U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
340B ADMINISTRATIVE DISPUTE RESOLUTION PANEL

OPEN DOOR COMMUNITY HEALTH CENTERS 1275 8TH STREET ARCATA, CA 95521 Petitioner, vs. ASTRAZENECA PHARMACEUTICALS, LP 1800 CONCORD PIKE WILMINGTON, DE 19803 Respondent.	ADR ID: 210112-1

PETITION FOR DAMAGES AND EQUITABLE RELIEF FROM RESPONDENT'S REFUSAL TO OFFER THE 340B CEILING PRICE FOR COVERED OUTPATIENT DRUGS DISTRIBUTED THROUGH PETITIONER'S CONTRACT PHARMACIES

INTRODUCTION

1. Open Door Community Health Centers ("Petitioner") submits this Petition to the Administrative Dispute Resolution Panel, established at 42 C.F.R. § 10.3 ("340B ADR Panel"), to seek an order stating that AstraZeneca Pharmaceuticals, LP ("Respondent") has violated the 340B statute and regulations by failing to offer covered outpatient drugs at the 340B ceiling price through Petitioner's contract pharmacy arrangements; to order Respondent to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies; and to order Respondent to pay Petitioner an amount equal to the 340B discounts that Respondent has failed to provide to Petitioner since October 1, 2020.

2. The 340B Program, established at 42 U.S.C. § 256b ("340B Program"), requires pharmaceutical manufacturers to sell discounted drugs to certain statutorily defined health care providers, known as "covered entities," as a condition of the manufacturers participating in the

Medicaid and Medicare Part B insurance programs. Petitioner is a covered entity that qualifies for and participates in the 340B Program. Petitioner purchases discounted drugs through the 340B Program, but because it does not own and operate a pharmacy, it relies exclusively on third-party pharmacies, referred to as "contract pharmacies," to dispense its drugs. Under these arrangements, Petitioner places orders for 340B discounted drugs that are billed to the covered entity and shipped to the contract pharmacy to be dispensed to the Petitioner's patients. Since 1996, the Secretary of Health and Human Services ("Secretary") has expressly recognized that the 340B statute requires pharmaceutical manufacturers to provide 340B discounts on covered outpatient drugs when ordered by covered entities via contract pharmacies. Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also* Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

3. In an Advisory Opinion dated December 30, 2020, the Department of Health and Human Services, Office of General Counsel ("HHS OGC") affirmed that all drug manufacturers that participate in the 340B Program are required to offer drugs at 340B discounted prices to covered entities when drugs are shipped to contract pharmacies. Robert P. Charrow, HHS OGC, Advisory Op. 20-06, Contract Pharmacies under the 340B Program (Dec. 30, 2020) ("HHS OGC Advisory Op."), Exhibit 1.

4. Beginning October 1, 2020, Respondent adopted a policy to deny 340B discounts to the Petitioner by refusing to sell Respondent's drugs through the 340B wholesaler accounts associated with contract pharmacies.

5. Respondent's actions are unlawful. The 340B statute unambiguously requires Respondent to sell covered outpatient drugs to Petitioner and places no limitation on the site of delivery. 42 U.S.C. § 256b. A 340B regulation expressly defines a manufacturer overcharge to

include an order placed through an "agent," such as a contract pharmacy. 42 C.F.R. § 10.11(b)(1). Accordingly, the 340B ADR Panel should order Respondent to sell covered outpatient drugs to Petitioner at 340B prices regardless of the delivery location and repay 340B discounts that Respondent has denied Petitioner.

JURISDICTION

6. The 340B ADR Panel has jurisdiction over the subject matter of this action under 42 U.S.C. § 256b(d)(3), which authorizes the Secretary of the Department of Health and Human Services ("HHS") to "implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section . . . including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B)."

7. The 340B ADR Panel has jurisdiction over this petition because it presents "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 42 C.F.R. § 10.21(c)(1).

