UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware Street
Indianapolis, IN 46225,

and

LILLY USA, LLC,
1500 South Harding Street
Indianapolis, IN 46221,

Plaintiffs,

v.

NORRIS COCHRAN, in his official capacity as Acting Secretary of Health & Human Services,
Office of the Secretary
200 Independence Avenue, S.W.
Washington, D.C. 20201,

ROBERT P. CHARROW, in his official capacity as General Counsel of Health & Human Services
Office of the General Counsel
200 Independence Avenue, S.W.
Washington, D.C. 20201,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington D.C. 20201,

DIANA ESPINOZA, in her official capacity as Acting Administrator of the Health Resources and Services Administration
5600 Fishers Lane,
Rockville, MD 20852,

and

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane,
Rockville, MD 20852,

Defendants.

No. 1:21-cv-81-SEB-MJD

Document Electronically Filed

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Federal Rule of Civil Procedure 65(a), Plaintiffs Eli Lilly and Company and Lilly USA, LLC (collectively, "Lilly") hereby moves this Court for a preliminary injunction barring Defendants, as well as their officers, agents, employees, attorneys, and all persons in active concert or participation with them who receive actual notice of the Order, from implementing or enforcing against Lilly the Administrative Dispute Resolution Regulation published at 85 Fed. Reg. 80,632 and codified at 42 C.F.R. §§ 10.20-24. This Motion is based upon all the files, records, and proceedings herein, including the accompanying memorandum of law and supporting declarations, as well as any evidence that may be submitted at a hearing on the motion. Lilly requests that the Court require no security because Defendants will suffer no injury from the issuance of a preliminary injunction.

Dated: January 25, 2021

Respectfully submitted,

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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on **January 25, 2021**, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system. I further certify that copies will be mailed by U.S. mail to the following addresses:

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MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

In setting up the 340B Drug Pricing Program ("340B Program" or "Program"), under which pharmaceutical manufacturers must offer certain hospitals and clinics known as "covered entities" deeply discounted pricing as a condition of participating in certain Medicare and Medicaid programs, Congress recognized the potential for abuse if other, attenuated entities could demand the discounted pricing solely intended to aid the needy. Congress thus made clear that only the covered entities—a narrow class of 15 specifically enumerated types of non-profit healthcare providers—could demand these steep discounts, and the agencies responsible for administering the Program followed that construct for nearly three decades. But all of that is out the window now, as those same agencies have permitted big-business "contract pharmacies" to hijack this carefully circumscribed program and siphon from it hundreds of millions of dollars in profit, all at the expense of the very individuals the Program was intended to serve, as well as manufacturers, insurers, and patients who all now subsidize the pharmacies' profits.

Despite nothing changing in the statute about the limitations regarding covered entities, the U.S. Department of Health and Human Services ("HHS") recently concluded that manufacturers must offer 340B discounts not just to covered entities, but also to those for-profit pharmacies that appear nowhere on Congress's list and that rarely (if ever) pass along substantial savings to patients. Worse still, after sitting on its hands for nearly a decade despite a congressional mandate to act within six months, HHS has now published and put into effect a final rule requiring an unconstitutional "administrative dispute resolution" process for 340B pricing disputes between manufacturers and covered entities. That rule flagrantly violates the United States Constitution in at least two ways. First, it empanels decision-makers to act as "principal" Executive officers without appointment by the President and confirmation by the Senate, in violation of Article II's Appointments Clause. Second, it vests those decision-makers with the power to adjudicate

disputes involving private rights and issue final judgments for money damages and equitable relief, usurping the exclusive power of the judiciary, in violation of Article III. What is more, the final rule creates a decidedly one-sided process that stacks the deck against manufacturers, all through a hasty enactment by HHS that flouted the procedural requirements of notice and comment.

None of that is remotely consistent with the Administrative Procedure Act ("APA"), let alone the Constitution. And all of it is currently causing Plaintiffs Eli Lilly and Company and Lilly USA, LLC (together, "Lilly") irreparable harm that will only get worse with time. Although Lilly continues to offer all covered entities all 340B discounts as the statute requires, and even continues to allow covered entities that lack an in-house pharmacy to partner with outside contract pharmacies to ensure that patients can get access to the medicines they need, Lilly will not offer such discounts to for-profit contract pharmacies as a general rule. In response, covered entities and their pharmacy partners have rushed to ask the decision-makers presiding over this dubious scheme to penalize Lilly to the tune of ***billions of dollars***, including the potential loss of Lilly's ability to participate in Medicaid and Medicare Part B at all—all before Lilly even has its day in court. The issues in this case thus go to the core of our constitutional system, and the need for a preliminary injunction preventing the enforcement of this regime could not be clearer.

