 WL 5150464, at *34-36, 42-45 (concluding that 340B statute is ambiguous on contract pharmacy arrangement but also holding that statute does not permit manufacturers to place conditions on offers; vacating violation letters and agency's determination that manufacturers owe refunds to covered entities for further consideration of how many contract pharmacies are permitted under statute); *Novartis*, 2021 WL 5161783, at *8-9 (concluding that agency's guidance "shifted over time" and setting aside violation letters

CONCLUSION

As the Court did previously (*see* D.I. 78 at 24), the Court concludes today by emphasizing what it is ***not*** deciding. The government spends much of its opening brief stressing that a ruling against it will make it harder, or even impossible, for some patients of covered entities to obtain their medications. (*See* D.I. 93 at 3-10) The Court takes these concerns seriously and hopes that all patients of covered entities receive appropriate medical treatment. But the only issue now before this Court is whether HRSA complied with its obligations under the APA when it issued the Violation Letter. It did not.[15]

For all the reasons explained above, the Court will vacate and set aside the Violation Letter and remand to the agency for further consideration. The Court will give the parties an opportunity to provide further input on how to dispose of the claims for relief in AstraZeneca's second amended complaint and how (if at all) this case should now proceed.

An appropriate order follows.

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without declaring manufacturers' policies permissible or impermissible).

[15] Given the Court's analysis, the Court does not reach other issues presented by the parties, including whether the Violation Letter is interpretive or legislative (*see* D.I. 91 at 15-20; D.I. 94 at 10-12), whether HRSA's threatened imposition of civil monetary penalties is improper (*see* D.I. 91 at 24-26; D.I. 94 at 7), or whether the evidence in the administrative record would support the imposition of such penalties (*see* D.I. 91 at 22-24; D.I. 94 at 3-5). On the last point, the government emphasizes that it assembled a "voluminous" administrative record of over 8,000 pages, including myriad instances of AstraZeneca allegedly overcharging covered entities. (*See* D.I. 93 at 1, 3, 25; D.I. 94 at 2; Tr. at 28) Given the Court's analysis of the legal questions presented here, the bulk of the administrative record is largely immaterial to the government's case. (*See* Tr. at 75-76) ("[I]f the government is right about the statutory interpretation, then [AstraZeneca's policy] would be a problem. But if we [AstraZeneca] are right about the statutory interpretation, then it's not a problem. And all of the government's evidence points to that same central fact.")

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. XAVIER BECERRA, DANIEL J. BARRY, DIANA ESPINOSA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and HEALTH RESOURCES AND SERVICES ADMINISTRATION, Defendants.	C.A. No. 21-27-LPS

ORDER

At Wilmington, this **16th** day of **February, 2022**, consistent with and for the reasons stated in the Memorandum Opinion issued this same date,

IT IS HEREBY ORDERED that the May 17, 2021 letter from HRSA to Plaintiff (*see* D.I. 66-1 Ex. 1) is **VACATED** and **SET ASIDE**. The letter is **REMANDED** to the agency for further consideration in light of the Court's Memorandum Opinion.

IT IS FURTHER ORDERED that the parties shall meet and confer and, no later than **February 23, 2022**, submit a joint status report, setting out their proposal(s) for: (i) what relief the Court should grant Plaintiff on the claims for relief in Plaintiff's second amended complaint, based on the analysis provided in the Memorandum Opinion; and (ii) how, if at all, this case should now proceed.

UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. XAVIER BECERRA, DANIEL J. BARRY, DIANA ESPINOSA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and HEALTH RESOURCES AND SERVICES ADMINISTRATION, Defendants.	C.A. No. 21-27-LPS

ORDER AND FINAL JUDGMENT

For the reasons set forth in the Court's Memorandum Opinion and Order issued on June 16, 2021 (D.I. 78, 79) and the Court's Memorandum Opinion and Order issued on February 16, 2022 (D.I. 112, 113),

IT IS HEREBY ORDERED that:

1. With respect to AstraZeneca's first and second claims in the Second Amended Complaint (D.I. 86 ¶¶ 152-65), AstraZeneca's first motion for summary judgment (D.I. 42) is **DENIED WITHOUT PREJUDICE**, and the government's first motion for summary judgment (D.I. 55) is **DENIED WITHOUT PREJUDICE**. (*See* D.I. 83 ¶ 3)

2. With respect to AstraZeneca's third claim in the Second Amended Complaint (D.I. 86 ¶¶ 166-73), AstraZeneca's first motion for summary judgment (D.I. 42) is **GRANTED**, and the government's first motion for summary judgment (D.I. 55) is **DENIED**. (*See* D.I. 83 ¶ 2)

3. Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (D.I. 40-3 at 1-8), issued by the general counsel of HHS on December 30, 2020, is **SET ASIDE** and **VACATED**. (*See* D.I. 83 ¶ 4)

4. With respect to AstraZeneca's fourth claim in the Second Amended Complaint (D.I. 86 ¶¶ 174-80), AstraZeneca's second motion for summary judgment (D.I. 90) is **DENIED WITHOUT PREJUDICE**, and the government's second motion for summary judgment (D.I. 92) is **DENIED WITHOUT PREJUDICE**.

5. With respect to AstraZeneca's fifth and sixth claims in the Second Amended Complaint (D.I. 86 ¶¶ 181-93), AstraZeneca's second motion for summary judgment (D.I. 90) is **GRANTED**, and the government's second motion for summary judgment (D.I. 92) is **DENIED**.

6. The May 17, 2021 letter from HRSA to AstraZeneca (D.I. 66-1 Ex. 1) is **VACATED** and **SET ASIDE**, and the letter is **REMANDED** to the agency for further consideration in light of the Court's February 16, 2022 Memorandum Opinion. (*See* D.I. 113)

7. Any other requests for relief are **DENIED AS MOOT**.

8. The Clerk of the Court is directed to enter this Order and Final Judgment and to close this case forthwith.

March 11, 2022
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

No. 22-1676

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff–Appellee,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Delaware (No. 21-27)

JOINT APPENDIX
VOLUME 2 of 2 (Pages 54-283)

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CLOSED,APPEAL

U.S. District Court
District of Delaware (Wilmington)
CIVIL DOCKET FOR CASE #: 1:21-cv-00027-LPS

AstraZeneca Pharmaceuticals LP v. Xavier Becerra et al
Assigned to: Judge Leonard P. Stark
Case in other court: Third Circuit, 22-01676
Cause: 05:702 Administrative Procedure Act

Date Filed: 01/12/2021
Date Terminated: 03/11/2022
Jury Demand: None
Nature of Suit: 899 Other Statutes: Administrative Procedures Act/Review or Appeal of Agency Decision
Jurisdiction: Federal Question

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V.

Defendant

Alex M. Azar, II
in his official capacity as Secretary of the U.S. Department of Health and Human Services
TERMINATED: 07/09/2021

represented by **Rachael Westmoreland**
DOJ-Civ
Federal Programs Branch
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Defendant

Robert P. Charrow
in his official capacity as General Counsel of the U.S. Department of Health and Human Services
TERMINATED: 07/09/2021

represented by **Rachael Westmoreland**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Defendant

Thomas J. Engels
in his official capacity as Administrator of the Health Resources and Services Administration
TERMINATED: 07/09/2021

represented by **Rachael Westmoreland**
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LEAD ATTORNEY
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Defendant

U.S. Department of Health and Human Services

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Defendant

Health Resources and Services Administration

represented by **Kate Talmor**
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Rachael Westmoreland
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Defendant

Norris Cochran
TERMINATED: 07/09/2021

represented by **Rachael Westmoreland**
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LEAD ATTORNEY
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Defendant

Daniel J. Barry
in his official capacity as Acting General Counsel of the U.S. Department of Health and Human Services

represented by **Kate Talmor**
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LEAD ATTORNEY
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Rachael Westmoreland
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Defendant

Diana Espinosa
in her official capacity as Acting Administrator of the Health Resources and Services Administration

represented by **Kate Talmor**
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LEAD ATTORNEY
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Rachael Westmoreland
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Defendant

The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of

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Defendant

Xavier Becerra
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Rachael Westmoreland
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Amicus

Aaron Vandervelde

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Amicus

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER
NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER

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Date Filed	#	Docket Text
01/12/2021	1	COMPLAINT filed against Alex M. Azar, II, Robert P. Charrow, Thomas J. Engels, Health Resources and Services Administration, U.S. Department of Health and Human Services - Magistrate Consent Notice to Pltf. (Filing fee $ 402, receipt number ADEDC-3458393.) - filed by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibit A-H, # 2 Civil Cover Sheet) (sam) (Entered: 01/12/2021)
01/12/2021	2	Notice, Consent and Referral forms re: U.S. Magistrate Judge jurisdiction. (sam) (Entered: 01/12/2021)
01/12/2021	3	Disclosure Statement pursuant to Rule 7.1: identifying Corporate Parent AstraZeneca plc for AstraZeneca Pharmaceuticals LP filed by AstraZeneca Pharmaceuticals LP. (sam) (Entered: 01/12/2021)
01/12/2021	4	Summonses Issued as to Robert P. Charrow, Thomas J. Engels, Health Resources and Services Administration, U.S. Department of Health and

		Human Services, Jeffrey A. Rosen (U.S. Attorney General), and David C. Weiss (U.S. Attorney). (Attachments: # 1 Summons- Robert P. Charrow, # 2 Summons- Thomas J. Engels, # 3 Summons- Health Resources and Services Administration, # 4 Summons- U.S. Department of Health and Human Services, # 5 Summons- Jeffrey A. Rosen, # 6 Summons- David C. Weiss) (sam) (Entered: 01/12/2021)
01/13/2021	5	MOTION for Pro Hac Vice Appearance of Attorney Allon Kedem, Jeffrey L. Handwerker, Sally L. Pei and Stephen K. Wirth - filed by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Pro Hac Certification of Allon Kedem, # 2 Pro Hac Certification of Jeffrey L. Handwerker, # 3 Pro Hac Certification of Sally L. Pei, # 4 Pro Hac Certification of Stephen K. Wirth) (Silver, Daniel) (Entered: 01/13/2021)
01/14/2021	6	SUMMONS Returned Executed on 1/13/21 as to David C. Weiss, U.S. Attorney for the District of Delaware, U.S. Department of Justice. (Silver, Daniel) (Entered: 01/14/2021)
01/15/2021	7	DECLARATION *of Service of the Summons, Complaint, and Related Papers upon Defendant Alex M. Azar, II* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibits A - B)(Joyce, Alexandra) (Entered: 01/15/2021)
01/15/2021	8	DECLARATION *of Service of Summons, Complaint, and Related Papers upon Defendant Robert P. Charrow* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibits A - B)(Joyce, Alexandra) (Entered: 01/15/2021)
01/15/2021	9	DECLARATION *of Service of Summons, Complaint, and Related Papers upon Defendant U.S. Department of Health and Human Services* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibits A - B)(Joyce, Alexandra) (Entered: 01/15/2021)
01/15/2021	10	DECLARATION *of Service of Summons, Complaint, and Related Papers upon Defendant Thomas J. Engels* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibits A - B)(Joyce, Alexandra) (Entered: 01/15/2021)
01/15/2021	11	DECLARATION *of Service of Summons, Complaint, and Related Papers upon Defendant Health Resources and Services Administration* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibits A - B)(Joyce, Alexandra) (Entered: 01/15/2021)
01/19/2021	12	DECLARATION *of Service of the Summons, Complaint, and Related Papers upon Jeffrey Rosen, Acting Attorney General at the U.S. Department of Justice* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibits A - B)(Joyce, Alexandra) (Entered: 01/19/2021)
01/20/2021		Case Assigned to Judge Leonard P. Stark. Please include the initials of the Judge (LPS) after the case number on all documents filed. (rjb) (Entered: 01/20/2021)
01/20/2021		SO ORDERED, re 5 MOTION for Pro Hac Vice Appearance of Attorney Allon Kedem, Jeffrey L. Handwerker, Sally L. Pei and Stephen K. Wirth filed by AstraZeneca Pharmaceuticals LP. Signed by Judge Leonard P. Stark on 1/20/21. (ntl) (Entered: 01/20/2021)
01/20/2021		Pro Hac Vice Attorney Allon Kedem for AstraZeneca Pharmaceuticals LP added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware

		counsel shall be the registered users of CM/ECF and shall be required to file all papers. (sam) (Entered: 01/20/2021)
01/21/2021		Pro Hac Vice Attorney Jeffrey L. Handwerker for AstraZeneca Pharmaceuticals LP added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (myr) (Entered: 01/21/2021)
01/21/2021		Pro Hac Vice Attorney Sally Pei for AstraZeneca Pharmaceuticals LP added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (myr) (Entered: 01/21/2021)
01/21/2021		Pro Hac Vice Attorney Stephen K. Wirth for AstraZeneca Pharmaceuticals LP added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (kmd) (Entered: 01/21/2021)
02/12/2021	13	First AMENDED COMPLAINT against Health Resources and Services Administration, U.S. Department of Health and Human Services, Norris Cochran, Dan Barry, Diana Espinosa- filed by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibit A-M, # 2 Certificate of Service)(Silver, Daniel) (Entered: 02/12/2021)
02/12/2021	14	MOTION for Preliminary Injunction - filed by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Text of Proposed Order, # 2 Rule 7.1.1. Certification, # 3 Certificate of Service)(Silver, Daniel) (Entered: 02/12/2021)
02/12/2021	15	OPENING BRIEF in Support re 14 MOTION for Preliminary Injunction filed by AstraZeneca Pharmaceuticals LP.Answering Brief/Response due date per Local Rules is 2/26/2021. (Attachments: # 1 Certificate of Service) (Silver, Daniel) (Entered: 02/12/2021)
02/12/2021	16	DECLARATION re 14 MOTION for Preliminary Injunction *of Odalys Caprisecca* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Certificate of Service)(Silver, Daniel) (Entered: 02/12/2021)
02/12/2021	17	MOTION for Expedition - filed by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Text of Proposed Order, # 2 Rule 7.1.1. Certification, # 3 Certificate of Service)(Silver, Daniel) (Entered: 02/12/2021)
02/12/2021	18	Letter to The Honorable Leonard P. Stark from Daniel M. Silver, Esq. regarding Requesting Telephonic Status Conference - re 17 MOTION for Expedition , 14 MOTION for Preliminary Injunction . (Attachments: # 1 Certificate of Service)(Silver, Daniel) (Entered: 02/12/2021)
02/15/2021	19	ORAL ORDER: Having reviewed Plaintiff's motion for a preliminary injunction and motion to expedite, IT IS HEREBY ORDERED that: (i) Defendants shall, by no later than 5:00 p.m. on Thursday, February 18, file a letter brief, not to exceed five pages single-spaced, setting out their response to the motion to expedite and their position on how this case should proceed; (ii) Plaintiff shall, by no later than 12:00 p.m. on Friday, February 19 file a reply letter brief, not to exceed two pages single-spaced; and (iii) the Court will hold a status teleconference on Friday, February 19 at 4:30 p.m. Plaintiff

		shall make the arrangements for the call. ORDERED by Judge Leonard P. Stark on 2/15/21. (ntl) (Entered: 02/15/2021)
02/18/2021	20	NOTICE of Appearance by Rachael Westmoreland on behalf of All Defendants (Westmoreland, Rachael) (Entered: 02/18/2021)
02/18/2021	21	Letter ANSWERING BRIEF in Opposition re 17 MOTION for Expedition filed by Dan Barry, Norris Cochran, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services.Reply Brief due date per Local Rules is 2/25/2021. (Westmoreland, Rachael) (Entered: 02/18/2021)
02/19/2021	22	Letter to The Honorable Leonard P. Stark from Daniel M. Silver, Esq. regarding Motion to Expedite. (Attachments: # 1 Exhibit A)(Silver, Daniel) (Entered: 02/19/2021)
02/19/2021		Minute Entry for proceedings held before Judge Leonard P. Stark - Telephone Conference held on 2/19/2021. (Court Reporter B. Gaffigan.) (ntl) (Entered: 02/19/2021)
02/23/2021	23	STIPULATION and Proposed Order re Joint Status Report and Proposed Briefing Schedule on Cross-Motions re Telephone Conference by AstraZeneca Pharmaceuticals LP. (Silver, Daniel) (Entered: 02/23/2021)
02/23/2021	24	DECLARATION *of Service of Dan Barry made on February 15, 2021* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibit A-B)(Joyce, Alexandra) (Entered: 02/23/2021)
02/23/2021	25	DECLARATION *of Service of Norris Cochran made on February 15, 2021* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibit A-B)(Joyce, Alexandra) (Entered: 02/23/2021)
02/23/2021	26	DECLARATION *of Service for Diana Espinosa made on February 15, 2021* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibit A-B)(Joyce, Alexandra) (Entered: 02/23/2021)
02/23/2021	27	DECLARATION *of Service for U.S. Department of Heath and Human Services made on February 15, 2021* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibit A-B)(Joyce, Alexandra) (Entered: 02/23/2021)
02/23/2021	28	DECLARATION *of Service for Health Resources and Services Administration made on February 15, 2021* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibit A-B)(Joyce, Alexandra) (Entered: 02/23/2021)
02/23/2021	29	DECLARATION *of Service for Monty Wilkinson made on February 15, 2021* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibit A-B)(Joyce, Alexandra) (Entered: 02/23/2021)
02/23/2021	30	SUMMONS Returned Executed on 2/15/2021 as to David C. Weiss, U.S. Attorney for the District of Delaware, U.S. Department of Justice. (Joyce, Alexandra) (Entered: 02/23/2021)
02/24/2021	31	SO ORDERED, re 23 STIPULATION and Proposed Order re Joint Status Report and Proposed Briefing Schedule on Cross-Motions -- An Oral Argument is set for 6/10/2021 at 1:30 PM in Courtroom 6B. Signed by Judge Leonard P. Stark on 2/24/21. (ntl) (Entered: 02/24/2021)

02/25/2021	32	Official Transcript of Telephone Conference on held on February 19, 2021 before Chief Judge Leonard P. Stark. Court Reporter Brian Gaffigan, email: gaffigan@verizon.net. Transcript may be viewed at the court public terminal or order/purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date, it may be obtained through PACER. Redaction Request due 3/18/2021. Redacted Transcript Deadline set for 3/29/2021. Release of Transcript Restriction set for 5/26/2021. (bpg) (Entered: 02/25/2021)
02/26/2021	33	MOTION to Intervene - filed by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of Health-System Pharmacists. (Butcher, Rebecca) (Entered: 02/26/2021)
02/26/2021	34	DECLARATION re 33 MOTION to Intervene by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J, # 11 Exhibit K, # 12 Exhibit L, # 13 Exhibit M, # 14 Exhibit N)(Butcher, Rebecca) (Entered: 02/26/2021)
02/26/2021	35	Disclosure Statement pursuant to Rule 7.1: identifying Corporate Parent The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of Health-System Pharmacists for The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of filed by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of. (Butcher, Rebecca) (Entered: 02/26/2021)
03/10/2021	36	MOTION for Pro Hac Vice Appearance of Attorney William B. Schultz, Margaret M. Dotzel, Casey Trombley-Shapiro Jonas, and Ariella Muller - filed by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of. (Attachments: # 1 Certification of William B. Schultz, # 2 Certification of Margaret M. Dotzel, # 3 Certification of Casey Trombley-Shapiro Jonas, # 4 Certification of Ariella Muller)(Butcher, Rebecca) (Entered: 03/10/2021)
03/10/2021		SO ORDERED, re 36 MOTION for Pro Hac Vice Appearance of Attorney William B. Schultz, Margaret M. Dotzel, Casey Trombley-Shapiro Jonas, and Ariella Muller filed by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of. Signed by Judge Leonard P. Stark on 3/10/21. (ntl) (Entered: 03/10/2021)
03/12/2021	37	ANSWERING BRIEF in Opposition re 33 MOTION to Intervene filed by AstraZeneca Pharmaceuticals LP.Reply Brief due date per Local Rules is 3/19/2021. (Silver, Daniel) (Entered: 03/12/2021)

03/12/2021	38	MEMORANDUM in Opposition re 33 MOTION to Intervene filed by Dan Barry, Norris Cochran, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services.Reply Brief due date per Local Rules is 3/19/2021. (Westmoreland, Rachael) (Entered: 03/12/2021)
03/19/2021	39	REPLY to Response to Motion re 33 MOTION to Intervene filed by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of. (Cree, Jennifer) (Entered: 03/19/2021)
03/23/2021	40	NOTICE of Filing Certified Administrative Record by Dan Barry, Norris Cochran, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services (Attachments: # 1 Certification, # 2 Index, # 3 Part 1, # 4 Part 2, # 5 Part 3, # 6 Part 4, # 7 Part 5)(Westmoreland, Rachael) (Entered: 03/23/2021)
03/24/2021	41	REQUEST for Oral Argument by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of. (Cree, Jennifer) (Entered: 03/24/2021)
04/01/2021		Pro Hac Vice Attorneys William B. Schultz, Margaret M. Dotzel, Casey T.S. Jonas, Ariella Muller for the American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (kmd) (Entered: 04/01/2021)
04/13/2021	42	MOTION for Summary Judgment - filed by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Text of Proposed Order)(Silver, Daniel) (Entered: 04/13/2021)
04/13/2021	43	OPENING BRIEF in Support re 42 MOTION for Summary Judgment filed by AstraZeneca Pharmaceuticals LP.Answering Brief/Response due date per Local Rules is 4/27/2021. (Attachments: # 1 Exhibit A)(Silver, Daniel) (Entered: 04/13/2021)
04/14/2021	44	MOTION (Unopposed Motion for Leave to File Brief as Amicus Curiae) - filed by Aaron Vandervelde. (Attachments: # 1 Exhibit 1, # 2 Text of Proposed Order)(Balick, Steven) (Entered: 04/14/2021)
04/16/2021	45	ORDER re 44 Unopposed Motion for Leave to File Brief as Amicus Curiae filed by Aaron Vandervelde. Signed by Judge Leonard P. Stark on 4/16/21. (ntl) (Entered: 04/16/2021)
04/16/2021	46	BRIEF of 340B Expert Aaron Vandervelde as Amicus Curiae and not in Support of any Party by Aaron Vandervelde. (Attachments: # 1 Exhibit A-E) (Balick, Steven) Modified on 4/16/2021 (ntl). (Entered: 04/16/2021)
04/20/2021	47	ORAL ORDER: IT IS HEREBY ORDERED that the Court will hear argument by teleconference on the motion to intervene (D.I. 33) on April 26, 2021 beginning at 11:00 a.m. Each side will be allocated up to fifteen (15)

		minutes to present its argument. Any party wishing to refer to slides or other materials shall provide a copy to the Court no later than 4:00 p.m. the day before the hearing. The parties can access the teleconference by dialing 877-336-1829 and using the access code 1408971. ORDERED by Judge Leonard P. Stark on 4/20/21. (ntl) (Entered: 04/20/2021)
04/21/2021	48	ORAL ORDER: For the upcoming argument by teleconference on the motion to intervene (D.I. 33) on April 26, 2021, IT IS HEREBY ORDERED that the allocated time for each side is increased to 20 minutes. The proposed intervenors will have 20 minutes to argue in favor of their motion, and Plaintiff and Defendants will also have 20 minutes (divided between them as they choose) to oppose the motion. ORDERED by Judge Leonard P. Stark on 4/21/21. (ntl) (Entered: 04/21/2021)
04/26/2021	49	NOTICE of Appearance by Jennifer L. Cree on behalf of The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of (Cree, Jennifer) (Entered: 04/26/2021)
04/26/2021		Minute Entry for proceedings held before Judge Leonard P. Stark - Telephone Conference held on 4/26/2021. (Court Reporter B. Gaffigan.) (ntl) (Entered: 04/26/2021)
04/26/2021	50	ORAL ORDER: For the reasons explained during today's teleconference, IT IS HEREBY ORDERED that: (i) the Proposed Intervenors' motion to intervene (D.I. 33) is DENIED, and (ii) the parties and the Proposed Intervenors shall meet and confer and, no later than April 28, 2021, submit a joint status report. ORDERED by Judge Leonard P. Stark on 4/26/21. (ntl) (Entered: 04/26/2021)
04/28/2021	51	Official Transcript of Oral Argument by Telephone Conference held on April 26, 2021 before Chief Judge Leonard P. Stark. Court Reporter Brian Gaffigan, email: gaffigan@verizon.net. Transcript may be viewed at the court public terminal or ordered/purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date, it may be obtained through PACER. Redaction Request due 5/19/2021. Redacted Transcript Deadline set for 6/1/2021. Release of Transcript Restriction set for 7/27/2021.(bpg) (Entered: 04/28/2021)
04/28/2021	52	Joint STATUS REPORT by AstraZeneca Pharmaceuticals LP. (Silver, Daniel) (Entered: 04/28/2021)
05/03/2021	53	ORAL ORDER: Having considered the joint status report (D.I. 52), IT IS HEREBY ORDERED that: (i) AHA Amici may file an amicus brief of no more than 20 pages no later than May 4, 2021, as the parties and AHA Amici agreed, and (ii) AHA Amici may file an amicus brief in reply of no more than 5 pages in accordance with the previously set schedule (D.I. 31). Any party or other amicus may seek leave to file additional short briefs (beyond those provided for by the current schedule) if they believe there is good cause to do so. IT IS FURTHER ORDERED that the oral argument currently scheduled for June 10, 2021, is rescheduled for June 7 beginning at 9:30 a.m. Argument will be held by videoconference, unless the parties jointly request that it be converted to an in-person proceeding. Plaintiff and Defendants will each be

		allocated 1 hour for argument and AHA Amici will have 15 minutes. Plaintiff and Defendants shall make arrangements for the videoconference, and no later than June 3, they shall submit by email to the Court (and not docket) a single letter containing all information for both the Court and the public to access the videoconference, including any necessary meeting numbers or passcodes. The Court will subsequently docket the information for public access, which shall permit the public to see and hear the argument without any ability to participate in or disrupt the proceedings. ORDERED by Judge Leonard P. Stark on 5/3/21. (ntl) (Entered: 05/03/2021)
05/04/2021	54	OPENING BRIEF in Support *Brief of American Hospital Association, 340B Health, Americas Essential Hospitals, Association of American Medical Colleges, Childrens Hospital Association, and American Society of Health-System Pharmacists as Amici Curiae in Support of Defendants* filed by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of.Answering Brief/Response due date per Local Rules is 5/18/2021. (Butcher, Rebecca) (Entered: 05/04/2021)
05/04/2021	55	MOTION to Dismiss for Failure to State a Claim , MOTION to Dismiss for Lack of Jurisdiction Over the Subject Matter , MOTION for Summary Judgment - filed by Dan Barry, Norris Cochran, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services. (Westmoreland, Rachael) (Entered: 05/04/2021)
05/04/2021	56	BRIEF (Combined Opening and Answering) re 55 MOTION to Dismiss for Failure to State a Claim MOTION to Dismiss for Lack of Jurisdiction Over the Subject Matter MOTION for Summary Judgment , 42 MOTION for Summary Judgment filed by Dan Barry, Norris Cochran, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services.Answering Brief/Response due date per Local Rules is 5/18/2021. Reply Brief due date per Local Rules is 5/11/2021. (Attachments: # 1 Exhibit Decl. of Kate Talmor)(Westmoreland, Rachael) (Entered: 05/04/2021)
05/04/2021	57	DECLARATION re 54 Opening Brief in Support,, *Of Rebecca L. Butcher in Support of Brief of American Hospital Association, 340B Health, Americas Essential Hospitals, Association of American Medical Colleges, Childrens Hospital Association, and American Society of Health-System Pharmacists as Amici Curiae in Support of Defendants* by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G)(Butcher, Rebecca) (Entered: 05/04/2021)
05/04/2021	58	MOTION for Leave to permit Leslie Spoltore to File an Amicus Brief - filed by NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER. (Spoltore, Leslie) (Entered: 05/04/2021)
05/04/2021	59	REPLY BRIEF *In Opposition To Plaintiffs Motion For Summary Judgement* filed by NATIONAL ASSOCIATION OF COMMUNITY HEALTH

		CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER. (Attachments: # 1 Appendix Index of Exhibits, # 2 Exhibit Exhibit A-K)(Spoltore, Leslie) (Entered: 05/04/2021)
05/04/2021	60	Disclosure Statement pursuant to Rule 7.1: No Parents or Affiliates Listed filed by NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER. (Spoltore, Leslie) (Entered: 05/04/2021)
05/05/2021	61	MOTION for Pro Hac Vice Appearance of Attorney Ronald S. Connelly - filed by NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER. (Spoltore, Leslie) (Entered: 05/05/2021)
05/05/2021	62	MOTION for Pro Hac Vice Appearance of Attorney Matthew Sidney Freedus - filed by NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER. (Spoltore, Leslie) (Entered: 05/05/2021)
05/05/2021	63	ORAL ORDER: Having considered the unopposed motion to file an amicus brief (D.I. 58), IT IS HEREBY ORDERED that the motion is GRANTED. ORDERED by Judge Leonard P. Stark on 5/5/21. (ntl) (Entered: 05/05/2021)
05/06/2021		SO ORDERED, re 62 MOTION for Pro Hac Vice Appearance of Attorney Matthew Sidney Freedus filed by NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER; 61 MOTION for Pro Hac Vice Appearance of Attorney Ronald S. Connelly filed by NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER. Signed by Judge Leonard P. Stark on 5/6/21. (ntl) (Entered: 05/06/2021)
05/14/2021	64	ORAL ORDER: IT IS HEREBY ORDERED that the hearing currently scheduled for June 7, 2021 (see D.I. 53), is rescheduled for June 9, starting at 12:30 p.m. The Court will recess from 2:00 to 4:00 p.m. to attend to other matters. Ordered by Judge Leonard P. Stark on 5/14/2021. (etg) (Entered: 05/14/2021)
05/14/2021	65	BRIEF (Combined Answering and Reply) re 55 MOTION to Dismiss for Failure to State a Claim MOTION to Dismiss for Lack of Jurisdiction Over the Subject Matter MOTION for Summary Judgment , 42 MOTION for Summary Judgment filed by AstraZeneca Pharmaceuticals LP.Reply Brief due date per Local Rules is 5/21/2021. (Silver, Daniel) (Entered: 05/14/2021)
05/19/2021	66	Emergency MOTION for Administrative Stay and, in the Alternative, for Expedition - filed by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibits 1-2, # 2 Local Rule 7.1.1 Certification, # 3 Proposed Order)(Silver, Daniel) (Entered: 05/19/2021)

05/19/2021	67	Letter to The Honorable Leonard P. Stark from Daniel M. Silver, Esq. regarding AstraZeneca's Emergency Motion for an Adminstrative Stay, or in the Alternative, for Expedition - re 66 Emergency MOTION for Administrative Stay and, in the Alternative, for Expedition . (Silver, Daniel) (Entered: 05/19/2021)
05/20/2021	68	ORAL ORDER: Having reviewed Plaintiff's emergency motion for an administrative stay (D.I. 66), IT IS HEREBY ORDERED that Defendants shall file a letter brief setting out their position, not to exceed five pages, no later than tomorrow, May 21 at 11:00 a.m., to which Plaintiff may reply, with a letter brief not to exceed two pages, no later than tomorrow at 6:00 p.m. Thereafter, the Court will determine how this case will proceed. ORDERED by Judge Leonard P. Stark on 5/20/21. (ntl) (Entered: 05/20/2021)
05/21/2021	69	Letter ANSWERING BRIEF in Opposition re 66 Emergency MOTION for Administrative Stay and, in the Alternative, for Expedition filed by Alex M. Azar, II, Dan Barry, Robert P. Charrow, Norris Cochran, Thomas J. Engels, Diana Espinosa, Health Resources and Services Administration.Reply Brief due date per Local Rules is 5/28/2021. (Talmor, Kate) (Entered: 05/21/2021)
05/21/2021	70	Letter to The Honorable Leonard P. Stark from Daniel M. Silver, Esq. regarding Motion for Administrative Stay or Expedition. (Silver, Daniel) (Entered: 05/21/2021)
05/24/2021	71	ORAL ORDER: Having considered the parties' briefing (see D.I. 66, 69, 70), IT IS HEREBY ORDERED that Plaintiff's motion for administrative stay and, in the alternative, for expedition (D.I. 66) is GRANTED IN PART, to the limited extent that the motions hearing set for June 9, 2021 is expedited and RESCHEDULED for Thursday, May 27 beginning at 1:00 p.m. The parties shall provide a joint letter with videoconference information (see D.I. 53) no later than May 25. In all other respects, Plaintiff's motion is DENIED. ORDERED by Judge Leonard P. Stark on 5/24/21. (ntl) (Entered: 05/24/2021)
05/24/2021	72	REPLY BRIEF *of American Hospital Association, 340B Health, Americas Essential Hospitals, Association of American Medical Colleges, Childrens Hospital Association, and American Society of Health-System Pharmacists as Amici Curiae in Support of Defendants* filed by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of. (Butcher, Rebecca) (Entered: 05/24/2021)
05/24/2021	73	DECLARATION re 72 Reply Brief, *of Rebecca L. Butcher in Support of Reply Brief of American Hospital Association, 340B Health, Americas Essential Hospitals, Association of American Medical Colleges, Childrens Hospital Association, and American Society of Health-System Pharmacists as Amici Curiae in Support of Defendants* by The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the American Society of. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F)(Butcher, Rebecca) (Entered: 05/24/2021)
05/24/2021	74	REPLY BRIEF re 55 MOTION to Dismiss for Failure to State a Claim MOTION to Dismiss for Lack of Jurisdiction Over the Subject Matter

		MOTION for Summary Judgment filed by Dan Barry, Norris Cochran, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services. (Attachments: # 1 Exhibit 1)(Westmoreland, Rachael) (Entered: 05/24/2021)
05/26/2021	75	Remark regarding the May 27, 2021 hearing -- 1) The Public can access the hearing by copying and pasting the following link into their web browser: https://mccarter.zoom.us/j/93933335669?pwd=QytUaG9iaEQ3b0FHTDNVY1dRME NRQT09 2) When prompted, enter the following code: 196063 3) Thereafter, the Public should be granted access to the hearing. Persons on this line will not be able to speak or otherwise participate during the hearing. 4) If the Public has any issues with the videoconference link, they may instead access the meeting using the following dial-in and passcode: Dial-In: 1-312-626-6799 Code: 939 3333 5669 One tap mobile dial-in: 13126266799,,93933335669# Again, persons on this line will not be able to speak or otherwise participate during the hearing, but are asked to mute their lines out of an abundance of caution. (ntl) (Entered: 05/26/2021)
05/27/2021		Minute Entry for proceedings held before Judge Leonard P. Stark - Oral Argument (by video) held on 5/27/2021. (Court Reporter B. Gaffigan.) (ntl) (Entered: 05/27/2021)
05/28/2021	76	Official Transcript of Zoom Oral Argument Hearing held on May 27, 2021 before Chief Judge Leonard P. Stark. Court Reporter Brian Gaffigan, email: gaffigan@verizon.net. Transcript may be viewed at the court public terminal or ordered/purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date, it may be obtained through PACER. Redaction Request due 6/18/2021. Redacted Transcript Deadline set for 6/28/2021. Release of Transcript Restriction set for 8/26/2021. (bpg) (Entered: 05/28/2021)
06/01/2021	77	Letter to The Honorable Leonard P. Stark from Daniel M. Silver, Esq.. (Silver, Daniel) (Entered: 06/01/2021)
06/16/2021	78	MEMORANDUM OPINION re 55 motion to dismiss. Signed by Judge Leonard P. Stark on 6/16/21. (ntl) (Entered: 06/16/2021)
06/16/2021	79	ORDER re 78 Memorandum Opinion -- 55 MOTION to Dismiss is DENIED in part and GRANTED in part. Signed by Judge Leonard P. Stark on 6/16/21. (ntl) (Entered: 06/16/2021)
06/18/2021	80	STIPULATION TO EXTEND TIME the Parties' Deadline to Submit a Joint Status Report to June 21, 2021 - filed by AstraZeneca Pharmaceuticals LP. (Silver, Daniel) (Entered: 06/18/2021)
06/18/2021	81	NOTICE of by Dan Barry, Norris Cochran, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services (Attachments: # 1 Exhibit 1)(Westmoreland, Rachael) (Entered: 06/18/2021)
06/21/2021	82	Joint STATUS REPORT by AstraZeneca Pharmaceuticals LP. (Silver, Daniel) (Entered: 06/21/2021)
06/21/2021		SO ORDERED, re 80 STIPULATION TO EXTEND TIME the Parties'

		Deadline to Submit a Joint Status Report to June 21, 2021 filed by AstraZeneca Pharmaceuticals LP. Signed by Judge Leonard P. Stark on 6/21/21. (ntl) (Entered: 06/21/2021)
06/24/2021		Pro Hac Vice Attorney Ronald S. Connelly for NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (twk) (Entered: 06/24/2021)
06/30/2021	83	MEMORANDUM ORDER re 42 MOTION for Summary Judgment filed by AstraZeneca Pharmaceuticals LP, 55 MOTION to Dismiss for Failure to State a Claim, MOTION to Dismiss for Lack of Jurisdiction Over the Subject Matter, MOTION for Summary Judgment filed by Diana Espinosa, Norris Cochran, Health Resources and Services Administration, Dan Barry, U.S. Department of Health and Human Services. Signed by Judge Leonard P. Stark on 6/30/2021. (etg) (Entered: 06/30/2021)
07/06/2021	84	Joint STATUS REPORT *and Stipulation and [Proposed] Order Regarding Second Amended Complaint and Briefing Schedule* by AstraZeneca Pharmaceuticals LP. (Silver, Daniel) (Entered: 07/06/2021)
07/07/2021	85	SO ORDERED re 84 Joint STATUS REPORT and Stipulation and [Proposed] Order Regarding Second Amended Complaint and Briefing Schedule by AstraZeneca Pharmaceuticals LP. The Court shall hear Oral Argument on the motions on 9/14/2021 at 01:30 PM in Courtroom 6B before Judge Leonard P. Stark. Each side will have one hour. Signed by Judge Leonard P. Stark on 7/7/2021. (etg) (Entered: 07/07/2021)
07/09/2021	86	Second AMENDED COMPLAINT against Dan Barry, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services, Xavier Becerra- filed by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibits A-M)(Silver, Daniel) (Entered: 07/09/2021)
07/09/2021	87	EXHIBIT re 86 Amended Complaint, *(Redline Comparison of First Amended Complaint and Second Amended Complaint)* by AstraZeneca Pharmaceuticals LP. (Silver, Daniel) (Entered: 07/09/2021)
07/15/2021	88	MOTION for Leave to File *(Unopposed) Administrative Record Manually* - filed by Daniel J. Barry, Xavier Becerra, Diana Espinosa, Health Resources and Services Administration. (Attachments: # 1 Index of Certified Administrative Record, # 2 Certification of Administrative Record) (Westmoreland, Rachael) (Entered: 07/15/2021)
07/16/2021	89	ORAL ORDER: Having considered the government's unopposed motion to manually file the administrative record (D.I. 88), IT IS HEREBY ORDERED that the motion is GRANTED. ORDERED by Judge Leonard P. Stark on 7/16/21. (ntl) (Entered: 07/16/2021)
07/23/2021	90	Second MOTION for Summary Judgment - filed by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Text of Proposed Order)(Silver, Daniel) (Entered: 07/23/2021)