8. The damages sought in this Petition exceed $25,000. *Id.* § 10.21(b). Exhibit 2. The damages at Exhibit 2 were incurred by the Petitioner from October 1, 2020, to January 5, 2021. Petitioner will continue to incur damages as long as Respondent does not offer 340B pricing at Petitioner's contract pharmacies. The first two spreadsheets at Exhibit 2 are a calculation of the amounts that Petitioner was forced to forgo as the result of Respondent's actions at certain of its contract pharmacies. The third spreadsheet at Exhibit 2 is a calculation of the amounts that Petitioner had to pay to certain of its contract pharmacies that dispensed drugs at 340B prices that were purchased at above the 340B price and could not be replenished before

October 1, 2020. These amounts include damages associated with Respondent's contract pharmacy arrangements with pharmacies other than Walgreen's. Thus, Petitioner's damages are even higher than reflected in Exhibit 2. Petitioner submits the documentation at Exhibit 2 in order to establish that the ADR Panel has jurisdiction because the Petitioner has met the requirements for the minimum amount in controversy and reserves the right to submit documentation of additional damages to the ADR Panel. Exhibit 2 does not include protected health information, but Petitioner can furnish additional information if necessary to prove its damages, subject to protecting patient information as required by law.

PARTIES

9. Petitioner's corporate address is 1275 8th Street, Arcata, CA 95521. Petitioner is a Federally-qualified health center ("FQHC") as a result of receiving grant funding under Section 330 of the Public Health Service Act. Petitioner has participated in the 340B Program as an FQHC since 1996. HRSA, *Office of Pharmacy Affairs Information System*, https://340bopais.hrsa.gov/SearchLanding (last updated Jan. 11, 2021).

10. Petitioner operates at numerous sites and provides services though three mobile vans. The Petitioner's sites and their 340B IDs are as follows:

Humboldt Open Door Clinic, CH091540: 770 10th St., Arcata, CA 95521

Eureka Community Health Center, CH09154A: 2200 Tydd St., Eureka, CA 95501

Del Norte Community Health Center, CH09154B: 550 E. Washington Blvd., Suite 100, Crescent City, CA 95531

North Country Clinic, CH09154D: 785 18th Street, Arcata, CA 95521

McKinleyville Community Health Center, CH09154F: 1644 Central Avenue, Suite F, McKinleyville, CA 95519

Willow Creek Community Health Center, CH09154H: 38883 Highway 299, Willow Creek, CA 95573

Burre Dental Center, CH09154I: 959 Myrtle Avenue, Eureka, CA 95501

Perinatal Services of Northcountry Clinic, CH09154J: 3800 Janes Rd., Suite 101, Arcata, CA 95521

Mobile Health Services/Telehealth & Visiting Specialist Center, CH09154K: 2426 Buhne St., Eureka, CA 95501

Ferndale Community Health Center, CH09154L: 638 Main Street, Ferndale, CA 95536

Fortuna Community Health and Wellness Center, CH09154M: 3750 Rohnerville Rd., Fortuna, CA 95540

Mobile Health Services Van #1, CH09154Q: 2412 Buhne St., Eureka, CA 95501

Redwood Community Health Center, CH09154R: 2350 Buhne Street A, Eureka, CA 95501

Open Door Women's Health, CH09154S: 3798 Janes Rd Ste. 5, Arcata, CA 95521

Harding Street Clinic, CH09154T: 833 W Washington Blvd., Crescent City, CA 95531

Burre Mobile Dental, CH09154U: 959 Myrtle Ave., Eureka, CA 95501

Open Door Downtown, CH09154V: 622 H St., Eureka, CA 95501

11. The mission of Open Door Community Health Centers is as follows: "Open Door Community Health Centers provides quality medical, dental, and mental health care and health education to all regardless of financial, geographic, or social barriers." Open Door Community Health Centers, *About*, https://opendoorhealth.com/about/ (last visited Jan. 11, 2021).

