IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, 59 Route 10, East Hanover, New Jersey 07936, *Plaintiff*, v. DIANA ESPINOSA, in her official capacity as ACTING ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, 5600 Fishers Lane, Rockville, Maryland 20852, and XAVIER BECERRA, in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W., Washington, D.C. 20201, *Defendants*.	Civil Action No. _____

VERIFIED COMPLAINT

Plaintiff Novartis Pharmaceuticals Corporation (Novartis) brings this Complaint against Defendants Diana Espinosa, in her official capacity as Acting Administrator of the Health Resources and Services Administration (HRSA), and Xavier Becerra, in his official capacity as Secretary of the Department of Health and Human Services (HHS), and alleges as follows:

PRELIMINARY STATEMENT

1. This is an action for preliminary and permanent injunctive relief to challenge a recent HRSA determination that Novartis's policy governing so-called "contract pharmacy" arrangements is not in compliance with the 340B statute, 42 U.S.C. § 256b, and an accompanying threat of enforcement action.

2. Under the 340B Drug Pricing Program, drug manufacturers that wish to participate in certain Medicaid and Medicare programs must offer deep discounts to specified hospitals and clinics benefiting underserved patient populations. To ensure that the discounts are appropriately targeted to the right recipients, the 340B statute carefully circumscribes the universe of hospitals and clinics that qualify as "covered entities" entitled to those steep discounts.

3. In recent years, there has been an explosion of so-called "contract pharmacy" arrangements, in which covered entities enter into contractual arrangements with third-party pharmacies—often large, national, for-profit pharmacy chains. Under a contract pharmacy arrangement, drugs are not shipped to the covered entity for dispensing at the covered entity. Instead they are shipped directly to the contract pharmacy—wherever in the country that pharmacy may be.

4. Nothing in the statute contemplates—let alone requires—that manufacturers agree to ship drugs nominally purchased by covered entities directly to "contract pharmacies" for dispensing to both patients and non-patients of the covered entity alike. And yet that is precisely what HRSA has purported to mandate here.

5. Under the plain language of the 340B statute, Novartis is not required to recognize *any* contract pharmacy arrangements. Nevertheless, in order to strike a reasonable

balance between redressing abuses of the 340B Program and serving the statute's goals, Novartis voluntarily recognizes [1] all contract pharmacies within a 40-mile radius of the covered entity, [2] all federal grantee covered entity contract pharmacy arrangements, regardless of location, and [3] an exemption to the 40-mile radius limitation when the facts and circumstances require.

6. On May 17, 2021, HRSA notified Novartis that it has concluded Novartis's policy violates the 340B statute. Exhibit 1 (the Decision Letter). HRSA demanded a response by June 1, and threatened enforcement action if Novartis did not drop its contract pharmacy policy.

7. HRSA's decision is unlawful under the Administrative Procedure Act (APA). First, it conflicts with the plain language of the statute. The 340B statute does not mandate—nor does it give the agency discretion to mandate—that manufacturers ship drugs to third-party pharmacies at the whim of covered entities.

8. HRSA's decision also is arbitrary, capricious, and an abuse of discretion. Under the agency's own guidance documents, contract pharmacy arrangements are eligible for 340B discounts only when specified requirements are met, including that the covered entity retains title to the drugs in question. But the Decision Letter made no finding that any of the covered entities at issue actually retained title to the drugs at issue. And due to limits on the ability of manufacturers to obtain even basic information about contract pharmacy arrangements, manufacturers have no way of knowing one way or the other.

9. HRSA has failed to offer an adequate explanation for its evolving position on whether and in what circumstances contract pharmacy arrangements trigger the 340B discount.

10. Absent prompt judicial relief, Novartis will suffer irreparable harm in the form of unlawful enforcement actions and significant reputational harm. The government's public

assertion that Novartis is knowingly and intentionally violating its federal obligations plainly injures Novartis's reputation.

11. For all of these reasons, HRSA's Decision Letter should be vacated and declared unlawful, and HHS should be enjoined from proceeding with its threatened actions.

PARTIES

12. Plaintiff Novartis Pharmaceuticals Corporation is a pharmaceutical company. It brings innovative medicines to market in order to enhance health outcomes for patients. Novartis is incorporated in the State of Delaware and has its principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

13. Defendant Diana Espinosa is the Acting Administrator of the Health Resources and Services Administration, an operating component within HHS. The Acting Administrator maintains an office at 5600 Fishers Lane, Rockville, Maryland 20852. The Administrator is sued in her official capacity only.

14. Defendant Xavier Becerra is the Secretary of HHS. Defendant Becerra maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201, and is sued in his official capacity only.

JURISDICTION AND VENUE

15. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States; 28 U.S.C. § 1346, in that this case involves claims against the federal government; 28 U.S.C. § 1361, in that this is an action to compel officers of the United States to perform their duty; and 28 U.S.C. §§ 2201–2202, in that there exists an actual justiciable controversy as to which Plaintiff requires a declaration of its

rights by this Court and injunctive relief to prohibit Defendants from violating laws and regulations.

16. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (e) because this is a civil action in which Defendants are officers of the United States acting in their official capacities and one of the Defendants maintains his office and conducts business in this judicial district.

FACTUAL BACKGROUND

The 340B Program

17. In 1992, Congress created the 340B Drug Pricing Program, which requires participating pharmaceutical manufacturers to provide deep discounts on their covered outpatient drugs to qualifying hospitals and clinics generally serving poor, uninsured, underinsured, or otherwise vulnerable patient groups. 42 U.S.C. § 256b(a). The stated purpose of the program was to provide "protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384 (II), at 12 (1992). As a condition of federal payment being available under Medicaid and Medicare Part B for its covered outpatient drugs, a manufacturer must agree to participate in the 340B Program. 42 U.S.C. § 1396r-8(a)(1).

18. At its core, the 340B Program requires a participating pharmaceutical manufacturer to charge a "covered entity" no more than the 340B ceiling price—a discounted price calculated under a prescribed statutory formula—for each unit of a covered outpatient drug. 42 U.S.C. §§ 256b(a)(1), (a)(4), (b)(1). A participating manufacturer must "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).

19. The statute defines the term "covered entity" narrowly, to ensure that the 340B program's steep discounts benefit only the qualified safety net providers and the neediest patient populations. 42 U.S.C. § 256b(a)(4). To count as a "covered entity," a provider must be a specifically enumerated type of safety-net entity. These include entities operating under a federal grant as well as particular types of hospitals, such as certain children's hospitals and freestanding cancer hospitals. *Id.*

20. The 340B Pharmaceutical Pricing Agreement (PPA), which a manufacturer must execute to participate in the 340B Program, states that "covered entities" means "certain Public Health Service grantees, 'look-alike' Federal Qualified Health Centers, and disproportionate share hospitals." PPA § 1(e). The PPA also clarifies that, "in the case of a covered entity that is a distinct part of a hospital, the hospital itself shall *not* be considered a covered entity unless it meets the" statutory definition of "covered entity" as a qualified hospital. *Id*. (emphasis added).

21. The 340B statute contains two important limitations to protect against abuse by covered entities. First, it prohibits "duplicate discounts"—a manufacturer cannot be required to both pay a Medicaid rebate *and* provide a 340B discount on the same unit of drug. To accomplish this, a covered entity is prohibited from requesting payment under Medicaid for a unit of a covered outpatient drug purchased under the 340B Program. 42 U.S.C. § 256b(a)(5)(A)(i).

22. Second, to prevent diversion, the statute prohibits a covered entity from reselling or otherwise transferring a 340B drug to "a person who is not a patient of the entity." *Id.* § 256b(a)(5)(A).

Contract Pharmacy Arrangements

23. At first, covered entities dispensed 340B-purchased drugs through their own in-house pharmacies. But shortly after the 340B statute was enacted, some covered entities without an in-house pharmacy began lobbying HRSA for permission to enter into a contractual arrangement with a third-party pharmacy (a so-called "contract pharmacy") for purposes of dispensing 340B-purchased drugs. Under these proposed arrangements, instead of drugs being shipped to the covered entity for dispensing by its in-house pharmacy, the drugs would be shipped to the contract pharmacy for dispensing to patients there.

24. Contract pharmacy arrangements typically involve a "virtual inventory" or "replenishment" model—a scheme that facilitates 340B-discounted units to be dispensed to individuals who are not patients of the covered entity. Under this model, the contract pharmacy maintains a single, common inventory—meaning it commingles units purchased at the commercial price with "replenishment" units purchased at the 340B price—and dispenses *all* units of the drug from this common inventory, regardless of whether the individual to whom a unit is dispensed is a patient of the covered entity.

25. The contract pharmacy itself typically does not know at the time of dispensing whether an individual is a patient of the covered entity. That determination is made afterwards. Where it is subsequently determined that the individual is a covered-entity patient, the covered entity purchases a "replenishment" unit at the 340B price and directs shipment to the contract pharmacy—which commingles the 340B-purchased unit with commercially purchased units in its common inventory. The kicker: the 340B replenishment unit is treated as it if had been purchased at the *commercial* price—and thus available for dispensing to a non-patient of the covered entity—even though it has in fact been purchased at the 340B price. *See* OIG,

Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 at 5 (Feb. 4, 2014), available at https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

HRSA's Evolving Guidance On Contract Pharmacies

26. In 1996, four years after the 340B Program came into being, HRSA issued non-binding guidance suggesting for the first time that a covered entity without an in-house pharmacy may contract with a single outside pharmacy site for the purpose of dispensing 340B-purchased drugs to the covered entity's patients. *See* HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549 (Aug. 23, 1996).

27. HRSA stated that it was implementing the new contract pharmacy policy because it believed the goals of the 340B Program were better served if a covered entity without an in-house pharmacy could use an outside pharmacy to dispense 340B-purchased drugs to its patients on its behalf. *Id.* at 43,550. Accordingly, HRSA provided that a covered entity could use either an in-house pharmacy or, *if* the covered entity did not have an in-house pharmacy, it could contract with a *single* outside pharmacy site, to "facilitate program participation for those eligible covered entities that do not have access to appropriate 'in-house' pharmacy services." *Id.* at 43,550, 43,555.

28. In issuing the 1996 guidance, HRSA did not require manufacturers to honor contract pharmacy arrangements. Nor did HRSA identify any statutory basis for its policy. It stated only that "[t]he 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." *Id.* at 43,549. It then stated that the 340B statute does not preclude a "[covered] entity direct[ing] the drug shipment to its contract pharmacy." *Id.* at 43,549–50. HRSA also

stated that, "[a]s 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." *Id.* at 43,550.

29. In 2007, HRSA summarized its 1996 guidance as follows: "[A] covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. Furthermore, if the contract pharmacy had multiple locations, the covered entity had to choose one, and only one, contract pharmacy location for provision of these services." HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 72 Fed. Reg. 1540 (Jan. 12, 2007).