07/23/2021	91	OPENING BRIEF in Support re 90 Second MOTION for Summary Judgment filed by AstraZeneca Pharmaceuticals LP.Answering Brief/Response due date per Local Rules is 8/6/2021. (Silver, Daniel) (Entered: 07/23/2021)
07/23/2021	92	MOTION for Summary Judgment - filed by Daniel J. Barry, Xavier Becerra, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services. (Westmoreland, Rachael) (Entered: 07/23/2021)
07/23/2021	93	OPENING BRIEF in Support re 92 MOTION for Summary Judgment filed by Daniel J. Barry, Xavier Becerra, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services.Answering Brief/Response due date per Local Rules is 8/6/2021. (Westmoreland, Rachael) (Entered: 07/23/2021)
08/06/2021	94	ANSWERING BRIEF in Opposition re 90 Second MOTION for Summary Judgment filed by Daniel J. Barry, Xavier Becerra, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services.Reply Brief due date per Local Rules is 8/13/2021. (Westmoreland, Rachael) (Entered: 08/06/2021)
08/06/2021	95	BRIEF (Combined Answering and Reply) re 92 MOTION for Summary Judgment , 90 Second MOTION for Summary Judgment filed by AstraZeneca Pharmaceuticals LP.Reply Brief due date per Local Rules is 8/13/2021. (Silver, Daniel) (Entered: 08/06/2021)
08/12/2021	96	ORAL ORDER: In light of the parties' agreed-upon case schedule (see D.I. 31), the Court's subsequent rulings on the merits (see D.I. 78, 79, 83), and the withdrawal of HHS's Advisory Opinion 20-06 (see D.I. 81), IT IS HEREBY ORDERED that AstraZeneca's motion for a preliminary injunction (D.I. 14) is DENIED WITHOUT PREJUDICE, and AstraZeneca's motion for expedition (D.I. 17) is DENIED AS MOOT. ORDERED by Judge Leonard P. Stark on 8/12/21. (ntl) (Entered: 08/12/2021)
08/16/2021	97	ORAL ORDER: IT IS HEREBY ORDERED that the oral argument on September 14, 2021 at 1:30 p.m. will be held remotely by videoconference. No later than September 13 at 4:00 p.m. the parties shall provide chambers with (i) the necessary information for it to connect to the hearing and (ii) a copy of any slides or demonstratives to which they may refer during the hearing. At the same time, the parties shall docket a public letter providing the necessary information to allow any member of the public to attend the hearing without having the ability to speak or interrupt the proceedings. ORDERED by Judge Leonard P. Stark on 8/16/21. (ntl) (Entered: 08/16/2021)
08/24/2021	98	ORAL ORDER: IT IS HEREBY ORDERED that the oral argument (by video) scheduled for September 14, 2021 is RESCHEDULED for October 18, 2021 at 3:00 p.m. ORDERED by Judge Leonard P. Stark on 8/24/21. (ntl) (Entered: 08/24/2021)
09/02/2021	99	NOTICE of Appearance by Kate Talmor on behalf of All Defendants (Talmor, Kate) (Entered: 09/02/2021)
09/24/2021	100	Letter to The Honorable Leonard P. Stark from Daniel M. Silver, Esq. regarding Important Developments to the Litigation. (Attachments: # 1

		Exhibit A-C)(Silver, Daniel) (Entered: 09/24/2021)
10/14/2021	101	Letter to The Honorable Leonard P. Stark from Daniel M. Silver, Esq. - re 97 Order,,. (Silver, Daniel) (Main Document 101 replaced on 10/14/2021) (ntl). (Entered: 10/14/2021)
10/14/2021		CORRECTING ENTRY: Corrected letter added to D.I. 101 per request of counsel. (ntl) (Entered: 10/14/2021)
10/15/2021	102	Letter to The Honorable Leonard P. Stark from Daniel M. Silver, Esq. regarding Case Developments. (Attachments: # 1 Attachment - Court Ruling) (Silver, Daniel) (Entered: 10/15/2021)
10/18/2021		Minute Entry for proceedings held before Judge Leonard P. Stark - Oral Argument held (by video) on 10/18/2021. (Court Reporter B. Gaffigan.) (ntl) (Entered: 10/20/2021)
10/22/2021	103	Official Transcript of Video Conference held on October 18, 2021 before Judge Leonard P. Stark. Court Reporter Brian Gaffigan, email: gaffigan@verizon.net. Transcript may be viewed at the court public terminal or ordered/purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date, it may be obtained through PACER. Redaction Request due 11/12/2021. Redacted Transcript Deadline set for 11/22/2021. Release of Transcript Restriction set for 1/20/2022. (bpg) (Entered: 10/22/2021)
10/25/2021	104	Joint STATUS REPORT by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 PhRMA v. Becerra Complaint (Referenced In Joint Status Report)) (Silver, Daniel) (Entered: 10/25/2021)
10/26/2021	105	ORAL ORDER: Having considered the parties' joint status report (D.I. 104), in which both sides requested the expeditious resolution of the parties' cross-motions for summary judgment (D.I. 90, 92), IT IS HEREBY ORDERED that the parties shall meet and confer and, no later than November 12, file another joint status report regarding any case developments. ORDERED by Judge Leonard P. Stark on 10/26/21. (ntl) (Entered: 10/26/2021)
11/02/2021	106	NOTICE of Supplemental Authority from Related Case by Daniel J. Barry, Xavier Becerra, Diana Espinosa, Health Resources and Services Administration, U.S. Department of Health and Human Services (Attachments: # 1 Exhibit Lilly Order on SJ)(Talmor, Kate) (Entered: 11/02/2021)
11/03/2021	107	Letter to The Honorable Leonard P. Stark from Daniel M. Silver regarding Defendants' Notice of Supplemental Authoritiy (DI 106). (Silver, Daniel) (Entered: 11/03/2021)
11/12/2021	108	Joint STATUS REPORT by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 Exhibit A, # 2 Exhibit B)(Silver, Daniel) (Entered: 11/12/2021)
01/05/2022	109	ORAL ORDER: Having considered the parties' joint status report (D.I. 108), IT IS HEREBY ORDERED that the parties shall meet and confer and, no later than January 7, 2022, submit another joint status report. The joint status report may include any updates that the parties would like to share with the Court, including any further developments in related cases in other district courts, in the ADR proceedings, or in any interactions with the Office

		of the Inspector General regarding potential civil monetary penalties. ORDERED by Judge Leonard P. Stark on 1/5/22. (ntl) (Entered: 01/05/2022)
01/07/2022	110	Joint STATUS REPORT by AstraZeneca Pharmaceuticals LP. (Joyce, Alexandra) (Entered: 01/07/2022)
02/14/2022	111	Letter to The Honorable Leonard P. Stark from Daniel M. SIlver, Esq. regarding further developments relevant to the Court's disposition of the litigation. (Attachments: # 1 Opinion)(Silver, Daniel) (Entered: 02/14/2022)
02/16/2022	112	MEMORANDUM OPINION. Signed by Judge Leonard P. Stark on 2/16/22. (ntl) (Entered: 02/16/2022)
02/16/2022	113	ORDER re 112 Memorandum Opinion -- IT IS HEREBY ORDERED that the May 17, 2021 letter from HRSA to Plaintiff (see D.I. 66-1 Ex. 1) is VACATED and SET ASIDE. The letter is REMANDED to the agency for further consideration in light of the Court's Memorandum Opinion. Signed by Judge Leonard P. Stark on 2/16/22. (ntl) (Entered: 02/16/2022)
02/23/2022	114	Joint STATUS REPORT *Pursuant to the Court's Memorandum Opinion and Order (D.I. Nos. 112 and 113)* by AstraZeneca Pharmaceuticals LP. (Attachments: # 1 AstraZeneca's Proposed Order and Final Judgment) (Silver, Daniel) (Entered: 02/23/2022)
03/11/2022	115	ORDER AND FINAL JUDGMENT: 1. With respect to AstraZeneca's first and second claims in the Second Amended Complaint (D.I. 86, para. 152-65), AstraZeneca's first motion for summary judgment (D.I. 42) is DENIED WITHOUT PREJUDICE, and the government's first motion for summary judgment (D.I. 55) is DENIED WITHOUT PREJUDICE. (See D.I. 83, para. 3) 2. With respect to AstraZeneca's third claim in the Second Amended Complaint (D.I. 86, para. 166-73), AstraZeneca's first motion for summary judgment (D.I. 42) is GRANTED, and the government's first motion for summary judgment (D.I. 55) is DENIED. (See D.I. 83) 3. Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (D.I. 40-3 at 1-8), issued by the general counsel of HHS on December 30, 2020, is SET ASIDE and VACATED. (See D.I. 83 para. 4) 4. With respect to AstraZeneca's fourth claim in the Second Amended Complaint (D.I. 86, para. 174-80), AstraZeneca's second motion for summary judgment (D.I. 90) is DENIED WITHOUT PREJUDICE, and the government's second motion for summary judgment (D.I. 92) is DENIED WITHOUT PREJUDICE. 5. With respect to AstraZeneca' s fifth and sixth claims in the Second Amended Complaint (D.I. 86 para. 181-93), AstraZeneca's second motion for summary judgment (D.I. 90) is GRANTED, and the government's second motion for summary judgment (D.I. 92) is DENIED. 6. The May 17, 2021 letter from HRSA to AstraZeneca (D.I. 66-1 Ex. 1) is VACATED and SET ASIDE, and the letter is REMANDED to the agency for further consideration in light of the Court's February 16, 2022 Memorandum Opinion. (See D.I. 113) 7. Any other requests for relief are DENIED AS MOOT. 8. The Clerk of the Court is directed to enter this Order and Final Judgment and to close this case forthwith. ***Civil Case Terminated. Signed by Judge Leonard P. Stark on 3/11/22. (ntl) (Entered: 03/11/2022)
04/12/2022	116	NOTICE OF APPEAL of 113 Order, 115 Order, 112 Memorandum Opinion. Appeal filed by Alex M. Azar, II, Daniel J. Barry, Xavier Becerra, Robert P.

		Charrow, Norris Cochran, Thomas J. Engels, Diana Espinosa. (Talmor, Kate) (Entered: 04/12/2022)
04/18/2022	117	NOTICE of Docketing Record on Appeal from USCA for the Third Circuit re 116 Notice of Appeal (Third Circuit) filed by Daniel J. Barry, Xavier Becerra, Diana Espinosa, Thomas J. Engels, Norris Cochran, Robert P. Charrow, Alex M. Azar, II. USCA Case Number 22-1676. USCA Case Manager: Kirsi (DOCUMENT IS RESTRICTED AND CAN ONLY BE VIEWED BY COURT STAFF) (kr) (Entered: 04/18/2022)

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Billable Pages:	16	**Cost:**	

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* ALEX M. AZAR II, in his official capacity as Secretary of the U.S. Department of Health and Human Services; ROBERT P. CHARROW, in his official capacity as General Counsel of the U.S. Department of Health and Human Services; THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; *and* HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Defendants*.	CIV. NO. _____ ADMINISTRATIVE PROCEDURE ACT REVIEW OF AGENCY DECISION

COMPLAINT

COMES NOW Plaintiff AstraZeneca Pharmaceuticals LP and alleges as follows:

INTRODUCTION

1. The 340B Drug Pricing Program, 42 U.S.C. § 256b (Section 340B), caps the prices that drug manufacturers can charge for out-patient medications sold to certain healthcare facilities, called "covered entities," that cater to underserved populations. Because Section 340B is targeted at assisting these vulnerable populations—not providing windfalls to for-profit corporations—Congress carefully circumscribed the types of "covered entities" that may participate in the

program, specifically identifying by statute fifteen eligible categories. Off-site, for-profit pharmacy chains (like CVS or Walgreens) conspicuously were *not* included on the list of covered entities.

2. In 2010, however, the Health Resources and Services Administration (HRSA), the agency within the U.S. Department of Health and Human Services (HHS) that administers Section 340B, issued nonbinding "interpretive" guidance suggesting a transformation of the scheme that Congress created. The guidance stated that covered entities could partner with an unlimited number of off-site, for-profit contract pharmacies that would obtain discounted prescription medicines for dispensing to eligible patients. Over the ensuing decade, use of contract pharmacies has exploded to more than 100,000 documented arrangements. That sharp increase in the role of for-profit pharmacies in the 340B program has led to the very abuses and diversion that Congress feared: 340B discounts are now rarely passed on to patients, going instead to intermediaries (including contract pharmacies themselves).

3. In response to these systemic abuses, some drug manufacturers, including AstraZeneca Pharmaceuticals LP, have limited the number of contract pharmacy arrangements they will recognize. Consistent with its statutory obligations, AstraZeneca has continued to offer 340B drugs to each covered entity on non-discriminatory terms at the 340B price; AstraZeneca has also gone beyond the requirements of the statute by permitting covered entities that lack on-site pharmacies to use an off-site contract pharmacy arrangement. But AstraZeneca has announced that, effective October 1, 2020, it no longer recognizes an *unlimited* number of contract pharmacy arrangements, instead recognizing one such arrangement per covered entity that does not maintain its own on-site pharmacy. AstraZeneca's policy is intended to bring balance back to the 340B program, by limiting the potential for abuse while also ensuring that all patients served by covered

entities have access to 340B drugs at 340B prices. And in the short time since it went into effect, more than 1,700 covered entities that lack an on-site pharmacy have registered a contract pharmacy, through which AstraZeneca has offered 340B pricing on 340B drugs.

4. AstraZeneca was open and transparent with HRSA about its policy from the beginning. Yet, despite repeated requests, HRSA has ignored AstraZeneca's requests for a meeting to discuss the new policy. And when AstraZeneca asked HRSA to post a Notice to Covered Entities on HRSA's 340B website—a step HRSA has taken numerous times in the past to facilitate the functioning of the 340B program, including 49 manufacturer notice letters in 2020 alone—HRSA refused. Instead, HRSA responded with a letter stating that it was considering whether AstraZeneca was in violation of Section 340B and threatening AstraZeneca with civil monetary penalties.

5. Now, several months later, HHS has finally and unequivocally (but without statutory authority) taken a firm stance on the contract pharmacy question: HHS General Counsel Robert P. Charrow issued an Advisory Opinion declaring that the agency has "conclude[d] that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." HHS Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 8 (Dec. 30, 2020) (Advisory Opinion), https://bit.ly/357nqfk.

6. That conclusion is patently wrong. Section 340B requires manufacturers to "offer" 340B drugs at 340B prices to covered entities, which is exactly what AstraZeneca's policy does. The statute, on its face, does not require manufacturers to recognize *any* contract pharmacies, much

less unlimited contract pharmacies. *A fortiori*, AstraZeneca's policy of recognizing one contract pharmacy per covered entity that does not have an on-site pharmacy fully complies with the law—indeed, it goes beyond AstraZeneca's obligations under Section 340B.

7. The agency's contrary reading of Section 340B is irreconcilable with the statute's plain text, history, and purpose. It was also issued without any authority: Section 340B does not authorize Defendants to "engag[e] in prophylactic non-adjudicatory rulemaking regarding the 340B program." *Pharmaceutical Research & Manufacturers of Am. v. HHS*, 43 F. Supp. 3d 28, 42-43 (D.D.C. 2014) (*Orphan Drug I*).

8. Beyond that, the Advisory Opinion has caused, and is continuing to cause, substantial harm to AstraZeneca (as well as the covered entities who buy its products). Under the Advisory Opinion, unless drug manufacturers like AstraZeneca offer 340B discounts to all contract pharmacies, they risk potential civil monetary penalties of up to $5,000 *per occurrence*; face the potential revocation of their ability to participate in Medicare and Medicaid; and risk penalties under the False Claims Act. Every day that the Advisory Opinion remains on the books, AstraZeneca is exposed to a threat of greater and greater potential liability.

9. AstraZeneca therefore brings this action seeking an order for preliminary and permanent injunctive relief: (1) declaring that the Advisory Opinion violates the Administrative Procedure Act because it was issued without following proper procedure, is in excess of statutory authority, and is otherwise not in accordance with law; (2) setting aside and vacating the Advisory Opinion; (3) declaring that AstraZeneca is not required to offer 340B discounts to contract pharmacies; (4) preliminarily and permanently enjoining enforcement of the Advisory Opinion and all actions by Defendants inconsistent with that declaratory relief; and (5) ordering HRSA to post AstraZeneca's notice.

JURISDICTION AND VENUE

10. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the laws of the United States), 28 U.S.C. § 1346 (United States as a defendant), and 5 U.S.C. §§ 701-06 (Administrative Procedure Act). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02 and 5 U.S.C. §§ 705-06.

11. Defendants' issuance of *Advisory Opinion 20-06 on Contract Pharmacies Under the 340b Program* on December 30, 2020, constitutes a final agency action and is therefore judicially reviewable under the APA. 5 U.S.C. §§ 704, 706.

12. Defendants' refusal to post AstraZeneca's Notice to Covered Entities on HRSA's website constitutes final agency action and is therefore judicially reviewable under the APA. 5 U.S.C. §§ 551(13), 704, 706. It also constitutes "agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

13. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1)(C) because this action seeks relief against federal agencies and officials acting in their official capacities, Plaintiff resides in this district, and no real property is involved in the action.

PARTIES TO THE ACTION

14. Plaintiff AstraZeneca Pharmaceuticals LP (AstraZeneca)—a limited partnership organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware—is a biopharmaceutical company focusing on the discovery, development, manufacturing, and commercialization of medicines. AstraZeneca participates in the 340B program.

15. Defendant Alex M. Azar II is the Secretary of the United States Department of Health and Human Services (HHS). His official address is in Washington, D.C. He has ultimate responsibility for oversight of the activities of the Health Resources and Services Administration (HRSA), including with regard to the administration of the 340B Program and the actions complained of herein. He is sued in his official capacity.

16. Defendant Robert P. Charrow is the General Counsel of HHS. His official address is in Washington, D.C. He issued the Advisory Opinion that sets forth HHS's legal opinion on contract pharmacies under the 340B program, which is a final agency action complained of herein. He is sued in his official capacity.

17. Defendant Thomas J. Engels is the Administrator of HRSA. His official address is in Rockville, Maryland. Administrator Engels is directly responsible for the administration of the 340B program and the actions complained of herein. Administrator Engels, among his other duties, has ultimate responsibility for the Office of Pharmacy Affairs, which is headed by Rear Admiral Krista M. Pedley of the Public Health Service and, as a constituent part of HRSA, is involved directly in the administration of the 340B Program. Administrator Engels is sued in his official capacity.

18. Defendant HHS is an executive department of the United States Government headquartered in Washington, D.C., and is responsible for HRSA and the 340B program.

19. Defendant HRSA is an administrative agency within HHS headquartered in Rockville, Maryland, and is responsible for administering the 340B Program.

FACTUAL ALLEGATIONS

The 340B Program Caps Drug Prices for Enumerated Covered Entities that Provide Healthcare to Certain Underserved Populations

20. Section 340B of the Public Health Services Act "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as covered entities, that provide healthcare to certain underserved populations. *Orphan Drug I*, 43 F. Supp. 3d at 31 (quoting *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011)). As a condition of receiving coverage and reimbursement for its drugs under Medicaid and Medicare Part B, a pharmaceutical manufacturer must enter into a pharmaceutical pricing agreement with HHS. *See* 42 U.S.C. § 256b(a)(1). In that agreement, the manufacturer must "offer each covered entity covered outpatient drugs for purchase" at a specified discount price "if such drug is made available to any other purchaser at any price." *Id.* This is known as Section 340B's "must-offer" requirement. Manufacturers that "knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the [340B discount price]" are subject to civil monetary penalties. *Id.* § 256b(d)(1)(B)(vi)(III).

21. Congress enacted Section 340B "to enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Balanced against its goal of increasing access, however, Congress also recognized the need to "assure the integrity of the drug price limitation program." *Id.* at 16.

22. To that end, Congress imposed three requirements on covered entities. *Id.* at 16-17. First, it prohibited covered entities from receiving 340B pricing on units of drugs for which a manufacturer pays a Medicaid rebate (known as "duplicate discounts"). 42 U.S.C. § 256b(a)(5)(A). Second, it forbade covered entities from reselling or otherwise transferring such

drugs to persons other than their patients (known as "diversion"). *Id.* § 256b(a)(5)(B). Third, it subjected covered entities to audits to verify compliance with these requirements. *Id.* § 256b(a)(5)(C).

23. Consistent with the purpose of benefiting underserved patients, covered entities under Section 340B as originally enacted were "generally disproportionate share hospitals—hospitals that serve indigent populations." *Orphan Drug I*, 43 F. Supp. 3d at 31. Congress has added to the list of 340B covered entities over time, and today there are fifteen clearly delineated categories, including: federally qualified health centers; certain healthcare providers that receive federal grants (such as black lung clinics, hemophilia treatment centers, urban Indian health organizations, and AIDS drug purchasing assistance programs); and certain types of hospitals (critical access hospitals, children's hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals). 42 U.S.C. § 256b(a)(4)(A)-(*O*).

24. Notably, Congress has *never* included contract pharmacies in the statutorily defined list of facilities that qualify as covered entities. Indeed, in drafting what would become the 340B statute, Congress considered proposed language that would have permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services. *See* S. Rep. No. 102-259 at 1-2 (1992) (requiring manufacturer to provide a discounted price for drugs that are "purchased and dispensed by, or under a contract entered into for *on-site pharmacy services* with" certain enumerated covered entities) (emphasis added). But that provision was not enacted.

HRSA Issues Non-Binding Guidance Permitting Contract Pharmacy Arrangements

25. Section 340B does not require manufacturers to provide discounts to contract pharmacies or to *any* entity not specifically enumerated in § 256b(a)(4). But over the last three decades, HRSA has issued two "guidance" documents, which HRSA concedes are non-binding

"interpretive" rules, purporting to authorize covered entities to enter into agreements with contract pharmacies to dispense outpatient drugs under Section 340B. HRSA issued this non-binding guidance despite the fact that Congress did not grant HHS general rulemaking authority, authority to promulgate regulations with respect to Section 340B(a), or authority to expand the list of 340B covered entities. *See Orphan Drug I*, 43 F. Supp. 3d at 41 (identifying the specific, limited grants of rulemaking authority in Section 340B).

26. In 1996, HRSA issued guidance asserting that "eligible covered entities that do not have access to appropriate 'in-house' pharmacy services" could now enter into an agreement with a *single* outside pharmacy of its choice to provide such services for 340B drugs. 61 Fed. Reg. 43,555 (1996 Guidance). HRSA explained that "only a very small number of the 11,500 covered entities used in-house pharmacies." *Id.* at 43,500. HRSA accordingly allowed a covered entity without its own in-house pharmacies to use a *single* affiliated outside pharmacy, an arrangement that would enable such entities to access the 340B program without having to "expend precious resources to develop their own in-house pharmacies (which for many would be impossible)." *Id*.

27. In response to questions about HRSA's authority to expand Section 340B in this manner, the 1996 Guidance acknowledged that "[t]he statute is silent as to permissible drug distribution systems." *Id.* at 43,549. HRSA thus asserted that it was "creat[ing] no new law and . . . no new rights or duties," but instead merely offering "[i]nterpretive rules and statements of policy [that] were developed to provide necessary program guidance" in view of "many gaps in the legislation." *Id.* at 43,550.

28. HRSA recognized that some manufacturers had raised concerns that its new approach would lead to drug diversion. HRSA thus announced that it "intend[ed] to study the use

of contracted pharmacy services for accessing 340B drugs to determine if there is evidence of drug diversion" and "w[ould] consider whether additional safeguards are necessary." *Id.* at 43,549.

29. In 2010, HRSA issued new guidelines designed to supersede the 1996 Guidance. The new guidance expanded its authorization of contract pharmacies under Section 340B—though again, HRSA denied that it was creating any new rights or obligations, and instead insisted that it was only issuing "interpretive guidance." 75 Fed. Reg. 10,273 (2010 Guidance). Although Section 340B's list of covered entities to which 340B drugs must be offered had not changed to allow contract pharmacies, HRSA nevertheless announced a new policy "proposal" designed to "permit covered entities to more effectively utilize the 340B program." *Id.* at 10,273.

30. Under this new policy, HRSA explained, covered entities must now be permitted to "use multiple pharmacy arrangements"—that is, an *unlimited* number of contract pharmacies, without any geographic limits—"as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." *Id.* To take advantage of this new set of arrangements, HRSA announced, a covered entity merely must have a written contract in place with each contract pharmacy through which it intends to dispense 340B drugs; the covered entity need not submit these contracts to HRSA. *Id.* at 10,277; *see* Gov. Accountability Office, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 1, GAO-18-480 (June 2018) (2018 GAO Report), https://www.gao.gov/assets/700/692697.pdf.

31. Numerous 340B stakeholders objected that allowing covered entities to use an unlimited number of contract pharmacies would exacerbate the problems of diversion and duplicate discounts. The 2010 Guidance rejected these objections, asserting that "there are appropriate safeguards in place" to protect program integrity, though it also emphasized "the

responsibility of the covered entity to ensure against diversion and duplicate discounts." 75 Fed. Reg. 10,274; *see id.* at 10,275. HRSA further rejected any suggestion that it should place reasonable limits on the number of contract pharmacies that a single covered entity could use, or that it should impose restrictions on the geographic location of contract pharmacies in relation to the covered entity they serve (such as preventing the use of pharmacies "over State lines"). *Id.* at 10,276.

32. As a result of its categorical stance, the 2010 Guidance purported to authorize a covered entity to enter into an unlimited number of contract pharmacy arrangements anywhere in the United States, even hundreds or thousands of miles away.

A Surge in Contract Pharmacy Arrangements Opens the Door to Profiteering and Undermines the Integrity of the 340B Program

33. HRSA's 2010 Guidance immediately triggered a massive surge in the number of contract pharmacies receiving and distributing 340B drugs. In 2018, the Government Accountability Office reported that the number of contract pharmacies had ballooned from 1,300 in 2010, to nearly 20,000 by 2017. 2018 GAO Report at 2. These numbers have continued to escalate. Today, more than 27,000 individual pharmacies participate in the 340B program, with a total of well over 100,000 individual contracts.[1] Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program* 4 (Oct. 2020) (BRG Report), https://bit.ly/3owtUwa. The vast majority of these contract pharmacies (75% as of 2018) are national, for-profit retail pharmacies; and the five largest national pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and

[1] The exact number of contract pharmacy arrangements currently in place is unknown because HRSA does not require a covered entity that has multiple sites to submit separate registrations for each of its sites. *See* 2018 GAO Report at 19-20. Thus, while HRSA's database includes well over 100,000 current contracts, *see* https://bit.ly/2HFB4gV, the real figure could be many multiples of that. *See* 2018 GAO Report at 20.

Kroger—accounted for a combined 60% of all 340B contract pharmacies, even though these chains represent only 35% of all pharmacies nationwide. 2018 GAO Report at 20-21.

34. Make no mistake: The boom in contract pharmacies has been fueled by the prospect of outsized profit margins on 340B discounted drugs. The determination whether a medicine is eligible for the 340B discount is not made until *after* the medicine is dispensed to the patient and paid for at a non-discounted, commercial price by the patient and his or her health plan. In practice, pharmacies generally buy their inventory of drugs from wholesalers in commercial transactions. Pharmacies then dispense those medicines to any patient with a valid prescription. Those patients could have been treated at a 340B entity or a non-340B entity. Either way, the pharmacy dispenses product from its inventory to the patient consistent with the patient's insurance. Later, for medications determined to be dispensed to a patient of the 340B entity, the wholesaler processes a chargeback reflecting the difference between the pharmacy acquisition price and the 340B price. This enables the pharmacy to enjoy the 340B discount even though it has *also* benefitted from the full insurance reimbursement. The pharmacy may well share some of its windfall with the covered entity or the covered entity's vendor, but the patient has still paid the full out-of-pocket amount designated under his or her insurance policy.

35. For example, in the Medicare Part B context, the Centers for Medicare & Medicaid Services (CMS)—an agency within HHS—found that prescription drugs dispensed to the patient of a covered entity typically cost between 20% and 50% less than the drugs' average sales price. *See, e.g.*, CMS, *Hospital Outpatient Prospective Payment System Proposed Rule Calendar Year 2021*, 85 Fed. Reg. 48,772, 48,886 (Aug. 12, 2020). Yet Medicare provides *full reimbursement* for dispensing the drugs to such a patient. GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June

2015), https://www.gao.gov/assets/680/670676.pdf. The same goes for patients with private insurance or who pay out of pocket. Through this process, pharmacies and covered entities have been able to generate substantial profits from the difference between the low acquisition price mandated by Section 340B and the higher reimbursement value of the drug.

36. As Senator Chuck Grassley put it in a letter to HRSA, for profit pharmacies "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Letter from Sen. Chuck Grassley, S. Comm. on the Judiciary, to Mary K. Wakefield, Administrator, Health Resources and Servs. Admin. (March 27, 2013), https://bit.ly/3kFquVS (Grassley Letter). This has resulted in a significant business opportunity for Walgreens (and other for-profit national pharmacy chains). *See* Raymond James, *340B Pharmacy Follow Up—Less Than $1.4B but Still Yuge* (Sept. 9, 2020) (Walgreens generated profits "in the hundreds of millions" through 340B contract pharmacy arrangements). Indeed, Walgreens' SEC filings report that any pricing changes "in connection with the federal 340B drug pricing program[] could significantly reduce our profitability." Walgreens Boots Alliance, Inc. Form 10-K (Oct. 15, 2020), https://bit.ly/2MoLX9d.

37. One study estimated that, due to the steep discounts mandated under Section 340B, "340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines"—a margin more than triple that ordinarily available to independent pharmacies. BRG Report at 7. The study found that "340B covered entities and their contract pharmacies generated over $13 billion in profits from 340B purchased medicines in 2018, which represents over 25 percent of the total $48 billion in profits realized by all providers that dispensed or administered brand medicines in 2018." *Id.* Most of these profits are *not* going to

federally qualified health centers or other federal grantees that provide services to underserved populations, such as black lung clinics, hemophilia treatment centers, urban Indian health organizations, and AIDS drug purchasing assistance program. Instead, they are being captured by 340B hospitals and contract pharmacies, which are responsible for nearly 90% of all 340B purchases. *Id.*

38. Nor are these huge profits being passed on to patients. For example, in response to a 2018 GAO survey, 45% of covered entities admitted they do not pass along *any* discount to *any* patients that use *any* of their contract pharmacies. 2018 GAO Report at 30. As for the remaining 55%, the GAO noted that entities using contract pharmacies may provide discounts to patients only in limited cases. *Id.* Likewise, the HHS Office of Inspector General has found that many contract pharmacies do not offer 340B discounted prices to uninsured patients at all. HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431. As a result, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies." By contrast, the GAO noted that 17 of 23 the surveyed covered entities that used *in-house* pharmacies reported offering discounts to their patients. *Id.*

39. In short, the widespread proliferation of contract pharmacy arrangements since 2010 has transformed the 340B program from one intended to assist vulnerable patients into a multi-billion-dollar arbitrage scheme that benefits national for-profit pharmacy chains and other for profit intermediaries.

40. At the same time, the explosive growth of contract pharmacy arrangements also has facilitated increased diversion and duplicate discounts—the very risks that Congress sought to avoid when it enacted Section 340B. A 2011 report from the Government Accountability Office

warned that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies. For example, contract pharmacies are more likely to serve both patients of covered entities and others in the community; in these cases more sophisticated inventory tracking systems must be in place to ensure that 340B drugs are not diverted—intentionally or unintentionally—to non-340B patients." Gov. Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28, GAO-11-836 (Sept. 23, 2011), https://www.gao.gov/assets/330/323702.pdf. The report further found that "HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance." *Id.* at 21.

41. These structural problems have only intensified over time, as the use of multiple contract pharmacies has become rampant. In 2014, for instance, HHS's Office of the Inspector General conducted a study of contract pharmacy arrangements, which led to a finding that such arrangements "create complications" for efforts to prevent abuse of the 340B program. Stuart Wright, Deputy Inspector General for Evaluation and Inspections, Office of the Inspector Gen., Dep't of Health and Human Servs., *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, at 1-2, OEI-05-13-00431 (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. The Inspector General also determined that self-policing by covered entities has been insufficient to stop these abuses, since "most covered entities . . . do not conduct all of the oversight activities recommended by HRSA." *Id.* at 2. The 2018 GAO Report similarly criticized the continuing "weaknesses in HRSA's oversight [that] impede its ability to ensure compliance with 340B Program requirements at contract pharmacies." 2018 GAO Report at 45; *see id.* ("As the 340B Program continues to grow, it is essential that HRSA address these shortcomings.").

42. Indeed, HRSA's own audits of covered entities continue to identify numerous instances of abuse. The 2018 GAO Report observed that "66 percent of the 380 diversion findings in HRSA audits [between 2012 and 2017] involved drugs distributed at contract pharmacies." *Id.* at 44. And based on information from HRSA's website, over 25% of covered entities audited since 2017 have had at least one finding related to contract pharmacy noncompliance. Indeed, out of 199 audits conducted in 2019, HRSA discovered dozens of instances of duplicate discounts, as well as evidence that at least 19 covered entities had permitted diversion of 340B drugs through contract pharmacies. *See* HRSA, *Program Integrity: FY19 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results.

AstraZeneca Updates Its Contract Pharmacy Policy to Remedy Abuse of the 340B Program, and HRSA Fails to Post AstraZeneca's Notice to Covered Entities

43. Against this legal and factual backdrop, in August 2020 AstraZeneca announced to covered entities that, effective October 1, 2020, it would revert to the contract pharmacy approach set forth in HRSA's 1996 Guidance. Moving forward as of October 1, AstraZeneca would "only . . . process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy." Letter from Odalys Caprisecca dated Aug. 17, 2020 (Exhibit A).

44. From the outset, AstraZeneca was open and transparent with HRSA about this policy change. AstraZeneca first explained its new planned policy to HRSA in a letter dated July 24, 2020. *See* Letter from Christie Bloomquist to Krista Pedley dated July 24, 2020 (Exhibit B). In that letter, AstraZeneca explained that Section 340B refers only to outpatient drugs that are "***purchased by*** a covered entity," and provides that such drugs must be offered at the discounted price, but "does not mention 'contract pharmacies.'" *Id.* at 2. Its policy of recognizing one contract pharmacy per covered entity that does not maintain an on-site pharmacy thus "complies

with operative 340B statutory provisions," AstraZeneca explained, because "AstraZeneca will make its products available to all covered entities at or below the applicable ceiling price." *Id.* AstraZeneca also cited to substantial evidence, drawn from HRSA's own audits, that the unlimited use of contract pharmacies had caused "significant increases in covered entity violations of the statutory prohibitions against product diversion and duplicate discounting." *Id.* at 3. AstraZeneca closed its letter to HRSA by proposing to meet to discuss its policy change. *Id.*

45. After nearly a month had passed without any response from HRSA, AstraZeneca began informing its distributors directly of its new policy. *See* Ex. A. Then, on August 20, AstraZeneca provided HRSA with a notice for distribution to covered entities regarding the changed policy and requested that HRSA post it on HRSA's website. *See* Notice to Covered Entities Regarding 340B Pricing (Exhibit C). Consistent with AstraZeneca's prior letter to HRSA, the notice explained that, effective October 1, "AstraZeneca will recognize one Contract Pharmacy per Covered Entity for those Covered Entities that do not maintain an on-site dispensing pharmacy." *Id.* at 1. The notice emphasized that the new policy would not disrupt any covered entity's access to 340B drugs at 340B prices, explaining that "Covered Entities will continue to be able to purchase our products at the statutory ceiling price from either their designated single Contract Pharmacy or the Covered Entity's on-site dispensing pharmacy." *Id.* The notice also described the process by which covered entities could designate a contract pharmacy under the policy. *Id.* In its cover email to HRSA, AstraZeneca reiterated its offer to meet with HRSA to explain these changes in more detail.

46. HRSA did not respond to AstraZeneca's July letter and August email until September 2. *See* Letter from Krista Pedley to Christie Bloomquist dated Sept. 2, 2020 (Exhibit D). In its response, HRSA warned that it was "considering whether AstraZeneca's proposed policy

constitutes a violation of the 340B statute and whether sanctions would apply," including "civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." *Id.* at 1. HRSA further asserted that it believed AstraZeneca's new policy "could have the effect of severely limiting access" to 340B drugs during the COVID-19 pandemic, which "would undermine the 340B Program and the Congressional intent behind enactment of the 340B statute." *Id.* at 1-2. HRSA neither responded to AstraZeneca's discussion of the text of Section 340B nor acknowledged AstraZeneca's citations to the agency's own reports as evidence that distribution to unlimited contract pharmacies has resulted in duplicate discounts and diversion. Instead, HRSA asked AstraZeneca to submit "evidence of specific duplicate discount and diversion violations, . . . including the alleged covered entities and drugs involved." *Id.* at 1.

47. Finally, HRSA refused to post AstraZeneca's notice, thus depriving covered entities of information on how to access AstraZeneca medicines: The agency stated that as it "continues to evaluate this issue, it will not be posting AstraZeneca's 'Notice to Covered Entities Regarding 340B Pricing' until this matter is resolved." *Id.* at 2.

48. AstraZeneca replied to HRSA's response letter on September 15. *See* Letter from Christie Bloomquist to Krista Pedley dated Sept. 15, 2020 (Exhibit E). AstraZeneca expressed surprise that HRSA would threaten sanctions, such as civil monetary penalties, given that its policy was fully compliant with Section 340B as written and with guidance that HRSA itself had endorsed for fourteen years. AstraZeneca also expressed disappointment that HRSA chose to convey this threat by letter, rather than taking AstraZeneca up on its two separate offers to meet with HRSA to discuss its new approach. *Id.* at 1.

49. As to the merits, AstraZeneca reiterated that its "planned approach complies fully with the 340B statute" because "[u]nder [AstraZeneca's] new structure, each covered entity will

be offered 340B drugs at the 340B price on non-discriminatory terms." *Id.* AstraZeneca further explained that its new policy in fact "will go beyond the statute's requirements by assuring access to 340B pricing through a contract pharmacy arrangement if a covered entity is unable to dispense 340B drugs from its own facilities." *Id.*

50. AstraZeneca's letter also rebutted HRSA's statement that the new policy could limit access to 340B drugs. "AstraZeneca's new approach to contract pharmacy recognition should not impact patient access," the letter explained, "as our medications will remain available to 340B entities at the 340B price." *Id.* Citing additional government data, AstraZeneca reaffirmed that its new approach was intended to "bolster the integrity of the 340B program" by ensuring that patients—rather than contract pharmacies—actually reap the benefits of the 340B program, while also eliminating opportunities for diversion and duplicate discounting. *Id.* at 1-2.