12. Open Door does not operate an in-house pharmacy. It stocks a small number of commonly needed medications at its facilities that it includes in the visit cost for patients whose income is under 200% of the Federal Poverty Level (FPL). Open Door does not have the space or the pharmacy staff to house the range of all medications its patients require.

13. Through its contract pharmacies, Petitioner provides covered outpatient drugs at reduced costs to its patients who are uninsured, underinsured, or otherwise unable to afford the cost of their drugs. For these patients, Petitioner provides the drug to its patients at the 340B cost, plus the dispensing fee charged by the pharmacy and a minor administrative fee. Exhibit 3.

14. In 2019, Petitioner served more than 60,000 patients, 16,898 of which had income at or below 200% of FPL, and 10,380 of which had income at or below 100% of the FPL. HRSA, *Health Center Program Data*, https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId (last visited Jan. 11, 2021). Of these patients, approximately 20% were racial and/or ethnic minorities. *Id.* More than 46% of patients were Medicaid recipients, and more than 7% of patients were uninsured. *Id.* Petitioner serves patients across two counties in Northern California, Del Norte and Humboldt, an area that spans 5,282 square miles and is larger than the state of Connecticut. *Id.*

15. Respondent is a manufacturer of covered outpatient drugs that participates in the 340B Program. As a manufacturer participating in the 340B Program, Respondent is required to sign a pharmaceutical pricing agreement ("PPA") and addendum. 42 U.S.C. § 256b(a)(1). The PPA and addendum require Respondent to offer covered outpatient drugs to covered entities at no more than the 340B ceiling price. *Id.*

BACKGROUND

I. The 340B Program

16. Congress established the 340B Program in 1992 by enacting Section 602 of the Veterans Health Care Act of 1992. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71. That legislation amended the Public Health Service Act with a new Section 340B, codified at 42 U.S.C. § 256b. Section 340B—in conjunction with certain related provisions in Section 1927 of the Social Security Act—requires the Secretary to execute

PPAs with manufacturers of certain outpatient drugs covered by the Medicaid program as a condition of the manufacturers' participation in the Medicaid and Medicare Part B insurance programs. 42 U.S.C. §§ 256b(a)(1), 1396r–8(a)(1).

17. The 340B Program is administered by the Office of Pharmacy Affairs ("OPA"), a part of Health Resources & Services Administration ("HRSA"), which is a unit of HHS.

18. The PPAs "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). The "ceiling price" is "equal to the average manufacturer price for the drug under title XIX of the Social Security Act [Medicaid] in the preceding calendar quarter," reduced by a rebate percentage calculated under Medicaid. *Id.* § 256b(a)(1)-(2).

19. Congress intended the 340B Program to allow 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); *see also Cares Cmty Health v. U.S. Dep't of Health & Human Servs.*, 944 F.3d 950, 955 (D.C. Cir. 2019) (340B savings "help safety-net providers fund the uncompensated care they supply and expand the services they offer."). 340B covered entities collectively serve as the nation's healthcare "safety net," providing care and treatment to the neediest individuals, regardless of ability to pay. The 340B Program is a vital and indispensable tool for 340B covered entities that qualify for the program based on receiving federal grants. The 340B Program helps them offset the costs of uncompensated or under-compensated care, enabling covered entities to maximize their resources to meet the health care and pharmaceutical needs of the fragile communities they serve. Without the 340B Program, many covered entities would be forced to restrict access

significantly or, in some cases, cease operations. For these reasons, ensuring access to 340B drugs and protecting against manufacturer overcharges that deplete covered entities' limited resources are of critical importance to covered entities and the individuals they serve.

20. The 340B statute enumerates several types of health care providers that may qualify as "covered entities" eligible to participate in and purchase discounted drugs under the 340B Program. 42 U.S.C. § 256b(a)(4).