30. Then things changed. In early 2010, HRSA issued another non-binding guidance that purported to greatly expand the agency's approach to contract pharmacies. HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010). Under the 2010 guidance, covered entities are permitted to use contract pharmacies even if they have an in-house pharmacy. *Id*. at 10,275. Covered entities also are permitted to use an unlimited number of outside contract pharmacy sites, so long as there is a written contract between the covered entity and the pharmacy, and the contract pharmacy meets certain compliance and certification requirements. *Id.* at 10,277–278. One of those requirements is that "[t]he covered entity will purchase the drug, *maintain title to the drug* and assume responsibility for establishing its price, pursuant to the terms of an HHS grant (if applicable) and any applicable Federal, State, and local laws." *Id.* at 10,277 (emphasis added). *See also* HRSA, *Contract Pharmacy: Important Tips*, *available at* https://www.hrsa.gov/opa/updates/2016/august.html (Aug. 2016).

31. The 2010 guidance, like its 1996 predecessor, does not state that manufacturers must honor contract pharmacy arrangements, nor (also like its predecessor) does it identify any

statutory basis for the contract pharmacy policy. In responding to a commenter suggesting that notice-and-comment rulemaking was required to adopt the policy, HRSA explained that it was not required to proceed via such rulemaking because its contract pharmacy policy does not "impose additional burdens upon manufacturers []or create[] any new rights for covered entities under the law." *Id.* at 10,273.

Contract Pharmacy Arrangements Explode In Popularity

32. Following HRSA's 2010 guidance, the number of contract pharmacy arrangements entered into by hospitals grew exponentially—with little evidence that patients were benefiting as a result.

33. Covered entities have an incentive to maximize 340B utilization because they profit off the "340B spread." Covered entities purchase the unit of the drug at the deeply discounted 340B price, then seek reimbursement from the patient's payer when the patient is insured. The covered entity captures the resulting "spread" between the (lower) 340B price and the inevitably higher reimbursement rate. The more contract pharmacies, the more opportunities to capture the spread, because more prescriptions can be filled through such arrangements. And there is no statutory obligation to share any of that revenue with those needy patients the 340B Program is intended to serve, through reduced prescription costs, for example.

34. The contract pharmacies with which covered entities began to contract, starting in 2010, are often national chain sites located hundreds or even thousands of miles from the covered entity and the community that it serves. Indeed, "contract pharmacy participation grew 4,228 percent between April 2010 and April 2020," with "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" now participating, and the number of contract pharmacy arrangements by hospitals increasing from 193 to more than 43,000 during

this period. BRG, *For-Profit Pharmacy Participation in the 340B Program*, at 4 (Oct. 2020), available at https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

35. In a subversion of statutory intent, the savings from the 340B Program—designed to benefit carefully selected beneficiaries—"are now distributed across a vertically integrated supply chain that includes not just the covered entities but also pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups." *Id*. at 7. And, as a result of the complete absence of transparency within such arrangements, it is unclear how much of the 340B Program savings actually inures to the benefit of these commercial interlopers. In this way, a statutory regime intended to benefit underserved populations is now being used to advantage large commercial profit-maximizing pharmacy chains and other commercial middlemen.

36. In the years following 2010, there has been an exponential increase in the number of contract pharmacies, a corresponding increase in the amount of drug products subject to the 340B discount, and a similar upsurge in the potential for abuse of the 340B Program. *See* Aaron Vandervelde and Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2012-2017*, Berkeley Research Group (Jul. 13, 2017), *available at* https://www.thinkbrg.com/insights/publications/measuring-the-relative-size-of-the-340b-program-2012-2017/; Adam Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (Jun. 9, 2020), *available at* https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html;

37. This explosive growth of contract pharmacy arrangements has greatly exacerbated longstanding systemic 340B program integrity concerns. Remember that, under the "virtual

inventory" ("replenishment") model, it is unknown at the time of dispensing whether an individual is a patient of the covered entity. This necessitates a retrospective determination (typically performed by third parties) of which units were dispensed to a covered-entity patient and thus would have been eligible for 340B pricing. There is no transparency into whether or how this determination is made.

38. There is, however, confirmation that the system is being abused. HRSA has identified hundreds of instances of diversion at contract pharmacies through its audit efforts, and many instances of the potential for duplicate discounts. GAO, *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,* at 37 (June 2018), available at https://www.gao.gov/assets/gao-18-480.pdf. In 2015, the HHS Office of Inspector General (OIG) concluded, in a triumph of understatement, that "[c]ontract pharmacy arrangements . . . create complications in preventing diversion . . . [and] duplicate discounts." OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, No. OEI-05-13-00431 at 1, 2 (Feb. 2014) (available at https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf).

39. Where a covered entity makes arrangements with pharmacies far outside its community, this risk of diversion is amplified by orders of magnitude. Because there is no reasonable proximity between such pharmacies and the local community of the covered entity (i.e., where patients of the covered entity obtain services), such pharmacies are highly unlikely to dispense drugs to patients *of the covered entity*. Thus, in the absence of meaningful oversight of covered entities, such arrangements cannot be squared with the statutory prohibition on diversion—one of the Congressionally established cornerstones of the 340B Program that mark its outer boundary.

Novartis's Contract Pharmacy Policy

40. Based on the plain language of the statute, Novartis is not legally bound to honor *any* contract pharmacy arrangement. The statute requires only that Novartis offer the 340B discount on sales to covered entities, which it does. 42 U.S.C. § 256b(a)(1). The statute does not require manufacturers to agree to ship the drugs to a third-party pharmacy for dispensing to patients (and non-patients) there.

41. Given the runaway proliferation of contract pharmacy arrangements and its attendant programmatic abuses, Novartis revised its contract pharmacy policy in order to appropriately align it with the 340B statute's purpose and requirements, while guarding against needless abuse.

42. Under its policy, Novartis honors all hospital covered entity contract pharmacy arrangements when the contract pharmacy is located within a 40-mile radius of the covered entity—which is to say, any contract pharmacy within an area that ranges about 5,000 square miles. *Id.* There is no limit on the number of contract pharmacies within that 40-mile radius with which the covered entity may have an arrangement. *Id*.

43. Federal grantee covered entities are exempted from the 40-mile radius policy. These entities are subject to independent requirements that encourage them to share the benefits of the 340B Program with their patients.

44. Finally, if a hospital covered entity brings a special circumstance to Novartis's attention (for example, if it has no in-house pharmacy and no contract pharmacy within 40 miles), Novartis works in good faith with the hospital to ensure appropriate access to a contract pharmacy through an exemption process. *Id.*

45. In adopting the 40-mile radius as a proxy for the patient community, Novartis drew on the federal Medicare provider-based policy governing hospitals and affiliated facilities, which generally utilizes a 35-mile radius. *See* 42 C.F.R. § 413.65(e)(3)(i).

46. The 40-mile radius limitation is also consistent with HRSA's statements that its contract pharmacy policy is designed to allow covered entities to enter into "arrangements in their communities" to dispense needed drugs to their patients. *See* 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). And the 40-mile radius is a generous policy: The vast majority of contract pharmacy hospitals are located within 40 miles of the covered entity. GAO, *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 23 (June 2018), available at https://www.gao.gov/assets/gao-18-480.pdf.

47. The Novartis policy does not prohibit any covered entity from purchasing Novartis medicines at 340B prices. Hospital covered entities are merely offered a choice of having the drug shipped to their own in-house pharmacy, or to an unlimited number of contract pharmacies located within a 40-mile radius of the hospital. And if there are no contract pharmacies within that 40-mile radius (a rare occurrence, according to GAO data), covered entities are encouraged to apply for an exemption.

48. Nor does Novartis's policy result in any overcharge to a covered entity. When Novartis does not recognize a contract pharmacy under its policy, it does not convert a 340B order to a commercial order. It simply declines to fill the 340B order, and the hospital is not charged.

49. On October 30, 2020—and again on November 13, 2020—Novartis notified HRSA that it would be implementing this approach to contract pharmacy arrangements. Exhibit 2.

The Advisory Opinion

50. On December 30, 2020, the HHS Office of the General Counsel (OGC) issued a non-binding Advisory Opinion on contract pharmacy arrangements under the 340B statute. *See* OGC, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020), available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

51. In the Advisory Opinion, OGC opined 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. To reach that conclusion, the Advisory Opinion argued that the "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." *Id.* In an odd flight of rhetoric, the Advisory Opinion asserted that the "situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." *Id.*

52. The agency based its position on its view that the statute is *unambiguous*: "It is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise." *Id.* (*citing Kisor v. Wilke*, 139 S. Ct. 2400, 2415 (2019)). In light of what the agency described as "the lack of ambiguity in the plain text of the statute," OGC concluded that "the above analysis is dispositive." *Id.* at 3.

53. In response to the Advisory Opinion, a number of manufacturers filed lawsuits against HRSA challenging its contract pharmacy policies. *See, e.g., AstraZeneca Pharmaceuticals LP v. Azar*, Case No. 1:21-cv-0027 (D. Del.); *Novo Nordisk Inc. v. HHS*, Case

No. 3:21-cv-00806 (D.N.J.); *Eli Lilly & Co. v. Cochran,* Case No. 1:21-cv-00081 (S.D. Ind.); *Sanofi-Aventis US, LLC v. HHS*, Case No. 3:21-cv-00634 (D.N.J.). Those cases remain pending.

HRSA's May 17, 2021 Decision Letter and Novartis's Response

54. On May 17, HRSA wrote to Novartis, asserting that the agency had "completed its review" of Novartis's contract pharmacy policy. Exhibit 1. HRSA appeared to have reviewed the wrong policy, however; in its Decision Letter, the agency asserted that Novartis's policy "places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform." *Id.* It does no such thing. [1]

55. The agency went on to assert that, after reviewing Novartis's (prior, inapplicable) policy, it had "determined that Novartis's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* The Decision Letter argued that "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." *Id.*

56. The Decision Letter demanded that Novartis

> immediately begin offering its covered patient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. Novartis must comply with its 340B statutory obligations and the [final rule governing civil monetary penalties (CMPs)] and credit or refund all covered entities for overcharges that have resulted from Novartis's policy. Novartis 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. [*Id.*]

[1] In August 2020, Novartis had considered requiring covered entities to submit claims data so that eligibility for the 340B discount could be verified; it ultimately decided not to implement that policy.

57. The Decision Letter requested a response by June 1, and ended with a threat: "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 CMPS final rule." *Id.*

58. Novartis responded on May 27, noting that HRSA's letter had mischaracterized the Novartis policy. Exhibit 3. Novartis also explained why its policy is consistent with the 340B statute: The statute requires that manufacturers offer the 340B discount on sales to covered entities. 42 U.S.C. § 256b(a)(1). Novartis does so. The statute does not require manufacturers to agree to ship the drugs to some remote pharmacy for dispensing to patients (and non-patients) there. Nor does the statute grant HRSA discretion to require manufacturers to ship drugs to a location potentially many miles away from the covered entity as it suggests in the Advisory Opinion, "be it the lunar surface, low-earth orbit, or a neighborhood pharmacy."