51. Regarding the notice that AstraZeneca had asked HRSA to post, AstraZeneca explained that "HRSA's refusal to post our notice to covered entities is causing very real and tangible harm, as it is denying covered entities access to vital information on how to register their designated pharmacy." *Id.* at 2. AstraZeneca again requested "that HRSA immediately post our notice on its website so that covered entities can learn how they may enroll and designate their pharmacy to receive AstraZeneca medicines." *Id.*

52. And AstraZeneca further requested that "HRSA confirm to us promptly in writing that it will not seek civil monetary penalties against AstraZeneca related to our impending change to contract pharmacy designation, which fully complies with applicable law." *Id.* Finally, AstraZeneca reiterated for a third time its offer to meet with HRSA "to discuss this critically important issue for 340B program integrity and to correct any misunderstandings that HRSA may have about our approach." *Id.* at 3.

53. In light of HRSA's failure to respond to its letters, or to honor AstraZeneca's request to post AstraZeneca's notice to covered entities on the agency's website, AstraZeneca sent letters to approximately 8,000 covered entities individually informing them of the new policy. *See* Letter from Odalys Caprisecca, *Re: 340B Contract Pharmacy Pricing*, dated Sept. 14, 2020 (Exhibit F). Those letters explained that "AstraZeneca will continue to provide [its] products directly to all Covered Entities . . . at the required statutory ceiling price," and encouraged "any Covered Entity that does not have an outpatient, on-site dispensing pharmacy [to] contact AstraZeneca" by email "to identify a single Contract Pharmacy of its choice." *Id.*

54. On November 2, 2020, AstraZeneca sent another letter to HRSA. *See* Letter from Odalys Caprisecca to Krista Pedley dated Nov. 2, 2020 (Exhibit G). As in its previous correspondence, AstraZeneca emphasized that, under its new policy "all covered entities will continue to have access to AstraZeneca medicines at the 340B price," and that the policy "is fully compliant with the 340B statute." *Id.* at 2. AstraZeneca reaffirmed that "[t]he change that AstraZeneca has implemented makes its products available to covered entities either through their own in-house pharmacy or through a designated contract pharmacy." *Id.* at 2. AstraZeneca also reiterated its request for a meeting with HRSA and asked the agency to advise whether it was "accepting or rejecting our formal meeting request." *Id.*

55. To this day, notwithstanding the passage of nearly *six months* since AstraZeneca's initial meeting request, HRSA has neither agreed to meet with AstraZeneca nor posted AstraZeneca's notice to covered entities on its website. *See* HRSA, Manufacturer Notices to Covered Entities, https://www.hrsa.gov/opa/manufacturer-notices/index.html (database of manufacturer notices posted by HRSA). Nor has HRSA corrected any of the erroneous public statements regarding AstraZeneca's approach to contract pharmacies. These failures have

inhibited AstraZeneca's ability to fully implement its policy and have led to confusion by covered entities and delays in their designating a single contract pharmacy of their choosing under the policy. The result has caused harm to AstraZeneca and to covered entities.

The HHS General Counsel Issues an Advisory Opinion that Pharmaceutical Manufacturers Must Honor Unlimited Contract Pharmacy Arrangements

56. On December 30, 2020, Defendants issued *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*. The Advisory Opinion sets out HHS's definitive response to the legal question of whether the 340B Statute requires manufacturers to sell 340B drugs to contract pharmacies. The Advisory Opinion "conclude[s]" that manufacturers' obligations to offer discounted drugs under the 340B Statute extend not just to purchases by covered entities, but also to purchases by contract pharmacies. Advisory Opinion 1. In the agency's view, "a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs" whenever a contract pharmacy acts as a covered entity's "agent." *Id.*; *see id.* at 8 ("[T]he Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients."); *see also* HHS, *HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies* (Dec. 30, 2020), https://bit.ly/38Qh0lB ("Through the new advisory opinion, HHS has clarified that drug manufacturers must provide 340B discounts when a contract pharmacy is acting as an agent of a covered entity, providing services on behalf of the covered entity.").

57. Although it purports to be grounded in "the plain text of the statute," Advisory Opinion 3, the opinion nowhere explains how its reading of Section 340B complies with the plain

statutory requirement that covered entities must "offer" discounted drugs to a "covered entity." 42 U.S.C. § 256b(a)(1). Nor does the opinion address the fact that Section 340B exhaustively lists fifteen types of non-profit healthcare providers that qualify as "covered entities," without mentioning contract pharmacies. *Id.* § 256b(a)(4). Nor does it acknowledge that Section 340B carefully distinguishes in other respects between "covered entities" and agents—including "associations or organizations representing the interests of [] covered entities," "wholesalers," and "distributors." *Id.* § 256b(d)(1)(B)(v), (2)(B)(iii), (3)(B)(vi).

58. Instead, to the extent the Advisory Opinion engages in any textual analysis at all, it focuses solely on the phrase "purchased by." Advisory Opinion 2-3. The opinion begins with the assertion that "[i]t is difficult to envision a less ambiguous phrase," *id.* at 2, thereby repudiating (without acknowledging that it is doing so) Defendants' own previous statements that the 1996 Guidance and 2010 Guidance were filling "gaps in the legislation," 61 Fed. Reg. at 43,550. The Advisory Opinion then contends that the phrase "purchased by" unambiguously grants covered entities the right to use a contract pharmacy to acquire 340B drugs on its behalf. Advisory Opinion 2. The opinion asserts that this conclusion is supported by current practice "as we understand it, [under which] the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and the covered entity pays the manufacturer either directly or through the manufacturer's distributor." *Id.* at 3. From that observation, the Advisory Opinion offers the hyperbole that "[t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant" to a manufacturer's Section 340B obligations. *Id.*

59. HHS issued the Advisory Opinion despite the fact that Congress did not grant Defendants general rulemaking authority or authority to promulgate regulations with respect to Section 340B(a).

60. The U.S. District Court for the District of Columbia has *twice* held that Section 340B does not grant HHS "broad rulemaking authority." *Orphan Drug I*, 43 F. Supp. 3d at 42; *see Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 33 (D.D.C. 2015) (*Orphan Drug II*). Instead, "Congress has specifically delineated the scope of HHS's rulemaking authority" with respect to the 340B program. *Orphan Drug I*, 43 F. Supp. 3d at 42 (citing 42 U.S.C. § 256b(d)(3)). This focused grant of rulemaking authority does not authorize the agency to "engag[e] in prophylactic non-adjudicatory rulemaking regarding the 340B program." *Id.* at 42-43.

HHS's Interpretation of Section 340B Is Contrary to the Statute's Plain Text, History, and Purpose

61. Notwithstanding the Advisory Opinion's claim that it engages in "straightforward textual interpretation," Advisory Opinion 3, the opinion ignores the statute's key provision: Section 340B's must-offer provision requires a manufacturer solely to "offer" discounted drugs to a "covered entity," an obligation that the manufacturer fully satisfies by making drugs available to the covered entity itself. Nothing in the statute supports that a manufacturer violates its obligation by declining *also* to make drugs available to contract pharmacies.

62. As relevant here, the statute provides that a manufacturer must enter into an agreement with the HHS Secretary that "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." 42 U.S.C. § 256b(a)(1). Section 340B(a)(4), in turn, enumerates fifteen types of healthcare providers that qualify as "covered entities." *Id.* § 256b(a)(4). This exhaustive list does *not* include "contract pharmacies," a term that appears nowhere in Section 340B.

63. Section 340B by its terms thus obliges a manufacturer to "offer" discounted drugs to a "covered entity." The word "offer" is not defined in the statute, but its ordinary meaning is to "make available," or to present for acceptance or rejection. *See* Black's Law Dictionary (11th ed. 2019). Under AstraZeneca's current policy, discounted drugs have been "ma[d]e available" for purchase by every covered entity, and presented for their acceptance or rejection, because every covered entity has the opportunity to buy drugs from AstraZeneca at the statutory ceiling price. Merely qualifying for covered entity status is sufficient to make this purchase opportunity available. Indeed, AstraZeneca has gone beyond Section 340B's textual requirements, by allowing a covered entity that lacks an in-house pharmacy to purchase drugs through a contract pharmacy of its choosing.

64. Also significant is what Section 340B does *not* say. Congress could easily have written the statute to require a manufacturer to offer 340B discounted drugs to "each covered entity *or pharmacies operating under an agency relationship with a covered entity*," but Congress did not do so. Notably, from enactment through 2010, HRSA itself did not read the Section 340B to require that manufacturers must make 340B drugs available to multiple contract pharmacies per covered entity. Instead, the agency's position from 1996-2010 was that, in light of "gaps in the legislation," the agency could reasonably interpret Section 340B(a)(1) to allow a manufacturer to make drugs available either to the covered entity directly or to *one* contract pharmacy per covered entity that lacked an on-site dispensing pharmacy. 61 Fed. Reg. at 43,550.

65. Defendants' new interpretation, as set forth in the Advisory Opinion, is that manufacturers must make drugs available to contract pharmacies because Section 340B requires drugs to be available for "purchase by" a covered entity, without limitation. According to the opinion, that means a manufacturer must make drugs available for purchase *anywhere* or through

any means—even on the "lunar surface." Advisory Opinion 3. But that interpretation focuses on the wrong words and thus reaches the wrong result. A manufacturer's statutory obligation is to "offer" 340B drugs to a covered entity; the manufacturer complies with that command when it makes the drugs available for purchase by the covered entity itself.

66. Indeed, the phrase "purchased by," on which the Advisory Opinion rests its interpretation, does not even appear in the must-offer provision. Instead, it appears in a *separate sentence* that imposes obligations on the HHS Secretary: It requires the Secretary to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity" at discounted prices. 42 U.S.C. § 256b(a)(1) (emphasis added). Even in that context, the phrase merely specifies which purchases give rise to *the Secretary's obligation* to reimburse the manufacturer—namely, those purchases made "by a covered entity" at 340B discount prices.

67. The Advisory Opinion also purports to rely on state agency law, asserting that contract pharmacies act solely as "agents" of the covered entities, which themselves retain title to the 340B drugs even as they are sold by the pharmacies. Advisory Opinion 6. Even on its own terms, that assertion is highly dubious: Whether one person acts as another's agent (as opposed to its contractor) turns on a variety of factors under the various laws of 50 different States. Among other things, state laws look to how liability is apportioned in practice between the two parties, the division of profits among them, the specific terms of each arrangement, and the parties' course of dealing. Resolving the status of any particular relationship between a covered entity and a contract pharmacy would likely be case-specific and fact-dependent—the opposite of the "straightforward textual interpretation" that the Advisory Opinion claims to engage in. Advisory Opinion 3.

68. But even if—contrary to fact—contract pharmacies were agents of covered entities, that still could hardly affect *a manufacturer's* obligations. The manufacturer fulfills its statutory obligation when it "offers" 340B drugs to the covered entity; that obligation does not turn on the covered entity's choice of agency relationships. The state-agency-law argument also ignores that when Congress intends to include agents within the scope of federal law, it does so expressly. *See, e.g.*, 42 U.S.C. § 1320a-7b(b)(3)(C) (creating safe harbor to Anti-Kickback Act liability for amounts "paid by a vendor of goods or services to *a person authorized to act as a purchasing agent for*" a reimbursement-seeker). Here, Congress made no such specification. Indeed, "covered entity" is a narrowly defined term, buttressing the inference that Congress did not want to include agency relationships for purposes of 340B obligations. As the Supreme Court recognized in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), when it comes to interpreting the obligations imposed by the 340B statute, Congress's words must control, not common-law principles. *See id.* at 118-21.

69. Section 340B's history and purpose also demonstrate that Congress did not intend to guarantee access to deeply discounted 340B drugs for an unlimited number of for-profit contract pharmacies. The Conference Report for the bill that eventually became Section 340B indicates that Congress intended "to enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). The report says nothing of creating an extensive system for the distribution of 340B drugs through contract pharmacies.

70. In fact, the legislative history shows the opposite—that despite its awareness that covered entities sometimes rely on contract pharmacies, Congress made a deliberate choice not to include them within Section 340B. Congress considered proposed statutory language in a prior

version of the bill that would have expressly permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services. *See* S. Rep. No. 102-259 at 1-2. That language, however, did not make it into the final version of the bill that Congress passed and the President signed into law. The statute's failure to mention contract pharmacies (even on-site ones) thus was no mere oversight. And certainly nothing in the legislative history suggests that Congress intended, through silence, to create a vast system of *off-site* contract pharmacies for the distribution of drugs to patients of Section 340B covered entities. *See Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

71. The agency's interpretation also raises substantial constitutional issues. In *Eastern Enterprises v. Apfel*, 524 U.S. 498 (1998), a plurality of Justices concluded that "legislation might be unconstitutional if it imposes severe retroactive liability on a limited class of parties that could not have anticipated the liability, and the extent of that liability is substantially disproportionate to the parties' experience." *Id.* at 528-29. The plurality found the law at issue there to be a regulatory taking because it essentially forced a company to assume $50-$100 million worth of liabilities to third-parties that the company had not created and could not have anticipated. In a separate opinion concurring in the judgment, Justice Kennedy agreed that the law was unconstitutional, but expressed the view that the appropriate constitutional lens was due process.

72. Here, the agency's approach, as set forth in the Advisory Opinion, forces manufacturers to offer steeply discounted 340B drugs to third-parties—the contract pharmacies, which resell the drugs at a massive profit—in essence requiring manufacturers to transfer sale proceeds to the pharmacies. That command reflects a new and unexpected assertion of

administrative power to impose financial obligations on manufacturers. In its 2010 Guidance, HRSA concluded that the agency *lacked* the power to require contract pharmacies to adopt use of a bill-to/ship-to approach, and instead issued non-binding interpretive guidance merely recommending its approach. *See* 75 Fed. Reg. at 10,273; 61 Fed. Reg. at 43,550.

73. As recently as summer 2020, in fact, HRSA continued to maintain its prior longstanding position that the contract pharmacy guidance was not enforceable. *See* Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020), https://bit.ly/2X0I1xe.

74. The agency's sudden reinterpretation of Section 340B, which now purports to obligate manufacturers to facilitate price arbitrage by an unlimited number of for-profit contract pharmacies, has no basis in preexisting law. And as in *Eastern Enterprises*, the "remedy created by the [reinterpretation] bears no legitimate relation to the interest which the Government asserts in support of the statute," 524 U.S. at 549 (Kennedy, J.), since the point of the statute is to make medical care accessible to underserved patients, not to provide windfalls for contract pharmacies.

75. Even if the interpretive question were close, therefore, because Defendants' construction of Section 340B "would raise serious constitutional problems," *United States v. Grier*, 475 F.3d 556, 567 (3d Cir. 2007) (citation omitted), the doctrine of constitutional avoidance favors AstraZeneca's alternative construction of the statute, which raises no such constitutional concerns. *See Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Const. Trades Council*, 485 U.S. 568, 575 (1988) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress."); *see also Ashwander v. Tennessee Valley Authority*, 297 U.S. 288, 345-48 (1936) (Brandeis, J., concurring).

HHS's Advisory Opinion and HRSA's Failure to Post AstraZeneca's Notice to Covered Entities Are Final Agency Action

76. The APA authorizes judicial review of any "final agency action for which there is no other adequate remedy in court." 5 U.S.C. § 704. An action is final if: (1) it "mark[s] the consummation of the agency's decision-making process," rather than being "of a merely tentative or interlocutory nature;" and (2) it is an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997); *see Sackett v. E.P.A.*, 566 U.S. 120, 126-27 (2012). The Advisory Opinion is final action under this test.

77. First, the Advisory Opinion marks the "consummation" of the agency's decision-making process: HHS's analysis is not contingent, tentative, or interlocutory. The opinion conclusively announces the agency's legal interpretation of the statute; it does not contemplate any further deliberation or the need for further factual development. The opinion finds that the plain text of Section 340B is unambiguous and thus "dispositive" of the legal question. Advisory Opinion 3. And the opinion's conclusion is unequivocal: "[T]he Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." *Id.* at 8.

78. Second, the Advisory Opinion adopts an interpretation of Section 340B from which "rights or obligations have been determined or from which legal consequences will flow." *Bennett*, 520 U.S. at 177-78. Potential liability (including for overcharges and claims for civil monetary penalties) will accrue every day that AstraZeneca does not submit to the agency's interpretation. *See Sackett*, 566 U.S. at 126-27.

79. This risk of potential liability is not speculative. For example, on January 7, 2021, a group representing 340B hospitals and hospital associations sent a letter to AstraZeneca declaring that, in light of the Advisory Opinion, "AstraZeneca's policy of not providing 340B discounts to 340B providers when AstraZeneca's drugs are dispensed through all but one contract pharmacy is in clear violation of the statute, and AstraZeneca should immediately discontinue its illegal practice." Letter from William B. Schultz dated Jan. 7, 2021 (Exhibit H). The letter demanded that AstraZeneca "reimburse 340B entities for the damages they have incurred due to AstraZeneca's policy." *Id.* at 2. And the letter further threatened that "[i]f AstraZeneca continues its illegal practice, we will continue to seek to require that HHS enforce the 340B statute, covered entities are reimbursed for damages caused by the illegal policy, and the matter is referred to the HHS Inspector General for the imposition of civil money penalties." *Id.* Defendants have put AstraZeneca to the "painful choice" of either complying with the incorrect "obligation[s]" that result from Defendants' mistaken interpretation of Section 340B or "risking the possibility of an enforcement action at an uncertain point in the future." *Orphan Drug II*, 138 F. Supp. 3d at 43 (quoting *CSI Aviation Servs., Inc. v. U.S. Dep't of Transp.*, 637 F.3d 408, 412 (D.C. Cir. 2011)); *see Bauer v. J.B. Hunt Transp., Inc.*, 150 F.3d 759, 763 (7th Cir. 1998) (holding that a letter from the Department of Labor constituted final agency action because "[l]egal consequences flow from it, both with respect to [plaintiffs'] obligations to their employees and with respect to [their] vulnerability to penalties should they disregard [it]").

80. The threat of liability has become even more concrete following HRSA's recent publication of final Administrative Dispute Resolution (ADR) procedures for resolving claims related to overcharging, duplicate discounts, or diversion. *See* 85 Fed. Reg. 80,632 (Dec. 14, 2020). ADR panel members must be drawn from the 340B Administrative Dispute Resolution

Board, which comprises "at least six members appointed by the Secretary with equal numbers from the Health Resources and Service Administration (HRSA), the Centers for Medicare & Medicaid Services (CMS), and the HHS Office of the General Counsel (OGC)." 85 Fed. Reg. at 80,634. Each three-member ADR panel must be composed of "one member from HRSA, CMS, and OGC with relevant expertise to review claims and make final agency decisions." *Id.*

81. HRSA has made clear that it intends to use the ADR process to impose liability on manufacturers for failure to follow the Advisory Opinion's approach to contract pharmacies. Although Section 340B vests HHS with limited authority to establish ADR procedures by which to resolve "claims," *see* 42 U.S.C. § 256b(d)(3)(A)-(C), the ADR Final Rule purports to arrogate authority to the ADR panel "to resolve related issues"—including purely *legal* questions "such as . . . whether a pharmacy is part of a 'covered entity.'" *Id.* at 80,633. Even if that were a proper exercise of authority, which it is not, the Advisory Opinion already conclusively announces HHS's legal position on the contract pharmacy issue. Accordingly, any attempt by a manufacturer to contest the Advisory Opinion on the contract pharmacy issue in proceedings before an ADR panel would be an exercise in futility. As was true in *Orphan Drug II*, "[t]here is nothing to indicate that the administrative record produced during a specific enforcement proceeding would change HHS's legal interpretation." 138 F. Supp. 3d at 43-44; *see Bimini Superfast Operations LLC v. Winkowski*, 994 F. Supp. 2d 106, 117 (D.D.C. 2014) (holding that a Customs and Border Protection (CBP) letter detailing the agency's interpretation of the Immigration and Nationality Act constituted final agency action, where "[t]here is no indication that any such enforcement process would change CBP's legal position or require that an agency record be developed given the purely legal nature of CBP's position").

82. Even apart from the effects of the Advisory Opinion, moreover, HRSA's refusal to post AstraZeneca's notice on the HRSA website—so that covered entities can view the notice and participate in AstraZeneca's new contract pharmacy policy—constitutes final agency action that is causing real harm now. Such a posting would inform all covered entities of how they may access AstraZeneca's medicines. Failing to post that notice denies those covered entities access to information that could be beneficial to them and to the 340B program; it has resulted in confusion by covered entities and delay in designating contract pharmacies under AstraZeneca's policy, to the detriment both of AstraZeneca and of covered entities.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – Defendants Failed to Observe Notice and Comment Procedure Required by Law Under 5 U.S.C. § 706(2)(D))

83. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

84. The APA provides that courts must "hold unlawful and set aside agency action" that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

85. The APA requires agencies to publish notice of all "proposed rulemaking" in the Federal Register, *id.* § 553(b), and to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," *id.* § 553(c). Likewise, the Social Security Act requires the HHS Secretary, before issuing the relevant types of regulations "in final form," to "provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. § 1395hh(b)(1).

86. The APA also generally requires "publication . . . of a substantive rule [to] be made not less than 30 days before its effective date." 5 U.S.C. § 553(d). Similarly, the Social Security

Act requires that relevant regulations "not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be," the regulation. 42 U.S.C. § 1395hh(e)(1)(B)(i).

87. The Advisory Opinion constitutes "final agency action[s] for which there is no other adequate remedy." 5 U.S.C. § 704.

88. Because the Advisory Opinion definitively "concludes" that manufacturers must provide contract pharmacies with 340B prices, it constitutes an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law." 5 U.S.C. § 551(4). It is thus a "rule" under the APA. The Advisory Opinion is not exempt from the APA notice-and-comment requirement under 5 U.S.C. § 553(b)(A) because, despite its label, it is not an "interpretive rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice." Instead, it is a legislative rule that creates rights and imposes obligations on drug manufacturers with which they must comply, on pain of potential civil monetary penalties and other potential monetary and administrative penalties. *See Pennsylvania Dep't of Human Servs. v. United States*, 897 F.3d 497, 505 (3d Cir. 2018) ("Legislative rules, which have the force of law, 'impose new duties upon the regulated party.'" (quoting *Chao v. Rothermel*, 327 F.3d 223, 227 (3d Cir. 2003))).

89. The Advisory Opinion was not adopted through required notice-and-comment procedures, nor did it provide for the required 30-day delay in effective date. There is no "good cause" that waives either requirement. The Advisory Opinion was therefore promulgated "without observance of procedure required by law" and must be set aside under 5 U.S.C. § 706(2)(D).

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SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – Defendants' Advisory Opinion Exceeds Defendants' Statutory Authority Under 42 U.S.C. § 256b)

90. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

91. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law" or is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

92. Independent of the APA, courts have a duty to set aside agency action that is *ultra vires*. *See Shalom Pentecostal Church v. Acting Sec'y U.S. Dep't of Homeland Sec.*, 783 F.3d 156, 167 (3d Cir. 2015); *see also Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1173 (D.C. Cir. 2003).

93. Section 340B does not grant Defendants general rulemaking authority or authority to promulgate regulations with respect to Section 340B(a). *See Orphan Drug I*, 43 F. Supp. 3d at 45; *Orphan Drug II*, 138 F. Supp. 3d at 32. Rather, HRSA possesses limited rulemaking authority in only three areas: (1) the establishment of an administrative dispute resolution process; (2) the issuance of precisely defined standards of methodology for calculation of ceiling prices; and (3) the imposition of monetary civil sanctions. *See Orphan Drug I*, 43 F. Supp. 3d at 45.

94. Section 340B does not empower Defendants to require drug manufacturers, on pain of potential civil monetary penalties and other sanctions, to provide discounted drugs under Section 340B to contract pharmacies because contract pharmacies are not covered entities as defined by Section 340B and the statute does not authorize Defendants to require manufacturers to offer discounts to any other type of entity. *See Orphan Drug I*, 43 F. Supp. 3d at 45; *Orphan Drug II*, 138 F. Supp. 3d at 32. Defendants likewise have no authority to broaden the scope of the

340B Statute to expand the statutory term "covered entities" to include contract pharmacies, as they have now purported to do in the Advisory Opinion.

95. The Advisory Opinion is not entitled to deference under *Chevron USA, Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984), because Congress has not delegated authority to the agency to resolve the status of contract pharmacies under the 340B statute, and because the text of the statute is unambiguous. And, for the same reasons, as well as the agency's failure to acknowledge its change of position, the Advisory Opinion fails to persuade under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

96. The Advisory Opinion is therefore "not in accordance with law," it is "in excess of statutory jurisdiction, authority, or limitations," and it must be set aside under 5 U.S.C. § 706(2)(A), (C). For the same reasons, the Advisory Opinion is also *ultra vires*.

THIRD CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The Advisory Opinion Is Arbitrary and Capricious Under 5 U.S.C. § 706(2)(A))

97. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

98. The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

99. Agency action is arbitrary and capricious if the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider,

entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

100. Any change to an agency's policy must also be adequately explained. The agency must "display awareness that it is changing position," "show that there are good reasons for the new policy," and be aware that longstanding policies may have "engendered serious reliance interests that must be taken into account." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). "[A]n unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (citation and alterations omitted).

101. The Advisory Opinion is arbitrary and capricious because Defendants did not consider the relevant factors. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 241 (D.C. Cir. 2008). Indeed, Defendants entirely failed to give adequate consideration to Section 340B's text, which limits the 340B program to the fifteen classes of covered entities Congress specifically enumerated.

102. The Advisory Opinion is also arbitrary and capricious because Defendants gave no apparent consideration to the abuses contract pharmacy arrangements have facilitated—abuses which the Section 340B was designed to avoid. Defendants' application of their legally incorrect reading of Section 340B to mandate that manufacturers offer 340B discounts for contract pharmacy transactions enables the very diversion by covered entities that the 340B statute expressly prohibits. *See* 42 U.S.C. § 256b(a)(5)(B). Contract pharmacy transactions result in covered entities selling or otherwise transferring covered outpatient drugs to entities that are not

"patients" of the covered entity. The use of contract pharmacies as authorized in the Advisory Opinion necessarily involves a prohibited "transfer" of 340B discounted products to a non-340B covered entity, the contract pharmacy.

103. Finally, the Advisory Opinion is arbitrary and capricious because Defendants did not even attempt to reconcile the "obligation" enshrined in it with their earlier pronouncements that manufacturers were under no legally enforceable obligation to offer 340B prices to contract pharmacies. The Advisory Opinion thus arbitrarily and capriciously fails to explain the Defendants' change in policy.

104. The Advisory Opinion is thus "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and must be set aside under 5 U.S.C. § 706(2)(A).

FOURTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – Defendants' Failure to Post AstraZeneca's Notice Exceeds Defendants' Statutory Authority Under 42 U.S.C. § 256b and Constitutes Agency Action Unlawfully Withheld under 5 U.S.C. § 706(1))

105. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

106. Defendants' failure to post AstraZeneca's Notice to Covered Entities on HRSA's website constitutes final agency action judicially reviewable under the APA. 5 U.S.C. §§ 551(13), 704, 706. It also constitutes "agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1).

107. For the reasons stated, Defendants' failure to post AstraZeneca's Notice to Covered Entities on HRSA's website—which is based on Defendants' erroneous and unlawful interpretation of Section 340B—is "not in accordance with law"; it is "in excess of statutory jurisdiction, authority, or limitations"; and it is *ultra vires*.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiff requests a judgment in their favor against Defendants as follows:

A. Declare that the Advisory Opinion is not in accordance with law, is without observance of procedure required by law, and is invalid;

B. Set aside and vacate the Advisory Opinion;

C. Declare that AstraZeneca is not required to offer 340B discounts to contract pharmacies;

D. Declare that AstraZeneca's approach of either selling direct to covered entities that have their own in-house pharmacy or, if the covered entity lacks an in-house pharmacy, allowing the covered entity to designate a single contract pharmacy through which to purchase AstraZeneca medicines at the 340B price, complies with Section 340B;

E. Issue preliminary and permanent injunctive relief preventing Defendants from implementing or enforcing the Advisory Opinion;

F. Direct Defendants to post AstraZeneca's Notice to Covered Entities on HRSA's website.

G. Award Plaintiff reasonable attorneys' fees and costs, plus interest accruing thereon, under the Equal Access to Justice Act, 28 U.S.C. § 2412; and

H. Grant such other and further relief as the Court may deem appropriate.

Dated: January 12, 2021

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver
Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King St., 8th Floor
Wilmington, DE 19801
Tel.: (302) 984-6300
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Exhibit A

AstraZeneca

Date: August 17, 2020

Re: 340B Contract Pharmacy Pricing

Dear Valued Partner,

AstraZeneca to date has processed chargebacks associated with Contract Pharmacy arrangements consistent with the approach proposed in the Health Resources and Services Administration's ("HRSA") April 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach such that AstraZeneca only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy.

To implement this new approach, AstraZeneca will stop processing 340B chargebacks for all 340B Contract Pharmacy arrangements effective October 1, 2020. Any 340B Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca to arrange for a Contract Pharmacy of its choice to be eligible to receive 340B pricing on behalf of the Covered Entity. To initiate this process, please contact Membership@AstraZeneca.com.

340B Pricing for Contract Pharmacies will be honored on all invoices, consistent with AstraZeneca's historic approach, through September 30, 2020. For additional information or questions, please contact your AstraZeneca Account Director.

Sincerely,

DocuSigned by:
0781790EE5034A7...

Odalys Caprisecca
Executive Director, Strategic Pricing & Operations

Exhibit B

July 24, 2020

BY FEDERAL EXPRESS & EMAIL

Rear Admiral Krista Pedley, PharmD, MS
Office of Pharmacy Affairs
Health Resources and Services Administration
Office of Pharmacy Affairs
5600 Fishers Lane, 08W10
Rockville, MD 20857

Re: AstraZeneca: 340B Contract Pharmacies

Dear Rear Admiral Pedley:

I am writing on behalf of AstraZeneca Pharmaceuticals, LP ("AstraZeneca" or the "Company") to address upcoming changes to the Company's approach to "contract pharmacy" arrangements in the 340B Program. AstraZeneca to date has honored chargebacks associated with contract pharmacy arrangements consistent with the Health Resources and Services Administration's ("HRSA") 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach for the products listed in the Attachment to this letter and any future products, such that AstraZeneca will recognize one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy.

AstraZeneca is deeply committed to the 340B Program and to ensuring that any patient prescribed an AstraZeneca product has access to that medicine. Our new approach to recognizing contract pharmacies will be fully consistent with HRSA's original 1996 guidance regarding the use of contract pharmacies and will continue to ensure that eligible covered entities are offered the 340B ceiling pricing consistent with the 340B statute. At the same time, we hope this new approach will help to mitigate the significant compliance issues that exist -- and that AstraZeneca has experienced -- with covered entity contract pharmacy arrangements. We explain the basis for our revised approach below and we would be pleased to discuss with HRSA at the agency's convenience.

Contract Pharmacy Background and HRSA Guidance

The 340B statute requires manufacturers that have signed a Pharmaceutical Pricing Agreement to make the statutory ceiling pricing available for covered outpatient drugs that are

"***purchased by*** a covered entity[.]"[1] The statute thus focuses exclusively on purchases by covered entities. It does not mention "contract pharmacies." The 340B statute requires manufacturers to provide discounted drug purchases for dispensing to eligible outpatients ***at a provider site*** -- not through contracted pharmacies.

HRSA first published guidelines regarding contract pharmacy arrangements in 1996. Shortly after the inception of the 340B Program, HRSA recognized that some covered entities lacked on-site pharmacies and therefore had no vehicle for dispensing outpatient drugs to their patients. To remedy this concern, HRSA allowed those covered entities who lacked their own in-house pharmacy to retain a contract pharmacy "to facilitate program participation for those eligible covered entities that do not have access to appropriate 'in house' pharmacy services."[2] HRSA limited covered entities to ***one contract pharmacy***: "The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple sites, ***as long as only one site is used for the contracted services***."[3]

But, in 2010, HRSA replaced its 1996 guidelines with new guidance that enabled covered entities to use multiple contract pharmacies per covered entity site without regard to geographic considerations or whether the covered entity itself maintained an in-house pharmacy.[4] This guidance has spurred dramatic growth in the use of contract pharmacies and has caused many implementation challenges. While many covered entities, including hospitals, maintain their own dispensing capabilities, they also have entered myriad contract pharmacy arrangements. In fact, a recent independent analysis identified over 25,000 contract pharmacy locations.[5] This number contrasts starkly with the fewer than 3,000 contract pharmacies that existed in 2010.[6] AstraZeneca also has determined that, as of the first quarter of 2018, 415 covered entities within California alone maintained 1,245 contract pharmacy arrangements, several of those contract pharmacies are located in states not contiguous with California. AstraZeneca does not believe that this overly-expansive use of contract pharmacies supports the mission and the central goals of the 340B Program.

When HRSA issued the 2010 contract pharmacy guidelines, it asserted that the Program had "appropriate safeguards in place" to combat covered entity statutory violations that could arise in connection with contract pharmacy arrangements.[7] But, since that time, the 340B Program has

[1] 42 U.S.C. § 256b(a)(1) (emphasis added).
[2] 61 Fed. Reg. 43549, 43555 (Aug. 23, 1996).
[3] 61 Fed. Reg. at 43555.
[4] *See* Final Notice Regarding 340B Drug Pricing Program - Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).
[5] *See* https://www.drugchannels.net/2019/07/walgreens-cvs-and-walmart-lead-25000.html.
[6] *See* https://www.drugchannels.net/2017/07/the-booming-340b-contract-pharmacy.html.
[7] 75 Fed. Reg. at 10274.

seen significant increases in covered entity violations of the statutory prohibitions against product diversion and duplicate discounting.

HRSA's audits of covered entities have identified considerable concerns with contract pharmacies. For example, based on information on the HRSA website, over 25% of covered entities audited since 2017 have had at least one finding related to contract pharmacy noncompliance. AstraZeneca itself has received numerous covered entity refund disclosures associated with contract pharmacy violations. Additionally, HRSA itself has raised concerns that contract pharmacy arrangements are correlated with product diversion. HRSA has reported, for example, that it is "aware of a resolution practice" utilized by contract pharmacies for instances of product diversion.[8] Where product dispensed at 340B pricing later is identified not to meet program criteria, contract pharmacies may issue "repayment to the manufacturer(s) for transactions the contract pharmacy/TPA no longer considers 340B-eligible." HRSA observed that covered entities may have no "prior knowledge or engagement" as to this practice. In HRSA's view, these arrangements do not comply with 340B Program rules and each "covered entity [must] retain responsibility for ensuring full compliance and integrity of its use of the 340B Program."

AstraZeneca's Contract Pharmacy Approach Beginning October 1, 2020

AstraZeneca fully supports the mission of the 340B Program to provide a healthcare safety net for the most vulnerable patients in our country. But the Company does not believe that today's contract pharmacy framework is necessary to further that mission. We also are cognizant of the statutory "must offer" provision, and we are committed to ensuring that our products remain available to patients of covered entities consistent with that provision. Accordingly, and balancing these considerations, AstraZeneca will change its approach to working with contract pharmacies going forward. For those products listed in the Attachment to this letter, beginning October 1, 2020, AstraZeneca will recognize one contract pharmacy arrangement per covered entity site in the event that the covered entity does not maintain its own, on-site pharmacy. This change is fully consistent with the guidelines that HRSA put in place in 1996 and that remained through 2010. This approach also complies with operative 340B statutory provisions because AstraZeneca will make its products available to all covered entities at or below the applicable ceiling price.

AstraZeneca plans to communicate this change in operations to its supply chain partners and customers by August 10, 2020. AstraZeneca also will ensure that Company personnel are well versed in this change in operations so that they will be able to field inquiries from any customers.

[8] *See* "Best Practices for Covered Entities: Resolving Contract Pharmacy Related Non-Compliance" *available at* https://www.hrsa.gov/opa/updates/2018/june.html.

AstraZeneca

* * *

AstraZeneca thanks HRSA for its attention to this important matter, and the Company looks forward to its continued participation in the 340B Program. As noted above, AstraZeneca will plan to communicate this change in approach to wholesalers and other stakeholders by August 10, 2020 and to implement this change effective October 1, 2020. We would be happy to discuss this change with the agency in more detail if helpful. Please note that the information contained in this letter is confidential and not subject to disclosure under Exemption 4 to the Freedom of Information Act, 5 U.S.C. § 552(b)(4), the Trade Secrets Act, 18 U.S.C. § 1905, and the Medicaid Drug Rebate Act, 42 U.S.C. §1396r-8(b)(3)(D).