21. One category of covered entity under the 340B statute is "[a] Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act)," 42 U.S.C. § 1396d(l)(2)(B). 42 U.S.C. § 256b(a)(4)(A). An FQHC is a community-based health care provider that receives federal grant funding and "provide[s] primary care services in underserved areas." HRSA, *Federally Qualified Health Centers*, https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html (last updated May 2018). FQHCs must provide "care on a sliding fee scale based on ability to pay." *Id.*

II. 340B Program Integrity Requirements

22. The Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA") amended the 340B statute to include "improvements in program integrity," including "manufacturer compliance." ACA, Pub. L. No. 111-148, § 7102, 124 Stat. 823 (2010) (codified at 42 U.S.C. § 256b(d)(1)).

23. The 340B statute requires the Secretary to establish "procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers." 42 U.S.C. § 256b(d)(1)(B)(ii).

24. The statute also mandates 340B ADR regulations:

> Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered

> entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions.

42 U.S.C. § 256b(d)(3). The ACA was enacted on March 23, 2010.

25. On December 14, 2020, the Secretary issued a final ADR rule to implement the ADR process, effective January 13, 2020. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020).

26. The ACA also required the imposition of civil monetary penalties ("CMPs") upon pharmaceutical manufacturers that "knowingly and intentionally" overcharge 340B covered entities. 42 U.S.C. § 256b(d)(1)(B)(vi). Congress directed that "each instance of overcharging" would be subject to a penalty not to exceed $5,000. *Id* § 256b(d)(1)(B)(vi)(II); *see also* 42 C.F.R. § 10.11(a).

27. The Secretary issued a CMP regulation on January 5, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017) ("CMP Final Rule") (codified at 42 C.F.R. § 10.11). The regulation defines an "instance of overcharging" as "any order for a covered outpatient drug, by NDC [national drug code], which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug." *Id.* § 10.11(b). Each order for an NDC is a single instance, regardless of the number of units ordered. *Id.* § 10.11(b)(1). An order "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.*

28. When finalizing the CMP rule, the Secretary stated, "Failure to ensure the covered entities are receiving the 340B ceiling prices through a third party may be grounds for the assessment of CMPs under this final rule." CMP Final Rule, 82 Fed. Reg. at 1,224. The

Secretary also stated, "All requirements as set forth in this final rule for offering the 340B ceiling price to covered entities apply regardless of the distribution system." *Id.* at 1,225.

III. 340B Contract Pharmacies

29. Many covered entities choose not "to expend precious resources to develop their own in-house pharmacies" because the requirements to obtain a pharmacy license are complex, and operating a pharmacy can be expensive. 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).

30. Thus, from the beginning of the 340B Program, HRSA recognized that the program could only function if certain covered entities could dispense their 340B discounted drugs through third-party pharmacy contractors:

> During the early period of program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500), although additional entities participated by buying drugs for their physician dispensing activities. In addition, many of the larger groups of covered entities, including community and migrant health centers, hemophilia clinics and most of the Ryan White HIV service programs (e.g., State AIDS Drug Assistance Programs) depend upon outside pharmacy services. Yet, because the delivery of pharmacy services is central to the mission of (and a legal mandate in some instances for) these providers, they rely on outside pharmacies to fill the need. It would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program. Otherwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether. Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law.

Id.

31. In 1995, HRSA published in the Federal Register proposed guidelines for contract pharmacy services under the 340B Program. Notice Regarding Section 602 of the Veterans

Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55,586 (proposed Nov. 1, 1995).

32. In 1996, after considering comments submitted in response to its November 1, 1995 notice, HRSA published "final guidelines" in the Federal Register regarding contract pharmacy services under the 340B statute. Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996).

33. "Contract pharmacy services," as HRSA's August 23, 1996, notice described it, means 340B covered entities' ability to contract with pharmacies as the covered entities' agents to dispense 340B drugs to the covered entities' patients. *Id.* at 43,550. Under such an arrangement, a covered entity purchases 340B drugs from a manufacturer and directs the manufacturer to ship the 340B drugs to an address other than the address listed in HRSA's database for the covered entity.