59. In its response, Novartis requested that HRSA withdraw its Decision Letter and threat of enforcement by May 31, in advance of the June 1 deadline set by the agency in the Decision Letter. Exhibit 3.

60. As of the filing of this Complaint, HRSA has failed to withdraw the Decision Letter.

HRSA's Decision Letter Is Unlawful

61. HRSA's Decision Letter is unlawful, for multiple reasons.

62. First and foremost, the Decision Letter violates the plain language of the 340B statute. The statute only requires a participating manufacturer to "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) (emphasis added).

63. The statute provides no basis on which a covered entity may force a manufacturer to ship a unit purchased at the 340B price to a *contract pharmacy*.

64. HRSA argues that the statute is silent "on how the *covered entity* chooses to distribute the covered outpatient drugs." Exhibit 1 (emphasis added). First of all, that is not true. The 340B statute specifically states that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. §256b(5)(B).

65. But in any event, the agency is wrong to equate the latitude that may or may not be given covered entities *after* their exercise of their limited statutory right to purchase the drug *at the statutorily specified price* with the right to require manufacturers to ship the purchased drug directly to contract pharmacies. So long as the manufacturer is willing to ship the unit to the covered entity, the manufacturer operates in compliance with the plain language of the statute. And here, Novartis has expressed a willingness to ship not just to covered entities, but to [1] *any* contract pharmacy within 40 miles of a hospital covered entity (an area that covers roughly 5,000 square miles); [2] *any* contract pharmacy, anywhere, affiliated with a federal grantee; and [3] *any other* contract pharmacy, when circumstances warrant making an exception to the general policy.

66. Moreover, the agency has boxed itself into a *Chevron* corner. By taking the position in the Advisory Opinion that the language of the statute is "unambiguous,"[2] and asserting in its Decision Letter that "the 340B statute *requires* manufacturers to honor such purchases regardless of the dispensing mechanism," Exhibit 1 (emphasis added), the agency has disavowed any argument that the statute is ambiguous and thus that any interpretation of the

[2] OGC, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020), available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

statute it may offer is entitled to deference. The agency's position therefore must rise and fall on its ability to demonstrate that the statute unambiguously requires manufacturers to honor all contract pharmacy arrangements, of whatever ilk. *See, e.g., Peter Pan Bus Lines, Inc. v. Federal Motor Carrier Safety Admin*., 471 F.3d 1350, 1354 (D.C. Cir. 2006) (explaining that "*Chevron* step 2 deference" is reserved only "for those instances when an agency recognizes that the Congress's intent is not plain from the statute's face").

67. The agency's own previous guidance documents undermine any suggestion that the 340B statute *requires* manufacturers to recognize all contract pharmacy arrangements. HRSA's 1996 non-binding guidance permitted *only* covered entities lacking an in-house pharmacy to contract with a *single* contract pharmacy site, in an effort to "facilitate program participation for those eligible covered entities that do not have access to appropriate 'in house' pharmacy services." 61 Fed. Reg. at 43,550, 43,555. HRSA reiterated that position in 2007. 72 Fed. Reg. 1540. The 1996 guidance would make no sense if the statute already mandated that *all* contract pharmacy arrangements be recognized, regardless of number and regardless of whether the covered entity had an in-house pharmacy. And even with respect to this limited universe of contract pharmacy arrangements, the guidance did not purport to require manufacturers to recognize any contract arrangement entered into by a covered entity under its terms. Indeed, the guidance expressly disclaimed that it was creating any rights or imposing any obligations at all. 61 Fed. Reg. at 43,550 ("We believe that these guidelines create no new law and create no new rights or duties.").

68. In its Decision Letter, HRSA also argues "manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs." But the agency identified no basis for asserting that Novartis has treated

covered entities differently than other purchasers. Nor could it. Novartis offers the same opportunity for 340B covered entities to *purchase* covered outpatient drugs as it does to any other purchaser. And it does not recognize any commercial arrangements equivalent to 340B contract pharmacy arrangements, where the purchaser is empowered to unilaterally direct shipment to some other distant third-party location. That simply does not happen outside of the world of contract pharmacies. The agency's statutory arguments therefore are unavailing.

69. The agency's position as reflected in the Decision Letter is also arbitrary and capricious, for a number of reasons. First, HRSA's *any contract pharmacy anywhere, including on the moon* position is illogical to the point of being arbitrary and capricious.

70. Second, HRSA has failed to offer an adequate explanation for its change in position between the 1996 guidance (only covered entities lacking an in-house pharmacy may contract with a single outside contract pharmacy site) and its later inconsistent positions in the 2010 guidance (covered entities may contract with an unlimited number of contract pharmacies, regardless of whether they also maintain an in-house pharmacy) and 2020 Advisory Opinion (same, and manufacturers must recognize such arrangements). In fact, HRSA has failed even to acknowledge its changes in position, repeatedly asserting that its policy has remained consistent all along. *See, e.g.*, Exhibit 1 at 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"). That is the dictionary definition of arbitrary and capricious.

71. Finally, the agency's decision is based on a faulty record. HRSA's own guidance documents make clear that the 340B discount is available only where specified conditions are met, including that the covered entity retains title to the drugs in question and the contract

pharmacy agreement contains specified terms relating to contract pharmacy services. 75 Fed. Reg. at 10,277. But the Decision Letter made no finding that—nor did it even address whether—any of the covered entities at issue actually retained title to the drugs at issue or otherwise comply with the enumerated conditions. Nor could it as any practical matter, given that the terms of these arrangements are not disclosed to HRSA or manufacturers and that contract pharmacies commingle 340B-purchased units with the rest of their stock for dispensing to both patients and non-patients of the covered entity alike.

72. This is not just a hypothetical problem. OIG's own analysis shows that covered entities use a variety of different contract pharmacy arrangements, and that "[t]he variety of data types and comparison methods used to identify 340B-eligible prescriptions can result in differing determinations of 340B eligibility across covered entities." OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program,* OEI-05-13-00431 at 9–10 (Feb. 4, 2014), available at https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. And yet neither HRSA nor any manufacturer has sufficient information to identify qualifying transactions. As GAO has noted, "HRSA does not have complete data on all contract pharmacy arrangements in the 340B program to inform its oversight efforts." *See* GAO, *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 36 (June 2018), available at https://www.gao.gov/assets/gao-18-480.pdf.

HRSA's Actions Will Cause Immediate and Irreparable Harm

73. The Decision Letter ends with a threat: HRSA will move to impose CMPs absent compliance by Novartis. That threat is unwarranted: CMPs are permissible only in the event of a knowing and intentional overcharge for a drug purchased by a covered entity. 42 U.S.C.

§ 256b(d)(1)(B)(vi); 42 C.F.R. § 10.11(a). But it is a threat nevertheless, and one with immediate real-world consequences for Novartis.

74. Novartis has not "overcharged" any covered entities, let alone done so knowingly and intentionally. Under Novartis's policy, when an order is made through a non-qualifying contract pharmacy arrangement, the order is *declined*. A covered entity is not charged any price, let alone overcharged, and Novartis at all times continues to offer the covered outpatient drug to the covered entity at the 340B price, including through qualifying contract pharmacy arrangements.

75. Novartis also has acted at all times in good faith, based on a reasonable, legally defensible understanding of the plain language of the 340B statute. Novartis provided HRSA with advance notice of its policy in November 2020, before implementation, and explained its legal justification for the policy in that notice. Novartis similarly gave covered entities advance notice of its intended course of action. The Decision Letter—with the threat—was the first time the agency provided a response addressing the Novartis policy.

76. CMPs are a harsh sanction, and the process for imposing them is a public one. In the Decision Letter, HRSA threatens to seek penalties up to nearly $6,000 for each instance in which the government believes Novartis sold a product to a covered entity at an incorrect price. That is a financial loss, but it is one that is irreparable because it threatens Novartis's ability to invest in pipeline products, talent, and research and development.

77. Despite the fact that HRSA's threat lacks merit, Novartis now faces a Hobson's choice: submit to the agency's demand that it continue to provide steep, unwarranted discounts that benefit large pharmacy chains, or face stiff penalties and a host of reputational harms from an unwarranted and unlawful enforcement proceeding.

78. Absent prompt judicial relief, Novartis will suffer irreparable harm. The government's public assertion that Novartis has knowingly and willfully violated its 340B obligations plainly injures Novartis reputation. Even the Decision Letter *threatening* enforcement action garnered immediate media attention highlighting the allegation that Novartis is out of compliance with the 340B program. *See, e.g.,* Jeff Legasse, *Six Drugmakers Are In Violation Of 340B Statute, Says HRSA,* Healthcare Finance (May 18, 2021), https://bit.ly/3u7qilU; Kathy Kelly, *340B Fight Escalates As Biden Administration Seeks Refunds From Manufacturers, Threatens Them With Fines,* Pink Sheet Daily (May 20, 2021), https://bit.ly/33XE9Rn.

COUNT I
(Administrative Procedure Act, 5 U.S.C. §§ 700, *et seq.*)

79. Novartis re-alleges and incorporates by reference the allegations in the foregoing numbered paragraphs.

80. The APA prohibits HRSA from carrying out the agency's statutory and regulatory duties in a manner that is unlawful, arbitrary, capricious, an abuse of discretion, or contrary to a constitutional right. *See* 5 U.S.C. § 706(2).

81. HRSA's contract pharmacy policy violates the plain language of the 340B statute and is otherwise unlawful and in excess of the agency's statutory powers. The statute provides no basis on which a covered entity may force a manufacturer to ship a unit purchased at the 340B price to a contract pharmacy. The statute entitles a covered entity only to "purchase" a covered outpatient drug at the 340B price. 42 U.S.C. § 256b(a)(1).

82. HRSA's contract pharmacy policy also is arbitrary and capricious, lacks a logical basis, and constitutes an abuse of discretion. First, HRSA's *any contract pharmacy, anywhere, including on the moon* position is illogical to the point of being arbitrary and capricious.

83. HRSA also has acted arbitrarily and capriciously because the agency has failed to offer an adequate explanation for its change in position between the 1996 guidance and its later inconsistent positions in the 2010 guidance and 2020 Advisory Opinion. In fact, HRSA has failed even to acknowledge that change in position, repeatedly asserting that its policy has remained consistent all along. The agency's failure to reconcile its change in position is arbitrary and capricious.