Sincerely,

CBloomquist

Christie Bloomquist

Vice President Corporate Affairs, North America

AstraZeneca

ATTACHMENT

Product Name		NDC
BEVESPI AEROSPHERE®		
	9/4.8 MCG 120 ACT INHALATION	00310-4600-12
	9/4.8 MCG 28 ACT INHALATION	00310-4600-39
BRILINTA®		
	TAB 90MG UD	00186-0777-39
	TAB 90MG	00186-0777-60
	TAB 60MG	00186-0776-60
BYDUREON®		
	PEN 2MG	00310-6530-04
	BCISE AUTOINJECTOR	00310-6540-04
BYETTA®		
	PEN 250MCG/ML	00310-6512-01
	PEN 250MCG/ML	00310-6524-01
CALQUENCE™		
	CAP 100MG	00310-0512-60
CRESTOR®		
	TAB 5MG	00310-0755-90
	TAB 10 MG	00310-0751-90
	TAB 20 MG	00310-0752-90

	TAB 40 MG	00310-0754-30
DALIRESP®		
	TAB 250MCG	00310-0088-28
	TAB 250MCG	00310-0088-39
	TAB 500MCG	00310-0095-30
	TAB 500MCG	00310-0095-90
FARXIGA®		
	TAB 5MG	00310-6205-30
	TAB 10MG	00310-6210-30
FASENRA®		
	SOLUTION 30MG/ML	00310-1730-30
FASLODEX®		
	INJ 250 MG/5 ML	00310-0720-10
KOMBIGLYZE® XR		
	TAB 5MG/500MG	00310-6135-30
	TAB 2.5MG/1000MG	00310-6125-60
	TAB 5MG/1000MG	00310-6145-30
LOKELMA™		
	ORAL SUSPENSION 5G	00310-1105-30
	ORAL SUSPENSION 5G	00310-1105-39
	ORAL SUSPENSION 10G	00310-1110-30
	ORAL SUSPENSION 10G	00310-1110-39
LUMOXITI™		
	POWDER 1MG	00310-4700-01
	IVSS FOR LUMOXITI	00310-4715-11
LYNPARZA®		
	TAB 100MG	00310-0668-12

	TAB 100MG	00310-0668-60
	TAB 150MG	00310-0679-12
	TAB 150MG	00310-0679-60
MOVANTIK®		
	TAB 12.5MG	00310-1969-30
	TAB 25MG	00310-1970-30
	TAB 25MG	00310-1970-39
NEXIUM®		
	CAPS 20MG	00186-5020-31
	CAPS 20MG	00186-5020-54
	CAPS 40MG	00186-5040-31
	CAPS 40MG	00186-5040-54
	CAPS 40MG	00186-5040-82
	IV INJ 40MG/5mL	00186-6040-01
	ORAL SUSPENSION 2.5MG	00186-4025-01
	ORAL SUSPENSION 5MG	00186-4050-01
	ORAL SUSPENSION 10MG	00186-4010-01
	ORAL SUSPENSION 20MG	00186-4020-01
	ORAL SUSPENSION 40MG	00186-4040-01
ONGLYZA®		
	TAB 2.5MG	00310-6100-30
	TAB 2.5MG	00310-6100-90
	TAB 5MG	00310-6105-30
	TAB 5MG	00310-6105-90
PULMICORT®		
	FLEXHALER 90-MCG	00186-0917-06
	FLEXHALER 180-MCG	00186-0916-12
	RESPULES .25 mg/2 ml	00186-1988-04

	RESPULES .5 mg/2 ml	00186-1989-04
	RESPULES 1 mg/2 ml	00186-1990-04
QTERN®		
	TAB 5MG/5MG	00310-6770-30
	TAB 10MG/5MG	00310-6780-30
SEROQUEL®		
	TAB 100MG	00310-0271-10
	TAB 200MG	00310-0272-10
	TAB 25MG	00310-0275-10
	TAB 300 MG	00310-0274-60
	TAB 50 MG	00310-0278-10
	TAB 400 MG	00310-0279-10
SEROQUEL XR®		
	TAB 50 MG	00310-0280-60
	TAB 150 MG	00310-0281-60
	TAB 200 MG	00310-0282-60
	TAB 300 MG	00310-0283-60
	TAB 400 MG	00310-0284-60
SYMBICORT®		
	80/4.5MCG	00186-0372-20
	160/4.5MCG	00186-0370-20
	80/4.5MCG Inst. Pack	00186-0372-28
	160/4.5MCG Inst. Pack	00186-0370-28
SYMLIN®		
	60-PEN 1000mcg/ml	00310-6615-02
	120-PEN 1000mcg/ml	00310-6627-02
SYNAGIS®		
	100 MG/ML VIAL	60574-4113-01
	50MG/0.5 ML VIAL	60574-4114-01

TAGRISSO®		
	TAB 40MG	00310-1349-30
	TAB 80MG	00310-1350-30
TUDORZA® PRESSAIR®		
	INHALER 400MCG	00310-0800-39
	INHALER 400MCG	00310-0800-60
XIGDUO® XR		
	TAB 2.5MG/1000MG	00310-6225-60
	TAB 5MG/500MG	00310-6250-30
	TAB 5MG/1000MG	00310-6260-60
	TAB 10MG/500MG	00310-6270-30
	TAB 10MG/1000MG	00310-6280-30

Exhibit C

Notice to Covered Entities Regarding 340B Pricing Eligibility

August 2020

AstraZeneca to date has provided 340B pricing to pharmacies associated with Contract Pharmacy arrangements consistent with the approach proposed in the Health Resources and Services Administration's ("HRSA") April 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach for the products listed on the enclosed attachment, such that AstraZeneca will recognize one Contract Pharmacy per Covered Entity for those Covered Entities that do not maintain an on-site dispensing pharmacy. AstraZeneca will continue to provide our products directly to all Covered Entities at the required statutory ceiling price. Covered Entities will continue to be able to purchase our products at the statutory ceiling price from either their designated single Contract Pharmacy or the Covered Entity's on-site dispensing pharmacy.

To implement this process, any Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca at the email below to identify a single Contract Pharmacy of its choice that would be eligible to receive 340B pricing on behalf of the Covered Entity. AstraZeneca deeply values its participation in the 340B program and with Covered Entities and is committed to complying with all applicable requirements of the program. Please contact us at Membership@AstraZeneca.com with any questions or to initiate the process of selecting a single Contract Pharmacy to receive 340B pricing on behalf of your Covered Entity.

NDCs

AstraZeneca

Product Name	NDC	Pkg Qty	Each Size/Description
BEVESPI AEROSPHERE®			
9/4.8 MCG 120 ACT INHALATION	00310-4600-12	1	1 INHALER
9/4.8 MCG 28 ACT INHALATION	00310-4600-39	1	1 INHALER
BRILINTA®			
TAB 90MG UD	00186-0777-39	1	100 COUNT BOX
TAB 90MG	00186-0777-60	1	60 COUNT BOTTLE
TAB 60MG	00186-0776-60	1	60 COUNT BOTTLE
BYDUREON®			
PEN 2MG	00310-6530-04	4	4 X 2MG Pen
BCISE AUTOINJECTOR	00310-6540-04	4	4 X 2MG AUTOINJECTOR
BYETTA®			
PEN 250MCG/ML	00310-6512-01	1	1 PEN X 1.2ML
PEN 250MCG/ML	00310-6524-01	1	1 PEN X 2.4ML
CRESTOR®			
TAB 5MG	00310-0755-90	1	90 COUNT BOTTLE
TAB 10 MG	00310-0751-90	1	90 COUNT BOTTLE
TAB 20 MG	00310-0752-90	1	90 COUNT BOTTLE
TAB 40 MG	00310-0754-30	1	30 COUNT BOTTLE
DALIRESP®			
TAB 250MCG	00310-0088-28	1	28 COUNT BLISTER
TAB 250MCG	00310-0088-39	1	2X10 HUD BLISTER PACK
TAB 500MCG	00310-0095-30	1	30 COUNT BOTTLE
TAB 500MCG	00310-0095-90	1	90 COUNT BOTTLE
FARXIGA®			
TAB 5MG	00310-6205-30	1	30 COUNT BOTTLE
TAB 10MG	00310-6210-30	1	30 COUNT BOTTLE
KOMBIGLYZE® XR			
TAB 5MG/500MG	00310-6135-30	1	30 COUNT BOTTLE
TAB 2.5MG/1000MG	00310-6125-60	1	60 COUNT BOTTLE
TAB 5MG/1000MG	00310-6145-30	1	30 COUNT BOTTLE
LOKELMA™			
ORAL SUSPENSION 5G	00310-1105-30	30	30 PACKETS
ORAL SUSPENSION 5G	00310-1105-39	11	11 PACKETS
ORAL SUSPENSION 10G	00310-1110-30	30	30 PACKETS
ORAL SUSPENSION 10G	00310-1110-39	11	11 PACKETS
NEXIUM®			
CAPS 20MG	00186-5020-31	1	30 COUNT BOTTLE
CAPS 20MG	00186-5020-54	1	90 COUNT BOTTLE
CAPS 40MG	00186-5040-31	1	30 COUNT BOTTLE
CAPS 40MG	00186-5040-54	1	90 COUNT BOTTLE

	IV INJ 40MG/5mL	00186-6040-01	10	10 x 5.0mL VIAL
	ORAL SUSPENSION 2.5MG	00186-4025-01	30	30 PACKETS
	ORAL SUSPENSION 5MG	00186-4050-01	30	30 PACKETS
	ORAL SUSPENSION 10MG	00186-4010-01	30	30 PACKETS
	ORAL SUSPENSION 20MG	00186-4020-01	30	30 PACKETS
	ORAL SUSPENSION 40MG	00186-4040-01	30	30 PACKETS
ONGLYZA®				
	TAB 2.5MG	00310-6100-30	1	30 COUNT BOTTLE
	TAB 2.5MG	00310-6100-90	1	90 COUNT BOTTLE
	TAB 5MG	00310-6105-30	1	30 COUNT BOTTLE
	TAB 5MG	00310-6105-90	1	90 COUNT BOTTLE
PULMICORT®				
	FLEXHALER 90-MCG	00186-0917-06	1	1 INHALER
	FLEXHALER 180-MCG	00186-0916-12	1	1 INHALER
	RESPULES .25 mg/2 ml	00186-1988-04	30	30 RESPULE BOX
	RESPULES .5 mg/2 ml	00186-1989-04	30	30 RESPULE BOX
	RESPULES 1 mg/2 ml	00186-1990-04	30	30 RESPULE BOX
QTERN®				
	TAB 5MG/5MG	00310-6770-30	30	30 COUNT BOTTLE
	TAB 10MG/5MG	00310-6780-30	30	30 COUNT BOTTLE
SEROQUEL®				
	TAB 100MG	00310-0271-10	1	100 COUNT BOTTLE
	TAB 200MG	00310-0272-10	1	100 COUNT BOTTLE
	TAB 25MG	00310-0275-10	1	100 COUNT BOTTLE
	TAB 300 MG	00310-0274-60	1	60 COUNT BOTTLE
	TAB 50 MG	00310-0278-10	1	100 COUNT BOTTLE
	TAB 400 MG	00310-0279-10	1	100 COUNT BOTTLE
SEROQUEL XR®				
	TAB 50 MG	00310-0280-60	1	60 COUNT BOTTLE
	TAB 150 MG	00310-0281-60	1	60 COUNT BOTTLE
	TAB 200 MG	00310-0282-60	1	60 COUNT BOTTLE
	TAB 300 MG	00310-0283-60	1	60 COUNT BOTTLE
	TAB 400 MG	00310-0284-60	1	60 COUNT BOTTLE
SYMBICORT®				
	80/4.5MCG	00186-0372-20	1	1 INHALER
	160/4.5MCG	00186-0370-20	1	1 INHALER
	80/4.5MCG Inst. Pack	00186-0372-28	1	1 INHALER
	160/4.5MCG Inst. Pack	00186-0370-28	1	1 INHALER
SYMLIN®				
	60-PEN 1000mcg/ml	00310-6615-02	2	2 PEN X 1.5ml
	120-PEN 1000mcg/ml	00310-6627-02	2	2 PEN X 2.7ml
XIGDUO® XR				
	TAB 2.5MG/1000MG	00310-6225-60	1	60 COUNT BOTTLE
	TAB 5MG/500MG	00310-6250-30	1	30 COUNT BOTTLE
	TAB 5MG/1000MG	00310-6260-60	1	60 COUNT BOTTLE
	TAB 10MG/500MG	00310-6270-30	1	30 COUNT BOTTLE
	TAB 10MG/1000MG	00310-6280-30	1	30 COUNT BOTTLE

Exhibit D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration
Office of Pharmacy Affairs

Rockville, MD 20857

September 2, 2020

Christie Bloomquist
Vice President Corporate Affairs, North America
AstraZeneca Pharmaceuticals, LP
701 Pennsylvania Avenue NW #500
Washington, DC 20004

Dear Ms. Bloomquist:

This in response to your July 24, 2020 correspondence regarding contract pharmacies in the 340B Drug Pricing Program (340B Program). Your letter states that beginning October 1, 2020, AstraZeneca Pharmaceuticals, LP (AstraZeneca) will recognize only one contract pharmacy arrangement per covered entity site for covered entities that do not maintain an on-site pharmacy for certain drug products.

Under 42 U.S.C. §256b(a)(1), manufacturers must offer covered entities outpatient drugs at specified prices. HRSA is considering whether AstraZeneca's proposed policy constitutes a violation of the 340B statute and whether sanctions would apply. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B(d)(1)(B)(vi) of the Public Health Service Act.

We understand that AstraZeneca's rationale is its concern that distribution to contract pharmacies can lead to duplicate discounts and diversion. To the extent that AstraZeneca has any evidence of specific duplicate discount and diversion violations, please share that evidence, including the alleged covered entities and drugs involved.

Contract pharmacies, which are only a mode for dispensing 340B drugs and not independent covered entities, serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Many health centers, and other safety net organizations receiving HRSA grants are able to participate in the 340B Program only through a contract pharmacy, and having multiple contract pharmacy arrangements allows them to reach to the patients they serve. In addition, certain covered entities serve communities where patients must travel great distances for health care services. In order to encourage medication adherence, these covered entities often contract with pharmacies that are closer to where their patients reside. AstraZeneca's policy could have the effect of severely limiting access for underserved and vulnerable populations served by these covered entities' access to 340B discounted drugs. This result would undermine

the 340B Program and the Congressional intent behind enactment of the 340B statute.[1] Even for those covered entities with in-house pharmacies, AstraZeneca's position to limit contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy to obtain their prescriptions.

AstraZeneca's limitation of the number of contract pharmacies a covered entity can use to obtain 340B discounts would significantly harm the nation's safety net, especially at a time when the health care community is under great pressure to address the current COVID-19 pandemic and maintain general public health, often in limited in-person settings.

AstraZeneca indicated in its letter that it considers its letter to be "confidential and proprietary not subject to release or disclosure under FOIA or otherwise." HRSA fails to see any confidential or proprietary information in the letter. If AstraZeneca believes that portions of its correspondence are confidential or proprietary, please respond by September 30 with an explanation and reference to the specific portions of the letter that AstraZeneca believes are confidential and proprietary.

As HRSA continues to evaluate this issue, it will not be posting AstraZeneca's "Notice to Covered Entities Regarding 340B Pricing" until this matter is resolved. If you have any further questions, please feel free to contact me. Thank you for your interest in the 340B Program.

Sincerely,

Krista M. Pedley

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs

[1] The intent of the 340B Program is to permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. (See: H.R. REP No. 102-384(II), at 12 (1992) (Conf. Report)).

Exhibit E

September 15, 2020

BY FEDERAL EXPRESS & EMAIL

Rear Admiral Krista Pedley, PharmD, MS
Health Resources and Services Administration
Office of Pharmacy Affairs
5600 Fishers Lane, 08W10
Rockville, MD 20857

Re: AstraZeneca: 340B Contract Pharmacies

Dear Rear Admiral Pedley:

I write in response to your letter of September 2, 2020 regarding the AstraZeneca Pharmaceuticals, LP ("AstraZeneca" or the "Company") plan to recognize one contract pharmacy per 340B covered entity for those covered entities that do not have an on-site dispensing pharmacy. We were surprised by your letter's warning that the Health Resources and Services Administration ("HRSA") "is considering whether" our plan may "constitute[] a violation of the 340B statute" and whether sanctions such as civil money penalties would apply. We are also disappointed that HRSA chose to convey this threat by letter rather than taking AstraZeneca up on our two separate offers to meet with HRSA to discuss our new approach.

As to the merits of the issues raised in your letter, our planned approach complies fully with the 340B statute. As we outlined in our July 24, 2020 letter, the must offer provision requires that manufacturers with a signed pharmaceutical pricing agreement must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." Under our new structure, each covered entity will be offered 340B drugs at the 340B price on non-discriminatory terms. Thus, the approach fully satisfies the must offer provision and all other operative 340B requirements. AstraZeneca will go beyond the statute's requirements by assuring access to 340B pricing through a contract pharmacy arrangement if a covered entity is unable to dispense 340B drugs from its own facilities. Indeed, our approach simply conforms to the contract pharmacy guidance that HRSA itself applied from 1996 through 2010.

Moreover, AstraZeneca's new approach to contract pharmacy recognition should not impact patient access, as our medicines will remain available to 340B entities at the 340B price. Our new approach is instead intended to bolster the integrity of the 340B program. For example,

according to the Government Accountability Office ("GAO"), patients -- even the low-income uninsured -- often receive no discount on drugs dispensed by contract pharmacies.[1] 340B in-house pharmacies, by contrast, are significantly more likely to offer discounts to patients.[2] The GAO also has expressed concern that the financial conflicts for covered entities created by the 340B program have distorted prescribing decisions, increased patient out-of-pocket costs, and jeopardized patient care.[3] HRSA's audits of covered entities have identified widespread contract pharmacy non-compliance. According to the HRSA website, over 25% of covered entities audited by HRSA since 2017 have had at least one finding related to contract pharmacy non-compliance. Our new approach responds to these systemic problems and seeks to restore balance to the 340B program.

HRSA's refusal to post our notice to covered entities is causing very real and tangible harm, as it is denying covered entities access to vital information on how to register their designated pharmacy. We fully recognize that AstraZeneca's change in contract pharmacy approach will require covered entities to make adjustments to their internal processes. Accordingly, we intended to give covered entities a 45-day advance notice in which they could work with our team to designate and enroll, if necessary, a contract pharmacy to dispense AstraZeneca medicines to the entity's 340B patients. We have a team of AstraZeneca personnel prepared to help covered entities navigate this process. HRSA's delay in posting our notice is depriving covered entities of the information they need to designate their contract pharmacy.

We request, therefore, that HRSA immediately post our notice on its website so that covered entities can learn how they may enroll and designate their pharmacy to receive AstraZeneca medicines. We also request that HRSA confirm to us promptly in writing that it will not seek civil monetary penalties against AstraZeneca related to our impending change to contract pharmacy designation, which fully complies with applicable law. As HRSA is aware, AstraZeneca has informed stakeholders that it intends to transition to its new approach by October 1, 2020. We accordingly request HRSA's written confirmation by October 1, 2020. Failure to post AstraZeneca's notice or to respond by that date could cause substantial confusion and disruption, interfering with AstraZeneca's ability to work with covered entities to implement its new approach.

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[1] See GAO, Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 30 (June 2018).

[2] See id. at n.46.

[3] See GAO, Medicare Part B Drugs, Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, "Highlights" page (June 2015) ("[Medicare] beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis. . . . The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status. . . . Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries as well, who would be financially liable for larger copayments as a result of receiving more drugs or more expensive drugs. In addition, this raises potential concerns about the appropriateness of the health care provided to these beneficiaries."). Although the government has taken steps to curb these incentives and risks for physician-administered drugs provided to Medicare patients, they remain unabated, for example, with respect to retail pharmacy drugs and drugs covered under commercial insurance.

As to the issue of confidentiality associated with AstraZeneca's communication to HRSA, AstraZeneca appreciates that these issues are subject to public awareness, however our intention was to work closely with HRSA during this transition process in an effort to receive the agency's direct feedback in a collaborative fashion. Once again, we would be very pleased to meet with HRSA at your earliest convenience to discuss this critically important issue for 340B program integrity and to correct any misunderstandings that HRSA may have about our approach. Thank you for your attention to this important matter.

Sincerely,

DocuSigned by:

0781790EE5034A7...

Odalys Caprisecca
Executive Director
US Strategic Pricing & Operations

Exhibit F

AstraZeneca

Date: September 14, 2020

Re: 340B Contract Pharmacy Pricing

AstraZeneca to date has provided 340B pricing to pharmacies associated with Contract Pharmacy arrangements consistent with the approach proposed in the Health Resources and Services Administration's ("HRSA") April 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach for the products listed on the enclosed attachment, such that AstraZeneca only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy. AstraZeneca will continue to provide our products directly to all Covered Entities at the required statutory ceiling price. Covered Entities will continue to be able to purchase our products at the statutory ceiling price from either their designated single Contract Pharmacy or the Covered Entity's on-site dispensing pharmacies.

To implement this process, any Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca at the email below to identify a single Contract Pharmacy of its choice that would be eligible to receive 340B pricing on behalf of the Covered Entity. AstraZeneca deeply values its participation in the 340B program and with Covered Entities and is committed to complying with all applicable requirements of the program. Please contact us at Membership@AstraZeneca.com with any questions or to initiate the process of selecting a single Contract Pharmacy to receive 340B pricing on behalf of your Covered Entity.

Sincerely,

DocuSigned by:

0791790EE5034A7...

Odalys Caprisecca
Executive Director, Strategic Pricing & Operations

NDCs

AstraZeneca

Product Name	NDC	Pkg Qty	Each Size/Description
BEVESPI AEROSPHERE®			
9/4.8 MCG 120 ACT INHALATION	00310-4600-12	1	1 INHALER
9/4.8 MCG 28 ACT INHALATION	00310-4600-39	1	1 INHALER
BRILINTA®			
TAB 90MG UD	00186-0777-39	1	100 COUNT BOX
TAB 90MG	00186-0777-60	1	60 COUNT BOTTLE
TAB 60MG	00186-0776-60	1	60 COUNT BOTTLE
BYDUREON®			
PEN 2MG	00310-6530-04	4	4 X 2MG Pen
BCISE AUTOINJECTOR	00310-6540-04	4	4 X 2MG AUTOINJECTOR
BYETTA®			
PEN 250MCG/ML	00310-6512-01	1	1 PEN X 1.2ML
PEN 250MCG/ML	00310-6524-01	1	1 PEN X 2.4ML
CRESTOR®			
TAB 5MG	00310-0755-90	1	90 COUNT BOTTLE
TAB 10 MG	00310-0751-90	1	90 COUNT BOTTLE
TAB 20 MG	00310-0752-90	1	90 COUNT BOTTLE
TAB 40 MG	00310-0754-30	1	30 COUNT BOTTLE
DALIRESP®			
TAB 250MCG	00310-0088-28	1	28 COUNT BLISTER
TAB 250MCG	00310-0088-39	1	2X10 HUD BLISTER PACK
TAB 500MCG	00310-0095-30	1	30 COUNT BOTTLE
TAB 500MCG	00310-0095-90	1	90 COUNT BOTTLE
FARXIGA®			
TAB 5MG	00310-6205-30	1	30 COUNT BOTTLE
TAB 10MG	00310-6210-30	1	30 COUNT BOTTLE
KOMBIGLYZE® XR			
TAB 5MG/500MG	00310-6135-30	1	30 COUNT BOTTLE
TAB 2.5MG/1000MG	00310-6125-60	1	60 COUNT BOTTLE
TAB 5MG/1000MG	00310-6145-30	1	30 COUNT BOTTLE
LOKELMA™			
ORAL SUSPENSION 5G	00310-1105-30	30	30 PACKETS
ORAL SUSPENSION 5G	00310-1105-39	11	11 PACKETS
ORAL SUSPENSION 10G	00310-1110-30	30	30 PACKETS
ORAL SUSPENSION 10G	00310-1110-39	11	11 PACKETS
NEXIUM®			
CAPS 20MG	00186-5020-31	1	30 COUNT BOTTLE
CAPS 20MG	00186-5020-54	1	90 COUNT BOTTLE
CAPS 40MG	00186-5040-31	1	30 COUNT BOTTLE
CAPS 40MG	00186-5040-54	1	90 COUNT BOTTLE

	IV INJ 40MG/5mL	00186-6040-01	10	10 x 5.0mL VIAL
	ORAL SUSPENSION 2.5MG	00186-4025-01	30	30 PACKETS
	ORAL SUSPENSION 5MG	00186-4050-01	30	30 PACKETS
	ORAL SUSPENSION 10MG	00186-4010-01	30	30 PACKETS
	ORAL SUSPENSION 20MG	00186-4020-01	30	30 PACKETS
	ORAL SUSPENSION 40MG	00186-4040-01	30	30 PACKETS
ONGLYZA®				
	TAB 2.5MG	00310-6100-30	1	30 COUNT BOTTLE
	TAB 2.5MG	00310-6100-90	1	90 COUNT BOTTLE
	TAB 5MG	00310-6105-30	1	30 COUNT BOTTLE
	TAB 5MG	00310-6105-90	1	90 COUNT BOTTLE
PULMICORT®				
	FLEXHALER 90-MCG	00186-0917-06	1	1 INHALER
	FLEXHALER 180-MCG	00186-0916-12	1	1 INHALER
	RESPULES .25 mg/2 ml	00186-1988-04	30	30 RESPULE BOX
	RESPULES .5 mg/2 ml	00186-1989-04	30	30 RESPULE BOX
	RESPULES 1 mg/2 ml	00186-1990-04	30	30 RESPULE BOX
QTERN®				
	TAB 5MG/5MG	00310-6770-30	30	30 COUNT BOTTLE
	TAB 10MG/5MG	00310-6780-30	30	30 COUNT BOTTLE
SEROQUEL®				
	TAB 100MG	00310-0271-10	1	100 COUNT BOTTLE
	TAB 200MG	00310-0272-10	1	100 COUNT BOTTLE
	TAB 25MG	00310-0275-10	1	100 COUNT BOTTLE
	TAB 300 MG	00310-0274-60	1	60 COUNT BOTTLE
	TAB 50 MG	00310-0278-10	1	100 COUNT BOTTLE
	TAB 400 MG	00310-0279-10	1	100 COUNT BOTTLE
SEROQUEL XR®				
	TAB 50 MG	00310-0280-60	1	60 COUNT BOTTLE
	TAB 150 MG	00310-0281-60	1	60 COUNT BOTTLE
	TAB 200 MG	00310-0282-60	1	60 COUNT BOTTLE
	TAB 300 MG	00310-0283-60	1	60 COUNT BOTTLE
	TAB 400 MG	00310-0284-60	1	60 COUNT BOTTLE
SYMBICORT®				
	80/4.5MCG	00186-0372-20	1	1 INHALER
	160/4.5MCG	00186-0370-20	1	1 INHALER
	80/4.5MCG Inst. Pack	00186-0372-28	1	1 INHALER
	160/4.5MCG Inst. Pack	00186-0370-28	1	1 INHALER
SYMLIN®				
	60-PEN 1000mcg/ml	00310-6615-02	2	2 PEN X 1.5ml
	120-PEN 1000mcg/ml	00310-6627-02	2	2 PEN X 2.7ml
XIGDUO® XR				
	TAB 2.5MG/1000MG	00310-6225-60	1	60 COUNT BOTTLE
	TAB 5MG/500MG	00310-6250-30	1	30 COUNT BOTTLE
	TAB 5MG/1000MG	00310-6260-60	1	60 COUNT BOTTLE
	TAB 10MG/500MG	00310-6270-30	1	30 COUNT BOTTLE
	TAB 10MG/1000MG	00310-6280-30	1	30 COUNT BOTTLE

Exhibit G

1800 Concord Pike
Legal
PO Box 15437
Wilmington, DE 19850-5437

November 02, 2020

BY FEDERAL EXPRESS & EMAIL

Rear Admiral Krista Pedley, PharmD, MS
Office of Pharmacy Affairs
Health Resources and Services Administration
Office of Pharmacy Affairs
5600 Fishers Lane, 08W10
Rockville, MD 20857

Dear Rear Admiral Pedley:

I write on behalf of AstraZeneca following up on our July 24 and September 15, 2020 letters concerning our approach under 340B to contract pharmacies, particularly in the wake of a lawsuit, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C.), recently filed by a 340B trade association and two covered entities against HHS, HRSA, Secretary Azar, and Administrator Engels. The lawsuit relates to the decision by AstraZeneca, and apparent decisions by other drug manufacturers, to change their approach to contract pharmacies.

Neither AstraZeneca nor any other manufacturers were named as defendants in this lawsuit. But plaintiffs seek relief that would significantly affect AstraZeneca's rights. For example, plaintiffs seek a declaration that they are entitled to purchase and dispense covered outpatient drugs through contract pharmacies at 340B discounts, as well as a variety of orders directing the government to seek various forms of penalties from AstraZeneca.* As the basis for these claims, plaintiffs allege that AstraZeneca "ha[s] flouted the 340B statute and regulation by openly refusing to sell 340B discounted drugs to covered entities when ordered via contract pharmacy arrangements." Compl. ¶ 2; *see id.* ¶¶ 52–64. The complaint excerpts selectively from a letter that AstraZeneca sent to 340B covered entities and claims that these excerpts demonstrate that AstraZeneca "ceased offering 340B pricing on drugs dispensed at contract pharmacies on October 1, 2020." *Id.* ¶ 62. The complaint further asserts that AstraZeneca has "denied 340B discounts to the Plaintiff Covered

* Plaintiffs also seek an order directing the Secretary to promulgate administrative dispute resolution (ADR) regulations within 60 days of the court's order.

Entities," *id.* ¶ 2, and that "[s]ince October 1, 2020," one of the named plaintiffs "has not been able to purchase 340B discounted drugs from AstraZeneca," *id.* ¶ 78.

As you know from our prior correspondence with HRSA, these allegations are not correct. As explained previously, under our approach, all covered entities will continue to have access to AstraZeneca medicines at the 340B price. The change that AstraZeneca has implemented makes its products available to covered entities either through their own in-house pharmacy or through a designated contract pharmacy. It is intended to mitigate program integrity risks associated with contract pharmacy transactions and, for the reasons articulated in our prior letters, is fully compliant with the 340B statute. We also note that, based on our investigations to date, none of the named plaintiffs has purchased AstraZeneca products through a contract pharmacy within the last 12 months; and all of the named plaintiffs continue to access our medicines at the statutory ceiling price through their on-site pharmacies.

Our prior correspondence requested meetings with HRSA to discuss our approach, with the first such request having been made in July 2020. HRSA unfortunately has not responded to any of our prior meeting requests. We continue to believe that such a meeting could resolve any misperceptions that may exist about AstraZeneca's contract pharmacy model. We therefore hereby formally request again to meet with HRSA to discuss this matter. Please advise us at your earliest convenience if the agency is accepting or rejecting our formal meeting request.

Sincerely,

DocuSigned by:
0781790EE5034A7...

Odalys Caprisecca
Executive Director
US Strategic Pricing & Operations

Exhibit H

William B. Schultz
PARTNER
Zuckerman Spaeder LLP
wschultz@zuckerman.com
202-778-1820

ZUCKERMAN SPAEDER

January 7, 2021

VIA EMAIL

Mariam Koohdary
U.S. General Counsel
AstraZeneca
1800 Concord Pike
Wilmington, DE 19803
mkoohdary@astrazeneca.com

Sharon D. Mayo
Arnold & Porter Kaye Scholer LLP
Three Embarcadero Center, 10th Floor
San Francisco, CA 94111
sharon.mayo@arnoldporter.com

Dear Ms. Koohdary and Ms. Mayo:

We represent the American Hospital Association, 340B Health, the Association of American Medical Colleges, America's Essential Hospitals, National Association of Children's Hospitals d/b/a the Children's Hospital Association, American Society of Health-System Pharmacists, Avera St. Mary's Hospital, Riverside Hospital, Inc., d/b/a Riverside Regional Medical Center, and Dignity Health d/b/a St. Mary's Medical Center in a lawsuit filed in the Northern District of California against Secretary Alex Azar and the Department of Health and Human Services (HHS) challenging the Department's failure to enforce the statutory requirement that AstraZeneca LP (AstraZeneca) and five other drugs companies provide 340B covered entities covered outpatient drugs at or below the 340B ceiling price when 340B drugs are dispensed from a contract pharmacy. *American Hospital Association et al v. Department of Health & Human Services et al.*, No. 3:20-cv-08806-YGR.

After the lawsuit was filed, the General Counsel of HHS issued an advisory opinion on December 30, 2020, in which the Department agrees with us that the 340B statute requires drug companies to provide 340B entities covered outpatient drugs at or below the 340B ceiling price when those covered entities use contract pharmacies to dispense the drugs. *See* Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program. Accordingly, AstraZeneca's policy of not providing 340B discounts to 340B providers when AstraZeneca's drugs are dispensed through all but one contract pharmacy is in clear violation of the statute, and AstraZeneca should

immediately discontinue its illegal practice. In addition, AstraZeneca should reimburse 340B entities for the damages they have incurred due to AstraZeneca's policy.

If AstraZeneca continues its illegal practice, we will continue to seek to require that HHS enforce the 340B statute, covered entities are reimbursed for damages caused by the illegal policy, and the matter is referred to the HHS Inspector General for the imposition of civil money penalties.

We look forward to your response.

Sincerely,

William B. Schultz

William B. Schultz
Margaret M. Dotzel

I. 340B Violation Letters

II. Statutes, Regulations, and Related Content

III. Notices, Guidance, and Proposed Guidance

Community Care TX
Community Health Care
Compass Health Care
Conway Med Center
Cook Children's Med Center
Crew Health
Dartmouth Hitchcock
Dubois Regional Med Center
East Valley CH C
ECHO Community Healthcare
El Rio Santa Cruz
Erie Family Health Centers
Excelth
Family Med Center Michigan
Family Medicine Health Center
Five Horizons
Fredericksburg Area
GA Carmichael
Genesis Healthcare
Gerald Champion Reg. MC
Harrisonburg Community Health Care
Health Point Family Care
Health Source of OH
Health West
HealthLinc
HealthNet Community Health
Hendrick Medical
Hendry Regional Med Center
Horizon Health Care
Hudson River Healthcare
Hudson Valley Community Services
Iowa Methodist
Johnson County Hospital
Kearney County Health Services
Kent County Memorial Hosp
Keystone Health
KIND clinic
Koerner Whipple Pharmacy
Lakeland Immediate
Lancaster Heath Center
Life Changers Intervention
Little Rivers Healthcare
Long Island Jewish
Lowcountry AIDS Services
Loyola University Med Center
Maine Health
Massac Memorial Hosp
Matthew 25 AIDS Service

MedStar Health System
Memorial Healthcare System
Mendocino Health Center
Meriter Health Services
Metro Health
MHC Health Care
MHEDS
Morehouse Community MC
MQVN Community
Nebraska Medical Center
Neighborhood Health Center
New Hanover Regional MC
NO AIDS task force
North Country
North Olympic Healthcare
Northwest Health Services
Northwest Human Services
Oakhurst Med Center
Oaklawn Hospital
Open Doors Community Health
Pascua Yaqui Health Services
Peace Health
Peninsula Institute for Community
Penobscot Community Health
Piedmont Care
Porter Hospital
Primary Health Network
RAIN
RAO Community
Regional Health Care Affiliates
Rhode Island Hospital
S. Central MO CHC
Salina Health Edu. Foundation
Sanford Health
Santa Barbara County Health
Shenandoah Community Health
St. Alphonsus
St. Anthony Regional Hospital
St. Charles Health
St. Luke's Methodist
St. Luke's Regional
Sunset Health Clinic
Tandem Health
Thundermist
Trinity Regional Med Center
Truman Medical Center
Tufts Medical Center
U Mass Memorial

V. Administrative Dispute Resolution Petitions and Supporting Documentation

VI. Correspondence

VII. Meeting Notes and Materials

VIII. Reports and Miscellaneous Content

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, v. XAVIER BECERRA *et al.* *Defendants.*	Case No. 21-cv-27-LPS

CERTIFICATION OF ADMINISTRATIVE RECORD

I, Krista M. Pedley, Director of the Office of Pharmacy Affairs, Health Resources and Services Administration ("HRSA"), United States Department of Health and Human Services, certify, based on information obtained during the performance of my official duties as the Director of the Office of Pharmacy Affairs, that the attached documents constitute a true and accurate copy of all non-privileged documents that were directly or indirectly considered in connection with the issuance of HRSA's May 17, 2021 letter to AstraZeneca Pharmaceuticals, LP.

Executed this 8th day of July 2021, in Frederick, MD.

Krista M. Pedley -S

Digitally signed by Krista M. Pedley -S
Date: 2021.07.08 10:34:26 -04'00'

Krista M. Pedley, PharmD, MS
RADM, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
United States Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 17, 2021

Ms. Odalys Caprisecca
Executive Director, US Strategic Price & Operations
AstraZeneca Pharmaceuticals, LP
1800 Concord Pike
Wilmington, DE 19803

Dear Ms. Caprisecca:

The Health Resources and Services Administration (HRSA) has completed its review of AstraZeneca Pharmaceuticals, LP's (AstraZeneca) policy that places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…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." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. AstraZeneca is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

AstraZeneca purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, AstraZeneca must 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. AstraZeneca must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from AstraZeneca's policy. AstraZeneca must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on AstraZeneca's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that AstraZeneca provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

/Diana Espinosa/

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: 26 Health **340B ID:** STD32803

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00186091612	PULMICORT FLEXHLR 180MCG 120DS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186091706	PULMICORT FLEXHLR 90MCG 60DS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037028	SYMBICORT MDI 160 4.5MCG HUD60	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037020	SYMBICORT MDI 160 4.5MCG 120DO	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037220	SYMBICORT MDI 80 4.5MCG 120DO	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037228	SYMBICORT MDI 80 4.5MCG HUD60	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186402001	NEXIUM DR OS PWD 20MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186404001	NEXIUM DR OS PWD 40MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

00186401001	NEXIUM DR OS PWD 10MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186402501	NEXIUM DR OS PWD 2.5MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186405001	NEXIUM DR OS PWD 5MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186003231	ATACAND TAB 32MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186604001	NEXIUM IV 40MG 5ML 10	AstraZeneca Pharmaceuticals LP	10		CT	McKesson
00186502031	NEXIUM CAP 20MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186502054	NEXIUM CAP 20MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00186504054	NEXIUM CAP 40MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00186504031	NEXIUM CAP 40MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186077760	BRILINTA TAB 90MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00186077739	BRILINTA TAB 90MG UD 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00186198904	PULMICORT RESPULE 0.5MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186198804	PULMICORT RESPULE .25MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186077660	BRILINTA TAB 60MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00186199004	PULMICORT RESPULE 1MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☒ No
- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

Table 1: Unavailable at 340B Price

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ✓ Other (*please describe*): Manufacturer 340B Price Violation
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ✓ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☐ Other (*please describe issue*):

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Table 2: Incorrect 340B Price

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)
    - Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*
- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
    - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
    - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
    - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
    - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

Price paid by the covered entity (including package size): _____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Dr David Baker-Hargrove **Phone**: 321-800-2922 xtn 1101

Email Address: drdavid@26health.org

Contact Role/Organizat: DocuSigned by: President/Co-CEO

Contact Signature: Dr David Baker-Hargrove AC361686FD3742C... **Date**: 11/2/2020

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: 26 Health **340B ID:** STD32803

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00310622560	XIGDUO XR TAB 2.5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310048230	MPB IRESSA 250MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310134930	MPB TAGRISSO 40MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310135030	MPB TAGRISSO 80MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310173030	MPB FASENRA 30MG PFS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310183030	MPB FASENRA 30MG PEN	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310450012	MPB IMFINZI VIAL 120MG 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310461150	MPB IMFINZI VIAL 500MG 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

00310066812	MPB LYNPARZA 100MG 120 TAB	AstraZeneca Pharmaceuticals LP	120		EA	McKesson
00310067912	MPB LYNPARZA 150MG 120 TAB	AstraZeneca Pharmaceuticals LP	120		EA	McKesson
00310067960	MPB LYNPARZA 150MG 60 TAB	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310066860	MPB LYNPARZA 100MG 60 TAB	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310470001	MPB LUMOXITI 1MG SDV	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310051260	MPB CALQUENCE 100MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310062560	MPB KOSELUGO 25MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310061060	MPB KOSELUGO 10MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310651201	BYETTA SINJ 250MCG ML	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310652401	BYETTA PEN 10MCG	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310661502	SYMLIN PEN 60 1.5ML 2	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310662702	SYMLIN PEN 120 2.7ML 2	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310625030	XIGDUO XR TAB 5 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310627030	XIGDUO XR TAB 10 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310628030	XIGDUO XR TAB 10 1000MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310620530	FARXIGA TAB 5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310621030	FARXIGA TAB 10MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310610090	ONGLYZA TAB 2.5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310610590	ONGLYZA TAB 5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310613530	KOMBIGLYZ XR TB 5MG 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

00310610530	ONGLYZA TAB 5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310610030	ONGLYZA TAB 2.5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310614530	KOMBIGLYZ XR TB 5MG 1000MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310626060	XIGDUO XR TAB 5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310612560	KOMBIGLYZ XR TB 2.5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310653004	BYDUREON PEN 2MG CT4	AstraZeneca Pharmaceuticals LP	4		CT	McKesson
00310075590	CRESTOR TAB 5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075290	CRESTOR TAB 20MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075190	CRESTOR TAB 10MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075430	CRESTOR TAB 40MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310072010	FASLODEX PFS 250MG 5ML 2X5.0ML	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310028060	SEROQUEL XR TAB 50MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028360	SEROQUEL XR TAB 300MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028260	SEROQUEL XR TAB 200MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028460	SEROQUEL XR TAB 400MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028160	SEROQUEL XR TAB 150MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310027510	SEROQUEL TAB 25MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027210	SEROQUEL TAB 200MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027110	SEROQUEL TAB 100MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310678030	QTERN 10MG 5MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

00310677030	QTERN 5MG 5MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310460012	BEVESPI AEROSPHERE 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310460039	BEVESPI AEROSPHERE HUD 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310027460	SEROQUEL TAB 300MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310009590	DALIRESP 500MCG TAB 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310009530	DALIRESP TAB 500MCG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310027810	SEROQUEL TAB 50MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027910	SEROQUEL TAB 400MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310196930	MOVANTIK TAB 12.5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310197039	MOVANTIK TAB 25MG BLSTR UD 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310197030	MOVANTIK TAB 25MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310654004	BYDUREON BCISE AUTOINJ 2MG CT4	AstraZeneca Pharmaceuticals LP	4		CT	McKesson
00310110530	LOKELMA O S 5G 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00310111030	LOKELMA O S 10G 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00310110539	LOKELMA O S 5G HUD 11	AstraZeneca Pharmaceuticals LP	11		CT	McKesson
00310111039	LOKELMA O S 10G HUD 11	AstraZeneca Pharmaceuticals LP	11		CT	McKesson
00310008828	DALIRESP TAB 250MCG UD 28	AstraZeneca Pharmaceuticals LP	28		EA	McKesson
00310008839	DALIRESP TAB 250MCG UD 20	AstraZeneca Pharmaceuticals LP	20		EA	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ✕ No

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

Table 1: Unavailable at 340B Price

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ✓ Other (*please describe*): Manufacturer 340B Price Violation
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ✓ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☐ Other (*please describe issue*):

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

From: Amanda Murray
To: HRSA HSB 340B Pricing
Subject: Manufacturer document
Date: Monday, April 26, 2021 3:33:24 PM
Attachments: image001.png
AstraZeneca for HHS.pdf
Sanofi for HHS.pdf
Lilly for HHS.pdf

Good afternoon,

I am sending this email with attached documents to inform HRSA that with the manufacturers with holding medications from 340B pricing this is hurting our patients.