34. In its August 23, 1996, guidance, HRSA noted that "many covered entities … do not operate their own licensed pharmacies." *Id.* at 43,549. HRSA explained why the 340B Program is essential for these covered entities:

> Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies.

Id. The agency's guidance "encouraged" covered entities that did not operate their own licensed pharmacies to use contract pharmacy services. *Id.* at 43,555.

35. HRSA's August 23, 1996, guidance was clear that the 340B statute requires pharmaceutical manufacturers to sell 340B discounted drugs to covered entities through contract pharmacy arrangements:

> Comment: The use of contract pharmacy services is inconsistent with section 340B of the PHS [Public Health Service] Act and results in an unauthorized expansion of the program.
>
> Response: Section 340B, which established the Drug Pricing Program, requires manufacturers to sell to covered entities at or below a ceiling price determined by a statutory formula. The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities.
>
> 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. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion.

Id. at 43,549-50.

36. Responding to a separate comment regarding the requirements of notice and comment rulemaking under the Administrative Procedure Act ("APA"), the agency stated:

> The guidelines explain how the Department intends to administer the 340B [program], further explain the statutory language by clarifying the meaning given by the Department to particular words or phrases, and do not exceed the purpose of 340B or conflict with any of its provisions. We believe that these guidelines create no new law and create no new rights or duties.

Id. at 43,550.

37. HRSA was also clear that covered entity arrangements with contract pharmacies are agency relationships:

> Comment: As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. As 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. Restatement of Agency 2d § 17 (1995). Hence, even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B

> drugs. By issuing guidelines in this area, ODP [Office of Drug Pricing] is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law.
>
> Response: We agree. However, entities, under any distribution system, must comply with the statutory prohibition against diversion of 340B drugs to individuals who are not patients of the covered entities. Further, the dispensing of drugs, purchased with a 340B discount, must not result in the generation of a Medicaid rebate.

Id.

38. Although HRSA indicated that its August 23, 1996, contract pharmacy guidance was "designed to facilitate program participation for those eligible covered entities that do not have access to an [sic] appropriate 'in-house' pharmacy services," it clarified that "this is not a bar to the use of the mechanism by any covered entity," and "[t]he statute does not limit the covered entities' access to [various] avenues of drug purchasing." *Id.* at 43,551.

39. In 2007, HRSA again published proposed guidelines for contract pharmacies in the Federal Register. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1,540 (proposed Jan. 12, 2007). Subsequently, HRSA published a final notice regarding contract pharmacies on March 5, 2010. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

40. HRSA's March 5, 2010, guidance permits covered entities to contract with multiple contract pharmacies. HRSA responded to a comment regarding its action as follows:

> Comment: The proposed revisions represent a substantive rulemaking under the APA because they constitute new obligations and burdens on manufacturers. They also create new rights for covered entities under the law.
>
> Response: HRSA disagrees. This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. HRSA has used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration. Contract pharmacy service guidelines have been considered by HRSA to be "interpretative rules and statements of policy" exempt from notice and comment rulemaking under the APA.

Id. at 10,273.

41. Contract pharmacy arrangements are not unique to the 340B Program. The Federal Trade Commission has recognized the right of non-profit organizations to contract with community pharmacies for purposes of dispensing drugs subject to discounts negotiated and used within the parameters of the Robinson-Patman Act and the Non-Profit Institutions Act. Federal Trade Commission, University of Michigan Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010).

IV. AstraZeneca's About-Face Rejection of Contract Pharmacy Arrangements

42. Despite honoring contract pharmacy arrangements for over 24 years, in the summer of 2020, Respondent announced its intention no longer to do so, effective October 1, 2020.