84. Finally, the HRSA decision is arbitrary because it was based on a faulty record. The agency's own guidance documents make clear that the 340B discount is available only where the contract pharmacy arrangement meets various specified criterion, including that the covered entity retains title to the drugs in question. But the Decision Letter made no finding that—nor did it even purport to address whether—any of the covered entities at issue actually retained title to the drugs at issue or satisfied any of the other conditions spelled out in agency guidance. And due to the lack of transparency into contract pharmacy arrangements, manufacturers have no way of knowing if the title for any given drug purchased at the 340B discount remains with the covered entity—particularly in light of the replenishment model, under which 340B-purchased drugs are commingled into the general stock of the pharmacy for dispensing to both patients and non-patients of the covered entity alike.

85. The Decision Letter constitutes final agency action for which Novartis has no other adequate remedy at law. It would be futile for Novartis to avail itself of any remaining administrative review.

86. Both Novartis and the public would be irreparably harmed if the Decision Letter (and the agency's reasoning as explained therein) were allowed to stand.

87. The intent of Congress and the public interest will be served by an Order vacating the Decision Letter and HRSA's contract pharmacy policy as explained therein.

PRAYER FOR RELIEF

For the foregoing reasons, Novartis prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that the agency's position regarding contract pharmacies is unlawful.

B. An order vacating and setting aside the Decision Letter on the grounds that it is unlawful, arbitrary, and capricious.

C. Temporary, preliminary, and permanent injunctive relief barring Defendants and any entities acting in concert with them from initiating and/or pursuing any enforcement actions against Novartis in connection with its 340B contract pharmacy policy.

D. An order awarding Novartis its costs, expenses, and attorneys' fees incurred in these proceedings pursuant to 28 U.S.C. § 2412; and

E. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ Catherine E. Stetson

Catherine E. Stetson (D.C. Bar No. 453221)
Susan M. Cook (D.C. Bar No. 462978)
Harrison Gray Kilgore (D.C. Bar No. 1630371)
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Facsimile: (202)637-5910
cate.stetson@hoganlovells.com

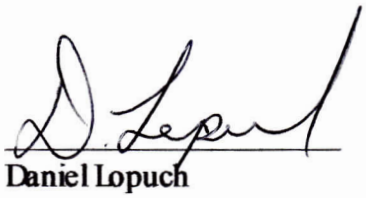
Attorneys for Plaintiff Novartis Pharmaceuticals Corporation

Dated: May 31, 2021

VERIFICATION

I, the undersigned, having read the allegations of the foregoing Verified Complaint, hereby declare under penalty of perjury and pursuant to 28 U.S.C. § 1746 that the factual allegations asserted in the Verified Complaint are true and correct.

Executed this 31st day of May, 2021.



Daniel Lopuch

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS
Novartis Pharmaceuticals Corporation

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF 88888
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS
Diana Espinosa, in her official capacity as Acting Administrator, Health Resources and Services Administration; and Xavier Becerra, in his official capacity as Secretary of U.S. Department of Health and Human Services

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Catherine E. Stetson
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004 Tel: (202) 637-5491

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ A. *Antitrust*
- ☐ 410 Antitrust

○ B. *Personal Injury/ Malpractice*
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

◉ C. *Administrative Agency Review*
- ☐ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☒ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ D. *Temporary Restraining Order/Preliminary Injunction*

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ E. *General Civil (Other)* OR **○ F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ **G. *Habeas Corpus/ 2255*** ☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	○ **H. *Employment Discrimination*** ☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	○ **I. *FOIA/Privacy Act*** ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	○ **J. *Student Loan*** ☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ **K. *Labor/ERISA (non-employment)*** ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	○ **L. *Other Civil Rights (non-employment)*** ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	○ **M. *Contract*** ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	○ **N. *Three-Judge Court*** ☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

Plaintiff challenges, under 5 U.S.C. § 706(2), HRSA's determination that Plaintiff's contract pharmacy policy is unlawful

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint **YES** ☐ **NO** ☒

VIII. RELATED CASE(S) IF ANY (See instruction) **YES** ☐ **NO** ☒ If yes, please complete related case form

DATE: 5/31/21 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Catherine E. Stetson

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

May 17, 2021

Mr. Dan Lopuch
Managed Market Finance
Novartis Pharmaceuticals Corporation
One Health Plaza, 135/4110F
East Hanover, NJ 07936

Dear Mr. Lopuch:

The Health Resources and Services Administration (HRSA) has completed its review of Novartis Pharmaceuticals Corporation's (Novartis) policy that places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Novartis' 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. Furthermore, the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data. 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. Novartis 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.

[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)

Novartis 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 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, Novartis 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. Novartis 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 Novartis' policy. Novartis 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 Novartis' willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that Novartis provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with 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).

NOVARTIS

Novartis Pharmaceuticals
One Health Plaza
East Hanover, NJ 07936

November 13, 2020

BY ELECTRONIC MAIL (Krista.Pedley@hrsa.hhs.gov) AND FEDERAL EXPRESS

Rear Admiral Krista M. Pedley, PharmD, MS, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

Re: Novartis Pharmaceuticals Corporation 340B Contract Pharmacy Policy

Dear Rear Admiral Pedley:

I am writing on behalf of Novartis Pharmaceuticals Corporation ("Novartis") in follow-up to our communication on August 17, 2020. We wish to disclose to the Health Resources and Services Administration ("HRSA") new steps that Novartis is taking as part of its 340B Drug Pricing Program ("340B program") integrity initiative. After careful consideration, we have decided to implement a more focused, criteria-based approach to contract pharmacy arrangements that will start to shift the 340B program back to its intended focus on the patients of covered entities, and thereby put the program on a pathway toward long-term sustainability.

As we had indicated by e-mail to you dated October 30, 2020, and as more fully described below, beginning on November 16, 2020, Novartis will continue to honor hospital contract pharmacy arrangements so long as the contract pharmacy is located within a 40-mile radius of the parent hospital. This policy will not restrict the number of contract pharmacies that a hospital may establish within its own community (as defined by the 40-mile radius). All federal grantee covered entities are exempt from the new policy, and these covered entities may continue to acquire 340B product through contract pharmacy arrangements exactly as before.

I. The Novartis Policy Is Necessary Because the Explosive Growth of Contract Pharmacy Arrangements Has Greatly Exacerbated Ongoing Systemic Program Integrity Concerns

Despite contract pharmacy arrangements having no basis in law, as detailed below, the number of contract pharmacy arrangements by hospitals has grown exponentially, with little evidence that patients are benefiting as a result. These contract pharmacies are often located hundreds or

NOVARTIS

even thousands of miles from their associated hospital covered entity and the community that it serves. As explained in a recent study by Berkeley Research Group ("BRG"), "contract pharmacy participation grew 4,228 percent between April 2010 and April 2020," with "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" now participating, and the number of contract pharmacy arrangements by hospitals increasing from 193 to more than 43,000 during this period.[1] Underscoring the profit-driven nature of this growth, the BRG study found that "340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines," which is "more than three times greater than the average margin realized by independent pharmacies."[2] In a subversion of program intent, the 340B savings generated by this profit margin "are now distributed across a vertically integrated supply chain that includes not just the covered entities but also pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups."[3] And, as a result of the complete absence of transparency, it is unclear how much of the 340B program savings is absorbed by these commercial actors.[4]

This explosive growth of contract pharmacy arrangements has greatly exacerbated longstanding systemic 340B program integrity concerns. Indeed, federal agencies have documented this program integrity risk. For example, in 2015, the Department of Health and Human Services Office of Inspector General ("OIG") concluded that "[c]ontract pharmacy arrangements . . . create complications in preventing duplicate discounts."[5] OIG also found that "most covered entities in [the] study do not conduct all of the oversight activities recommended by HRSA . . . . Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance. Without adequate oversight, the complications created by the contract pharmacy arrangements may introduce vulnerabilities to the 340B Program."[6] And, in 2018, GAO found that "weaknesses in HRSA's oversight impede its ability to ensure compliance with 340B Program requirements at contract pharmacies," and that "HRSA's audit process does not adequately identify compliance issues, nor does it ensure that identified issues are corrected."[7]

In particular, the explosive growth of contract pharmacy arrangements has significantly increased the inherent risk of non-compliance with the diversion prohibition. By their nature,

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[1] BRG, For-Profit Pharmacy Participation in the 340B Program, at 4 (Oct. 2020), *available at* https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

[2] *Id.* at 7.

[3] *Id.*

[4] A recent review by the Government Accountability Office ("GAO") of a comparatively small sample of only thirty contract pharmacy agreements found that, in some cases, the contract pharmacy was entitled to a flat fee of $15 for each prescription, plus twenty percent of the reimbursement for the drug, by both the patient and her payer. GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, No. GAO-18-480, at 51 (Jun. 2018), *available at* https://www.gao.gov/assets/700/692697.pdf.

[5] OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, No. OEI-05-13-00431 at 16 (Feb. 2014) (available at https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf).

[6] *Id.*

[7] GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, No. GAO-18-480, at 45 (Jun. 2018) (available at https://www.gao.gov/assets/700/692697.pdf).

contract pharmacy arrangements pose such risk, as it is unknown at the time of the dispensing whether an individual is a patient of the covered entity. This necessitates a retrospective determination, and there is no transparency into whether or how this determination is made. Where a covered entity makes arrangements with pharmacies well outside of its community, this risk of diversion is amplified by orders of magnitude. Simply put, because there is no reasonable proximity between such pharmacies and the covered entity (i.e., where patients of the covered entity obtain services), such pharmacies are highly unlikely to dispense drugs to patients of the covered entity in fact. Thus, such arrangements cannot be squared with the statutory prohibition on diversion – one of the Congressionally established cornerstones of the 340B program that mark its outer boundary.[8]

II. The Novartis Policy's Modest Steps Will Start to Redress the Significant Concerns Posed by the Contract Pharmacy Program

Novartis takes seriously its obligations under the 340B program and remains committed to supporting its core mission – to serve uninsured, low-income, and other vulnerable patients. As set forth below, our intended actions are entirely consistent with this mission, even as they start to redress the well-documented, long-standing, and significant program integrity risks occasioned by the contract pharmacy program in its current form.

Under the Novartis approach, we will continue to honor all contract pharmacy arrangements of all federal grantee covered entities, i.e., there will be no restriction on such arrangements. Federal grantee covered entities are subject to independent requirements that encourage them to share the benefits of the 340B program with their patients.[9] Thus, the unintended financial incentives to maximize 340B utilization in order to maximize profit, potentially at the expense of program integrity, are less pronounced where federal grantee covered entities are concerned.

For hospital covered entities, beginning November 16, 2020, with respect to all Novartis covered outpatient drugs, we will continue to honor contract pharmacy arrangements to the extent that the contract pharmacy is within a 40-mile radius of the hospital. There will not be a limit on the number of contract pharmacies within that radius with which the hospital may have an arrangement. This geographic restriction represents a common-sense approach toward ensuring that the 340B program benefits the hospital's patients, as intended. In adopting the 40-mile radius as a proxy for the community of patients served by the hospital, we were informed by Medicare provider-based policy governing hospitals and affiliated facilities, which generally utilizes a 35-mile radius.[10]

Additionally, if a hospital covered entity were to bring a special circumstance to our attention, e.g., if the hospital were to have no in-house pharmacy and our approach would leave it with no contract pharmacy, we intend to work in good faith with the hospital to ensure appropriate access to a contract pharmacy.