Thank you,

Amanda C. Murray CPhT, 340B ACE
340B Program Manager

3033 N. Central Ave. Suite 145
Phoenix, AZ 85012
P: 1.623.583.3001 ext 011312
C: 480.993.6079
amurray@adelantehealthcare.org
340B@adelantehealthcare.org

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: Adelante Healthcare **340B ID:CH093030**

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
1. 00310651201	BYETTA 5 MCG DOSE PEN INJ	ASTRAZENECA PHARMACEUTICALS LP	1.200	1	Milliliter	
2. 00310662702	SYMLINPEN 120 PEN INJECTOR	ASTRAZENECA PHARMACEUTICALS LP	2.700	2	Milliliter	
3. 00310610590	ONGLYZA 5 MG TABLET	ASTRAZENECA PHARMACEUTICALS LP	90.000	1	Tablet	

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes X No
- The issue reported is limited to a contract pharmacy purchase X Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes X No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 1: Unavailable at 340B Price
AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ■ Other (*please describe*): **Manufacturers are blocking 340B prices for drugs shipped to my contract pharmacies**
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ■ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ■ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ■ Other (*please describe issue*): **AstraZeneca is blocking 340B prices for their drugs ordered by my covered entity that are shipped to my contract pharmacies. I am forced to pay WAC for these products for my contract pharmacies. Additional labeler codes from AstraZeneca are affected - ***this is not a complete list of affected NDCs from AstraZeneca*****.

Date issue first observed: **October 1, 2020**

Date drug last available at 340B price (enter NEVER if has never been available): **September 30, 2020**

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

  Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*

- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

  _____
  _____
  _____
  _____
  _____
  _____

Price paid by the covered entity (including package size):_____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Eric Battis **Phone**: 623.583.3001

Email Address: ebattis@adelantehealthcare.org

Contact Role/Organization: Chief Administrative Officer Adelante Healthcare

Contact Signature: EB **Date**: 4/21/21

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

From: Notification Server
To: HRSA HSB 340B Pricing
Cc: Rick.Fischer@amitahealth.org
Subject: Pricing Notification
Date: Thursday, October 22, 2020 1:46:16 PM
Attachments: PriceNotification33.pdf

Please see the attached pricing notification form.

Thank you.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: Adventist GlenOaks Hospital **340B ID:** DSH140292

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

NDC	Drug Name	Manufacturer	Package Size	Case Package Size	Unit of Measure	CE Wholesaler
00310-0679-12	MPB LYNPARZA 150MG 120 TAB	ASTRAZENECA / MCK SP/MPB	120	1	Tablet	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

This drug is commonly referred to as a specialty drug	Yes
The issue reported is limited to a contract pharmacy purchase?	Yes
If shortage-related, is this a recurrent/intermittent availability issue?	No
If shortage-related, is this due to a local/regional/national or global shortage?	

Table 1: Unavailable at 340B Price

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug Shortage
- ☐ Drug Subject to limited distribution or specialty pharmacy plan
- ☒ Other (please describe): Astra Zeneca no longer providing 340B pricing
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)
- ☐ Other (please describe):

Date issue first observed: 10/01/2020

Date drug last available at 340B price (enter NEVER if has never been available): 09/21/2020

Table 2: Incorrect 340B Price

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☒ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

  Note: For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term “covered outpatient drug” does not include orphan drugs

- ☒ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - o Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - o The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - o For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - o Adjust the purchase price for your wholesaler distribution charge/markdown

- ☐ Attempted to work with the entity’s wholesaler and directly with the manufacturer to resolve the pricing issue

- ☒ Other (please describe): Manufacturer no longer offering 340B price.

Price paid by the covered entity (including package size):

Date issue first observed: 10/01/2020

Date drug last available at 340B price (enter NEVER if has never been available): 09/21/2020

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Rick Fischer **Phone**: 630-914-2872

Email Address: Rick.Fischer@amitahealth.org

Contact Role/Organization: 340B Program Director

Contact Signature: Rick Fischer **Date:** 10/22/2020

From: Vance, Kathryn B.
To: HRSA HSB 340B Pricing
Subject: 340B Ceiling Price Unavailable/Incorrect 340B Ceiling Price Notification for HRSA - AIDS Response Effort, Inc.
Date: Wednesday, December 2, 2020 3:25:32 PM
Attachments: image001.png
HRSA_PrEP_AIDSResponseEffortInc.pdf
HRSA_RyanWhite_AIDSResponseEffortInc..pdf

I have attached two letters regarding the 340B Ceiling Price Unavailable/Incorrect 340B Pricing Notification from AIDS Response Effort, Inc. Thank you.

Katie Vance (she/her/hers)
Executive Director
AIDS Response Effort, Inc.

124 West Piccadilly Street
Winchester, VA 22601
Phone: 540-536-5291
Fax: 540-431-5996

valley health

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: AIDS Response Effort PrEP **340B ID:** STD226011

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00310622560	XIGDUO XR TAB 2.5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310048230	MPB IRESSA 250MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310134930	MPB TAGRISSO 40MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310135030	MPB TAGRISSO 80MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310173030	MPB FASENRA 30MG PFS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310183030	MPB FASENRA 30MG PEN	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310450012	MPB IMFINZI VIAL 120MG 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310461150	MPB IMFINZI VIAL 500MG 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

00310066812	MPB LYNPARZA 100MG 120 TAB	AstraZeneca Pharmaceuticals LP	120		EA	McKesson
00310067912	MPB LYNPARZA 150MG 120 TAB	AstraZeneca Pharmaceuticals LP	120		EA	McKesson
00310067960	MPB LYNPARZA 150MG 60 TAB	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310066860	MPB LYNPARZA 100MG 60 TAB	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310470001	MPB LUMOXITI 1MG SDV	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310051260	MPB CALQUENCE 100MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310062560	MPB KOSELUGO 25MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310061060	MPB KOSELUGO 10MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310651201	BYETTA SINJ 250MCG ML	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310652401	BYETTA PEN 10MCG	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310661502	SYMLIN PEN 60 1.5ML 2	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310662702	SYMLIN PEN 120 2.7ML 2	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310625030	XIGDUO XR TAB 5 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310627030	XIGDUO XR TAB 10 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310628030	XIGDUO XR TAB 10 1000MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310620530	FARXIGA TAB 5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310621030	FARXIGA TAB 10MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310610090	ONGLYZA TAB 2.5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310610590	ONGLYZA TAB 5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310613530	KOMBIGLYZ XR TB 5MG 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

00310610530	ONGLYZA TAB 5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310610030	ONGLYZA TAB 2.5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310614530	KOMBIGLYZ XR TB 5MG 1000MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310626060	XIGDUO XR TAB 5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310612560	KOMBIGLYZ XR TB 2.5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310653004	BYDUREON PEN 2MG CT4	AstraZeneca Pharmaceuticals LP	4		CT	McKesson
00310075590	CRESTOR TAB 5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075290	CRESTOR TAB 20MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075190	CRESTOR TAB 10MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075430	CRESTOR TAB 40MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310072010	FASLODEX PFS 250MG 5ML 2X5.0ML	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310028060	SEROQUEL XR TAB 50MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028360	SEROQUEL XR TAB 300MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028260	SEROQUEL XR TAB 200MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028460	SEROQUEL XR TAB 400MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028160	SEROQUEL XR TAB 150MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310027510	SEROQUEL TAB 25MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027210	SEROQUEL TAB 200MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027110	SEROQUEL TAB 100MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310678030	QTERN 10MG 5MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus | 340B Prime Vendor PROGRAM

00310677030	QTERN 5MG 5MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310460012	BEVESPI AEROSPHERE 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310460039	BEVESPI AEROSPHERE HUD 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310027460	SEROQUEL TAB 300MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310009590	DALIRESP 500MCG TAB 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310009530	DALIRESP TAB 500MCG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310027810	SEROQUEL TAB 50MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027910	SEROQUEL TAB 400MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310196930	MOVANTIK TAB 12.5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310197039	MOVANTIK TAB 25MG BLSTR UD 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310197030	MOVANTIK TAB 25MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310654004	BYDUREON BCISE AUTOINJ 2MG CT4	AstraZeneca Pharmaceuticals LP	4		CT	McKesson
00310110530	LOKELMA O S 5G 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00310111030	LOKELMA O S 10G 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00310110539	LOKELMA O S 5G HUD 11	AstraZeneca Pharmaceuticals LP	11		CT	McKesson
00310111039	LOKELMA O S 10G HUD 11	AstraZeneca Pharmaceuticals LP	11		CT	McKesson
00310008828	DALIRESP TAB 250MCG UD 28	AstraZeneca Pharmaceuticals LP	28		EA	McKesson
00310008839	DALIRESP TAB 250MCG UD 20	AstraZeneca Pharmaceuticals LP	20		EA	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☒ No

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

Table 1: Unavailable at 340B Price

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ✓ Other (*please describe*): Manufacturer 340B Price Violation
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ✓ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☐ Other (*please describe issue*):

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price
PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)
  - Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*
- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

Price paid by the covered entity (including package size): _____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Katie Vance **Phone**: 540-536-5291

Email Address: Kvance3@valleyhealthlink.com

Contact Role/Organization: Executive Director, AIDS Response Effort

Contact Signature: Katie Vance **Date**: 11/30/2020

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus | 340B Prime Vendor PROGRAM™

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: AIDS Response Effort PrEP **340B ID:** STD226011

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00186091612	PULMICORT FLEXHLR 180MCG 120DS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186091706	PULMICORT FLEXHLR 90MCG 60DS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037028	SYMBICORT MDI 160 4.5MCG HUD60	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037020	SYMBICORT MDI 160 4.5MCG 120DO	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037220	SYMBICORT MDI 80 4.5MCG 120DO	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037228	SYMBICORT MDI 80 4.5MCG HUD60	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186402001	NEXIUM DR OS PWD 20MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186404001	NEXIUM DR OS PWD 40MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

00186401001	NEXIUM DR OS PWD 10MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186402501	NEXIUM DR OS PWD 2.5MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186405001	NEXIUM DR OS PWD 5MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186003231	ATACAND TAB 32MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186604001	NEXIUM IV 40MG 5ML 10	AstraZeneca Pharmaceuticals LP	10		CT	McKesson
00186502031	NEXIUM CAP 20MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186502054	NEXIUM CAP 20MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00186504054	NEXIUM CAP 40MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00186504031	NEXIUM CAP 40MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186077760	BRILINTA TAB 90MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00186077739	BRILINTA TAB 90MG UD 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00186198904	PULMICORT RESPULE 0.5MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186198804	PULMICORT RESPULE .25MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186077660	BRILINTA TAB 60MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00186199004	PULMICORT RESPULE 1MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☒ No
- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

Table 1: Unavailable at 340B Price

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ✓ Other (*please describe*): Manufacturer 340B Price Violation
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ✓ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☐ Other (*please describe issue*):

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price
PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)
  - Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*
- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

Price paid by the covered entity (including package size): _____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Katie Vance **Phone**: 540-536-5291

Email Address: Kvance3@valleyhealthlink.com

Contact Role/Organization: Executive Director, AIDS Response Effort

Contact Signature: Katie Vance **Date**: 11/30/2020

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: AIDS Response Effort **340B ID:** RWII22601

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00186091612	PULMICORT FLEXHLR 180MCG 120DS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186091706	PULMICORT FLEXHLR 90MCG 60DS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037028	SYMBICORT MDI 160 4.5MCG HUD60	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037020	SYMBICORT MDI 160 4.5MCG 120DO	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037220	SYMBICORT MDI 80 4.5MCG 120DO	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037228	SYMBICORT MDI 80 4.5MCG HUD60	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186402001	NEXIUM DR OS PWD 20MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186404001	NEXIUM DR OS PWD 40MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

00186401001	NEXIUM DR OS PWD 10MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186402501	NEXIUM DR OS PWD 2.5MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186405001	NEXIUM DR OS PWD 5MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186003231	ATACAND TAB 32MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186604001	NEXIUM IV 40MG 5ML 10	AstraZeneca Pharmaceuticals LP	10		CT	McKesson
00186502031	NEXIUM CAP 20MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186502054	NEXIUM CAP 20MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00186504054	NEXIUM CAP 40MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00186504031	NEXIUM CAP 40MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186077760	BRILINTA TAB 90MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00186077739	BRILINTA TAB 90MG UD 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00186198904	PULMICORT RESPULE 0.5MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186198804	PULMICORT RESPULE .25MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186077660	BRILINTA TAB 60MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00186199004	PULMICORT RESPULE 1MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☒ No
- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

Table 1: Unavailable at 340B Price

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ✓ Other (*please describe*): Manufacturer 340B Price Violation
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ✓ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☐ Other (*please describe issue*):

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price
PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)
  - Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*
- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

Price paid by the covered entity (including package size): _____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Katie Vance **Phone**: 540-536-5291

Email Address: kvance3@valleyhealthlink.com

Contact Role/Organization: Executive Director, AIDS Response Effort

Contact Signature: Katie Vance **Date**: 11/30/2020

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: AIDS Support Group of Cape Cod **340B ID:** RWII02657

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00186091612	PULMICORT FLEXHLR 180MCG 120DS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186091706	PULMICORT FLEXHLR 90MCG 60DS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037028	SYMBICORT MDI 160 4.5MCG HUD60	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037020	SYMBICORT MDI 160 4.5MCG 120DO	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037220	SYMBICORT MDI 80 4.5MCG 120DO	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037228	SYMBICORT MDI 80 4.5MCG HUD60	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186402001	NEXIUM DR OS PWD 20MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186404001	NEXIUM DR OS PWD 40MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

00186401001	NEXIUM DR OS PWD 10MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186402501	NEXIUM DR OS PWD 2.5MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186405001	NEXIUM DR OS PWD 5MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186003231	ATACAND TAB 32MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186604001	NEXIUM IV 40MG 5ML 10	AstraZeneca Pharmaceuticals LP	10		CT	McKesson
00186502031	NEXIUM CAP 20MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186502054	NEXIUM CAP 20MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00186504054	NEXIUM CAP 40MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00186504031	NEXIUM CAP 40MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186077760	BRILINTA TAB 90MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00186077739	BRILINTA TAB 90MG UD 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00186198904	PULMICORT RESPULE 0.5MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186198804	PULMICORT RESPULE .25MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186077660	BRILINTA TAB 60MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00186199004	PULMICORT RESPULE 1MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☒ No
- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

Table 1: Unavailable at 340B Price

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ✓ Other (*please describe*): Manufacturer 340B Price Violation
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ✓ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____
  _____
- ☐ Other (*please describe issue*):

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  _____
  _____
  _____

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Table 2: Incorrect 340B Price

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)
    - Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*
- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
    - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
    - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
    - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
    - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

Price paid by the covered entity (including package size): _____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Paul E Goddu **Phone**: 508-487-9445

Email Address: pgoddu@asgcc.org

Contact Role/Organization: CFO, AIDS Support Group of Cape Cod, Inc

Contact Signature: Paul E Goddu **Date**: 02/09/2021

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: __Alcona Citizens for Health, Inc._____ **340B ID:** _CH051980_____

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00186037020	SYMBICORT 160-4.5 MCG INHALER	ASTRAZENECA PHARMACEUTICALS LP	10.2	1	Gram	McKesson
00310654004	BYDUREON BCISE 2 MG AUTOINJECT	ASTRAZENECA PHARMACEUTICALS LP	0.85	4	Milliliter	McKesson
00310610590	ONGLYZA 5 MG TABLET	ASTRAZENECA PHARMACEUTICALS LP	90.000	1	Tablet	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes X No
- The issue reported is limited to a contract pharmacy purchase X Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes X No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 1: Unavailable at 340B Price
AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ☑ Other (*please describe*): **Manufacturers are blocking 340B prices for drugs shipped to my contract pharmacies**
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☑ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.

- ☐ Confirmed shortage issues by reviewing validated resources*
- ☑ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____

- ☑ Other (*please describe issue*): **AstraZeneca is blocking 340B prices for their drugs ordered by my covered entity that are shipped to my contract pharmacies. I am forced to pay WAC for these products for my contract pharmacies. Additional labeler codes from AstraZeneca are affected - ***this is not a complete list of affected NDCs from AstraZeneca*****.

Date issue first observed: **October 1, 2020**

Date drug last available at 340B price (enter NEVER if has never been available): **September 30, 2020**

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Table 2: Incorrect 340B Price
PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

  Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*

- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

  _____
  _____
  _____
  _____
  _____
  _____

Price paid by the covered entity (including package size):_____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Anna Rumbles **Phone**: 989-358-3922

Email Address: arumbles@alconahc.org

Contact Role/Organization: Director of Pharmacy, Alcona Citizens for Health, Inc.

Contact Signature:  **Date**: 10/29/2020

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: Alliance for Living **340B ID:** RWII06320

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00186091612	PULMICORT FLEXHLR 180MCG 120DS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186091706	PULMICORT FLEXHLR 90MCG 60DS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037028	SYMBICORT MDI 160 4.5MCG HUD60	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037020	SYMBICORT MDI 160 4.5MCG 120DO	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037220	SYMBICORT MDI 80 4.5MCG 120DO	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186037228	SYMBICORT MDI 80 4.5MCG HUD60	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00186402001	NEXIUM DR OS PWD 20MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186404001	NEXIUM DR OS PWD 40MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

00186401001	NEXIUM DR OS PWD 10MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186402501	NEXIUM DR OS PWD 2.5MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186405001	NEXIUM DR OS PWD 5MG PKT 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186003231	ATACAND TAB 32MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186604001	NEXIUM IV 40MG 5ML 10	AstraZeneca Pharmaceuticals LP	10		CT	McKesson
00186502031	NEXIUM CAP 20MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186502054	NEXIUM CAP 20MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00186504054	NEXIUM CAP 40MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00186504031	NEXIUM CAP 40MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00186077760	BRILINTA TAB 90MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00186077739	BRILINTA TAB 90MG UD 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00186198904	PULMICORT RESPULE 0.5MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186198804	PULMICORT RESPULE .25MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00186077660	BRILINTA TAB 60MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00186199004	PULMICORT RESPULE 1MG 2ML 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☒ No
- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

Table 1: Unavailable at 340B Price

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ✓ Other (*please describe*): Manufacturer 340B Price Violation
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ✓ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____
  _____
- ☐ Other (*please describe issue*):

  _____
  _____
  _____
  _____
  _____
  _____

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Purchased Drugs for Table 2							
NDC	Drug Name	Manufacturer	CE Wholesaler	Package Size	Purchased Price	Purchased Date	Last Available
00186037020	SYMBICORT MDI 160/4.5MCG 120DO	ASTRAZENECA	McKesson	1	346.16	10/21/2020	09/30/2020

Table 2: Incorrect 340B Price

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)
  - Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*
- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

Price paid by the covered entity (including package size): See "Purchased Drugs for Table 2" above

Date issue first observed: See "Purchased Drugs for Table 2" above

Date product last available at correct price (enter NEVER if has never been available): See above

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Kelly Thompson **Phone**: 860-447-0884

Email Address: kthompson@allianceforliving.org

Contact Role/Organization: CEO

Contact Signature: Kelly Thompson **Date**: 2/11/21

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: Alliance for Living **340B ID:** RWII06320

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00310622560	XIGDUO XR TAB 2.5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310048230	MPB IRESSA 250MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310134930	MPB TAGRISSO 40MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310135030	MPB TAGRISSO 80MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310173030	MPB FASENRA 30MG PFS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310183030	MPB FASENRA 30MG PEN	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310450012	MPB IMFINZI VIAL 120MG 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310461150	MPB IMFINZI VIAL 500MG 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

00310066812	MPB LYNPARZA 100MG 120 TAB	AstraZeneca Pharmaceuticals LP	120		EA	McKesson
00310067912	MPB LYNPARZA 150MG 120 TAB	AstraZeneca Pharmaceuticals LP	120		EA	McKesson
00310067960	MPB LYNPARZA 150MG 60 TAB	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310066860	MPB LYNPARZA 100MG 60 TAB	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310470001	MPB LUMOXITI 1MG SDV	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310051260	MPB CALQUENCE 100MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310062560	MPB KOSELUGO 25MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310061060	MPB KOSELUGO 10MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310651201	BYETTA SINJ 250MCG ML	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310652401	BYETTA PEN 10MCG	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310661502	SYMLIN PEN 60 1.5ML 2	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310662702	SYMLIN PEN 120 2.7ML 2	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310625030	XIGDUO XR TAB 5 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310627030	XIGDUO XR TAB 10 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310628030	XIGDUO XR TAB 10 1000MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310620530	FARXIGA TAB 5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310621030	FARXIGA TAB 10MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310610090	ONGLYZA TAB 2.5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310610590	ONGLYZA TAB 5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310613530	KOMBIGLYZ XR TB 5MG 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

00310610530	ONGLYZA TAB 5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310610030	ONGLYZA TAB 2.5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310614530	KOMBIGLYZ XR TB 5MG 1000MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310626060	XIGDUO XR TAB 5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310612560	KOMBIGLYZ XR TB 2.5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310653004	BYDUREON PEN 2MG CT4	AstraZeneca Pharmaceuticals LP	4		CT	McKesson
00310075590	CRESTOR TAB 5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075290	CRESTOR TAB 20MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075190	CRESTOR TAB 10MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075430	CRESTOR TAB 40MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310072010	FASLODEX PFS 250MG 5ML 2X5.0ML	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310028060	SEROQUEL XR TAB 50MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028360	SEROQUEL XR TAB 300MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028260	SEROQUEL XR TAB 200MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028460	SEROQUEL XR TAB 400MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028160	SEROQUEL XR TAB 150MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310027510	SEROQUEL TAB 25MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027210	SEROQUEL TAB 200MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027110	SEROQUEL TAB 100MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310678030	QTERN 10MG 5MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

00310677030	QTERN 5MG 5MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310460012	BEVESPI AEROSPHERE 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310460039	BEVESPI AEROSPHERE HUD 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310027460	SEROQUEL TAB 300MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310009590	DALIRESP 500MCG TAB 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310009530	DALIRESP TAB 500MCG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310027810	SEROQUEL TAB 50MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027910	SEROQUEL TAB 400MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310196930	MOVANTIK TAB 12.5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310197039	MOVANTIK TAB 25MG BLSTR UD 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310197030	MOVANTIK TAB 25MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310654004	BYDUREON BCISE AUTOINJ 2MG CT4	AstraZeneca Pharmaceuticals LP	4		CT	McKesson
00310110530	LOKELMA O S 5G 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00310111030	LOKELMA O S 10G 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00310110539	LOKELMA O S 5G HUD 11	AstraZeneca Pharmaceuticals LP	11		CT	McKesson
00310111039	LOKELMA O S 10G HUD 11	AstraZeneca Pharmaceuticals LP	11		CT	McKesson
00310008828	DALIRESP TAB 250MCG UD 28	AstraZeneca Pharmaceuticals LP	28		EA	McKesson
00310008839	DALIRESP TAB 250MCG UD 20	AstraZeneca Pharmaceuticals LP	20		EA	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ✕ No

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

Table 1: Unavailable at 340B Price

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ✓ Other (*please describe*): Manufacturer 340B Price Violation
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ✓ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☐ Other (*please describe issue*):

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Table 2: Incorrect 340B Price

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)
    - Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*
- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
    - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
    - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
    - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
    - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

Price paid by the covered entity (including package size): _____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Kelly Thompson **Phone**: 860-447-0884

Email Address: kthompson@allianceforliving.org

Contact Role/Organization: CEO

Contact Signature: Kelly Thompson **Date**: 2/11/21

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

From: Hannah Rowell
To: HRSA HSB 340B Pricing
Subject: Reporting instances of 340B Ceiling Price Unavailable
Date: Thursday, October 15, 2020 7:12:59 PM
Attachments: image504007.png
image189644.png
image921528.png
image152793.png
image974974.png
AstraZeneca 340B-ceiling-price-unavailable-incorrect-340b-ceiling-price-notification-for-hrsa (2).docx
Eli Lilly 340B-ceiling-price-unavailable-incorrect-340b-ceiling-price-notification-for-hrsa (2).docx
Sanofi 340B-ceiling-price-unavailable-incorrect-340b-ceiling-price-notification-for-hrsa (2).docx

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To HRSA Pricing,
The fine folks at Apexus and NACHC showed me how to report when 340B drugs are unavailable at the ceiling price.
I have completed three of the "340B Ceiling Price Unavailable/Incorrect 340B Ceiling Price Notification for HRSA" forms, one for each of the following manufacturers.

- Eli Lilly & Co
- Sanofi
- AstraZeneca

For supporting documentation, I am have prepared files showing the current pricing available to me through one of my Contract Pharmacies, Walgreens. I did not attach those files to this email, because I am very cautious about sharing anything related to 340B pricing or other pricing, because I know that they are confidentiality and proprietary issues around sharing that data. If those files are needed to elucidate the current situation, and if HRSA deems it safe to share contract pharmacy pricing for this purpose, I would be more than happy to provide those files.
Please let me know if you need any additional documentation.
Many thanks,
Hannah

Hannah Rowell (She/Her/Hers) What's this?
340B Program Manager
Erie Family Health Centers
1701 West Superior Street
Chicago, IL 60622
Tel: 312-432-7467
Email: hrowell@eriefamilyhealth.org

Gerald Champion
Regional Medical Center
Our Family Caring For Yours

2669 Scenic Drive
Alamogordo, NM 88310
575-439-6100
www.gcrmc.org

March 31, 2021

Via 340Bpricing@hrsa.gov

Krista Pedley, RADM, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W05A
Rockville, MD 20857

RE: Unavailability of 340B Pricing and Request for Enforcement Action

Dear Rear Admiral Pedley:

We participate in the 340B drug pricing program as Gerald Champion Regional Medical Center (GCRM; 340B ID DSH320004). We are writing to report instances of overcharging by drug manufacturers that participate in the 340B program in violation of the 340B statute and to request that the Health Resources and Services Administration (HRSA) use its statutory authority to take enforcement action against drug manufacturers that have caused 340B overcharges.

We are no longer able to access 340B pricing for a number of products when we attempt to place orders to be shipped to our contract pharmacy locations.

Manufacturer	Date
Sanofi	Effective October 1, 2020
Astra-Zeneca	Effective October 1, 2020
Novartis Pharmaceuticals	New policy effective Nov. 16, 2020 (40 mile range)
Eli Lilly (including subsidiaries and affiliates)	Effective September 1, 2020
Novo Nordisk	Effective January 1, 2021

Attached is a list of some products for which 340B pricing is no longer available.

As you know, drug manufacturers must offer 340B pricing to covered entities, including for drugs dispensed through contract pharmacies. The 340B statute obligates drug manufacturers to offer 340B pricing to covered entities for covered outpatient drugs and does not permit a manufacturer to pick and choose when to make 340B pricing available.[1] Denying 340B pricing

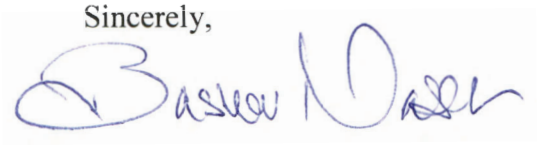
[1] 42 U.S.C. § 256b(a)(1).

to a covered entity on the basis of a drug being dispensed through a contract pharmacy is a violation of the 340B statute's obligation to offer 340B pricing.

In addition, HRSA regulations call for the imposition of civil monetary penalties (CMPs) in cases where a manufacturer knowingly and intentionally overcharges a 340B covered entity.[2] Our inability to access 340B pricing for the products listed in the attachment constitute overcharges. Statements made by the manufacturers of the listed products indicate that the decisions to deny 340B pricing are knowing and intentional. Therefore, we request that HRSA exercise its authority under the 340B statute and the agency's regulations to penalize manufacturers that are committing overcharges.

We appreciate your assistance with this matter. For questions, we can be reached at (575) 443-7848.

Sincerely,



Bashar Naser
Chief Financial Officer/Authorized Official

Enclosure

[2] 42. C.F.R. § 10.11.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: Piedmont Care **340B ID:** RWII29302

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00310622560	XIGDUO XR TAB 2.5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310048230	MPB IRESSA 250MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310134930	MPB TAGRISSO 40MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310135030	MPB TAGRISSO 80MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310173030	MPB FASENRA 30MG PFS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310183030	MPB FASENRA 30MG PEN	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310450012	MPB IMFINZI VIAL 120MG 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310461150	MPB IMFINZI VIAL 500MG 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

00310066812	MPB LYNPARZA 100MG 120 TAB	AstraZeneca Pharmaceuticals LP	120		EA	McKesson
00310067912	MPB LYNPARZA 150MG 120 TAB	AstraZeneca Pharmaceuticals LP	120		EA	McKesson
00310067960	MPB LYNPARZA 150MG 60 TAB	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310066860	MPB LYNPARZA 100MG 60 TAB	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310470001	MPB LUMOXITI 1MG SDV	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310051260	MPB CALQUENCE 100MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310062560	MPB KOSELUGO 25MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310061060	MPB KOSELUGO 10MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310651201	BYETTA SINJ 250MCG ML	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310652401	BYETTA PEN 10MCG	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310661502	SYMLIN PEN 60 1.5ML 2	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310662702	SYMLIN PEN 120 2.7ML 2	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310625030	XIGDUO XR TAB 5 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310627030	XIGDUO XR TAB 10 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310628030	XIGDUO XR TAB 10 1000MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310620530	FARXIGA TAB 5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310621030	FARXIGA TAB 10MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310610090	ONGLYZA TAB 2.5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310610590	ONGLYZA TAB 5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310613530	KOMBIGLYZ XR TB 5MG 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

00310610530	ONGLYZA TAB 5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310610030	ONGLYZA TAB 2.5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310614530	KOMBIGLYZ XR TB 5MG 1000MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310626060	XIGDUO XR TAB 5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310612560	KOMBIGLYZ XR TB 2.5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310653004	BYDUREON PEN 2MG CT4	AstraZeneca Pharmaceuticals LP	4		CT	McKesson
00310075590	CRESTOR TAB 5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075290	CRESTOR TAB 20MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075190	CRESTOR TAB 10MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075430	CRESTOR TAB 40MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310072010	FASLODEX PFS 250MG 5ML 2X5.0ML	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310028060	SEROQUEL XR TAB 50MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028360	SEROQUEL XR TAB 300MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028260	SEROQUEL XR TAB 200MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028460	SEROQUEL XR TAB 400MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028160	SEROQUEL XR TAB 150MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310027510	SEROQUEL TAB 25MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027210	SEROQUEL TAB 200MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027110	SEROQUEL TAB 100MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310678030	QTERN 10MG 5MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

00310677030	QTERN 5MG 5MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310460012	BEVESPI AEROSPHERE 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310460039	BEVESPI AEROSPHERE HUD 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310027460	SEROQUEL TAB 300MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310009590	DALIRESP 500MCG TAB 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310009530	DALIRESP TAB 500MCG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310027810	SEROQUEL TAB 50MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027910	SEROQUEL TAB 400MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310196930	MOVANTIK TAB 12.5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310197039	MOVANTIK TAB 25MG BLSTR UD 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310197030	MOVANTIK TAB 25MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310654004	BYDUREON BCISE AUTOINJ 2MG CT4	AstraZeneca Pharmaceuticals LP	4		CT	McKesson
00310110530	LOKELMA O S 5G 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00310111030	LOKELMA O S 10G 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00310110539	LOKELMA O S 5G HUD 11	AstraZeneca Pharmaceuticals LP	11		CT	McKesson
00310111039	LOKELMA O S 10G HUD 11	AstraZeneca Pharmaceuticals LP	11		CT	McKesson
00310008828	DALIRESP TAB 250MCG UD 28	AstraZeneca Pharmaceuticals LP	28		EA	McKesson
00310008839	DALIRESP TAB 250MCG UD 20	AstraZeneca Pharmaceuticals LP	20		EA	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ✕ No

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

Table 1: Unavailable at 340B Price

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ✓ Other (*please describe*): Manufacturer 340B Price Violation
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ✓ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☐ Other (*please describe issue*):

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price
PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)
  - Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*
- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

Price paid by the covered entity (including package size): _____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Tracey Jackson **Phone**: 8045827773

Email Address: tracey@piedmontcare.org

Contact Role/Organization: Executive Director - Piedmont Care

Contact Signature: Tracey Jackson **Date**: 11/12/2020

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

From: HRSA HSB 340B Pricing
To: O"Dierno, Jacquelyn; HRSA HSB 340B Pricing
Subject: RE: 340B Drug Discount Dispute Update/AVITA Guidance
Date: Tuesday, November 17, 2020 1:51:24 PM
Attachments: image003.png
image009.jpg
image010.png

Thank you for your submission. One national drug code (NDC) reported in your documentation, NDC 49281079051, is from a labeler who does not have an active Pharmaceutical Pricing Agreement (PPA) with HRSA; and therefore, is not subject to 340B discounts. For the other products reported with 340B prices that are unavailable at contract pharmacies, HRSA continues to monitor the situation.

Thank you for your commitment to the 340B Program.

The Office of Pharmacy Affairs
Health Resources and Services Administration
Email: 340bPricing@hrsa.gov

From: O'Dierno, Jacquelyn <J.ODierno@carolinarain.org>
Sent: Thursday, November 12, 2020 9:27 AM
To: HRSA HSB 340B Pricing <340BPricing@hrsa.gov>
Subject: RE: 340B Drug Discount Dispute Update/AVITA Guidance

See attached.

JACKI O'DIERNO
OFFICE MANAGER
o: 704-973-9817
f: 704-372-7418
601 E. 5th Street | Suite 470 | Charlotte, NC 28202

From: Veleria M. Levy <Veleria.Levy@avitapharmacy.com>
Sent: Wednesday, October 28, 2020 11:29 PM
To: Warren, Debbie <D.Warren@carolinarain.org>; Gulden, Chelsea <c.gulden@carolinarain.org>
Cc: Brad Kramer <Brad.Kramer@avitapharmacy.com>
Subject: 340B Drug Discount Dispute Update/AVITA Guidance

Hi Deborah & Chelsea,

I hope you are doing well. As you know a few of the Big Pharma companies are pushing back against providing 340B pricing to covered entities. Without a voice from the entities affected, HRSA does not have the needed ammunition to fight back against Big Pharma.

As your strategic partner, AVITA wants to help you express that voice and protect your 340B discounts.

OVERVIEW

- Several manufacturers removed the 340B discount program for covered entities in the last few months. In some cases, only Covered Entities that provided claims data and/or selected one contract pharmacy were able to maintain 340B pricing.
- HRSA has informed AVITA that Covered Entities should complete the OPAIS complaint form identifying drugs that are no longer offered at 340B pricing (Table 1) and identify drugs that

have been purchased at WAC prices because 340B pricing is no longer offered (Table 2)

- This is one action that Covered Entities can do as part of communicating back to HRSA the impact of the removal of 340B pricing by Eli Lilly, AstraZeneca, and Sanofi.

Attached are complaint forms that we have pre-populated with the drugs that are impacted by the actions taken by the three drug companies. Please let me know if I can help you understand this and/or submit these forms. I am available to schedule time to help you with this.

ACTION NEEDED: Please fill in the requested contact information under each pharmaceutical company's list of drugs and then email to: 340Bpricing@hrsa.gov .

If you need any additional information around the manufacturers removing the 340B discount, Avita has developed an Advocacy page: https://avitapharmacy.com/advocacy-toolkit/

These complaint forms can be electronically completed using Adobe Acrobat Reader DC. Should you need it, you can be download the software from the website (http://get.adobe.com/reader/).

Please reach out with any questions.