43. By letter dated July 24, 2020, Respondent informed HRSA of its plan to cease offering 340B discounts on drugs purchased by covered entities and distributed by contract pharmacies. Exhibit 4. HRSA responded by letter dated September 2, 2020, stating that the 340B statute requires manufacturers to offer covered outpatient drugs at the ceiling price and that HRSA was considering whether Respondent's actions violate the 340B statute. Exhibit 5. In response to HRSA's letter, Respondent sent a letter dated September 15, 2020, to HRSA informing it again of its plans. Exhibit 6.

44. On or around August 17, 2020, Respondent issued a letter to approximately 6,800 covered entities, stating that Respondent would no longer honor most 340B contact pharmacy arrangements effective October 1, 2020:

> 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.[1] 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.

Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC (Aug. 17, 2020), http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf. Exhibit 7.

45. In response to the notice from Respondent, Petitioner's drug wholesaler blocked drugs manufactured by Respondent from being available for purchase through Petitioner's 340B accounts at contract pharmacies.

46. Petitioner notified HRSA that it was unable to purchase covered outpatient drugs manufactured by Respondent for distribution by its contract pharmacies through a form provided by HRSA's prime vendor. Exhibit 8.

V. HHS Response to Manufacturer Actions

47. On December 30, 2020, the HHS OGC issued an Advisory Opinion in response to numerous requests by both drug manufacturers and covered entities to address whether manufacturers may refuse to provide covered outpatient drugs to covered entities at the 340B ceiling price when those drugs are distributed through contract pharmacies. HHS OGC Advisory Opinion 1, Exhibit 1. The HHS OGC Advisory Opinion states unequivocally that drug manufacturers must offer covered outpatient drugs to covered entities at or below the 340B

[1] A "chargeback" describes the method by which drug wholesalers request reimbursement from manufacturers for 340B discounts provided to entities for 340B covered outpatient drugs. Wholesalers purchase drugs from the manufacturer at a non-340B price and sell to 340B entities at the contracted 340B price, which is typically significantly lower than the non-340B price. The wholesaler submits a chargeback request to the manufacturer to account for the difference. *See* Apexus 340B Glossary of Terms, https://docs.340bpvp.com/documents/public/resourcecenter/340b-glossary-of-terms.pdf. HRSA has contracted with Apexus as its "prime vendor" to provide technical assistance to covered entities and manufacturers and to secure sub-340B discounts on covered outpatient drugs.

ceiling price regardless of how the covered entity distributes those drugs. As the HHS OIG succinctly stated, "[t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." HHS OGC Advisory Op. 3, Exhibit 1 .

48. The HHS OGC Advisory Opinion makes three principal points. First, the HHS OGC Advisory Opinion recognizes that the plain language of the 340B statute requires manufacturers to offer drugs to covered entities at the ceiling price regardless of whether the covered entity opts to use contract pharmacies to dispense those drugs. HHS OGC Advisory Op. 4, Exhibit 1. The 340B statute requires drug manufacturers to enter into a PPA with HHS, under which the manufacturer agrees to offer any covered outpatient drugs "purchased by a covered entity" at the 340B ceiling price. The PPA also obligates the manufacturer to offer covered outpatient drugs at the ceiling price if those drugs are made available to any other purchaser at any price. HHS OGC Advisory Op. 2, Exhibit 1. The HHS OIG Advisory Opinion states as follows:

> 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.

HHS OGC Advisory Op. 2, Exhibit 1.