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[8] Public Health Service Act (PHSA) § 340B(a)(5)(B).

[9] *See, e.g.*, PHSA § 330(k)(3)(G)(iii).

[10] *See* 42 C.F.R. § 413.65(e)(3)(i).

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Notably, when Novartis does not recognize a contract pharmacy under its approach, Novartis will not convert a 340B order to a commercial order. Rather, Novartis will simply decline to fill the 340B order, and the hospital will not be charged. In addition, under the Novartis approach, covered entities will not be disadvantaged relative to non-covered entities. That is because Novartis does not have commercial arrangements that are equivalent to 340B contract pharmacy arrangements.

Most importantly, the Novartis policy will not harm patient access to medicines, because the Novartis policy applies to arrangements between covered entities and contract pharmacies, and not to patients. Patients of a covered entity will still be able to obtain 340B-purchased drugs from a contract pharmacy in the community.

Additionally, in the interest of improving transparency and program integrity (by mitigating the risk of duplicate discounts), we are encouraging covered entities to upload all contract pharmacy claims data to the Second Sight Solutions' 340B ESP™ web-based platform. This action is not required, however, and declining to take this action will not have an effect on 340B purchasing through contract pharmacies or otherwise.

Novartis believes that these steps, taken together, are necessary to help ensure the integrity of the 340B program, and therefore protect the sustainability of this critical program.

III. The Novartis Contract Pharmacy Approach Is Fully Consistent With the Law

A. Legal Background

HRSA has issued guidance providing that a covered entity may contract with one or more pharmacies for the purpose of dispensing 340B-purchased drugs to its patients on its behalf.[11] HRSA first issued contract pharmacy guidance in the mid-1990s.[12] After soliciting comment on a proposed notice,[13] HRSA issued a final notice implementing its original contract pharmacy policy.[14] In that 1996 final notice, HRSA stated that it was implementing its policy because, in its view, it would defeat the purpose of the 340B program if a covered entity without an in-house pharmacy could not use an outside pharmacy to dispense 340B-purchased drugs to its patients on its behalf.[15] Accordingly, HRSA provided that a covered entity could use either an in-house

[11] HRSA, *Contract Pharmacy: Important Tips* (Aug. 2016) (available at https://www.hrsa.gov/opa/updates/2016/august.html) ("Covered entities participating in the 340B Program are permitted to use contract pharmacies for the dispensing of 340B drugs, in addition to or in lieu of an in-house pharmacy.").

[12] *See* 75 Fed. Reg. 10,272, 10,272-73 (Mar. 5, 2010) (setting forth the history of HRSA's contract pharmacy guidance).

[13] 60 Fed. Reg. 55,586 (Nov. 1, 1995).

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

[15] *Id.* at 43,550.

pharmacy or, if the covered entity did not have an in-house pharmacy, a single contracted outside pharmacy site.[16]

In issuing the 1996 final notice, HRSA did not expressly state that manufacturers were obligated to honor contract pharmacy arrangements. Nor did HRSA identify any statutory basis for its policy. Rather, the agency stated only that "[t]he 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."[17] It then stated that the 340B statute does not preclude a "[covered] entity direct[ing] the drug shipment to its contract pharmacy."[18] HRSA also stated that, "[a]s 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."[19]

In 2010, HRSA issued a revised notice that significantly expanded its contract pharmacy policy.[20] Under that revised notice, which remains in effect today, covered entities are permitted to use a contracted outside pharmacy, even if they have an in-house pharmacy.[21] In addition, covered entities are permitted to use an unlimited number of contracted outside pharmacy sites, so long as there is a written contract between the covered entity and the pharmacy, and the contract pharmacy meets certain limited compliance and certification requirements.[22]

The 2010 revised notice, like its 1996 predecessor, does not expressly state that manufacturers are obligated to honor contract pharmacy arrangements or identify any statutory basis for the contract pharmacy policy. To the contrary, in responding to a commenter that had argued that a notice-and-comment rulemaking was required to adopt the policy, HRSA explained that it was not required to proceed via such rulemaking because its contract pharmacy policy does not "impose additional burdens upon manufacturers []or create[] any new rights for covered entities under the law."[23]

As discussed above, HRSA's revised contract pharmacy policy has resulted in the rapid growth of contract pharmacy arrangements, with an attendant increase in the risk of program non-compliance.

B. Legal Analysis

Manufacturers are not legally bound to abide by HRSA's contract pharmacy policy, which merely constitutes agency guidance, and not a binding legal standard. The policy appears

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16 *Id.* at 43,551.

17 *Id.* at 43,549.

18 *Id.* at 43,549-50.

19 *Id.* at 43,550.

20 75 Fed. Reg. at 10,277 (HRSA solicited comment on a proposed notice before issuing this revised notice).

21 *Id.* at 10,275 (stating that covered entities "with an in-house pharmacy could use any acceptable contract pharmacy arrangement to supplement the in-house pharmacy").

22 *Id.* at 10,277-78.

23 *Id.* at 10,273. HRSA also failed to provide a convincing rationale for its departure from the 1996 contract pharmacy guidance.

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nowhere in the 340B statute.[24] Moreover, it appears nowhere in any regulation implementing the 340B statute.[25] Rather, the policy is set forth only in guidance which, by its nature, is not legally binding.[26] This is a black letter principle of administrative law, and it is a universally accepted proposition. HRSA itself has correctly acknowledged it – publicly, repeatedly, and recently.[27] Covered entities have recognized it as well.[28]

Notably, HRSA has not only embraced the general notion that guidance is not legally binding, but has specifically acknowledged that this is the case with respect to its contract pharmacy policy.

First, HRSA denominated its contract pharmacy policy issuance as a mere "notice."[29] In addition, HRSA characterized its contract pharmacy policy as a mere "interpretive rule [or] statement of policy."[30] This is significant because an agency's own characterizations are a factor that courts consider in determining whether its policies are legally binding.[31]

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[24] The same holds true with respect to the Pharmaceutical Pricing Agreement (and its addendum) implementing the 340B statute.

[25] Indeed, there could be no such regulation: The 340B statute does not grant HRSA general rulemaking authority, and instead grants HRSA rulemaking authority only with respect to "(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. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014).

[26] *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (informal interpretations do not "carry the force of law" and therefore are not entitled to "judicial deference"); *Chrysler Corp. v. Brown*, 441 U.S. 281, 296 & n.31 (1979) (informal interpretations have no power to bind regulated parties because they do not carry the force and effect of law); *Am. Tort Reform Ass'n v. Occupational Health & Safety Admin.*, 738 F.3d 387, 393 (D.C. Cir. 2013) ("When an agency issues an interpretative rule or statement, an interpretative guideline, or a policy statement with respect to a matter that it is not empowered to decide, the interpretative rule, statement, guideline, or policy statement merely informs the public of the agency's views on the subject. It does not, however, create 'adverse effects of a strictly legal kind' because it cannot 'command anyone to do anything or to refrain from doing anything.'") (citing and quoting *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 809 (2003)).

[27] *See also* Executive Order on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (Oct. 19, 2019) (available at https://www.whitehouse.gov/presidential-actions/executive-order-promoting-rule-law-transparency-fairness-civil-administrative-enforcement-adjudication/) ("When an agency takes an administrative enforcement action, engages in adjudication, or otherwise makes a determination that has legal consequence for a person, it must establish a violation of law by applying statutes or regulations. The agency may not treat noncompliance with a standard of conduct announced solely in a guidance document as itself a violation of applicable statutes or regulations."); Executive Order on Promoting the Rule of Law Through Improved Agency Guidance Documents (Oct. 9, 2019) (available at https://www.whitehouse.gov/presidential-actions/executive-order-promoting-rule-law-improved-agency-guidance-documents/) ("[G]uidance documents lack the force and effect of law, except as authorized by law or as incorporated into a contract.").

[28] *See Genesis Health Care, Inc. v. Azar*, No. 4:19-cv-1531-RBH (D.S.C.).

[29] 75 Fed. Reg. at 10,272.

[30] *Id.* at 10,273.

[31] *See Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999) ("To determine whether a regulatory action constitutes promulgation of a regulation, we look to three factors: (1) the Agency's own characterization of the action; (2) whether the action was published in the Federal Register or the Code of Federal Regulations; and (3) whether the action has binding effects on private parties or on the agency.").

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Second, HRSA's contract pharmacy policy nowhere expressly states that manufacturers are obligated to honor contract pharmacy arrangements. To the contrary, in issuing the 2010 revised notice, HRSA stated that its contract pharmacy policy does not "impose additional burdens upon manufacturers []or create[] any new rights for covered entities under the law."[32] This is significant because legally binding rules create new obligations or rights.[33] By conceding that its contract pharmacy policy does not do so, HRSA conceded that the policy is not legally binding.

Finally, HRSA has expressly stated that it does not have authority to enforce the policy.[34]

HRSA's acknowledgement that its contract pharmacy policy is not legally binding reflects the fact that the 340B statute nowhere can be read to require a manufacturer to ship a covered outpatient drug purchased by a covered entity to the covered entity's contract pharmacy for dispensing to the covered entity's patient on the covered entity's behalf. There is simply no statutory text supporting the contract pharmacy policy. The statute entitles a covered entity only to purchase a covered outpatient drug from the manufacturer at the 340B price. It in no way suggests that the covered entity is also entitled to dictate to the manufacturer the destination of shipment, particularly if a third party. Rather, so long as the manufacturer ships to a reasonable destination, such as the covered entity itself, the manufacturer cannot be held out of compliance with the statute.

While Novartis is not legally bound to honor contract pharmacy arrangements at all, Novartis currently does not propose to cease to honor contract pharmacy arrangements altogether, notwithstanding the patent abuse engendered by the contract pharmacy expansion. Rather, we are willing to recognize such arrangements within reasonable limits. Thus, we have adopted the revised policy to impose a set of limits that seek to strike a reasonable balance. In short, we will honor contract pharmacy arrangements on the reasonable terms of our approach set forth above.

* * * * *

[32] 75 Fed. Reg. at 10,273.

[33] *See Chrysler Corp.*, 441 U.S. at 296 & n.31; *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (informal interpretations cannot "impose new obligations or prohibitions or requirements on regulated parties"); *Batterton v. Marshall*, 648 F.2d 694, 702 (D.C. Cir. 1980) (unlike a legally binding rule, "[n]on-binding . . . actions or statements are not determinative of issues or rights addressed. They express the agency's intended course of action . . . [or] its tentative view of the meaning of a particular statutory term . . . . They do not, however, foreclose alternate courses of action or conclusively affect rights of private parties.").