STATEMENT OF FACTS

I. The 340B Program And Contract Pharmacies

A. Congress Establishes the 340B Program to Benefit the Needy.

In 1992, Congress established a drug-discount regime called the 340B Program, named for Section 340B of the Public Health Service Act. *See* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967. As explained below, the 340B Program requires pharmaceutical manufacturers to provide steep discounts on their products to certain "covered entities" that serve disadvantaged populations. *See* 42 U.S.C. § 256b(a). The purpose of the 340B Program was to "reduce

pharmaceutical costs for safety-net medical providers and the indigent populations they serve" by "creat[ing] a low-cost source of pharmaceutical medication for the indigent patients themselves." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 WM. & MARY L. REV. 637, 638 (2015); *see* H.R. Rep. No. 102-384 (II), at 12 (1992) (340B "provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans").

An important obligation under the Program is known as the "must offer" requirement. Under 42 U.S.C. § 256b(a)(1), pharmaceutical manufacturers 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." The resulting 340B "ceiling prices," which are calculated according to a prescribed statutory formula, *see id.* § 256b(a)(1), (a)(4), (b)(1), are significantly lower than what other purchasers would pay and can even be as low as one penny per pill. The Program thus requires pharmaceutical manufacturers, under certain narrow and carefully defined circumstances, to give their property to other private parties without receiving equivalent compensation.

Manufacturers have no real option but to participate in the 340B Program. Under federal law, they cannot receive coverage or reimbursement for their products under Medicaid and Medicare Part B unless they "opt into" the 340B Program. *Astra U.S.A., Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). That is no choice at all, since Medicaid and Medicare not only "touch[] the lives of nearly all Americans," *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019), but contribute a significant portion of manufacturers' annual revenues. *See Astra*, 563 U.S. at 113.

To enter the Program, manufacturers are required to sign a form contract with HHS known as the Pharmaceutical Pricing Agreement ("PPA"). *Id.*; *see* 42 U.S.C. § 1396r-8(a)(1), (5). A PPA

is not an ordinary contract. PPAs are entirely composed by HHS, "have no negotiable terms," and "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Astra*, 563 U.S. at 118. "The statutory and contractual obligations, in short, are one and the same." *Id.* The government may terminate a PPA—and with it a manufacturer's ability to receive coverage and reimbursement under Medicare and Medicaid—if it determines that a manufacturer has failed to comply with its 340B obligations. *See* 42 U.S.C. 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412-65,413 (Dec. 12, 1996); PPA §§ IV(c), VI(c).

Cognizant of the constitutional limits on forcing private parties to effectively subsidize other private parties, however, Congress took pains to define the universe of "covered entities" narrowly. The 340B statute not only defines the term to include only 15 specifically enumerated types of non-profit healthcare providers (such as Federally Qualified Health Centers, non-profit children's hospitals, and other non-profit healthcare clinics serving similar populations), but makes clear that only these specifically enumerated types of entities are entitled to 340B discounts. *See* 42 U.S.C. § 256b(a)(4). Entities not included on Congress's list of covered entities, such as for-profit hospitals or big businesses like Walgreens and CVS, thus have no legal basis to demand prescription medications or other product from manufacturers at 340B prices. *See id.*

In addition to narrowly circumscribing the universe of private parties eligible to demand discounts from manufacturers, Congress also imposed protections designed to prevent covered entities from abusing their special discount. Congress first prohibited covered entities from requesting "duplicate discounts or rebates," *id.* § 256b(a)(5)(A), which means that covered entities may not request both a 340B discount and a Medicaid rebate for the same drug. And to help ensure that covered entities and others do not inappropriately benefit from the opportunity of 340B price arbitrage, Congress further forbade any "covered entity" from engaging in "diversion," *i.e.*, the

practice of "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). In other words, covered entities may not transfer, sell, or otherwise arbitrage the discounted drugs to any person or entity except their own patients.

