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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.

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.").

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.

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[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.").

NOVARTIS

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