[34] Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (Jul. 9, 2020) (available at https://340breport.substack.com/p/hrsa-says-its-340b-contract-pharmacy) (quoting HRSA as stating, "The 2010 [contract pharmacy] guidance is still in effect. However, guidance is not legally enforceable. Regarding the 340B Program's guidance documents, HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute. Without comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program.").

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We ask that, if you have any legal concern with the Novartis approach to contract pharmacy arrangements, you communicate such concern to us in writing as soon as possible. If you have any questions about our approach, please contact me at (862) 778-1590 or Daniel.Lopuch@Novartis.com. We would be happy to make time to discuss any questions at your convenience. We look forward to continuing to work together to further strengthen this important program.

Sincerely,

Dan Lopuch
VP, Managed Markets Finance
Novartis Pharmaceuticals Corporation

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May 27, 2021

BY ELECTRONIC MAIL

Diana Espinosa
Acting Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Acting Administrator Espinosa:

I am writing in response to your May 17, 2021 letter to Novartis Pharmaceuticals Corporation (Novartis) regarding Novartis's 340B contract pharmacy policy. Your letter appears to be based on a mistaken understanding of Novartis's policy. Novartis does not "place restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform." Novartis's policy does not require covered entities to provide claims data to a third-party platform or otherwise, but only invites covered entities to provide claims data on a voluntary basis to promote 340B program integrity.

Novartis continues to support the goal of the 340B program to increase access to covered outpatient drugs among uninsured and other vulnerable patients. Novartis's policy helps ensure that the 340B discount serves vulnerable patients within hospital covered entities' local communities—something HRSA itself has touted as consistent with the goals of the agency's 340B policies. As the agency noted in a guidance document, the goal of the agency's contract pharmacy policy is to "permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive *arrangements in their communities* which would benefit covered entities, pharmacies and patients served."[1]

As explained in its letter to HRSA dated November 13, 2020, Novartis honors all grantee covered entity contract pharmacy arrangements, as well as all hospital covered entity contract pharmacy arrangements so long as the contract pharmacy is in the hospital's community or neighborhood—i.e., within a 40-mile radius of the parent hospital—or an exception is granted.[2] There is no limit on the number of contract pharmacies within the 40-mile radius with which the hospital covered entity may have an arrangement. Novartis' approach to ensuring the 340B program goals are met is also based

[1] *See* 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (emphasis added); *see also* HRSA's Opp. to Emergency Motion for Administrative Stay, ECF No. 69, *AstraZeneca Pharms. LP v. Becerra*, Civil Action No. 1:21-cv-00027-LPS (D. Del.) (characterizing pharmacies as "requiring access to discounted drugs for safety-net healthcare providers . . . and their patients when the patients fill their prescriptions at outside, *neighborhood pharmacies*") (emphasis added).

[2] *See* Letter from D. Lopuch to K. Pedley dated November 13, 2020 (attached as Exhibit 1).

on and consistent with a geographic proxy set forth in Medicare policy. In adopting the 40-mile radius as a proxy for the community of patients served by the hospital, Novartis was informed by Medicare provider-based policy governing hospitals and affiliated facilities, which generally utilizes a 35-mile radius.[3] Additionally, if a hospital covered entity brings special circumstances to Novartis's attention (e.g., if the hospital notifies Novartis that it lacks an in-house pharmacy and our approach would leave it with no contract pharmacy), Novartis works with the hospital to ensure appropriate access to a contract pharmacy.

Novartis is confident that its contract pharmacy policy is fully compliant with the 340B statute, the 340B Pharmaceutical Pricing Agreement and Addendum (340B PPA), and all applicable binding agency regulations. Based on the plain language of the statute, Novartis is not legally bound to honor *any* contract pharmacy arrangement, notwithstanding the recent and expressly non-binding Advisory Opinion issued by the Department of Health and Human Services (HHS) Office of the General Counsel (OGC).[4] Nonetheless, as spelled out in its letter to HRSA, Novartis has decided to voluntarily recognize grantee covered entity contract pharmacy arrangements, as well as hospital covered entity contract pharmacy arrangements within a specified 40-mile radius, and to provide for exceptions that extend that radius when circumstances require, in order to strike a reasonable balance in redressing ongoing abuses of the 340B program. In doing so, Novartis continues to support the goal of the 340B program to increase access to covered outpatient drugs among uninsured and other vulnerable patients.

A. Novartis's Policy Complies with the 340B Statute

1. A manufacturer is not required to honor a contract pharmacy arrangement

Novartis's contract pharmacy policy is fully within the bounds of applicable law. The 340B statute requires a participating manufacturer to offer the 340B-discounted price only to a "covered entity."[5] Specifically, a pharmaceutical manufacturer participating in the program must "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."[6]

The statute defines the term "covered entity" narrowly.[7] To count as a "covered entity," a provider must be one of 15 specifically enumerated types of safety net providers. These include entities operating under a grant by the federal government, such as a federally-qualified health center, as well as certain types of hospitals, such as certain children's hospitals and free-standing cancer hospitals.[8] Similarly, the 340B PPA, which a manufacturer must execute to participate in the 340B program, states

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[3] *See* 42 C.F.R. § 413.65(e)(3)(i).

[4] *See* Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

[5] 42 U.S.C. § 256b(a)(1).

[6] *Id.* (emphasis added).

[7] *See id.* § 256b(a)(4).

[8] *Id.*

that "covered entities" means "certain Public Health Service grantees, 'look-alike' Federal Qualified Health Centers, and disproportionate share hospitals."[9] A contract pharmacy does not qualify as a "covered entity" under these legally binding definitions.

Furthermore, under a contract pharmacy arrangement, the unit of the drug is *purchased* at the 340B price by the covered entity (which, again, is the only type of entity entitled to purchase a covered outpatient drug at the 340B price), but is *shipped* to the contract pharmacy. The statute provides no basis on which a covered entity may force a manufacturer to ship a unit that it purchases at the 340B price to a contract pharmacy, as opposed to the covered entity itself. The statute entitles a covered entity only to purchase from a manufacturer a covered outpatient drug at the 340B price. It in no way entitles the covered entity to dictate to the manufacturer the shipping destination for a purchased unit.

The agency's current views on contract pharmacy arrangements as expressed in the recent Advisory Opinion are not supported by any language in the 340B statute or the 340B PPA. OGC correctly recognizes 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." However, under any established definition of the term "offer," the purchaser (here, the covered entity) does not have a right to unilaterally dictate the terms of the offer, such as, of relevance here, the location of shipment. As the Advisory Opinion itself correctly notes, a 340B sale is an "*arrangement* between the manufacturer and covered entity" that constitutes "a *straightforward sale*" (emphases added). But, where a manufacturer is required by statute to offer a drug for purchase by a covered entity at the 340B price, the purchaser is not entitled by statute to establish the non-pricing terms of the "offer … for purchase." Otherwise, the transaction would not be a "straightforward sale" and would involve no purchasing "arrangement" at all, rendering meaningless the statute's language that a manufacturer "must offer" a drug "for purchase."

2. A manufacturer is not required to honor a virtual inventory model

The notion that a sale through a contract pharmacy arrangement triggers the 340B discount is incorrect for another reason. Such an arrangement necessarily employs a "virtual inventory model"—a scheme that enables a 340B-purchased unit to be dispensed to an individual who is *not* a patient of the covered entity, in direct violation of the statutory prohibition on diversion.

The 340B statute defines the term "covered entity" to include only an entity that, among other things, is compliant with the statute's diversion prohibition.[10] That statutory requirement prohibits a covered entity from reselling or transferring a unit of a covered outpatient drug purchased at the 340B price to an individual who is not a patient of the covered entity: "With respect to any covered outpatient drug that is subject to [a 340B PPA], a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."[11] Thus, the 340B price for a given unit of a covered outpatient drug is mandated only if the unit is to be dispensed to an individual who is a patient of the covered entity.

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[9] PPA § 1(e)(1).

[10] 42 U.S.C. § 256b(a)(4).

[11] *Id.* § 256b(a)(5)(B). HRSA has defined the term "patient" in guidance. *See* 61 Fed. Reg. 55,156, 55,158 (Oct. 24, 1996).

Because, at the time a drug is dispensed to an individual, a contract pharmacy cannot know whether the individual is a patient of a covered entity, contract pharmacy arrangements are necessarily predicated upon a "virtual inventory model," pursuant to which the covered entity retrospectively determines if a unit of product was eligible for the 340B price *after* the unit of product is dispensed, and then replenishes its inventory with a unit purchased at such price, as opposed to the commercial price. The replenishment unit then is treated as if it had been purchased at the commercial price, even though it was in fact purchased at the 340B price—meaning that such unit is made available for dispensing to *any* individual, including an individual who is not a patient of the covered entity, the diversion prohibition notwithstanding. The cycle then repeats itself. Because offering the 340B discount to a covered entity via a contract pharmacy arrangement using the virtual inventory model allows a 340B-purchased unit to be dispensed to an individual who is not a patient of the covered entity—in contravention of the diversion prohibition—a manufacturer has no obligation to make such an offer under the terms of the 340B statute.[12]

While Novartis has no obligation to honor a virtual inventory model—and, accordingly, a contract pharmacy arrangement, which is necessarily predicated on such a model—Novartis has nonetheless elected to do so, albeit within the reasonable parameters set forth under its contract pharmacy policy.

* * *

For these reasons, the statute does not require manufacturers to offer the 340B discount in the context of a sale under a contract pharmacy arrangement. Nonetheless, Novartis has voluntarily agreed to continue to honor grantee covered entity contract pharmacy arrangements as well as hospital covered entity contract pharmacy arrangements to the extent that the contract pharmacy is located within a 40-mile radius of the hospital (i.e., in the hospital's community) or an exception is granted.[13] This geographic restriction represents a common-sense approach toward ensuring that the 340B program benefits *the hospitals' patients*, as the statute specifically requires.

B. Novartis's Policy Does Not Discriminate

Your letter suggests that Novartis's policy may violate the requirement that manufacturers provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs, including the "manner in which 340B drugs are made available to covered entities." We disagree. Novartis does not discriminate between covered entities and non-covered entities with respect to contract pharmacy or any comparable arrangements. Under its 340B contract pharmacy policy, Novartis treats covered entities with 340B contract pharmacy arrangements and non-covered entities with comparable bill-to/ship-to arrangements similarly.

C. The Enforcement Measure Threatened In Your Letter Is Neither Appropriate Nor Lawfully Available

For all the reasons stated above, Novartis is not in violation of the 340B statute, and no penalties or remedies of any sort are warranted based on the facts presented here. That is particularly true with respect to the threatened assertion of civil monetary penalties (CMPs) as spelled out in your letter.