49. Second, the HHS OGC Advisory Opinion states that the purpose and history of the 340B Program reflect the plain meaning of the statute as it relates to contract pharmacy arrangements. The HHS OGC Advisory Opinion notes that the purpose of the 340B Program is to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." HHS OGC Advisory Op. 3, Exhibit 1 (quoting H.R. Rept. No. 102–384(II), at 12 (1992)). It also states that many covered entities are only able to participate in the 340B Program by using contract pharmacies, as

reflected by only 5% of covered entities operating in-house pharmacies at the beginning of the program. HHS OGC Advisory Op. 4, Exhibit 1. In addition, the HHS OGC Advisory Opinion states that HHS has interpreted the 340B statute for the last 24 years to require manufacturers to offer 340B discounted drugs through contract pharmacies and that manufacturers have been honoring contract pharmacy arrangements for 24 years. HHS OGC Advisory Op. 4, Exhibit 1. The HHS OGC Advisory Opinion correctly notes that courts, when interpreting statutes, typically defer to the expertise of an agency that oversees a complex administrative program and may look to the actions of regulated parties. HHS OGC Advisory Op. 4, Exhibit 1.

50. Third, the HHS OGC Advisory Opinion repudiates the purported reasoning that certain manufacturers, including Respondent, offered as the basis for their unilateral decisions to stop offering 340B discounted drugs through contract pharmacy arrangements. Manufacturers have asserted that they are not distributing 340B drugs to contract pharmacies to obviate the alleged risk of diversion and duplicate discounts. HHS OGC Advisory Op. 5, Exhibit 1. The HHS OGC Advisory Opinion states that manufacturers are attempting "to circumvent 340B's procedures for resolving disputes between manufacturers and covered entities." HHS OGC Advisory Op. 5, Exhibit 1.

51. Moreover, the HHS OGC Advisory Opinion refutes the argument made by certain manufacturers that contract pharmacy arrangements constitute diversion through transfer of 340B drugs to pharmacies, which are not covered entities, and use of an inventory replenishment model. The HHS OGC Advisory Opinion states that "[t]he notion that the legitimate transfer of drugs to contract pharmacies 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." HHS OGC Advisory Op. 6, Exhibit 1. It also states that the use of "complex" inventory

models does not, by itself, constitute diversion. Lastly, the HHS OGC Advisory Opinion states that the manufacturers' argument ignores the reality that a covered entity's purchase of outpatient drugs often occurs through an agent, such as a wholesaler. HHS OGC Advisory Op. 7, Exhibit 1.

52. According to media reports, Respondent has no plans to resume offering 340B discounts to covered entities for drugs distributed at contract pharmacies despite the strongly worded HHS OGC Advisory Opinion that Respondent is acting unlawfully. A spokesperson for AstraZeneca told Modern Healthcare the following:

> We changed our approach to help mitigate the significant compliance issues that have been well documented in audits performed by GAO [the U.S. Government Accountability Office] regarding contract pharmacy arrangements. AstraZeneca's approach to contract pharmacy arrangements fully complies with all operative requirements and continues to support the mission of the program to provide a healthcare safety net for the most vulnerable patients in our country.

Rachel Cohrs, *Some Drugmakers May Not Comply with HHS' 340B Opinion on Contract Pharmacies*, Modern Healthcare (Jan. 4, 2021), https://www.modernhealthcare.com/supply-chain/some-drugmakers-may-not-comply-hhs-340b-opinion-contract-pharmacies. For this reason, Petitioner contends that any good faith attempt to resolve this issue with Respondent would not have been fruitful. Indeed, on January 12, 2021, Respondent filed suit in the U.S. District of Delaware seeking to invalidate the HHS OGC Advisory Opinion. *AstraZeneca Pharmaceuticals LP v. Azar*, No. 1:21-cv-00027 (D. Del. filed Jan. 12, 2021).

VI. Facts Related to Petitioner's Contract Pharmacy Arrangements

53. Petitioner has contract pharmacy arrangements registered with HRSA. HRSA, *340B Office of Pharmacy Affairs Information System*, https://340bopais.hrsa.gov/ContractPharmacySearch (Last updated Jan. 11, 2021).

54. Petitioner serves a very large service area and has made arrangements with pharmacies across its service area to serve as contract pharmacies. By having contract pharmacy arrangements across its service area, Petitioner is able to provide covered outpatient drugs to patients that qualify for its community benefits program at the patient's local pharmacy.