Thanks,

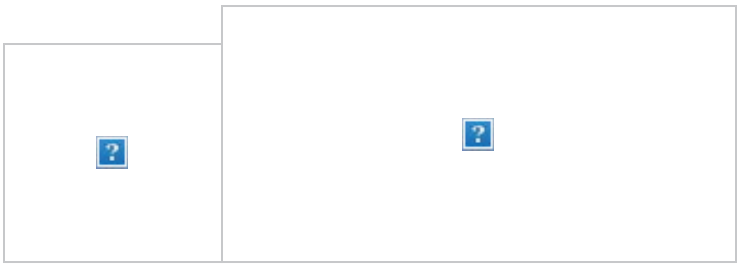
Veleria

Veleria M Levy

Veleria M Levy, 340B ACE

Senior Account Executive • Avita Pharmacy

(704) 550-1900 tel • (800) 615-0075 fax



340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: RAO Community Health **340B ID:** STD28202

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00310622560	XIGDUO XR TAB 2.5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310048230	MPB IRESSA 250MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310134930	MPB TAGRISSO 40MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310135030	MPB TAGRISSO 80MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310173030	MPB FASENRA 30MG PFS	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310183030	MPB FASENRA 30MG PEN	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310450012	MPB IMFINZI VIAL 120MG 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310461150	MPB IMFINZI VIAL 500MG 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

00310066812	MPB LYNPARZA 100MG 120 TAB	AstraZeneca Pharmaceuticals LP	120		EA	McKesson
00310067912	MPB LYNPARZA 150MG 120 TAB	AstraZeneca Pharmaceuticals LP	120		EA	McKesson
00310067960	MPB LYNPARZA 150MG 60 TAB	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310066860	MPB LYNPARZA 100MG 60 TAB	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310470001	MPB LUMOXITI 1MG SDV	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310051260	MPB CALQUENCE 100MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310062560	MPB KOSELUGO 25MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310061060	MPB KOSELUGO 10MG CAP 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310651201	BYETTA SINJ 250MCG ML	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310652401	BYETTA PEN 10MCG	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310661502	SYMLIN PEN 60 1.5ML 2	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310662702	SYMLIN PEN 120 2.7ML 2	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310625030	XIGDUO XR TAB 5 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310627030	XIGDUO XR TAB 10 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310628030	XIGDUO XR TAB 10 1000MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310620530	FARXIGA TAB 5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310621030	FARXIGA TAB 10MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310610090	ONGLYZA TAB 2.5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310610590	ONGLYZA TAB 5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310613530	KOMBIGLYZ XR TB 5MG 500MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

00310610530	ONGLYZA TAB 5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310610030	ONGLYZA TAB 2.5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310614530	KOMBIGLYZ XR TB 5MG 1000MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310626060	XIGDUO XR TAB 5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310612560	KOMBIGLYZ XR TB 2.5 1000MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310653004	BYDUREON PEN 2MG CT4	AstraZeneca Pharmaceuticals LP	4		CT	McKesson
00310075590	CRESTOR TAB 5MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075290	CRESTOR TAB 20MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075190	CRESTOR TAB 10MG 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310075430	CRESTOR TAB 40MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310072010	FASLODEX PFS 250MG 5ML 2X5.0ML	AstraZeneca Pharmaceuticals LP	2		CT	McKesson
00310028060	SEROQUEL XR TAB 50MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028360	SEROQUEL XR TAB 300MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028260	SEROQUEL XR TAB 200MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028460	SEROQUEL XR TAB 400MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310028160	SEROQUEL XR TAB 150MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310027510	SEROQUEL TAB 25MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027210	SEROQUEL TAB 200MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027110	SEROQUEL TAB 100MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310678030	QTERN 10MG 5MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

00310677030	QTERN 5MG 5MG TAB 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310460012	BEVESPI AEROSPHERE 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310460039	BEVESPI AEROSPHERE HUD 1	AstraZeneca Pharmaceuticals LP	1		EA	McKesson
00310027460	SEROQUEL TAB 300MG 60	AstraZeneca Pharmaceuticals LP	60		EA	McKesson
00310009590	DALIRESP 500MCG TAB 90	AstraZeneca Pharmaceuticals LP	90		EA	McKesson
00310009530	DALIRESP TAB 500MCG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310027810	SEROQUEL TAB 50MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310027910	SEROQUEL TAB 400MG 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310196930	MOVANTIK TAB 12.5MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310197039	MOVANTIK TAB 25MG BLSTR UD 100	AstraZeneca Pharmaceuticals LP	100		EA	McKesson
00310197030	MOVANTIK TAB 25MG 30	AstraZeneca Pharmaceuticals LP	30		EA	McKesson
00310654004	BYDUREON BCISE AUTOINJ 2MG CT4	AstraZeneca Pharmaceuticals LP	4		CT	McKesson
00310110530	LOKELMA O S 5G 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00310111030	LOKELMA O S 10G 30	AstraZeneca Pharmaceuticals LP	30		CT	McKesson
00310110539	LOKELMA O S 5G HUD 11	AstraZeneca Pharmaceuticals LP	11		CT	McKesson
00310111039	LOKELMA O S 10G HUD 11	AstraZeneca Pharmaceuticals LP	11		CT	McKesson
00310008828	DALIRESP TAB 250MCG UD 28	AstraZeneca Pharmaceuticals LP	28		EA	McKesson
00310008839	DALIRESP TAB 250MCG UD 20	AstraZeneca Pharmaceuticals LP	20		EA	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ✕ No

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

Table 1: Unavailable at 340B Price

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ✓ Other (*please describe*): Manufacturer 340B Price Violation
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ✓ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☐ Other (*please describe issue*):

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)
  - Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*
- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

Price paid by the covered entity (including package size): _____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Bernard Davis **Phone**: (704) 237-8193

Email Address: bdavis@raoassist.org

Contact Role/Organization: CEO / RAO Community Health

Contact Signature: [signature] **Date**: 11/2/2020

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: South Central Missouri Community Health Center DBA Your Community Health Center

340B ID: _CHC26564-03

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
1. 00310651201	BYETTA 5 MCG DOSE PEN INJ	ASTRAZENECA PHARMACEUTICALS LP	1.200	1	Milliliter	McKesson
2. 00310662702	SYMLINPEN 120 PEN INJECTOR	ASTRAZENECA PHARMACEUTICALS LP	2.700	2	Milliliter	McKesson
3. 00310610590	ONGLYZA 5 MG TABLET	ASTRAZENECA PHARMACEUTICALS LP	90.000	1	Tablet	McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes X No
- The issue reported is limited to a contract pharmacy purchase X Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes X No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 1: Unavailable at 340B Price
AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ● Other (*please describe*): **Manufacturers are blocking 340B prices for drugs shipped to my contract pharmacies**
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ● Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ● Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ● Other (*please describe issue*): **AstraZeneca is blocking 340B prices for their drugs ordered by my covered entity that are shipped to my contract pharmacies. I am forced to pay WAC for these products for my contract pharmacies. Additional labeler codes from AstraZeneca are affected - ***this is not a complete list of affected NDCs from AstraZeneca*****.

Date issue first observed: **October 1, 2020**

Date drug last available at 340B price (enter NEVER if has never been available): **September 30, 2020**

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price
PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☒ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

  Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*

- ☒ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown

- ☒ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue

- ☒ Other (*please describe issue*):
  AstraZeneca will not honor 340B pricing in our rural area contract pharmacy locations. We serve 5 rural counties and our patients are not able to access 340B pricing.

Price paid by the covered entity (including package size): Byetta 10mcg -1 box $780.78

Date issue first observed: 10/01/2020

Date product last available at correct price (enter NEVER if has never been available): 09/30/2020

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): __Angie Brooks_____ **Phone**: _573-242-6311_____

Email Address: __abrooks@your-chc.org_____

Contact Role/Organization:____340B Program Manager_____

Contact Signature: Angela Brooks **Date**: 04/06/2021

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: Shenandoah Medical Center **340B ID:** CAH161366-00

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
1. 00310460012	BEVESPI AEROSPHERE INHALER	AstraZeneca	1x10.7GM	1 EA	Each	McKesson
2.						
3.						

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ■ No
- The issue reported is limited to a contract pharmacy purchase ■ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☐ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 1: Unavailable at 340B Price

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ☐ Other (*please describe*): _____
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☐ Other (*please describe issue*):

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: _____

Date drug last available at 340B price (enter NEVER if has never been available): _____

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ■ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

  Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*

- ■ Validated the ceiling price using the 340B OPAIS pricing system on (date): 11/13/2020
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ■ Other (*please describe issue*):

  The manufacturer contacted our entity in a series of letters to state they would no longer be allowing their NDCs to be purchased at 340B price at contract pharmacy locations. We have not been able to replenish the qualified medications at the correct price for our contract pharmacies.

Price paid by the covered entity (including package size): $398.95/1x10.7GM

Date issue first observed: 09/24/2020

Date product last available at correct price (enter NEVER if has never been available): 08/24/2020

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Stephanie Priest **Phone**: (712)246-7132

Email Address: spriest@smchospital.com

Contact Role/Organization: 340B Program Coordinator/Shenandoah Medical Center

Contact Signature: Stephanie Priest **Date**: 11/18/2020

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

AstraZeneca

Date: August 17, 2020

Re: 340B Contract Pharmacy Pricing

Dear Valued Partner,

AstraZeneca to date has processed chargebacks associated with Contract Pharmacy arrangements consistent with the approach proposed in the Health Resources and Services Administration's ("HRSA") April 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach such that AstraZeneca only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy.

To implement this new approach, AstraZeneca will stop processing 340B chargebacks for all Contract Pharmacy arrangements effective October 1, 2020. Any 340B Covered Entity that does not have an out-patient, on-site dispensing pharmacy should contact AstraZeneca to arrange for a Contract Pharmacy of its choice to be eligible to receive 340B pricing on behalf of the Covered Entity. To initiate this process, please contact Membership@AstraZeneca.com.

Pricing will be honored on all chargeback invoices prior to this date consistent with AstraZeneca's historic approach, but AstraZeneca asks for the removal of Contract Pharmacy eligibility prior to or by the end of business September 30, 2020.

For additional information or questions, please contact your AstraZeneca Account Director.

Sincerely,

DocuSigned by:
0781790EE5034A7...

Odalys Caprisecca
Executive Director, Strategic Pricing & Operations

EXHIBIT J

NDCs Impacted by AstraZeneca Overcharging

**Note that NDCs are displayed in XXXX-XXXX form, without the final two-digit product size code or labeler code leading zero.*

Labeler Codes 00186 and 00310

NDC*	Brand Name	Generic Name	Dosage Form
0310-4600	Bevespi Aerosphere	Glycopyrrolate And Formoterol Fumarate	Aerosol, Metered
0310-4616	Breztri	Budesonide, Glycopyrrolate, And Formoterol Fumarate	Aerosol, Metered
0186-0776	Brilinta	Ticagrelor	Tablet
0186-0777	Brilinta	Ticagrelor	Tablet
0310-7370	Budesonide And Formoterol Fumarate Dihydrate	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0310-7372	Budesonide And Formoterol Fumarate Dihydrate	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0310-6530	Bydureon	Exenatide	Injection, Suspension, Extended Release
0310-6540	Bydureon Bcise	Exenatide	Injection, Suspension, Extended Release
0310-6512	Byetta	Exenatide	Injection
0310-6524	Byetta	Exenatide	Injection
0310-0512	Calquence	Acalabrutinib	Capsule, Gelatin Coated
0310-0751	Crestor	Rosuvastatin Calcium	Tablet, Film Coated

0310-0752	Crestor	Rosuvastatin Calcium	Tablet, Film Coated
0310-0754	Crestor	Rosuvastatin Calcium	Tablet, Film Coated
0310-0755	Crestor	Rosuvastatin Calcium	Tablet, Film Coated
0310-0088	Daliresp	Roflumilast	Tablet
0310-0095	Daliresp	Roflumilast	Tablet
0186-0382	Esomeprazole Magnesium	Esomeprazole Magnesium	Capsule, Delayed Release
0186-0384	Esomeprazole Magnesium	Esomeprazole Magnesium	Capsule, Delayed Release
0310-6205	Farxiga	Dapagliflozin	Tablet, Film Coated
0310-6210	Farxiga	Dapagliflozin	Tablet, Film Coated
0310-1730	Fasenra	Benralizumab	Injection, Solution
0310-1830	Fasenra	Benralizumab	Injection, Solution
0310-0720	Faslodex	Fulvestrant	Injection
0310-7720	Fulvestrant	Fulvestrant	Injection
0310-0482	Iressa	Gefitinib	Tablet, Coated
0310-6125	Kombiglyze XR	Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6135	Kombiglyze XR	Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6145	Kombiglyze XR	Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-0610	Koselugo	Selumetinib	Capsule

0310-0625	Koselugo	Selumetinib	Capsule
0310-1105	Lokelma	Sodium Zirconium Cyclosilicate	Powder, For Suspension
0310-1110	Lokelma	Sodium Zirconium Cyclosilicate	Powder, For Suspension
0310-0668	Lynparza	Olaparib	Tablet, Film Coated
0310-0679	Lynparza	Olaparib	Tablet, Film Coated
0310-1969	Movantik	Naloxegol Oxalate	Tablet, Film Coated
0310-1970	Movantik	Naloxegol Oxalate	Tablet, Film Coated
0186-4010	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4020	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4025	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4040	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4050	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-5020	Nexium	Esomeprazole Magnesium	Capsule, Delayed Release
0186-5040	Nexium	Esomeprazole Magnesium	Capsule, Delayed Release
0310-6100	Onglyza	Saxagliptin	Tablet, Film Coated
0310-6105	Onglyza	Saxagliptin	Tablet, Film Coated
0186-0916	Pulmicort FLEXHALER	Budesonide	Aerosol, Powder

0186-0917	Pulmicort FLEXHALER	Budesonide	Aerosol, Powder
0186-1988	Pulmicort Respules	Budesonide	Suspension
0186-1989	Pulmicort Respules	Budesonide	Suspension
0186-1990	Pulmicort Respules	Budesonide	Suspension
0310-6770	Qtern	Dapagliflozin And Saxagliptin	Tablet, Film Coated
0310-6780	Qtern	Dapagliflozin And Saxagliptin	Tablet, Film Coated
0310-6925	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-6950	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-6975	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-6990	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-8284	Quetiapine Fumarate Extended Release	Quetiapine Fumarate	Tablet, Film Coated, Extended Release
0310-0271	Seroquel	Quetiapine	Tablet, Film Coated
0310-0272	Seroquel	Quetiapine	Tablet, Film Coated
0310-0274	Seroquel	Quetiapine	Tablet, Film Coated
0310-0275	Seroquel	Quetiapine	Tablet, Film Coated
0310-0278	Seroquel	Quetiapine	Tablet, Film Coated

0310-0279	Seroquel	Quetiapine	Tablet, Film Coated
0310-0280	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0281	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0282	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0283	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0284	Seroquel XR	Quetiapine	Tablet, Extended Release
0186-0370	Symbicort	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0186-0372	Symbicort	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0310-6615	Symlinpen	Pramlintide Acetate	Injection
0310-6627	Symlinpen	Pramlintide Acetate	Injection
0310-1349	Tagrisso	Osimertinib	Tablet, Film Coated
0310-1350	Tagrisso	Osimertinib	Tablet, Film Coated
0186-1088	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0186-1090	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0186-1092	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0186-1094	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0310-0800	Tudorza Pressair	Aclidinium Bromide	Powder, Metered

0310-6225	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6250	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6260	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6270	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6280	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. 1:20-cv-03032
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of Lee Francis, MD, MPH

I, Lee Francis, MD, MPH, declare as follows:

1. I am the President and CEO of Erie Family Health Center, Inc. ("Erie"), located in and around Chicago, Illinois. I joined Erie in 1991 and have held the role of President and CEO since 2007. As President and CEO, I am charged with enacting Erie's strategic vision of serving as a national leader in the provision of community-based health care. I am responsible for the overall health of the organization, including financial stability, operational success, and clinical quality.

2. Regarding the 340B Drug Pricing Program ("340B Program"), as President and CEO, I have regular access to 340B financial and operational updates. I also receive regular updates on the 340B Program from Erie's Chief Financial Officer, who serves as the federal OPAIS Authorizing Official. As part of my regular duties, I am also made aware of provider and staff feedback related to 340B successes and barriers. Additionally, in my role as an Internal Medicine physician at Erie, I am keenly aware of the benefit the 340B Program offers for my own patients. To prepare this declaration, I have reviewed 340B Program metrics and feedback from providers and staff.

3. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

4. Erie is a Federally-qualified health center, and a member of the National Association of Community Health Centers. The health center receives federal funding under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population residing across over 185 zip codes in the Chicagoland region.

5. Erie is an approximately 63-year-old primary healthcare provider that delivers integrated and affordable medical, dental, and behavioral health care for patients of all ages. We also encourage good health in our underserved patient population through ongoing health education, case/care management, strong hospital partnerships, and community outreach.

6. Motivated by our belief that high-quality health care is a human right, Erie serves more than 80,000 patients per year at 12 locations throughout Chicago and the surrounding suburbs, regardless of patient insurance status, immigration status, or ability to pay for Erie's services. Almost all of Erie's patients are low income, and approximately 27% of Erie's patients are uninsured. Approximately 71% of patients are Hispanic and about 44% are best served in a language other than English.

7. Erie is a "covered entity" for purposes of the 340B Program. Erie has been registered with the Health Resources and Services Administration ("HRSA") as a 340B covered entity since on or about January 1, 1997. As required, we maintain accurate management of our clinic registrations within HRSA's OPAIS database. We recertify our 340B covered entity status annually, and most recently recertified for all twelve of our participating 340B locations on or about February 18, 2020. A list of our covered entity locations, downloaded from HRSA's 340B OPAIS database on October 7, 2020, is attached as Exhibit A.

8. The 340B Program allows Erie to purchase significantly discounted outpatient prescription drugs for pharmacy dispensing and as clinic-administered drugs. We acquire 340B discounted drugs for pharmacy dispensing through wholesaler AmerisourceBergen; we are also in the process of adding Cardinal Health as another 340B wholesaler account. For clinic-administered medications, we have 340B drug purchasing accounts with Allergan, Henry Schein, Paragard Direct, Theracom, and R&S Northeast, LLC.

9. Erie's participation in the 340B Program allows us to help our low-income uninsured and underinsured patients afford their medications. Without 340B discounts, critical medications—including, among many others, insulin, asthma inhalers, blood pressure medications, Pre-Exposure Prophylaxis (PrEP) for HIV, Suboxone and Narcan to treat opioid use disorder—would be unaffordable and inaccessible for these patients. 340B contract pharmacies enable our patients to access, and many other medications.

10. As required by federal law and regulations, and in keeping with our mission, we reinvest 100% of 340B savings and revenue from third-party reimbursement into expanding access for our underserved patients. For example, this money is used to cover costs associated with comprehensive care, a Medication-Assisted Treatment Program for opioid use disorder, and telemedicine and electronic population health tools, which enable Erie to serve patients at greatest risk for missing health screenings or services.

11. Many Erie patients have chronic conditions exacerbated by social challenges. Improving health outcomes depends on Erie providing: 1:1 Care Management, Maternal and Child Case Management, HIV/AIDS Case Management, Health Coaching, Referrals support,

Care Coordination and Outreach, Public Benefits navigation, Resource navigation, and PrEP navigation services. Because robust comprehensive care and case management are not usually reimbursed by third-party payers, Erie would not be able to offer these services without 340B savings.

12. As a covered entity, Erie is permitted to choose how it will deliver pharmacy services to its patients. While we use drugs purchased at 340B pricing for a select portion of our in-clinic medication supply, Erie contracts with local pharmacies to dispense all other 340B medications to its patients. We do not own or operate our own pharmacies. We currently contract with many local Walgreens pharmacy stores and one independent community pharmacy, Allcare Discount Pharmacy, which is co-located within one of our clinic sites.

13. Erie has a written agreement with Walgreens to dispense the 340B drugs we purchase to eligible Erie patients. We first contracted with Walgreens in or around 2011 and received HRSA approval for our first Walgreens contract pharmacy location on or about August 22, 2011. In the intervening years—following guidance from HRSA and Apexus—we have registered additional Walgreens locations. Our current Pharmacy Services Agreement with Walgreens—which applies to of all our active Walgreens pharmacy locations and all of our active covered entity locations, as registered in HRSA's 340B OPAIS database—was executed on or about April 4, 2017.

14. Erie likewise has a written agreement with Allcare Discount Pharmacy to dispense 340B drugs to eligible patients. We first contracted with Allcare Discount Pharmacy in or around September 2010; HRSA approved the pharmacy arrangement on or about May 23, 2011. Our current Pharmacy Services Agreement with Allcare Discount Pharmacy was executed on or about August 7, 2019.

15. As described in our Pharmacy Services Agreements, Erie purchases 340B drugs from wholesalers and directs those drugs to be shipped to the contract pharmacy as part of a "bill-to, ship-to" arrangement. Under this arrangement, Erie maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the drugs and provide dispensing services to our eligible patients. Some of our contract pharmacies use a precise accumulation software to dispense a retail pharmacy product to patients and perform a careful 340B eligibility assessment; if the dispense meets all eligibility criteria, the accumulator will be replenished with an Erie-purchased 340B drug for that dispense.

16. Understanding that 340B compliance falls squarely on Erie, we have multiple compliance safeguards in place and perform extensive auditing, including an audit of all contract pharmacy 340B dispenses for patient and provider eligibility and audits to verify that Medicaid Fee-For-Service was not billed for any contract pharmacy 340B claim (to avoid prohibited duplicate discounts). All audits are completed on a monthly basis and reported out quarterly to our 340B Compliance Committee. We also commission an annual external 340B audit. Our most recent external audit, in January 2020, yielded positive feedback on Erie meeting HRSA 340B compliance standards.

17. Our contract pharmacies dispense over 115,000 340B discounted prescriptions annually to our eligible patients. On average, Erie spends approximately $470,000 on 340B drug products monthly for dispensing through our contract pharmacies.

18. The critical benefit the 340B drug discount to patient outcomes is illustrated in an email from an Erie pediatrician attached as Exhibit B. In the email, the pediatrician explains how one of her patients benefited from access to affordable insulin through the 340B Program. The patient turned 18 this year, moved out to live independently, started working, and lost his Medicaid coverage. Previously, the patient's Type 1 diabetes had been managed by providers at the local children's hospital. During this transition to adulthood, he was unable to stay with his care team and could no longer afford the insulin he was prescribed. The Erie pediatrician was able to work collaboratively with the patient's previous provider to assume care for his diabetic condition and prescribed an affordable Lantus pen (a Sanofi product) through the 340B Program. Aligning the patient with access to the affordable 340B drug helped to keep his sugars under control, keep him out of diabetic ketoacidosis, and keep him out of the hospital until he was able to get his insurance reinstated. The 340B Program helped this young adult access life-saving medicine and avoid hospitalization.

19. Erie's ability to offer our patients—who are dispersed across more than 185 zip codes—access to affordable life-saving and life-sustaining medications is entirely dependent on our contract pharmacy partnerships.

20. Our contracts with local pharmacies to dispense 340B medications allow our patients to receive their critical 340B medication at a pharmacy close to their home. Erie patients generally experience multiple barriers to accessing care, including significant transportation barriers. Even though Erie has twelve clinic locations, some Erie patients still have significant travel times to attend their visit at the health center. The trip for some patients requires multiple segments on public transportation, as well as walking. Providing medication access near a patient's home supports that patient's ability to take their medication regularly, without potentially dangerous gaps around refills.

21. Many of our patients are hourly wage-earners, essential workers, work long hours, hold multiple jobs, or have care-giving responsibilities during the business day, and most will not get paid to take time away from work to obtain medications. Our contract pharmacy partners include 24-hour pharmacies and those with home delivery capabilities, providing crucial access to our patients, both day-to-day and in times of crisis.

22. Beginning on or about July 7, 2020, I became aware that certain drug manufacturers—starting first with Eli Lilly and its Cialis products and now including Eli Lilly, Sanofi, and AstraZeneca, Merck, and Novartis—had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of Erie's contract pharmacies.

23. Eli Lilly's notification affecting all products made or distributed by the company was implemented without advance notice on September 1, 2020, which did not allow Erie adequate time to respond to protect our patients' access to Lilly medication. Sanofi, Merck, and Novartis, for their parts, have requested that covered entities enroll in an unsanctioned and burdensome data collection platform called 340B ESP. Erie will not be participating in this data collection; our patients have thus lost access to Sanofi products. To date, Novartis has not yet followed through on threats to block 340B price access at contract pharmacies.

24. Because of these actions, our ability to provide patients with affordable medications has been dramatically reduced—Erie patients who were regularly receiving a 340B drug made by Eli Lilly, Sanofi, or AstraZeneca no longer have access to that medication at the discounted 340B price. Without the 340B discount, these medications are inaccessible for an Erie patient paying out-of-pocket. The following table provides Erie's average annual 340B prescription volumes prior to the manufacturers' actions:

Medication Impacted	Medication Type	Average number of Erie 340B prescription fills annually at contract pharmacies, prior to recent manufacturer limitations
Eli Lilly		
Basaglar	Insulin (diabetes)	840
Humalog	Insulin (diabetes)	1080
Humulin	Insulin (diabetes)	240
Trulicity	GLP-1 Agonist (diabetes)	120
Sanofi		
Admelog	Insulin (diabetes)	300
Lantus	Insulin (diabetes)	2400
AstraZeneca		
Brilinta	Antiplatelet (heart, circulation)	120
Bydureon	GLP-1 Agonist (diabetes)	240
Byetta	GLP-1 Agonist (diabetes)	480
Farxiga	SGLT2 Inhibitor (diabetes)	180
Symbicort	Inhaler (LABA+ICS) (asthma)	840

25. Erie is in communication with AstraZeneca regarding designating one exception contract pharmacy. This process is not finalized, and at present, our contract pharmacies are unable to purchase 340B priced AstraZeneca drugs. Even if the AstraZeneca exception process comes to fruition, it would only allow 340B access at one of our contract

pharmacies. To provide just one example of how unworkable this will be for our patients, patients of our Erie HealthReach Waukegan clinic would need to travel nearly three hours one-way on public transportation to arrive at our one remaining contract pharmacy in the Humboldt Park neighborhood of Chicago.

26. Erie is actively assessing opportunities to switch patients to affordable alternative medications. But I know as a medical provider that it is neither easy nor seamless to switch patients from one product to another. Many medication alternatives require a medical provider to review the patient chart, consider comorbidities, and assess appropriate dosing for the substitute medication. Several of the impacted diabetic treatments have very different dosing—for example daily versus weekly dosing—which requires extensive patient education and provider troubleshooting.

27. Language barriers add another layer of difficulty for patients who proceed to the pharmacy to pick-up their 340B refill and are told the price will potentially be hundreds of dollars more than it was last month. Forty-four percent of Erie patients are best served in a language other than English, and in 2019 Erie, through our interpretation service, provided care in 77 unique languages.

28. Erie has teams of Diabetes Educators who help teach patients how to use their insulin, diabetes medications, and glucose monitoring systems. As an Erie clinician, I directly see how important it is for my patients to thoroughly understand how to use their medication as directed. Frequent and/or rushed switching between medication formulations increases the opportunity for medication errors.

29. The loss of 340B savings and revenue—100% of which is reinvested into expanding access for our underserved patients—threatens Erie's ability to (1) provide comprehensive care to existing patients and (2) expand services to reach more individuals in its underserved target population. During the COVID-19 pandemic especially, 340B savings have been critical to our ability to continue serving patients and to maintain capacity to provide future services.

30. We already know that critical patient programs will need to be reduced or eliminated because of the decline in 340B savings and revenue. Erie is proud of the work of our care managers, case managers, health educators, and patient navigators, who provide personalized services that address social determinants of health and help Erie patients navigate their chronic health conditions. Without 340B savings, we would not have the capacity to fund these unreimbursed comprehensive care programs.

31. Erie is exploring all available options, but there is no action we can take to promptly remedy the drug manufacturers' refusal to provide 340B discount pricing. Erie has always used contract pharmacy partnerships to provide 340B medication access to patients. We do not have the pharmacy infrastructure to participate in the 340B program as an in-house pharmacy, and creating that infrastructure would involve a lengthy and expensive endeavor. Our patients cannot wait, they need access to affordable medications now.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: _____

By: _____ *December 2, 2020*
Lee Francis, MD, MPH, President and CEO
Erie Family Health Center, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

June 11, 2020

Mr. Derek L. Asay
Senior Director, Government Strategy
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Dr. Siegel:

The Health Resources and Services Administration (HRSA) is responding to Lilly USA's (Lilly) May 18, 2020, correspondence regarding contract pharmacies in the 340B Drug Pricing Program (340B Program). Many of the arguments advanced in Lilly's letter are not persuasive, and we do not address the arguments here. Our primary point is the importance for manufacturers to observe the guidance so that the program can meet its statutory objectives. Contract pharmacies, which are only a mode for dispensing 340B drugs and not independent covered entities, serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Therefore, HRSA strongly encourages Lilly to reconsider its decision to discontinue contract pharmacy 340B discounts.

Many health centers and other safety net organizations receiving HRSA grants do not have an in-house pharmacy and are able to participate in the 340B Program only through a contract pharmacy. Lilly's position, especially if expanded to other drugs, would have the effect of denying underserved and vulnerable populations served by these covered entities access to 340B discounted drugs. This result would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute. [1] Even for those covered entities with in-house pharmacies, Lilly's refusal to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point obtaining their prescriptions.

[1] The intent of the 340B Program is to permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. (See: [1] See: H.R. REP No. 102-384(II), at 12 (1992) (Conf. Report).

While HRSA has published contract pharmacy advice in guidance, rather than through binding regulations, HRSA strongly encourages Lilly to reconsider its position. Lilly's refusal to sell 340B priced drugs to covered entities through contract pharmacy arrangements would have a significant negative impact on the nation's safety net, especially at a time when the health care community is under great pressure to address the current COVID-19 pandemic. We note that the contract pharmacy guidance was issued only after notice and public comment, and that stakeholders had the opportunity to address any concerns about the scope of the guidance before its final adoption.

Lilly indicated in its letter that it considers its letter to be "confidential and proprietary not subject to release or disclosure under FOIA or otherwise." HRSA fails to see any confidential or proprietary information in the letter. If Lilly believes that portions of its correspondence are confidential or proprietary, please respond with an explanation and reference to the specific portions of the letter that Lilly believes are confidential and proprietary.

Sincerely,

Krista M. Pedley

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs

cc: Josh O'Harra, Assistant General Counsel, Eli Lilly and Company

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857
Office of Pharmacy Affairs

November 3, 2020

Ms. Sherri P. Ferrell
Chief Executive Officer
West Virginia Primary Care Association
1700 MacCorkle Avenue SE
Charleston, West Virginia 25314

Dear Ms. Ferrell:

Thank you for your letter regarding recent actions by several drug manufacturers impacting covered entities that participate in the 340B Drug Pricing Program (340B Program).

Your letter raises concerns about specific actions that limit access to 340B drugs. For example, Eli Lilly USA (Lilly) is no longer providing 340B discounts on several of its drug products to covered entities through contract pharmacy arrangements. Several other manufacturers have also announced plans not to sell 340B drugs to contract pharmacies, while others are limiting sales by requiring specific data requirements or selling drug products only after a covered entity has demonstrated 340B compliance.

The Health Resources and Services Administration (HRSA) is continuing to review the various proposals and considering whether these actions by manufacturers violate the 340B statute and whether sanctions may apply. Under section 340B(a)(1) of the Public Health Service Act (PHSA), a manufacturer participating in the 340B Program must offer its covered outpatient drugs for purchase at or below the 340B ceiling price. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B(d)(1)(B)(vi) of the PHSA. In a letter to Lilly posted on the 340B website, the U.S. Department of Health and Human Services reiterates its concern with these policies.[1]

The 340B statute does not specify the mode by which 340B drugs may be dispensed. However, HRSA believes contract pharmacies serve a vital function in covered entities' ability to serve underserved and vulnerable populations, particularly as many covered entities do not operate in-house pharmacies. Without comprehensive regulatory authority, HRSA has only limited ability to issue enforceable regulations to ensure clarity in program requirements across all the interdependent aspects of the 340B Program. HRSA has requested regulatory authority in the President's Budget each year since fiscal year (FY) 2017 and has again requested this in the FY

[1] See: https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf

2021 President's Budget. Binding and enforceable regulations for all aspects of the 340B Program would provide HRSA the ability to more clearly define and enforce policy and would significantly strengthen HRSA's oversight of the Program.

HRSA believes that manufacturers that refuse to honor contract pharmacy orders could limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions. To this end, HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements.

Some covered entities have reached out to HRSA expressing concern that they are unable to receive the 340B ceiling price on certain drug products due to these recent actions. HRSA is working closely with each impacted covered entity and is actively investigating the matter in order to make a final determination as to any potential action. I will also provide this response to Mr. Joe Letnaunchyn.

Sincerely,

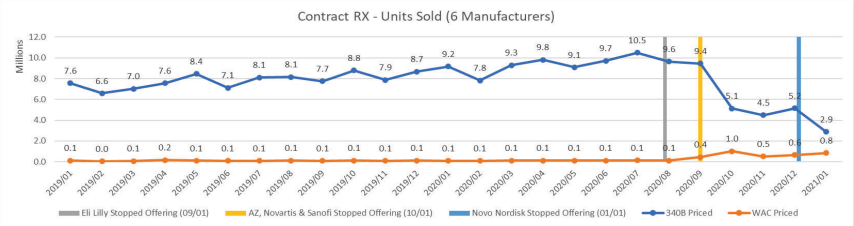
Krista M. Pedley

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration

Summary and Background

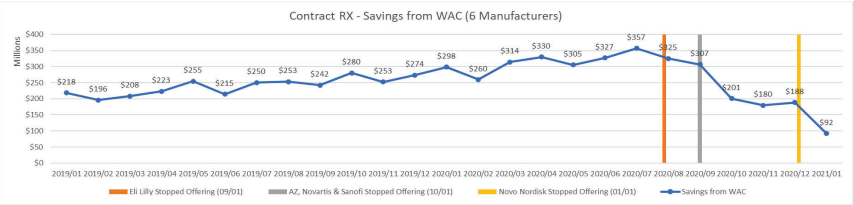
There are 6 manufacturers that have stopped or added limitations to offering 340B price in contract pharmacy arrangements. This analysis attempts to quantify the loss of units sold and savings.
There is not a longterm reciprocal increase in the WAC price purchasing when 340B contract pharmacy pricing is not available. This is because the third party administrator will stop identifying the newly WAC priced products as 340B eligible. There may be a transient spike in WAC purchases initially, but once the entities/software block these products from 340B purchasing, the NDC won't be used moving forward. This analysis demonstrates a decrease in 340B priced units sold from a high of 10.5M prior to the manufacturers' actions in 2020 to 2.9M in January 2021. Annualized this equates to a reduction in 340B units sold of nearly 83M. Note that the "By Units Sold (Contract RX)" tab outlines the consolidated and individual manufactures' units sold, and has units impact on grantees and hospitals.

Figure 1 - Monthly 340B Units Sold Before and After Manufacturers' Actions



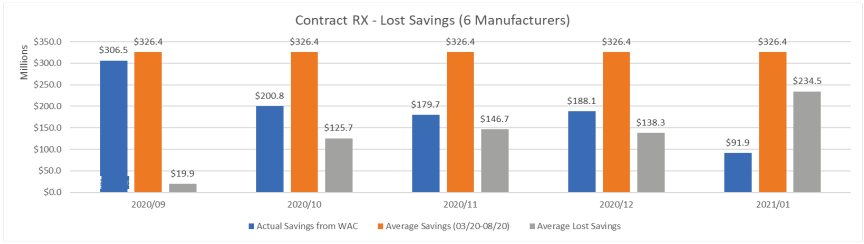
There are two tabs related to savings lost from the manufacturers' actions "Savings from WAC (Contract RX)" and "AverageLostSavings(ContractRX)". The "Savings from WAC (Contract RX)" tab outlines the monthly savings from the 6 manufacturers from January 2019 to January 2021. The highest month of savings before the changes was July 2020 and the savings was $357M with the lowest savings in January 2021, with $92M in savings. The annualized savings lost between the high and low savings months was $3.2B. Figure 2 is a roll up of all 6 manfacturers and the tab has a breakdown by each manufacturer and then by grantee and hospital savings.

Figure 2 - Monthly 340B Contract Pharmacy Savings Before and After 6 Manufacturers' Actions- Lost Annualized Savings = $3.2B



The "AverageLost Savings(ContractRX)" outlines the impact on covered entities in lost savings until January 2021, by comparing the savings from the period of 3/2020-8/2020 as a control to the actual savings in that month. Figure 3 demonstrates the loses from 9/2020 to 1/2021.

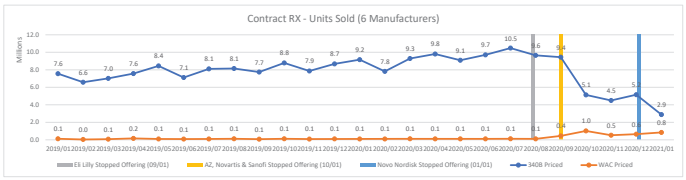
Figure 3 - Lost Savings from 9/2020 to 1/2021



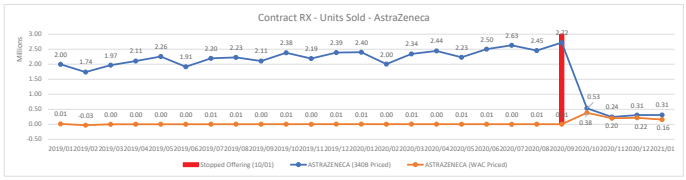
Key to Remaining Tabs

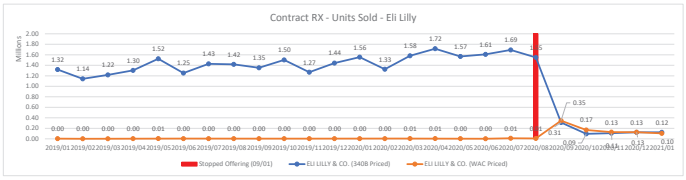
"By Sales (Contract RX)": Provides contract pharmacy sales at 340B and the WAC prices for all 6 manufacturers, for each manufacturer, and then by grantees and hospitals.
"Total Contract RX Sales": Outlines all manufacturers sales to contract pharmacy arrangements.
"By Units Sold (non-Contract RX): Outlines the monthly units sold for the 6 manufacturers rolled up, individually and by grantees and hospitals for all non-contract pharmacy sales.
"By Sales (non-Contract RX): Outlines the monthly sales for the 6 manufacturers rolled up, individually and by grantees and hospitals for all non-contract pharmacy sales.