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[12] A comparable concern exists with regard to the group purchasing organization prohibition. *See* 42 U.S.C. § 256b(a)(4)(L)(iii), (M).

[13] *See* Ex. 1.

Even putting aside the lack of a violation of the statute or other unlawful act, CMPs would be neither appropriate nor legally available in the present case.

By statute and rule, CMPs may be assessed only when a manufacturer "knowingly and intentionally" charges a covered entity more than 340B ceiling price for a covered outpatient drug—i.e., engages in "overcharging."[14] Novartis has not "overcharged" any covered entities, let alone done so in a manner that is knowing and intentional. Under the Novartis 340B contract pharmacy policy, when a replenishment order is initiated between a covered entity and its wholesaler via a non-qualifying contract pharmacy arrangement, the order is declined by the wholesaler. A covered entity is not charged *any* price, let alone overcharged, and Novartis continues to otherwise offer the covered outpatient drug to the covered entity at the 340B price, including through qualifying contract pharmacy arrangements.

As for the "knowingly and intentionally" element of a CMP violation, Novartis has acted at all times in good faith, based on a reasonable, legally defensible understanding of the plain language of the 340B statute. Novartis provided HRSA with advance notice of its policy in November 2020, before implementation, and explained its legal justification for the policy in that notice. Novartis similarly gave covered entities advance notice of its intended course of action. There simply is no basis for asserting that Novartis has engaged in a "knowing and intentional" violation of the statute under the facts presented here.

* * *

Novartis is confident that its contract pharmacy policy fully complies with all applicable laws and regulations. Moreover, its policy is fully consistent with the main goal of the 340B program—to serve vulnerable patients within hospital covered entities' local communities.

We respectfully request that HRSA withdraw its threat of enforcement as spelled out in your May 17, 2021 letter immediately—and in any event **by May 31, 2021**, particularly in light of your June 1, 2021 deadline.

We look forward to your prompt response.

Best regards,

Alice Valder Curran
Partner
D: 202-637-5997

[14] 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. § 10.11(a).

EXHIBIT 1

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Novartis Pharmaceuticals
One Health Plaza
East Hanover, NJ 07936

November 13, 2020

BY ELECTRONIC MAIL (Krista.Pedley@hrsa.hhs.gov) AND FEDERAL EXPRESS

Rear Admiral Krista M. Pedley, PharmD, MS, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

Re: Novartis Pharmaceuticals Corporation 340B Contract Pharmacy Policy

Dear Rear Admiral Pedley:

I am writing on behalf of Novartis Pharmaceuticals Corporation ("Novartis") in follow-up to our communication on August 17, 2020. We wish to disclose to the Health Resources and Services Administration ("HRSA") new steps that Novartis is taking as part of its 340B Drug Pricing Program ("340B program") integrity initiative. After careful consideration, we have decided to implement a more focused, criteria-based approach to contract pharmacy arrangements that will start to shift the 340B program back to its intended focus on the patients of covered entities, and thereby put the program on a pathway toward long-term sustainability.

As we had indicated by e-mail to you dated October 30, 2020, and as more fully described below, beginning on November 16, 2020, Novartis will continue to honor hospital contract pharmacy arrangements so long as the contract pharmacy is located within a 40-mile radius of the parent hospital. This policy will not restrict the number of contract pharmacies that a hospital may establish within its own community (as defined by the 40-mile radius). All federal grantee covered entities are exempt from the new policy, and these covered entities may continue to acquire 340B product through contract pharmacy arrangements exactly as before.

I. The Novartis Policy Is Necessary Because the Explosive Growth of Contract Pharmacy Arrangements Has Greatly Exacerbated Ongoing Systemic Program Integrity Concerns

Despite contract pharmacy arrangements having no basis in law, as detailed below, the number of contract pharmacy arrangements by hospitals has grown exponentially, with little evidence that patients are benefiting as a result. These contract pharmacies are often located hundreds or

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even thousands of miles from their associated hospital covered entity and the community that it serves. As explained in a recent study by Berkeley Research Group ("BRG"), "contract pharmacy participation grew 4,228 percent between April 2010 and April 2020," with "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" now participating, and the number of contract pharmacy arrangements by hospitals increasing from 193 to more than 43,000 during this period.[1] Underscoring the profit-driven nature of this growth, the BRG study found that "340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines," which is "more than three times greater than the average margin realized by independent pharmacies."[2] In a subversion of program intent, the 340B savings generated by this profit margin "are now distributed across a vertically integrated supply chain that includes not just the covered entities but also pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups."[3] And, as a result of the complete absence of transparency, it is unclear how much of the 340B program savings is absorbed by these commercial actors.[4]

This explosive growth of contract pharmacy arrangements has greatly exacerbated longstanding systemic 340B program integrity concerns. Indeed, federal agencies have documented this program integrity risk. For example, in 2015, the Department of Health and Human Services Office of Inspector General ("OIG") concluded that "[c]ontract pharmacy arrangements . . . create complications in preventing duplicate discounts."[5] OIG also found that "most covered entities in [the] study do not conduct all of the oversight activities recommended by HRSA . . . . Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance. Without adequate oversight, the complications created by the contract pharmacy arrangements may introduce vulnerabilities to the 340B Program."[6] And, in 2018, GAO found that "weaknesses in HRSA's oversight impede its ability to ensure compliance with 340B Program requirements at contract pharmacies," and that "HRSA's audit process does not adequately identify compliance issues, nor does it ensure that identified issues are corrected."[7]

In particular, the explosive growth of contract pharmacy arrangements has significantly increased the inherent risk of non-compliance with the diversion prohibition. By their nature,

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[1] BRG, For-Profit Pharmacy Participation in the 340B Program, at 4 (Oct. 2020), *available at* https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

[2] *Id.* at 7.

[3] *Id.*

[4] A recent review by the Government Accountability Office ("GAO") of a comparatively small sample of only thirty contract pharmacy agreements found that, in some cases, the contract pharmacy was entitled to a flat fee of $15 for each prescription, plus twenty percent of the reimbursement for the drug, by both the patient and her payer. GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, No. GAO-18-480, at 51 (Jun. 2018), *available at* https://www.gao.gov/assets/700/692697.pdf.

[5] OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, No. OEI-05-13-00431 at 16 (Feb. 2014) (available at https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf).

[6] *Id.*

[7] GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, No. GAO-18-480, at 45 (Jun. 2018) (available at https://www.gao.gov/assets/700/692697.pdf).

contract pharmacy arrangements pose such risk, as it is unknown at the time of the dispensing whether an individual is a patient of the covered entity. This necessitates a retrospective determination, and there is no transparency into whether or how this determination is made. Where a covered entity makes arrangements with pharmacies well outside of its community, this risk of diversion is amplified by orders of magnitude. Simply put, because there is no reasonable proximity between such pharmacies and the covered entity (i.e., where patients of the covered entity obtain services), such pharmacies are highly unlikely to dispense drugs to patients of the covered entity in fact. Thus, such arrangements cannot be squared with the statutory prohibition on diversion – one of the Congressionally established cornerstones of the 340B program that mark its outer boundary.[8]

II. The Novartis Policy's Modest Steps Will Start to Redress the Significant Concerns Posed by the Contract Pharmacy Program

Novartis takes seriously its obligations under the 340B program and remains committed to supporting its core mission – to serve uninsured, low-income, and other vulnerable patients. As set forth below, our intended actions are entirely consistent with this mission, even as they start to redress the well-documented, long-standing, and significant program integrity risks occasioned by the contract pharmacy program in its current form.

Under the Novartis approach, we will continue to honor all contract pharmacy arrangements of all federal grantee covered entities, i.e., there will be no restriction on such arrangements. Federal grantee covered entities are subject to independent requirements that encourage them to share the benefits of the 340B program with their patients.[9] Thus, the unintended financial incentives to maximize 340B utilization in order to maximize profit, potentially at the expense of program integrity, are less pronounced where federal grantee covered entities are concerned.

For hospital covered entities, beginning November 16, 2020, with respect to all Novartis covered outpatient drugs, we will continue to honor contract pharmacy arrangements to the extent that the contract pharmacy is within a 40-mile radius of the hospital. There will not be a limit on the number of contract pharmacies within that radius with which the hospital may have an arrangement. This geographic restriction represents a common-sense approach toward ensuring that the 340B program benefits the hospital's patients, as intended. In adopting the 40-mile radius as a proxy for the community of patients served by the hospital, we were informed by Medicare provider-based policy governing hospitals and affiliated facilities, which generally utilizes a 35-mile radius.[10]

Additionally, if a hospital covered entity were to bring a special circumstance to our attention, e.g., if the hospital were to have no in-house pharmacy and our approach would leave it with no contract pharmacy, we intend to work in good faith with the hospital to ensure appropriate access to a contract pharmacy.

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[8] Public Health Service Act (PHSA) § 340B(a)(5)(B).

[9] *See, e.g.*, PHSA § 330(k)(3)(G)(iii).

[10] *See* 42 C.F.R. § 413.65(e)(3)(i).

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Notably, when Novartis does not recognize a contract pharmacy under its approach, Novartis will not convert a 340B order to a commercial order. Rather, Novartis will simply decline to fill the 340B order, and the hospital will not be charged. In addition, under the Novartis approach, covered entities will not be disadvantaged relative to non-covered entities. That is because Novartis does not have commercial arrangements that are equivalent to 340B contract pharmacy arrangements.

Most importantly, the Novartis policy will not harm patient access to medicines, because the Novartis policy applies to arrangements between covered entities and contract pharmacies, and not to patients. Patients of a covered entity will still be able to obtain 340B-purchased drugs from a contract pharmacy in the community.

Additionally, in the interest of improving transparency and program integrity (by mitigating the risk of duplicate discounts), we are encouraging covered entities to upload all contract pharmacy claims data to the Second Sight Solutions' 340B ESP™ web-based platform. This action is not required, however, and declining to take this action will not have an effect on 340B purchasing through contract pharmacies or otherwise.

Novartis believes that these steps, taken together, are necessary to help ensure the integrity of the 340B program, and therefore protect the sustainability of this critical program.

III. The Novartis Contract Pharmacy Approach Is Fully Consistent With the Law

A. Legal Background

HRSA has issued guidance providing that a covered entity may contract with one or more pharmacies for the purpose of dispensing 340B-purchased drugs to its patients on its behalf.[11] HRSA first issued contract pharmacy guidance in the mid-1990s.[12] After soliciting comment on a proposed notice,[13] HRSA issued a final notice implementing its original contract pharmacy policy.[14] In that 1996 final notice, HRSA stated that it was implementing its policy because, in its view, it would defeat the purpose of the 340B program if a covered entity without an in-house pharmacy could not use an outside pharmacy to dispense 340B-purchased drugs to its patients on its behalf.[15] Accordingly, HRSA provided that a covered entity could use either an in-house

[11] HRSA, *Contract Pharmacy: Important Tips* (Aug. 2016) (available at https://www.hrsa.gov/opa/updates/2016/august.html) ("Covered entities participating in the 340B Program are permitted to use contract pharmacies for the dispensing of 340B drugs, in addition to or in lieu of an in-house pharmacy.").