55. Petitioner has also entered into arrangements with specialty pharmacies to obtain drugs that are only available through those pharmacies and are not available through community pharmacies.

COUNT I
VIOLATION OF THE 340B STATUTE

56. Petitioner reallege and incorporates by reference paragraphs 1–55 as if fully set forth below.

57. Respondent has violated the clear mandate of the 340B statute. In pertinent part, the 340B statute states that manufacturers of covered outpatient drugs must enter into a PPA under which the manufacturer agrees to sell covered outpatient drugs to covered entities at or below the 340B ceiling price:

> 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 … purchased by a covered entity…. does not exceed an amount equal to the [340B ceiling price].

42 U.S.C. § 256b(a)(1).

58. The 340B statute also states that the PPA must include a provision to "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.*

59. Indeed, since 1996, the Secretary has expressly interpreted the 340B statute to require pharmaceutical manufacturers to provide 340B discounts when ordered by covered entities via contract pharmacies. Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550

(Aug. 23, 1996). In 2010, the Secretary reconfirmed the agency's longstanding interpretation that covered entities are entitled to 340B discounts on drugs shipped to contract pharmacies. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

60. Just last month, the HHS OGC reaffirmed that the plain language of the 340B statute entitles covered entities "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 OGC Advisory Op. 8, Exhibit 1. The HHS OGC affirmed that "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." HHS OGC Advisory Op. 2, Exhibit 1.

61. Therefore, the 340B statute unambiguously requires Respondent to offer covered outpatient drugs at the 340B ceiling price to Petitioner and does not place any limitation on the site for the delivery of those drugs. The ADR Panel must give effect to the unambiguous text to the statute. *See 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."). Accordingly, Respondent has violated the 340B statute by refusing to provide covered outpatient drugs to Petitioner at its contract pharmacies since October 1, 2020.

COUNT II
VIOLATION OF 340B REGULATIONS

62. Petitioner reallege and incorporates by reference paragraphs 1–55 as if fully set forth below.

63. Respondent has violated a 340B regulation by refusing to offer 340B pricing for drugs shipped to Respondent's contract pharmacies. A 340B regulation defines an "instance of overcharging" as "any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug." 42 CFR § 10.11(b). Each order for an NDC is a single instance, regardless of the number of units ordered. *Id.* § 10.11(b)(1). An order "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.* The Secretary explained that an instance of overcharging includes an order placed "through a third party" and "regardless of the distribution system." CMP Final Rule, 82 Fed. Reg. at 1,224, 1,225.

64. The HHS OGC affirmed that "the covered entity and contract pharmacy are not distinct, but function as principal-agent." HHS OGC Advisory Op. 6, Exhibit 1.

65. HRSA has confirmed that contract pharmacies function as agents of covered entities. Contract Pharmacy Notice, 61 Fed. Reg. at 43,550.

66. Accordingly, Respondent has overcharged Petitioner for each instance in which Respondent did not offer the 340B ceiling price on an "order placed . . . through . . . [an] agent" contract pharmacy. 42 C.F.R. § 10.11(b)(1).

RELIEF REQUESTED

WHEREFORE, Petitioner respectfully requests relief as follows:

1. A declaration that Respondent is in violation of the 340B statute and HRSA's contract pharmacy guidelines by refusing to provide covered outpatient drugs at the 340B ceiling price through contract pharmacy arrangements.

2. An order directing Respondent to resume offering covered outpatient drugs to Petitioner at the 340B ceiling price through contract pharmacy agreements.

3. An order directing Respondent to pay to Petitioner any 340B discounts that Respondent has withheld from Petitioner for covered outpatient drugs distributed through contract pharmacies since October 1, 2020.

4. An order directing HRSA to take any other "appropriate action regarding refunds, penalties, removal or referral to appropriate Federal authorities." 42 C.F.R. § 10.24(e).

Respectfully submitted,

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