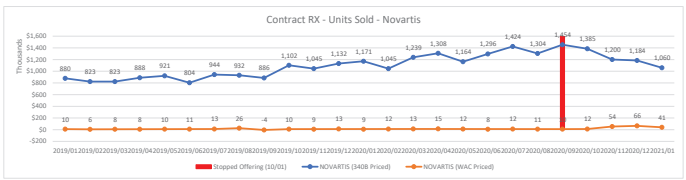
Sale type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B Price	7,552,965	6,580,202	7,015,318	7,571,563	8,448,783	7,119,865	8,111,379	8,146,720	7,740,482	8,790,498	7,859,882	8,681,258	9,158,240	7,824,473	9,295,598	9,805,474	9,088,852	9,706,344	10,482,697	9,648,675	9,446,163	5,131,307	4,494,375	5,150,687	2,882,688
WAC Price	117,257	39,222	72,466	164,015	99,981	84,535	94,210	118,600	75,454	119,954	87,441	110,382	96,657	95,354	115,964	106,877	106,038	108,063	123,102	109,945	445,096	1,015,051	521,761	647,288	845,724
Eli Lilly Stopped Offering (09/01)																				12,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					12,000,000				
Novo Nordisk Stopped Offering (01/01)																								12,000,000	

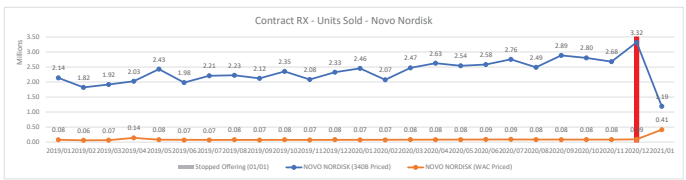


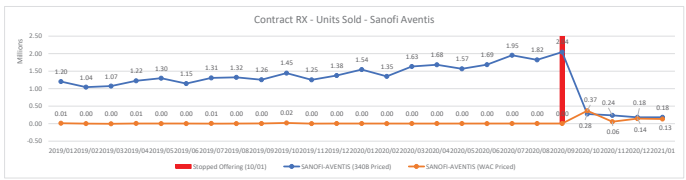
Sale type	Manufacturer	Manufacturer	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B	ASTRAZENEC	ASTRAZENEC	1,998,712	1,739,242	1,968,534	2,107,359	2,257,358	1,913,786	2,196,264	2,226,694	2,105,130	2,381,596	2,188,639	2,387,922	2,401,066	2,003,315	2,340,905	2,441,548	2,228,982	2,501,787	2,629,031	2,452,825	2,719,494	534,773	244,521	306,482	311,210
WAC	ASTRAZENEC	ASTRAZENEC	14,144	-28,444	403	4,553	4,822	2,290	5,273	5,922	3,621	5,241	2,340	6,235	6,195	4,926	8,128	4,028	5,020	5,399	2,401	5,199	5,102	384,787	201,627	217,649	156,204
		Stopped Offering (10/01)																					3,000,000				
340B	ELI LILLY & C	ELI LILLY & C	1,319,983	1,142,145	1,217,714	1,303,748	1,524,679	1,252,729	1,427,013	1,419,225	1,352,628	1,502,821	1,268,730	1,443,154	1,555,998	1,325,501	1,580,931	1,715,723	1,568,058	1,608,907	1,692,781	1,550,370	310,292	94,811	107,136	125,075	124,134
WAC	ELI LILLY & C	ELI LILLY & C	3,512	1,018	2,062	4,019	5,069	3,702	3,154	3,800	3,727	3,410	4,503	3,075	4,311	4,026	6,278	5,170	4,457	2,663	11,102	7,536	345,761	167,380	127,493	126,721	104,215
		Stopped Offering (09/01)																				2,000,000					
340B	NOVARTIS	NOVARTIS (3	879,808	823,276	822,953	888,065	921,269	803,538	943,648	931,998	886,287	1,101,776	1,045,489	1,132,481	1,171,197	1,045,481	1,239,245	1,308,137	1,163,811	1,295,602	1,423,690	1,304,216	1,454,065	1,385,358	1,200,306	#######	#######
WAC	NOVARTIS	NOVARTIS (\	9,518	6,428	7,785	7,884	9,811	10,791	12,547	25,875	-4,058	10,283	8,570	12,860	8,996	12,318	13,412	14,927	11,886	7,729	12,494	10,794	10,214	12,218	53,855	65,653	40,951
		Stopped Offering (10/01)																					1,600,000				
340B	NOVO NORD	NOVO NORD	2,136,916	1,820,302	1,918,451	2,025,451	2,428,105	1,982,299	2,207,817	2,225,149	2,121,566	2,351,448	2,084,486	2,327,073	2,455,256	2,073,740	2,471,838	2,626,907	2,540,323	2,584,100	2,755,221	2,490,662	2,886,577	2,802,020	2,677,460	#######	#######
WAC	NOVO NORD	NOVO NORD	76,755	59,568	65,385	139,512	79,573	67,276	65,784	80,760	68,585	80,252	70,283	84,551	73,697	71,098	84,026	79,293	80,257	89,590	92,902	82,928	80,070	81,983	83,027	92,791	411,585
		Stopped Offering (01/01)																								#######	
340B	SANOFI-AVE	SANOFI-AVE	1,202,433	1,043,040	1,072,812	1,223,742	1,299,603	1,145,878	1,307,758	1,323,118	1,255,091	1,445,102	1,250,943	1,375,718	1,544,893	1,351,079	1,632,413	1,683,305	1,568,555	1,686,781	1,954,766	1,823,862	2,044,945	275,917	237,835	181,832	182,269
WAC	SANOFI-AVE	SANOFI-AVE	13,328	652	-3,169	8,047	707	477	7,452	2,244	3,579	20,767	1,745	3,661	3,459	2,987	4,121	3,461	4,418	2,682	4,203	3,488	3,949	368,683	55,760	144,474	132,769
		Stopped Offering (10/01)																					2,500,000				
340B	UNITED THE	UNITED THE	15,113	12,197	14,856	23,199	17,769	21,634	28,879	20,536	19,781	7,755	21,596	14,911	29,831	25,359	30,268	29,856	19,124	29,168	27,209	26,740	30,790	38,428	27,118	30,102	13,722

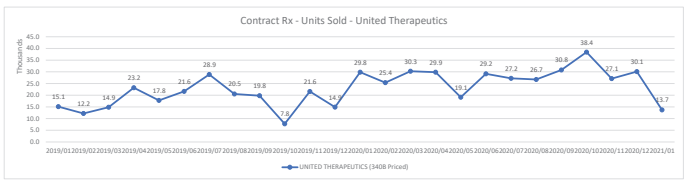




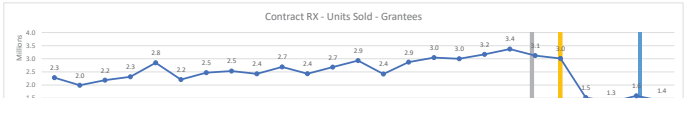


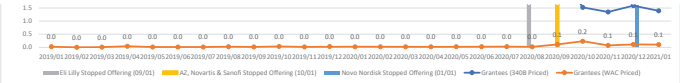


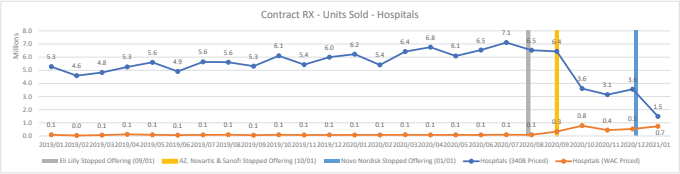




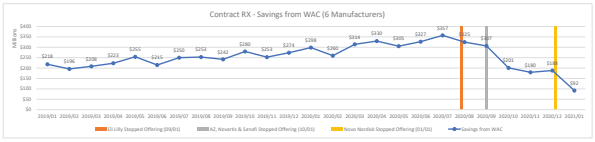
Entity Type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees	2,280,420	1,992,511	2,187,386	2,315,154	2,847,660	2,208,062	2,473,405	2,534,883	2,427,625	2,689,858	2,430,162	2,684,283	2,934,068	2,421,545	2,874,069	3,046,538	3,000,116	3,168,578	3,370,808	3,123,130	3,011,456	1,524,702	1,349,553	1,589,823	1,393,951
Grantees	26,763	2,793	9,522	42,905	14,751	15,947	15,991	26,151	17,299	35,546	16,844	31,726	21,377	21,520	23,042	23,198	26,929	24,515	30,065	20,586	111,574	235,643	77,892	114,771	105,630
Eli Lilly Stopped Offering (09/01)																				4,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					4,000,000				
Novo Nordisk Stopped Offering (01/01)																								4,000,000	
Hospitals	5,272,545	4,587,691	4,827,932	5,256,409	5,601,122	4,911,803	5,637,974	5,611,837	5,312,857	6,100,639	5,429,719	5,996,974	6,224,172	5,402,928	6,421,528	6,758,936	6,088,736	6,537,767	7,111,889	6,525,545	6,434,707	3,606,605	3,144,822	3,560,864	1,488,737
Hospitals	90,495	36,430	62,944	121,110	85,230	68,588	78,219	92,449	58,155	84,408	70,598	78,656	75,280	73,834	92,923	83,679	79,109	83,548	93,037	89,359	333,522	779,408	443,869	532,517	740,094
Eli Lilly Stopped Offering (09/01)																				8,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					8,000,000				
Novo Nordisk Stopped Offering (01/01)																								8,000,000	



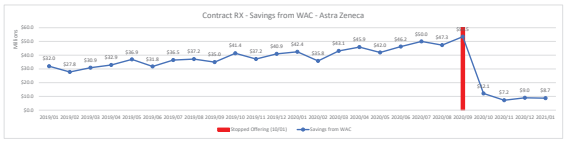

1.5
1.0
0.5
0.0
2019/01 2019/02 2019/03 2019/04 2019/05 2019/06 2019/07 2019/08 2019/09 2019/10 2019/11 2019/12 2020/01 2020/02 2020/03 2020/04 2020/05 2020/06 2020/07 2020/08 2020/09 2020/10 2020/11 2020/12 2021/01
Eli Lilly Stopped Offering (09/01)
AZ, Novartis & Sanofi Stopped Offering (10/01)
Novo Nordisk Stopped Offering (01/01)
Grantees (340B Priced)
Grantees (WAC Priced)

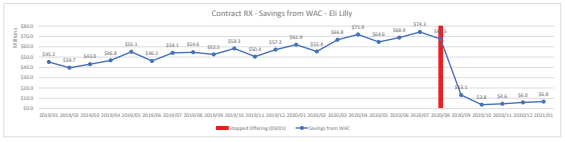

Contract RX - Units Sold - Hospitals
Millions
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
5.3 4.6 4.8 5.3 5.6 4.9 5.6 5.6 5.3 6.1 5.4 6.0 6.2 5.4 6.4 6.8 6.1 6.5 7.1 6.5 6.4 3.6 3.1 3.6 1.5
0.1 0.0 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.8 0.4 0.7
2019/01 2019/02 2019/03 2019/04 2019/05 2019/06 2019/07 2019/08 2019/09 2019/10 2019/11 2019/12 2020/01 2020/02 2020/03 2020/04 2020/05 2020/06 2020/07 2020/08 2020/09 2020/10 2020/11 2020/12 2021/01
Eli Lilly Stopped Offering (09/01)
AZ, Novartis & Sanofi Stopped Offering (10/01)
Novo Nordisk Stopped Offering (01/01)
Hospitals (340B Priced)
Hospitals (WAC Priced)

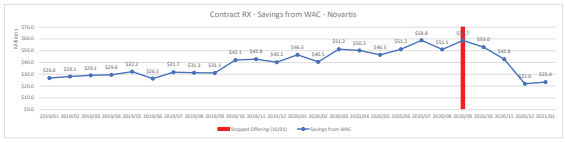
	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Savings from WAC	$218,236,006		$195,997,254	$208,374,595	$223,400,167	$254,509,076	$214,589,045	$250,206,876	$252,895,575	$241,972,098	$280,021,994	$252,600,296	$273,677,477	$298,478,790	$259,595,764	$314,122,762	$329,683,546	$305,324,535	$327,100,735	$357,368,890	$324,970,091	$306,501,169	$200,773,880	$179,701,615	$188,132,591	$91,884,890
Eli Lilly Stopped Offering (09/01)																					$400,000,000				
AZ, Novartis & Sanofi Stopped Offering (10/01)																						$400,000,000			
Novo Nordisk Stopped Offering (01/01)																								$400,000,000	

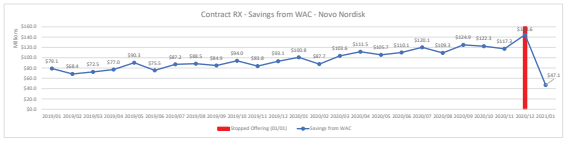


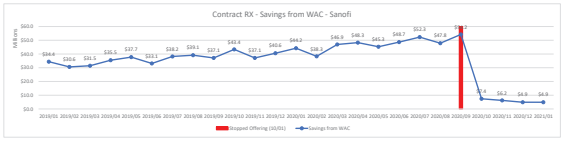
			2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Savings from WAC	ASTRAZENECA	Savings from WAC Stopped Offering (10/01)	$31,987,191	$27,800,118	$30,878,354	$32,879,113	$36,934,324	$31,799,552	$36,471,421	$37,186,394	$34,989,723	$41,396,744	$37,237,664	$40,948,134	$42,443,421	$35,833,551	$43,121,007	$45,902,943	$41,986,004	$46,246,770	$50,028,632	$47,324,434	$53,477,351 $60,000,000	$12,127,989	$7,229,308	$9,001,091	$8,726,284
Savings from WAC	ELI LILLY & CO.	Savings from WAC Stopped Offering (09/01)	$45,172,066	$39,658,299	$43,042,392	$46,776,458	$55,143,309	$46,187,649	$54,078,947	$54,649,521	$52,516,469	$58,309,269	$50,385,315	$57,223,052	$61,944,782	$55,408,635	$66,775,351	$71,893,338	$64,617,091	$68,901,655	$74,307,111	$67,536,605 $80,000,000	$13,089,875	$3,786,056	$4,625,274	$5,972,528	$6,751,854
Savings from WAC	NOVARTIS	Savings from WAC Stopped Offering (10/01)	$26,764,299	$28,095,082	$29,085,099	$29,559,111	$32,207,877	$26,346,691	$31,723,978	$31,131,431	$31,059,207	$42,057,285	$42,773,795	$40,203,100	$46,512,416	$40,497,057	$51,247,026	$50,181,455	$46,464,295	$51,201,738	$58,801,128	$51,087,935 $70,000,000	$58,677,825	$52,996,432	$42,804,901	$21,965,723	$23,361,175
Savings from WAC	NOVO NORDISK	Savings from WAC Stopped Offering (01/01)	$79,050,248	$68,444,521	$72,506,334	$76,982,417	$90,301,290	$75,516,328	$87,164,407	$88,504,526	$84,866,379	$94,014,252	$83,780,413	$93,120,854	$100,774,255	$87,660,395	$103,611,905	$111,528,019	$105,669,572	$110,113,532	$120,128,165	$109,335,765	$124,917,354	$122,288,114	$117,251,750	$144,630,419 $160,000,000	$47,071,806
Savings from WAC	SANOFI-AVENTIS	Savings from WAC Stopped Offering (10/01)	$34,391,418	$30,581,862	$31,479,901	$35,454,878	$37,740,967	$33,122,552	$38,230,409	$39,128,648	$37,127,065	$43,370,426	$37,116,310	$40,569,552	$44,218,810	$38,292,941	$46,931,876	$48,265,295	$45,257,173	$48,654,307	$52,301,943	$47,825,773 $60,000,000	$54,238,892	$7,399,059	$6,209,635	$4,895,540	$4,910,149
Savings from WAC	UNITED THERAP	Savings from WAC	$870,784	$1,417,372	$1,382,516	$1,748,190	$2,181,310	$1,616,273	$2,537,714	$2,095,055	$1,413,254	$874,018	$1,306,800	$1,612,786	$2,585,107	$1,903,186	$2,435,597	$1,912,495	$1,330,400	$1,982,733	$1,801,912	$1,859,578	$2,099,872	$2,176,229	$1,580,747	$1,667,289	$1,063,623

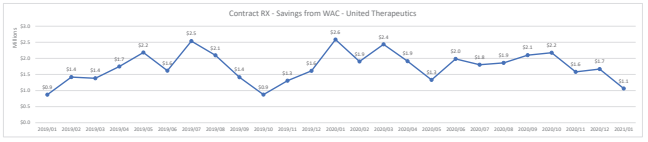




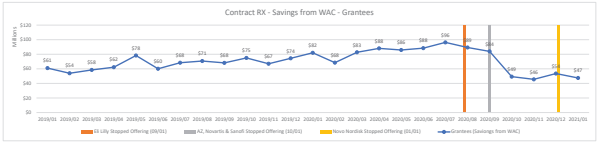




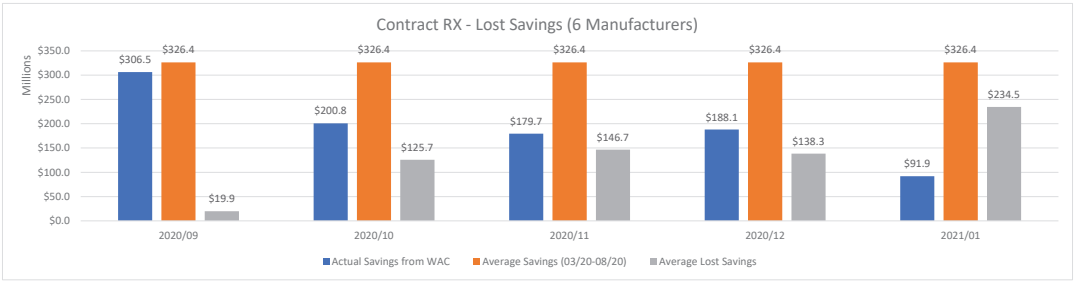




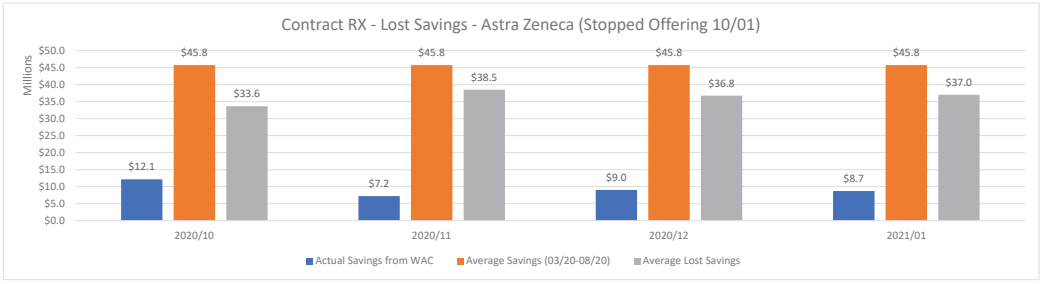
	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees (Savings from WAC)	$60,963,356		$53,894,259	$58,420,019	$62,179,463	$78,310,959	$60,084,096	$68,395,945	$70,737,015	$68,140,115	$74,891,608	$67,004,896	$74,383,384	$82,013,232	$68,497,073	$82,683,472	$88,075,893	$85,870,254	$88,360,046	$96,291,397	$89,320,923	$83,970,126	$49,294,890	$45,578,255	$53,532,159	$47,456,461
Eli Lilly Stopped Offering (09/01)																					$120,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																						$120,000,000				
Novo Nordisk Stopped Offering (01/01)																								$120,000,000	
Hospitals (Savings from WAC)	$157,272,650		$142,102,996	$149,954,575	$161,220,704	$176,198,117	$154,504,949	$181,810,931	$182,158,560	$173,831,984	$205,130,385	$185,595,400	$199,294,093	$216,465,559	$191,098,691	$231,439,290	$241,607,653	$219,454,281	$238,740,689	$261,077,493	$235,649,168 $300,000,000	$222,531,043	$151,478,990	$134,123,361	$134,600,431	$44,428,429
Eli Lilly Stopped Offering (09/01)																						$300,000,000				
AZ, Novartis & Sanofi Stopped Offering (10/01)																										
Novo Nordisk Stopped Offering (01/01)																								$300,000,000	

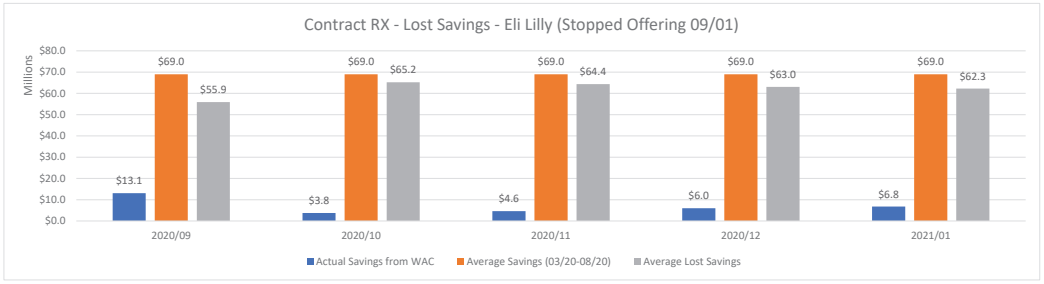


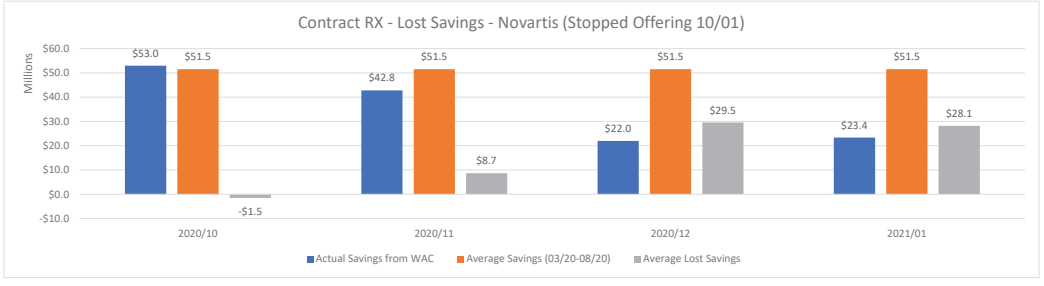
	2020/09	2020/10	2020/11	2020/12	2021/01
Actual Savings from WAC	$306,501,169	$200,773,880	$179,701,615	$188,132,591	$91,884,890
Average Savings (03/20-08/20)	$326,428,427	$326,428,427	$326,428,427	$326,428,427	$326,428,427
Average Lost Savings	$19,927,258	$125,654,547	$146,726,812	$138,295,836	$234,543,537

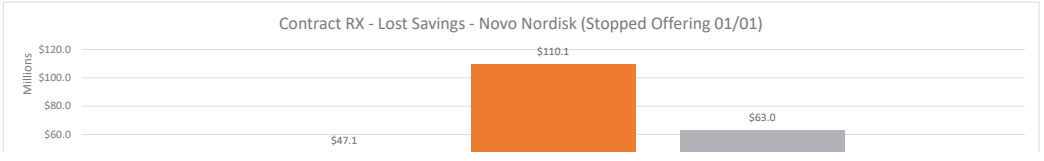


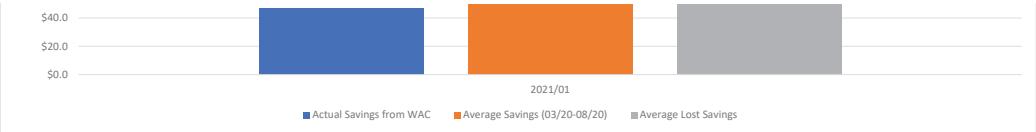
			2020/09	2020/10	2020/11	2020/12	2021/01
Savings from WAC	ASTRAZENECA	Actual Savings from WAC	$53,477,351	$12,127,989	$7,229,308	$9,001,091	$8,726,284
		Average Savings (03/20-08/20)	$45,768,298	$45,768,298	$45,768,298	$45,768,298	$45,768,298
		Average Lost Savings		$33,640,309	$38,538,990	$36,767,207	$37,042,015
Savings from WAC	ELI LILLY & CO.	Actual Savings from WAC	$13,089,875	$3,786,056	$4,625,274	$5,972,528	$6,751,854
		Average Savings (03/20-08/20)	$69,005,192	$69,005,192	$69,005,192	$69,005,192	$69,005,192
		Average Lost Savings	$55,915,317	$65,219,136	$64,379,918	$63,032,664	$62,253,338
Savings from WAC	NOVARTIS	Actual Savings from WAC	$58,677,825	$52,996,432	$42,804,901	$21,965,723	$23,361,175
		Average Savings (03/20-08/20)	$51,497,263	$51,497,263	$51,497,263	$51,497,263	$51,497,263
		Average Lost Savings		-$1,499,169	$8,692,362	$29,531,539	$28,136,087
Savings from WAC	NOVO NORDISK	Actual Savings from WAC	$124,917,354	$122,288,114	$117,251,750	$144,630,419	$47,071,806
		Average Savings (03/20-08/20)	$110,064,493	$110,064,493	$110,064,493	$110,064,493	$110,064,493
		Average Lost Savings					$62,992,687
Savings from WAC	SANOFI-AVENTIS	Actual Savings from WAC	$54,238,892	$7,399,059	$6,209,635	$4,895,540	$4,910,149
		Average Savings (03/20-08/20)	$48,206,061	$48,206,061	$48,206,061	$48,206,061	$48,206,061
		Average Lost Savings		$40,807,002	$41,996,426	$43,310,521	$43,295,913
Savings from WAC	UNITED THERAP	Actual Savings from WAC	$2,099,872	$2,176,229	$1,580,747	$1,667,289	$1,063,623

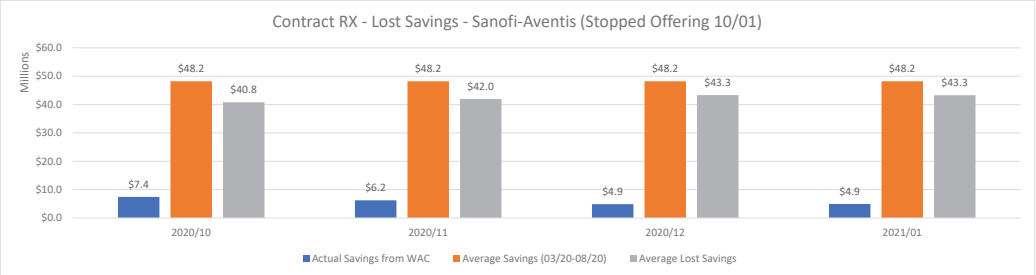




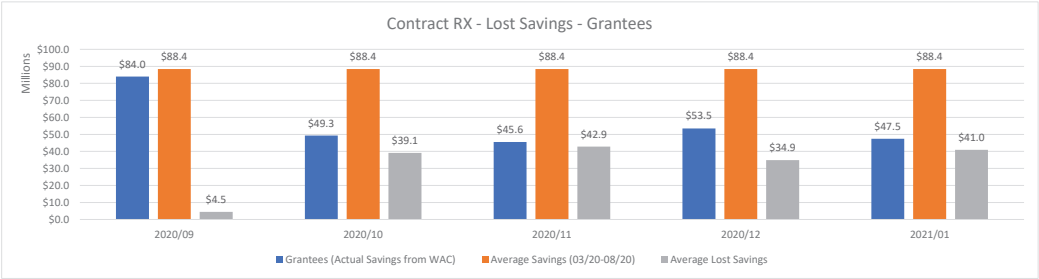


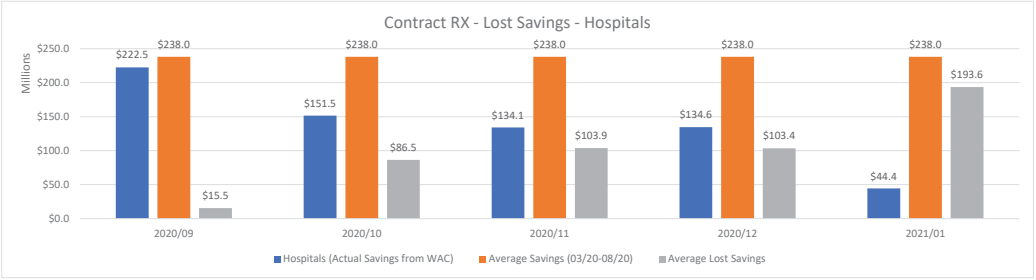




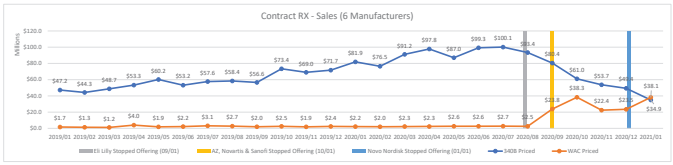


	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees (Actual Savings from WAC)	$83,970,126	$49,294,890	$45,578,255	$53,532,159	$47,456,461
Average Savings (03/20-08/20)	$88,433,664	$88,433,664	$88,433,664	$88,433,664	$88,433,664
Average Lost Savings	$4,463,538	$39,138,774	$42,855,410	$34,901,505	$40,977,203
Hospitals (Actual Savings from WAC)	$222,531,043	$151,478,990	$134,123,361	$134,600,431	$44,428,429
Average Savings (03/20-08/20)	$237,994,762	$237,994,762	$237,994,762	$237,994,762	$237,994,762
Average Lost Savings	$15,463,719	$86,515,773	$103,871,402	$103,394,331	$193,566,334

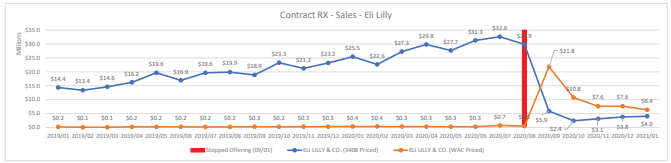


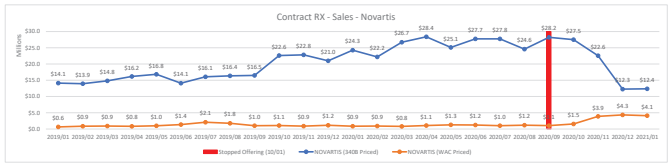


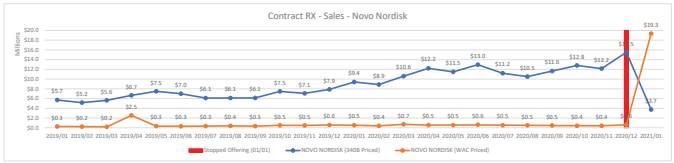
Sale type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B Pric	$47,233,754	$44,268,176	$48,717,162	$53,342,884	$60,184,419	$53,150,047	$57,648,828	$58,390,695	$56,637,970	$73,382,014	$69,044,375	$71,686,914	$81,876,125	$76,514,954	$91,218,227	$97,759,228	$86,984,799	$99,301,110	##########	$93,437,305	$80,388,069	$61,009,921	$53,694,659	$49,361,871	$34,936,559
WAC Pricii	$1,672,435	$1,301,437	$1,176,144	$3,985,431	$1,911,959	$2,171,506	$3,136,259	$2,722,887	$1,975,478	$2,512,029	$1,893,616	$2,357,752	$2,156,962	$2,016,086	$2,317,429	$2,316,780	$2,601,683	$2,591,927	$2,692,876	$2,540,922	$23,843,621	$38,320,383	$22,377,816	$23,507,403	$38,127,622
Eli Lilly Stopped Offering (09/01)																				##########					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					##########				
Novo Nordisk Stopped Offering (01/01)																								##########	

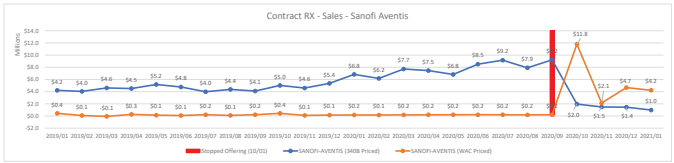


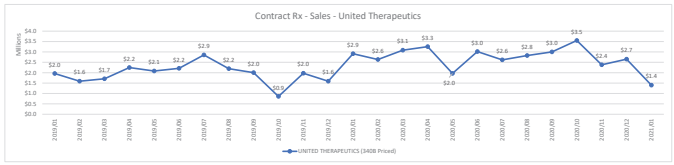
Sale type	Manufacturer	Manufacturer	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B	ASTRAZENECA	ASTRAZENECA	$6,847,909	$6,160,751	$7,342,797	$7,515,468	$8,960,327	$8,116,067	$8,970,604	$9,465,034	$9,022,974	$14,128,115	$11,337,985	$12,670,924	$12,989,809	$13,999,429	$15,863,675	$16,596,233	$13,939,296	$15,770,541	$16,768,319	$17,736,939	$22,393,442	$12,751,382	$11,999,781	##########	$12,386,476
WAC	ASTRAZENECA	ASTRAZENECA	$123,358	$39,796	$66,189	$126,312	$203,716	$168,487	$305,778	$281,104	$145,842	$258,508	$187,839	$238,051	$267,295	$192,466	$298,868	$223,245	$305,023	$262,228	$219,563	$224,899	$266,778	$13,808,408	$8,336,125	$6,245,794	$4,099,236
		Stopped Offering (10/01)																					$25,000,000			
340B	ELI LILLY & CC	ELI LILLY & CC	$14,381,859	$13,366,802	$14,608,372	$16,232,631	$19,646,923	$16,948,139	$19,645,824	$19,891,968	$18,885,911	$23,291,323	$21,245,210	$23,178,397	$25,459,716	$22,649,526	$27,250,162	$29,844,153	$27,664,193	$31,287,638	$32,625,382	$29,875,200	$5,896,218	$2,425,997	$3,100,516	$3,775,024	$4,038,926
WAC	ELI LILLY & CC	ELI LILLY & CC	$203,796	$83,880	$78,747	$220,290	$231,188	$249,715	$202,870	$193,604	$274,749	$248,225	$262,887	$261,845	$363,154	$379,937	$326,915	$292,549	$272,040	$282,426	$729,139	$452,316	$21,830,860	$10,755,206	$7,619,844	$7,642,672	$6,366,458
		Stopped Offering (09/01)																				$35,000,000					
340B	NOVARTIS	NOVARTIS (34	$14,139,724	$13,946,332	$14,836,196	$16,175,991	$16,837,899	$14,105,251	$16,085,275	$16,366,225	$16,499,703	$22,613,891	$22,839,890	$20,994,713	$24,270,885	$22,180,487	$26,698,479	$28,380,005	$25,115,690	$27,749,078	$27,753,762	$24,575,399	$28,226,589	$27,518,310	$22,568,070	##########	$12,388,314
WAC	NOVARTIS	NOVARTIS (W	$647,149	$873,055	$909,575	$845,059	$1,004,827	$1,374,354	$2,080,140	$1,761,646	$1,012,988	$1,075,844	$881,110	$1,151,669	$862,086	$911,682	$813,468	$1,067,626	$1,284,746	$1,240,564	$1,031,395	$1,193,493	$1,055,162	$1,549,723	$3,886,876	$4,349,388	$4,102,164
		Stopped Offering (10/01)																					$30,000,000			
340B	NOVO NORDI	NOVO NORDI	$5,693,848	$5,164,681	$5,618,821	$6,665,797	$7,486,560	$6,999,830	$6,108,672	$6,103,533	$6,124,622	$7,468,570	$7,059,205	$7,890,643	$9,411,552	$8,875,378	$10,606,197	$12,225,522	$11,482,760	$12,963,427	$11,203,543	$10,503,343	$11,649,469	$12,804,742	$12,163,091	##########	$3,744,566
WAC	NOVO NORDI	NOVO NORDI	$257,393	$225,075	$188,757	$2,531,218	$335,069	$299,209	$335,561	$388,464	$339,036	$492,629	$470,081	$559,687	$504,509	$386,036	$701,208	$527,413	$533,581	$616,663	$510,549	$486,334	$477,065	$404,963	$401,459	$600,293	$19,333,972
		Stopped Offering (01/01)																								##########	
340B	SANOFI-AVEN	SANOFI-AVEN	$4,207,821	$4,039,119	$4,602,132	$4,503,904	$5,171,014	$4,769,350	$3,983,734	$4,371,122	$4,103,828	$5,022,206	$4,589,540	$5,361,532	$6,831,723	$6,175,612	$7,716,041	$7,458,899	$6,816,411	$8,511,936	$9,169,058	$7,919,908	$9,223,676	$1,959,768	$1,482,514	$1,442,193	$979,648
WAC	SANOFI-AVEN	SANOFI-AVEN	$438,739	$79,632	-$67,124	$262,552	$137,159	$79,741	$211,910	$98,069	$202,863	$436,823	$91,699	$146,502	$159,919	$145,965	$176,972	$205,947	$206,292	$190,045	$202,231	$183,880	$213,756	$11,802,083	$2,133,513	$4,669,257	$4,225,792
		Stopped Offering (10/01)																					$14,000,000			
340B	UNITED THER	UNITED THER	$1,962,593	$1,590,492	$1,708,843	$2,249,094	$2,081,695	$2,211,411	$2,854,721	$2,192,813	$2,000,933	$857,910	$1,972,545	$1,590,705	$2,912,440	$2,634,522	$3,083,673	$3,254,414	$1,966,449	$3,018,490	$2,617,394	$2,826,517	$2,998,676	$3,549,722	$2,380,686	$2,652,317	$1,398,629