[12] *See* 75 Fed. Reg. 10,272, 10,272-73 (Mar. 5, 2010) (setting forth the history of HRSA's contract pharmacy guidance).

[13] 60 Fed. Reg. 55,586 (Nov. 1, 1995).

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

[15] *Id.* at 43,550.

pharmacy or, if the covered entity did not have an in-house pharmacy, a single contracted outside pharmacy site.[16]

In issuing the 1996 final notice, HRSA did not expressly state that manufacturers were obligated to honor contract pharmacy arrangements. Nor did HRSA identify any statutory basis for its policy. Rather, the agency stated only that "[t]he 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."[17] It then stated that the 340B statute does not preclude a "[covered] entity direct[ing] the drug shipment to its contract pharmacy."[18] HRSA also stated that, "[a]s 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."[19]

In 2010, HRSA issued a revised notice that significantly expanded its contract pharmacy policy.[20] Under that revised notice, which remains in effect today, covered entities are permitted to use a contracted outside pharmacy, even if they have an in-house pharmacy.[21] In addition, covered entities are permitted to use an unlimited number of contracted outside pharmacy sites, so long as there is a written contract between the covered entity and the pharmacy, and the contract pharmacy meets certain limited compliance and certification requirements.[22]

The 2010 revised notice, like its 1996 predecessor, does not expressly state that manufacturers are obligated to honor contract pharmacy arrangements or identify any statutory basis for the contract pharmacy policy. To the contrary, in responding to a commenter that had argued that a notice-and-comment rulemaking was required to adopt the policy, HRSA explained that it was not required to proceed via such rulemaking because its contract pharmacy policy does not "impose additional burdens upon manufacturers []or create[] any new rights for covered entities under the law."[23]

As discussed above, HRSA's revised contract pharmacy policy has resulted in the rapid growth of contract pharmacy arrangements, with an attendant increase in the risk of program non-compliance.

B. Legal Analysis

Manufacturers are not legally bound to abide by HRSA's contract pharmacy policy, which merely constitutes agency guidance, and not a binding legal standard. The policy appears

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16 *Id.* at 43,551.
17 *Id.* at 43,549.
18 *Id.* at 43,549-50.
19 *Id.* at 43,550.
20 75 Fed. Reg. at 10,277 (HRSA solicited comment on a proposed notice before issuing this revised notice).
21 *Id.* at 10,275 (stating that covered entities "with an in-house pharmacy could use any acceptable contract pharmacy arrangement to supplement the in-house pharmacy").
22 *Id.* at 10,277-78.
23 *Id.* at 10,273. HRSA also failed to provide a convincing rationale for its departure from the 1996 contract pharmacy guidance.

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nowhere in the 340B statute.[24] Moreover, it appears nowhere in any regulation implementing the 340B statute.[25] Rather, the policy is set forth only in guidance which, by its nature, is not legally binding.[26] This is a black letter principle of administrative law, and it is a universally accepted proposition. HRSA itself has correctly acknowledged it – publicly, repeatedly, and recently.[27] Covered entities have recognized it as well.[28]

Notably, HRSA has not only embraced the general notion that guidance is not legally binding, but has specifically acknowledged that this is the case with respect to its contract pharmacy policy.

First, HRSA denominated its contract pharmacy policy issuance as a mere "notice."[29] In addition, HRSA characterized its contract pharmacy policy as a mere "interpretive rule [or] statement of policy."[30] This is significant because an agency's own characterizations are a factor that courts consider in determining whether its policies are legally binding.[31]

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[24] The same holds true with respect to the Pharmaceutical Pricing Agreement (and its addendum) implementing the 340B statute.

[25] Indeed, there could be no such regulation: The 340B statute does not grant HRSA general rulemaking authority, and instead grants HRSA rulemaking authority only with respect to "(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. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014).

[26] *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (informal interpretations do not "carry the force of law" and therefore are not entitled to "judicial deference"); *Chrysler Corp. v. Brown*, 441 U.S. 281, 296 & n.31 (1979) (informal interpretations have no power to bind regulated parties because they do not carry the force and effect of law); *Am. Tort Reform Ass'n v. Occupational Health & Safety Admin.*, 738 F.3d 387, 393 (D.C. Cir. 2013) ("When an agency issues an interpretative rule or statement, an interpretative guideline, or a policy statement with respect to a matter that it is not empowered to decide, the interpretative rule, statement, guideline, or policy statement merely informs the public of the agency's views on the subject. It does not, however, create 'adverse effects of a strictly legal kind' because it cannot 'command anyone to do anything or to refrain from doing anything.'") (citing and quoting *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 809 (2003)).

[27] *See also* Executive Order on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (Oct. 19, 2019) (available at https://www.whitehouse.gov/presidential-actions/executive-order-promoting-rule-law-transparency-fairness-civil-administrative-enforcement-adjudication/) ("When an agency takes an administrative enforcement action, engages in adjudication, or otherwise makes a determination that has legal consequence for a person, it must establish a violation of law by applying statutes or regulations. The agency may not treat noncompliance with a standard of conduct announced solely in a guidance document as itself a violation of applicable statutes or regulations."); Executive Order on Promoting the Rule of Law Through Improved Agency Guidance Documents (Oct. 9, 2019) (available at https://www.whitehouse.gov/presidential-actions/executive-order-promoting-rule-law-improved-agency-guidance-documents/) ("[G]uidance documents lack the force and effect of law, except as authorized by law or as incorporated into a contract.").

[28] *See Genesis Health Care, Inc. v. Azar*, No. 4:19-cv-1531-RBH (D.S.C.).

[29] 75 Fed. Reg. at 10,272.

[30] *Id.* at 10,273.

[31] *See Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999) ("To determine whether a regulatory action constitutes promulgation of a regulation, we look to three factors: (1) the Agency's own characterization of the action; (2) whether the action was published in the Federal Register or the Code of Federal Regulations; and (3) whether the action has binding effects on private parties or on the agency.").

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Second, HRSA's contract pharmacy policy nowhere expressly states that manufacturers are obligated to honor contract pharmacy arrangements. To the contrary, in issuing the 2010 revised notice, HRSA stated that its contract pharmacy policy does not "impose additional burdens upon manufacturers []or create[] any new rights for covered entities under the law."[32] This is significant because legally binding rules create new obligations or rights.[33] By conceding that its contract pharmacy policy does not do so, HRSA conceded that the policy is not legally binding.

Finally, HRSA has expressly stated that it does not have authority to enforce the policy.[34]

HRSA's acknowledgement that its contract pharmacy policy is not legally binding reflects the fact that the 340B statute nowhere can be read to require a manufacturer to ship a covered outpatient drug purchased by a covered entity to the covered entity's contract pharmacy for dispensing to the covered entity's patient on the covered entity's behalf. There is simply no statutory text supporting the contract pharmacy policy. The statute entitles a covered entity only to purchase a covered outpatient drug from the manufacturer at the 340B price. It in no way suggests that the covered entity is also entitled to dictate to the manufacturer the destination of shipment, particularly if a third party. Rather, so long as the manufacturer ships to a reasonable destination, such as the covered entity itself, the manufacturer cannot be held out of compliance with the statute.

While Novartis is not legally bound to honor contract pharmacy arrangements at all, Novartis currently does not propose to cease to honor contract pharmacy arrangements altogether, notwithstanding the patent abuse engendered by the contract pharmacy expansion. Rather, we are willing to recognize such arrangements within reasonable limits. Thus, we have adopted the revised policy to impose a set of limits that seek to strike a reasonable balance. In short, we will honor contract pharmacy arrangements on the reasonable terms of our approach set forth above.

* * * * *

[32] 75 Fed. Reg. at 10,273.

[33] *See Chrysler Corp.*, 441 U.S. at 296 & n.31; *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (informal interpretations cannot "impose new obligations or prohibitions or requirements on regulated parties"); *Batterton v. Marshall*, 648 F.2d 694, 702 (D.C. Cir. 1980) (unlike a legally binding rule, "[n]on-binding . . . actions or statements are not determinative of issues or rights addressed. They express the agency's intended course of action . . . [or] its tentative view of the meaning of a particular statutory term . . . . They do not, however, foreclose alternate courses of action or conclusively affect rights of private parties.").

[34] Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (Jul. 9, 2020) (available at https://340breport.substack.com/p/hrsa-says-its-340b-contract-pharmacy) (quoting HRSA as stating, "The 2010 [contract pharmacy] guidance is still in effect. However, guidance is not legally enforceable. Regarding the 340B Program's guidance documents, HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute. Without comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program.").

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We ask that, if you have any legal concern with the Novartis approach to contract pharmacy arrangements, you communicate such concern to us in writing as soon as possible. If you have any questions about our approach, please contact me at (862) 778-1590 or Daniel.Lopuch@Novartis.com. We would be happy to make time to discuss any questions at your convenience. We look forward to continuing to work together to further strengthen this important program.

Sincerely,

Dan Lopuch
VP, Managed Markets Finance
Novartis Pharmaceuticals Corporation

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Novartis Pharmaceuticals Corporation

Plaintiff(s)

v.

Diana Espinosa, in her official capacity as Acting Administrator, Health Resources and Services Administration; and Xavier Becerra, in his official capacity as Secretary of U.S. Department of HHS

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Diana Espinosa
Acting Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20852

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Catherine E. Stetson
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: 05/31/2021

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

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Novartis Pharmaceuticals Corporation

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Diana Espinosa, in her official capacity as Acting Administrator, Health Resources and Services Administration; and Xavier Becerra, in his official capacity as Secretary of U.S. Department of HHS

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Merrick Garland
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-001

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Catherine E. Stetson
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: 05/31/2021

Signature of Clerk or Deputy Clerk

Civil Action No.

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

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Date: _____

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UNITED STATES DISTRICT COURT

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District of Columbia

Novartis Pharmaceuticals Corporation

Plaintiff(s)

v.

Diana Espinosa, in her official capacity as Acting Administrator, Health Resources and Services Administration; and Xavier Becerra, in his official capacity as Secretary of U.S. Department of HHS

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Catherine E. Stetson
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: 05/31/2021

Signature of Clerk or Deputy Clerk

Civil Action No.

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❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

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Date: _____

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Diana Espinosa, in her official capacity as Acting Administrator, Health Resources and Services Administration; and Xavier Becerra, in his official capacity as Secretary of U.S. Department of HHS

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Channing D. Phillips
Acting United States Attorney for the District of Columbia
United States Attorney's Office
555 4th Street, NW
Washington, DC 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Catherine E. Stetson
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: 05/31/2021

Signature of Clerk or Deputy Clerk

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❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

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My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

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