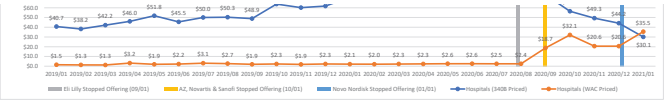








Entity Typ	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees	$6,543,342	$6,070,358	$6,558,481	$7,315,311	$8,394,288	$7,601,253	$7,653,990	$8,048,114	$7,759,275	$9,601,237	$8,848,681	$9,937,690	$11,097,196	$10,060,387	$11,982,352	$13,745,320	$13,011,150	$13,876,865	$14,330,007	$13,122,594	$6,968,089	$4,544,230	$4,396,038	$5,183,018	$4,853,317
Grantees	$147,494	-$12,601	-$90,794	$770,247	-$27,325	-$7,885	$45,832	$36,870	$28,979	$171,587	$33,500	$29,279	$15,767	$16,505	$10,565	$19,995	$22,620	$7,260	$240,630	$91,110	$5,163,772	$6,204,579	$1,802,904	$2,930,799	$2,626,763
Eli Lilly Stopped Offering (09/01)																				$16,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					$16,000,000				
Novo Nordisk Stopped Offering (01/01)																								$16,000,000	
Hospitals	$40,690,413	$38,197,818	$42,158,681	$46,027,573	$51,790,130	$45,548,794	$49,994,838	$50,342,581	$48,878,696	$63,780,778	$60,195,694	$61,749,224	$70,778,929	$66,454,568	$79,235,876	$84,013,908	$73,973,649	$85,424,245	$85,807,451	$80,314,711	$73,419,980	$56,465,692	$49,298,621	$44,178,853	$30,083,242
Hospitals	$1,524,940	$1,314,038	$1,266,938	$3,215,184	$1,939,284	$2,179,391	$3,090,427	$2,686,017	$1,946,499	$2,340,443	$1,860,116	$2,328,473	$2,141,195	$1,999,582	$2,306,865	$2,296,785	$2,579,063	$2,584,667	$2,452,247	$2,449,812	$18,679,849	$32,115,804	$20,574,913	$20,576,604	$35,500,859
Eli Lilly Stopped Offering (09/01)																				##########					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					##########				
Novo Nordisk Stopped Offering (01/01)																								##########	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$30.1
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$2.2
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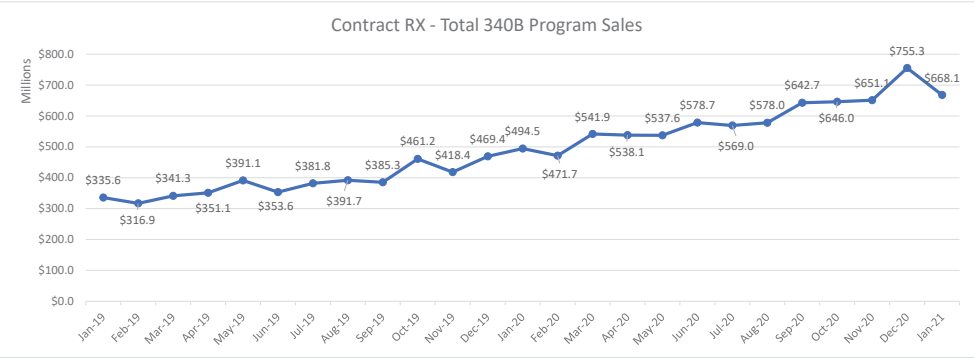
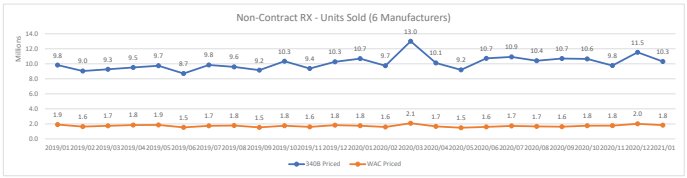
2019/01 2019/02 2019/03 2019/04 2019/05 2019/06 2019/07 2019/08 2019/09 2019/10 2019/11 2019/12 2020/01 2020/02 2020/03 2020/04 2020/05 2020/06 2020/07 2020/08 2020/09 2020/10 2020/11 2020/12 2021/01
Eli Lilly Stopped Offering (09/01)
AZ, Novartis & Sanofi Stopped Offering (10/01)
Novo Nordisk Stopped Offering (01/01)
Hospitals (340B Priced)
Hospitals (WAC Priced)

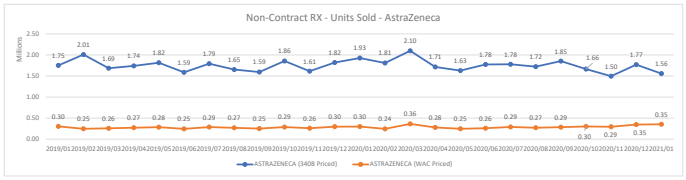
month_id		340B Program Sales
201901	Jan-19	$335,648,321
201902	Feb-19	$316,934,962
201903	Mar-19	$341,299,952
201904	Apr-19	$351,079,369
201905	May-19	$391,096,101
201906	Jun-19	$353,597,659
201907	Jul-19	$381,818,209
201908	Aug-19	$391,679,711
201909	Sep-19	$385,337,284
201910	Oct-19	$461,206,439
201911	Nov-19	$418,384,234
201912	Dec-19	$469,353,000
202001	Jan-20	$494,507,259
202002	Feb-20	$471,675,485
202003	Mar-20	$541,858,892
202004	Apr-20	$538,138,207
202005	May-20	$537,570,794
202006	Jun-20	$578,699,218
202007	Jul-20	$569,024,130
202008	Aug-20	$577,998,591
202009	Sep-20	$642,698,059
202010	Oct-20	$646,020,439
202011	Nov-20	$651,097,296
202012	Dec-20	$755,342,588
202101	Jan-21	$668,146,966
202102	Feb-21	$49,965

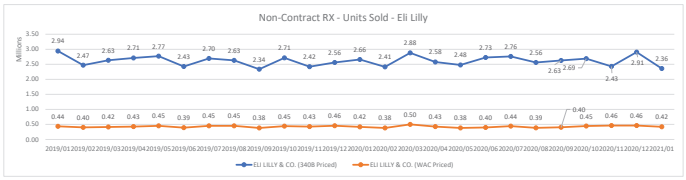


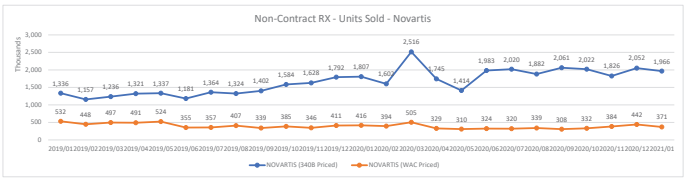
Sale type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B Price	9,829,705	9,045,070	9,267,129	9,512,558	9,738,373	8,706,660	9,848,616	9,586,697	9,153,628	10,345,448	9,374,296	10,267,586	10,686,262	9,736,714	13,003,772	10,114,669	9,196,249	10,724,490	10,923,193	10,411,793	10,704,500	10,649,424	9,773,403	11,535,451	########
WAC Price	1,898,528	1,632,847	1,743,902	1,842,632	1,851,799	1,537,554	1,738,691	1,778,358	1,529,681	1,757,526	1,600,014	1,822,791	1,750,566	1,587,024	2,085,811	1,665,593	1,487,533	1,598,279	1,727,909	1,657,593	1,617,251	1,753,227	1,759,613	2,004,193	1,830,951

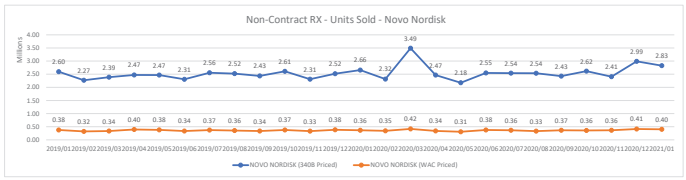


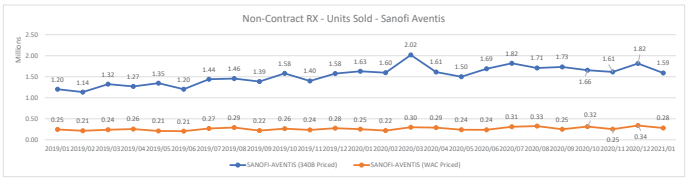
Sale type	Manufacturer	Manufacturer	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B	ASTRAZENEC	ASTRAZENEC	1,752,155	2,009,957	1,685,943	1,740,990	1,816,354	1,587,303	1,793,907	1,653,237	1,594,435	1,855,965	1,614,166	1,820,854	1,927,918	1,808,007	2,099,239	1,714,191	1,628,641	1,775,529	1,779,156	1,721,356	1,853,601	1,664,717	1,495,746	########	########
WAC	ASTRAZENEC	ASTRAZENEC	302,650	247,129	257,188	271,661	283,977	245,016	286,225	270,106	251,573	287,592	259,044	296,499	298,298	244,783	362,123	278,858	245,953	258,938	288,762	271,676	285,154	301,402	293,646	347,456	354,055
340B	ELI LILLY & C	ELI LILLY & C	2,941,878	2,470,779	2,633,648	2,710,543	2,771,848	2,428,412	2,695,400	2,631,474	2,337,180	2,713,108	2,421,183	2,560,030	2,661,594	2,414,558	2,880,291	2,576,380	2,478,621	2,727,329	2,762,601	2,562,415	2,628,638	2,687,830	2,430,225	########	########
WAC	ELI LILLY & C	ELI LILLY & C	438,278	401,649	415,016	426,611	454,085	394,190	452,720	453,523	383,023	445,204	427,362	455,305	418,725	383,318	501,715	427,150	383,188	400,643	444,780	385,688	404,622	445,673	463,373	462,037	422,983
340B	NOVARTIS	NOVARTIS (I	1,336,108	1,156,533	1,235,953	1,321,264	1,336,625	1,181,452	1,363,570	1,324,090	1,401,717	1,583,849	1,628,054	1,792,147	1,806,863	1,601,959	2,515,526	1,744,875	1,413,522	1,982,521	2,019,971	1,881,569	2,061,032	2,022,040	1,825,754	########	########
WAC	NOVARTIS	NOVARTIS (I	531,384	448,272	496,790	491,120	524,224	354,677	357,443	407,313	338,854	385,319	346,035	411,112	416,275	394,154	504,859	328,590	309,801	323,848	319,535	339,242	308,243	331,959	384,482	442,468	371,198
340B	NOVO NORD	NOVO NORD	2,595,595	2,272,300	2,387,623	2,470,086	2,466,531	2,305,624	2,555,638	2,521,341	2,434,974	2,611,710	2,312,132	2,518,395	2,658,876	2,315,937	3,490,762	2,467,170	2,175,061	2,549,455	2,541,258	2,537,829	2,428,674	2,619,493	2,407,615	########	########
WAC	NOVO NORD	NOVO NORD	377,613	321,011	335,318	396,092	379,935	337,174	371,218	355,009	335,365	374,795	331,306	383,434	363,979	345,108	417,054	339,232	308,613	377,694	364,865	333,785	366,303	357,854	364,690	412,033	401,924
340B	SANOFI-AVE	SANOFI-AVE	1,203,830	1,135,250	1,323,843	1,269,631	1,346,886	1,203,805	1,440,016	1,456,464	1,385,073	1,580,568	1,398,621	1,575,785	1,630,902	1,595,998	2,017,793	1,611,889	1,500,395	1,689,343	1,820,001	1,708,585	1,732,134	1,655,032	1,613,724	########	########
WAC	SANOFI-AVE	SANOFI-AVE	247,210	214,057	239,069	256,538	209,068	205,927	270,315	291,868	220,172	263,936	235,682	275,431	252,460	218,965	299,425	290,907	239,348	236,372	309,327	325,967	251,923	315,035	252,747	339,404	280,386
340B	UNITED THE	UNITED THE	140	252	120	45	130	65	85	92	250	248	140	376	110	255	160	165	10	315	205	40	421	311	340	370	132
WAC	UNITED THE	UNITED THE	793	730	522	610	510	570	770	540	695	680	585	1010	830	695	635	855	630	785	640	1235	1005	1305	675	795	405

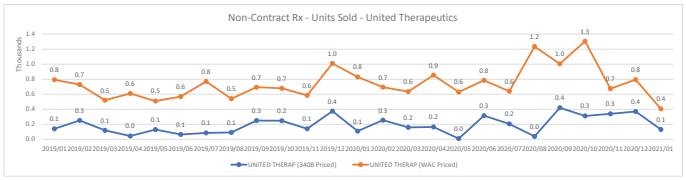




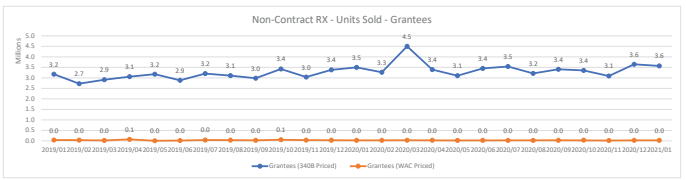


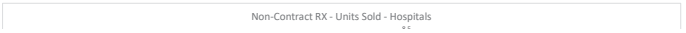


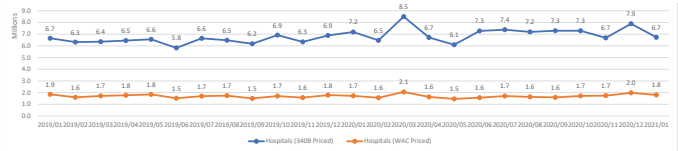




Entity Typ	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees	3,174,423	2,724,460	2,913,122	3,058,251	3,177,089	2,884,321	3,202,627	3,108,903	2,982,386	3,424,958	3,038,159	3,381,093	3,498,737	3,269,794	4,503,726	3,395,172	3,102,174	3,449,788	3,542,723	3,215,120	3,408,486	3,355,189	3,090,279	3,645,975	3569165
Grantees	38,921	34,751	24,125	72,956	6,634	18,919	40,112	36,240	27,814	52,539	35,231	33,890	27,350	26,624	29,821	29,631	23,756	27,733	23,380	21,808	25,244	36,336	17,923	25,768	26670.8
Hospitals	6,655,282	6,320,610	6,354,008	6,454,307	6,561,284	5,822,340	6,645,990	6,477,794	6,171,242	6,920,490	6,336,137	6,886,493	7,187,525	6,466,921	8,500,046	6,719,497	6,094,075	7,274,703	7,380,470	7,196,673	7,296,015	7,294,235	6,683,123	7,889,476	6732305
Hospitals	1,859,607	1,598,097	1,719,777	1,769,676	1,845,165	1,518,634	1,698,580	1,742,118	1,501,867	1,704,987	1,564,783	1,788,902	1,723,216	1,560,400	2,055,989	1,635,962	1,463,777	1,570,547	1,704,529	1,635,785	1,592,007	1,716,891	1,741,690	1,978,425	1804280






Millions
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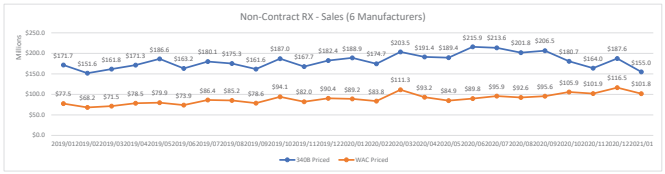
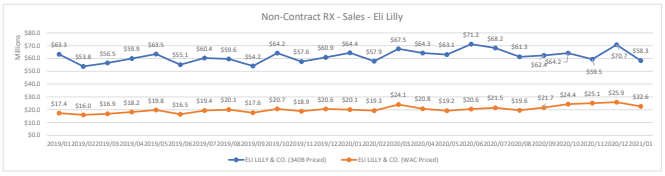
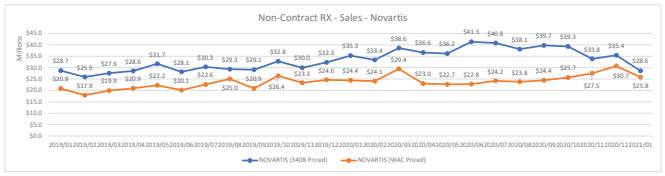
6.7 6.3 6.4 6.5 6.6 5.8 6.6 6.5 6.2 6.9 6.3 6.9 7.2 6.5 8.5 6.7 6.1 7.3 7.4 7.2 7.3 7.3 6.7 7.9 6.7
1.9 1.6 1.7 1.8 1.8 1.5 1.7 1.7 1.5 1.7 1.6 1.8 1.7 1.6 2.1 1.6 1.5 1.6 1.7 1.6 1.6 1.7 1.7 2.0 1.8
2019/01 2019/02 2019/03 2019/04 2019/05 2019/06 2019/07 2019/08 2019/09 2019/10 2019/11 2019/12 2020/01 2020/02 2020/03 2020/04 2020/05 2020/06 2020/07 2020/08 2020/09 2020/10 2020/11 2020/12 2021/01
Hospitals (340B Priced)
Hospitals (WAC Priced)

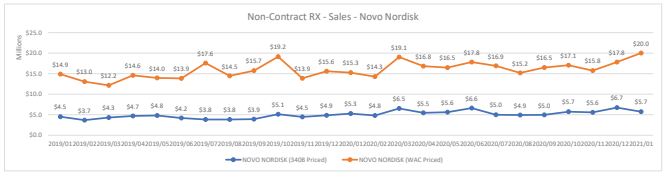
Sale type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B Pric	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########
WAC Price	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$93,195,650	##########	$89,815,433	$95,850,383	$92,604,603	##########	##########	##########	##########	##########

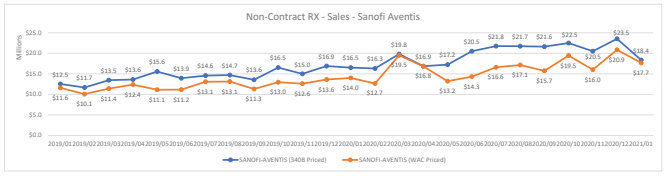


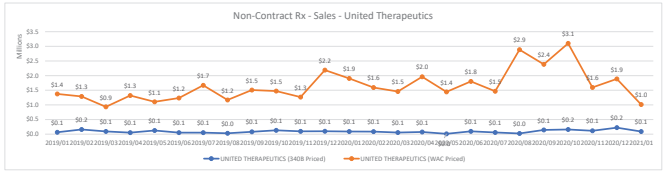
Sale type	Manufacture	Manufacture	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B	ASTRAZENEC	ASTRAZENEC	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$62,135,146	##########	$68,040,633	$67,284,586	$76,095,377	##########	##########	##########	##########	$44,501,174	##########	##########
WAC	ASTRAZENEC	ASTRAZENEC	##########	$9,896,407	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$11,869,377	##########	$13,758,999	$11,809,788	$12,509,331	##########	##########	##########	##########	$15,912,933	##########	##########
340B	ELI LILLY & C	ELI LILLY & C	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$57,941,570	##########	$64,323,284	$63,086,763	$71,212,851	##########	##########	##########	##########	$59,464,216	##########	##########
WAC	ELI LILLY & C	ELI LILLY & C	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$19,316,192	##########	$20,762,494	$19,241,649	$20,568,777	##########	##########	##########	##########	$25,143,179	##########	##########
340B	NOVARTIS	NOVARTIS (3	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$33,377,676	##########	$36,594,049	$36,180,645	$41,333,342	##########	##########	##########	##########	$33,825,574	##########	##########
WAC	NOVARTIS	NOVARTIS (V	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$24,065,806	##########	$23,028,996	$22,676,101	$22,770,661	##########	##########	##########	##########	$27,499,128	##########	##########
340B	NOVO NORD	NOVO NORD	$4,510,976	$3,680,141	$4,301,591	$4,683,337	$4,811,406	$4,206,428	$3,844,114	$3,824,175	$3,916,144	$5,117,100	$4,459,566	$4,859,514	$5,271,339	$4,816,275	$6,532,649	$5,464,951	$5,613,756	$6,614,817	$4,984,848	$4,909,618	$4,958,706	$5,737,008	$5,568,077	$6,731,314	$5,741,159
WAC	NOVO NORD	NOVO NORD	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$14,272,415	##########	$16,837,304	$16,484,964	$17,830,450	##########	##########	##########	##########	$15,758,944	##########	##########
340B	SANOFI-AVE	SANOFI-AVE	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$16,324,801	##########	$16,882,651	$17,249,632	$20,527,074	##########	##########	##########	##########	$20,522,262	##########	##########
WAC	SANOFI-AVE	SANOFI-AVE	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$12,661,830	##########	$16,845,637	$13,208,365	$14,335,216	##########	##########	##########	##########	$16,029,856	##########	##########
340B	UNITED THE	UNITED THE	$65,147	$160,386	$93,272	$51,516	$126,885	$52,473	$51,329	$31,194	$81,523	$132,789	$95,899	$99,196	$89,819	$87,794	$55,629	$74,110	$12,666	$95,530	$58,074	$22,931	$145,626	$161,275	$115,100	$222,260	$91,254
WAC	UNITED THE	UNITED THE	$1,372,965	$1,288,315	$933,292	$1,321,606	$1,104,491	$1,235,215	$1,668,633	$1,169,853	$1,506,691	$1,473,684	$1,266,758	$2,189,579	$1,904,481	$1,593,859	$1,457,833	$1,962,220	$1,445,149	$1,800,998	$1,466,844	$2,887,025	$2,385,178	$3,100,166	$1,597,642	$1,889,041	$1,012,918



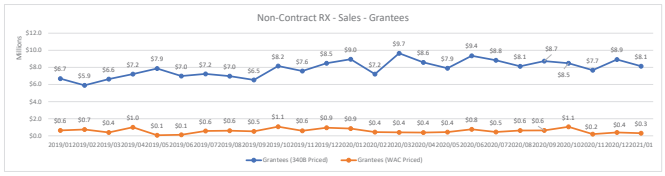








Entity Typ	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees i	$6,688,096	$5,904,276	$6,638,527	$7,217,040	$7,867,776	$6,990,614	$7,236,303	$6,979,319	$6,537,129	$8,160,162	$7,576,645	$8,490,188	$8,956,892	$7,214,426	$9,655,012	$8,592,097	$7,901,435	$9,361,045	$8,838,079	$8,131,320	$8,742,479	$8,493,050	$7,677,161	$8,922,429	$8,137,870
Grantees i	$629,481	$742,837	$387,255	$1,005,086	$67,678	$116,901	$566,726	$598,886	$525,668	$1,068,719	$589,909	$949,723	$851,115	$434,361	$398,887	$383,761	$436,070	$764,790	$450,757	$622,568	$631,938	$1,053,344	$192,877	$391,587	$303,901
Hospitals	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########
Hospitals	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$92,811,889	##########	$89,050,643	$95,399,626	$91,982,035	##########	##########	##########	##########	##########



DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

ADVISORY OPINION 20-06 ON CONTRACT PHARMACIES UNDER THE 340B PROGRAM
DECEMBER 30, 2020

The 340B Program, established by section 340B of the Public Health Service Act ("PHSA"), 42 U.S.C. § 256b, imposes limitations on the prices manufacturers may charge for medications sold to specified health care facilities, referred to as "covered entities." Those facilities include public hospitals and community health centers, many of which provide safety-net services to the poor. The 340B Program requires drug manufacturers, as a condition of coverage of their products under Medicaid (*see* Social Security Act ("SSA") § 1902(a)(54)) and Medicare Part B (*see, e.g.*, SSA §§ 1842(o)(1), 1847A), to agree to sell their covered outpatient drugs to covered entities at no more than the statutorily-set "ceiling price." *See* SSA § 1927(a)(1).

Many covered entities enter into written agreements with pharmacies ("contract pharmacies") to distribute their covered outpatient drugs to the entities' patients. Under those agreements, the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy. Although the contact pharmacy has physical possession of the drug, it has been purchased by the covered entity.

Recently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price.

The Office of the General Counsel ("OGC") has received numerous requests from both manufacturers and covered entities to address whether it is proper for a drug manufacturer participating in the 340B Program to refuse to provide covered outpatient drugs at the 340B ceiling price to a covered entity for drugs distributed at the entity's contract pharmacies. For the reasons set forth below, we conclude that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs.

I. Analysis

A. The Plain Meaning of Section 340B Requires Manufacturers to Sell Covered Drugs to Covered Entities at or Below the Ceiling Price, Independent of Whether the Entity Opts to Use Contract Pharmacies to Dispense the Drugs

"[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004). Section 340B of the PHSA, entitled "Limitation on prices of drugs purchased by covered entities," states, in relevant part, that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1) (emphasis supplied). Furthermore, "[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 a result, the obligations placed on manufacturers by 340B are set out in a Pharmaceutical Pricing Agreement ("PPA") between the Secretary and the respective manufacturer. *See generally Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110 (2011) (describing role of PPAs in 340B Program). The exemplar PPA provides, in pertinent part, as follows:

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following: (a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to [the ceiling price].

PPA § II(a). The exemplar PPA Addendum provides that a "[m]anufacturer shall 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." PPA Addendum ¶ 2.

Thus, the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity. In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute. *See Radovich v. Nat'l Football League*, 352 U.S. 445, 454 (1957) ("Congress itself has placed the private antitrust litigant in a most favorable position . . . . In the face of such a policy this Court should not add requirements to burden the private litigant beyond what is specifically set forth by Congress in those laws."); *Financial Planning Ass'n v. SEC,* 482 F.3d 481 (D.C. Cir. 2007); *Baker v. Bell Textron, Inc*., 2020 WL 5513431, at *4 (N.D. Tex. 2020) ("The Court will not add requirements to the law that Congress could have included but did not.").

It is against this backdrop that we examine the 340B phrase "purchased by." It is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise. The Court recently cautioned against seeing ambiguity where none exists. For

example, a regulation must be "genuinely ambiguous" before resorting to deference. *Kisor v. Wilkie*, ___U.S.___, 139 S.Ct. 2400, 2415 (2019). Here, as we understand it, the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and the covered entity pays the manufacturer either directly or through the manufacturer's distributor. In either event, the arrangement between the manufacturer and covered entity is a straightforward "sale" which "consists of the passing of title from the seller [drug manufacturer] to the buyer [covered entity] for a price." Uniform Commercial Code (U.C.C.) § 2-106.[1] A "buyer" is, by definition, a "purchaser." BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "buyer" as "[s]omeone who makes a purchase"). The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant. *See* U.C.C. § 2-401(2) ("Unless otherwise explicitly agreed title passes to the buyer at the time and place at which the seller completes his performance with reference to the physical delivery of the goods . . . ").

Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive. *Bostock v. Clayton Cty.*, ___U.S.___, 140 S. Ct. 1731, 1739 (2020) ("[W]hen the meaning of the statute's terms is plain, our job is at an end."). This straightforward textual interpretation, aside from dutifully reflecting the plain meaning of the statute, has the added benefit of comporting with the statute's purpose and history.

B. The Purpose and History of the 340B Program Reflect the Provision's Plain Meaning

1. Contract Pharmacies Have Been an Integral Part of the 340B Program Since Its Outset

The 340B Program was created to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rept. No. 102–384(II), at 12 (1992). As the Health Resources and Services Administration ("HRSA")—the agency primarily responsible for administering the 340B Program—has explained in prior guidance, a substantial number of covered entities are practically constrained to rely on contract pharmacies to access the 340B Program; if manufacturers can simply shut off this means of access, the Program's effectiveness will be greatly diminished. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (proposed Feb. 6, 2019) (OIG proposed rule discussing distribution of pharmaceuticals).[2]

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[1] The U.C.C. can be used for statutory construction, even if it does not directly apply. *See Comm'r of Internal Revenue v. Brown*, 380 U.S. 563, 571 (1965) (interpreting provision of the Internal Revenue Code by pointing to U.C.C. as support for the "ordinary sense" of the word "sale").

[2] The argument that the statute also evinces a purpose to prevent drug diversion or duplicate discounting, and therefore prohibits contract-pharmacy arrangements, is not persuasive. That is like arguing that the main purpose of federal healthcare programs are their antifraud provisions. In the absence of the core 340B discount mechanism, there would be no need for the duplicate-discount or diversion provisions.

This is particularly pertinent given that at the outset of the 340B Program only approximately 500 out of 11,500 covered entities (less than 5 percent) used in-house pharmacies. *See* 61 Fed. Reg. at 43,550. This is not surprising: the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations. *See, e.g.*, 42 U.S.C. § 256b(a)(4) (defining covered entities); *Astra USA*, 563 U.S. at 113. These are the poster children of providers that one would expect to lack an in-house pharmacy. To champion a policy, ungrounded in the language of the statute, that would foreclose 340B discounts to 95 percent of covered entities and foreclose discounts to the neediest of this cohort is inconsistent with purpose of the Program and common sense. Had Congress intended to reach such a bizarre result, it would have used language affirmatively precluding the use of contract pharmacies as arms in the distribution channel, but it did not. *Doe v. Hesketh*, 828 F.3d 159, 167 (3d Cir. 2016) (the result is "so bizarre that Congress could not have intended it").

2. The Department's Longstanding Interpretation of Section 340B Reflects the Plain Language of the Section by Recognizing the Use of Contract Pharmacies

The Department's longstanding interpretation of the statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used. In 1996, HRSA issued the aforementioned guidance and stated, "[i]t has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price." 61 Fed. Reg. at 43,549. HRSA's assertion cannot be attacked as impermissible legislative rulemaking,[3] because the guidance only sought to "explain the statutory language by clarifying the meaning given by the Department to particular words or phrases"—it "create[d] no new law and create[d] no new rights or duties" not otherwise present in the statute. *See id.* at 43,550. HRSA reaffirmed its interpretation of the statute in guidance issued in 2010. *See* HRSA, *Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

The Department's consistent position over the past 24-plus years would factor into a court's interpretation of the statute. Courts defer to agency expertise in the interpretation of statutes, especially where they govern complex administrative regimes. *See, e.g.*, *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001). Conversely, a court would be skeptical of an abrupt about-face. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 577–81 (2009). Courts may also look to agency implementation and the actions of regulated parties to determine the meaning of a statute. *See, e.g.*, *S.D. Warren Co. v. Me. Bd. of Env't Prot.*, 547 U.S. 370, 377–78 (2006) (even though relevant agencies had not "formally settled the definition, or even set out agency reasoning," the "administrative usage of [the disputed term] in this way confirm[ed the Court's]

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[3] *See, generally*, *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) ("Within section 340B, Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions."); *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 138 F. Supp. 3d 31, 39 (D.D.C. 2015) (even if "HHS lacks the authority to promulgate the rule as a binding statement of law, HHS is not forbidden altogether from proffering its interpretation of the statute").

understanding"); *Bd. of the Trs. of Leland Stanford Jr. Univ. v. Roche Molecular Sys.*, 563 U.S. 776, 792–93 (2011) ("[I]t is worth noting that our construction of the [statute in question] is reflected in the common practice among parties operating under the Act."). Here, contract-pharmacy arrangements have been utilized, and honored by manufacturers, since 1996 and earlier.[4]

C. Manufacturers' Rationale for Precluding the Use of Contract Pharmacies Is Not Supported by the Language of the Statute and Leads to Absurd Results

The primary rationale offered for cutting off contract pharmacies—that such arrangements lead to a heightened risk of diversion and duplicate discounts—makes clear that manufacturers are attempting to circumvent section 340B's procedures for resolving disputes between manufacturers and covered entities. *See, e.g.*, *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1984) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole.") (emphasis supplied). Not surprisingly, the manufacturers have been unable to point to any language in the statute that would support this hobbling interpretation. If a manufacturer is concerned that a covered entity has engaged in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must (1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ("ADR") process, *see* §256b(d)(3)(A). The PPA even provides that a covered entity's failure to comply with the audit requirement does not "relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of the Act and the Agreement." PPA § IV(d). Moreover, the Department specifically rejected this reasoning when issuing regulations regarding the calculation of the 340B ceiling price. In responding to a comment regarding perceived 340B violations, HRSA stated "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017). In addition, "[m]anufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly." *Id.* Certain manufacturers' newfound and unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute.[5]

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[4] The fact that Congress has not amended the 340B statute to expressly exclude contract-pharmacy arrangements from coverage can be read as supporting the agency's longstanding construction. *See* Valerie C. Brannon, Cong. Rsch. Serv., R45153, *Statutory Interpretation: Theories, Tools, and Trends* 63 (2018) (discussing "presumption of legislative acquiescence").

[5] For 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution. To the extent manufacturers now have sincere concerns about diversion or duplicate discounting, the 340B statute speaks directly to how they should proceed. *See also 340B Drug Pricing Program; Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) ("The purpose of the ADR process is to resolve . . . claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts."). Manufacturers who shut off contract-pharmacy access may have also skipped over any effort to resolve disputes with covered entities in "good faith." PPA § IV(a)(1) ("If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A) . . . [t]he Manufacturer shall attempt in good faith to resolve the matter with the covered entity."); 85 Fed. Reg. at 80,633 ("Historically, HHS has

Relatedly, it has also been argued that the use of contract pharmacies is inconsistent with the 340B statute's prohibition on diversion of discount drugs. We start with the basic proposition that subsection (a)(5)(B) was intended to prohibit the diversion of 340B drugs. *See* 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). According to one court, the 340B Program places a "ban on 'diversion,' *i.e.*, a requirement that covered entities refrain from reselling or otherwise transferring covered drugs to non–340B entities[.]" *Cty. of Santa Clara v. Astra USA, Inc*., 257 F.R.D. 207, 211–12 (N.D. Cal. 2009), *vacated on other grounds*, *Astra USA,* 563 U.S. 110; *see also* 85 Fed. Reg. at 80,636 (subsection (a)(5)(B) prohibits diversion).

Diversion means that, on net, covered outpatient drugs end up in the hands of persons who are not patients of the covered entity. The movement of drugs purchased by the covered entity and ultimately dispensed to the patient by a contract pharmacy can involve complex inventory models. Whether diversion occurs, however, should be independent of the inventory-accounting model contemplated by the agreement between the contract pharmacy and the covered entity. *See Toyota Motor Sales, U.S.A., Inc. v. United States,* 35 Ct. Int'l Trade 1205 (2011) (noting that inventory-accounting methods are authorized to determine tariffs and drawbacks); *Sears, Roebuck & Co. v. King County*, 487 P.2d 221, 223, 5 Wash. App. 273, 276 (1971) (for tax purposes "identification by any reasonable and reliable [inventory-accounting] method [is proper], rather than by a strict tracing method.").

The notion that the legitimate transfer of drugs to contract pharmacies so that they can be dispensed to patients of the covered entity constitutes diversion not only ignores the realities of accounting, but also that the covered entity and contract pharmacy are not distinct, but function as principal-agent. As explained, the covered entity remains the purchaser whether it chooses to have discount drugs distributed through an in-house pharmacy or a contract pharmacy. *See also* 61 Fed. Reg. at 43,550 ("The mechanism does not in any way extend this pricing to entities which do not meet program eligibility."); *id.* (agreeing that "[a]s a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance") (citing Restatement (Second) of Agency § 17 (Am. L. Inst. 1995)); *id.* ("The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy."); *id.* at 43,552 (under "bill to/ship to" arrangement contemplated in guidance, "[t]he contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity" and "the manufacturer is still selling to the covered entities"); *cf. Abramski v. United States*, 573 U.S. 169, 186 (2014) ("[t]he individual who sends a straw [purchaser] to a gun store to buy a firearm is transacting with the dealer, in every way but the most formal" such that "straw arrangements are not a part of the secondary market, separate and apart from the dealer's sale") (emphasis in original).[6]

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encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith.").

[6] Similar reasoning still applies under the so-called "replenishment" model, where the contract pharmacy dispenses medications from a general inventory to the covered entity's patient and "replenishes" its general

In addition, the argument that use of contract pharmacies constitutes an illicit "transfer" leads to absurd results. For instance, if a covered entity uses a courier service to send discount drugs to its patient, this, too, would be appear to be an illegal "transfer" to the shipper. Any arrangement that did not involve a physical hand-off from the employee of a covered entity to the patient him or herself could be an unauthorized "transfer" under the 340B statute. To avoid such absurdities, and under the canon of *noscitur a sociis*,[7] the phrase "otherwise transfer" must be interpreted in conjunction with the word "resell" and the title of that specific provision ("Prohibiting resale of drugs") (emphasis supplied).[8]

This conclusion is reinforced by an understanding of the practical realities of drug distribution. Such distribution often functions through intermediaries. For example, covered entities often purchase 340B discounted drugs from wholesalers, not directly from manufacturers. And yet, the obligations of § 256b(a) are placed on manufacturers. If it were correct that distribution to any entity other than a covered entity freed the manufacturer from the obligation to charge no more than the ceiling price, then there would be no firm basis for the wholesalers to charge-back discounts to the manufacturer. Large portions of the current 340B Program would seem to turn on solely manufacturers' voluntary choice to offer the ceiling price,

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inventory with discount medications purchased by the covered entity. The inventory commingling (drugs purchased by covered entity(ies) under the auspices of 340B, commingled with what the contract pharmacy might otherwise have) does not change the analysis. *Cf. Martin Marietta Corp. v. N.J. Nat'l Bank*, 612 F.2d 745, 749 (3d Cir. 1979) ("identification" of goods for purposes of U.C.C. § 2-501 not broken even if "seller removes some of the fungibles and later replaces them . . . because such conduct is quite natural with fungibles and cannot be taken as an intent to negate the buyer's interest in the goods"); *Apex Oil Co. v. Belcher Co. of N.Y., Inc.*, 855 F.2d 997, 1,003–05 (2d Cir. 1988) ("[W]here fungible goods are concerned, identification is not always an irrevocable act and does not foreclose the possibility of substitution."); *Matter of Bevill, Bresler & Schulman Asset Mgmt. Corp.*, 67 B.R. 557, 588 (D.N.J. 1986) (under U.C.C. § 9-207, "a secured party is allowed to commingle fungible collateral, including certain types of securities, and may sell the collateral and replace it with instruments which are equivalent in kind and value without breaching his duty to exercise reasonable care in the custody and preservation of the pledged collateral"). Nor does the ordering of events. If the contract pharmacy's dispensing of the drugs is event "A" and the contract pharmacy's receipt of the drugs is event "B," the ordering of events does not matter if repeated over time. Whether the series looks like ...BABABA... or ...ABABAB... is simply a function of the reference timeframe. In sum, where the contract pharmacy is replenished by the covered entity and dispenses to the covered entity's patients on a rolling basis, it is still true that the covered entity's patients are receiving the covered entity's drugs—they are not re-sold or "otherwise transfer[red]" to the contract pharmacy.

It also bears mention that the replenishment inventory model is currently an integral part of many patient assistance programs operated by drug manufacturers. *See, e.g.*, *Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005); Merck & Co., Inc. *For Health Care Professionals*, MERCK HELPS, https://www.merckhelps.com/HCPs.aspx (last visited Dec. 21, 2020); Pfizer, Inc., *The Pfizer Institutional Patient Assistance Program (IPAP) At-a-Glance* (April 2019), https://www.pfizerrxpathways.com/sites/default/files/attachment/PP-PAT-USA1032%20RxPathways_IPAP_Factsheet%202019.pdf (last visited Dec. 21, 2020).

[7] "[W]e rely on the principle of *noscitur a sociis*—a word is known by the company it keeps—to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Yates v. United States*, 574 U.S. 528, 543 (2015) (plurality op.) (quotes omitted).

[8] An exact delineation of the scope of the phrase "otherwise transfer" is beyond the scope of the Advisory Opinion. The point here is simply that the phrase must have some limiting principle to avoid sweeping in innocuous conduct that is inevitable in the functioning of the 340B Program.

not a statutory mandate. Thus, manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies.

II. Conclusion and Limitations

For these reasons, the Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.[9]

This Advisory Opinion may be supplemented or modified by the Office of the General Counsel. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.[10] It is not a final agency action or a final order, and it does not have the force or effect of law.

Robert Charrow

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General Counsel
December 30, 2020

[9] This Advisory Opinion is limited to interpretation of the 340B statutory requirements in general and does not opine on the legality of any specific contract-pharmacy model, under either the 340B statute or other laws that may apply (such as the anti-kickback statute, 42 U.S.C. § 1320a-7b).

[10] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647–48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]"); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).