B. Defendants Unlawfully Expand the 340B Program to Protect For-Profit "Contract Pharmacies" Not Covered by the Statute.

Congress gave HHS specific, but limited, authority to implement and administer the 340B Program. (HHS, in turn, has delegated these responsibilities to the Health Resources and Services Administration ("HRSA").) HHS must notify manufacturers of the identity of covered entities, *see id.* § 256b(a)(9), monitor diversion by covered entities, *see id.* § 256b(d)(1)(B)(vi), and audit both covered entities and manufacturers, *see id.* But Congress did not give HHS any substantive rulemaking authority to define, much less expand, the narrow scope of the 340B Program itself. Instead, Congress carefully confined HHS's limited 340B rulemaking authority to three specific areas: (1) establishing an administrative dispute resolution ("ADR") process to resolve disputes between manufacturers and covered entities; (2) issuing standards for calculating 340B ceiling prices; and (3) imposing monetary penalties for overcharging covered entities. *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014); *see* 42 U.S.C. § 256b(d)(1)(B)(vi). Defendants thus have no lawful authority to expand the universe of"covered entities" that may demand to receive 340B discounts.

For the first few years of the Program, covered entities purchased and dispensed 340B drugs exclusively through in-house pharmacies. But in 1996, HRSA began allowing covered entities that lacked an in-house pharmacy to contract with an outside pharmacy to dispense 340B drugs to the covered entity's patients. *See* 61 Fed. Reg. 43,549 (Aug. 23, 1996). That guidance restricted covered entities to just one contract pharmacy, and—consistent with HRSA's narrow authority—imposed no requirement on manufacturers to offer 340B discounts to those contract

pharmacies. Then, in 2010, HRSA authorized covered entities to use as many contract pharmacies as they wanted, even if they have an in-house pharmacy. *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010). Again, though, HRSA made clear that this allowance imposed no requirement on manufacturers.

Recently, however, the Defendants have behaved as if they ***do*** have the power to alter Congress's design and expand the 340B Program beyond its carefully drawn limits. Defendants have undertaken final agency action that requires manufacturers to offer 340B discounts to so-called "contract pharmacies"—generally, large for-profit corporations like CVS and Walgreens that have contracted with covered entities. Contract pharmacies neither appear on the statutory list of covered entities nor resemble any of the 15 categories of entities Congress enumerated. Yet, on December 30, 2020, Defendants issued an "Advisory Opinion" that purports to "obligate" each "drug manufacturer in the 340B Program … to deliver its covered outpatient drugs to [ ] contract pharmacies and to charge … no more than the 340B ceiling price for those drugs" whenever a contract pharmacy purports to act as a covered entity's common-law "agent." U.S. Dep't of Health & Human Servs. Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 1 (Dec. 30, 2020), https://bit.ly/357nqfk ("December 30 Decision") In issuing that decision, Defendants did not address the fact that the statute contemplates that certain third parties may step into the shoes of covered entities in limited circumstances, but contract pharmacies (which are retailers) are not among them. *See* 42 U.S.C. § 256b(d)(3)(B)(vi) (trade "associations or organizations … of which the covered entities are members"); *id.* § 256b(d)(1)(B)(v) ("wholesalers"); *id*. § 256b(d)(2)(B)(iv) ("distributors").

In addition to being *ultra vires*, Defendants' decision to "obligat[e]" manufacturers to offer 340B discounts to contract pharmacies is a terrible idea. In 2018, the House Energy and Commerce Committee found that nearly half (and in some years more than half) of covered entities audited

by HRSA unlawfully sold or transferred 340B drugs to non-patients, in violation of the statutory prohibition on diversion. *See* House Energy and Commerce Committee, *Review of the 340B Drug Pricing Program*, at 38 (Jan. 2018). Adding contract pharmacies to the mix only exacerbates the problem. Indeed, even HRSA has acknowledged that contract pharmacies violate the prohibitions on diversion and duplicate discounts at outsized and staggering rates. *See, e.g.*, HRSA, *340B Program Integrity, Audits of Covered Entity Results* (Apr. 2020) (consistently finding dozens of instances of diversion involving contract pharmacies each year, even though HRSA audits fewer than 200 total entities annually), https://bit.ly/3fcAALF; *see also* GAO, *Discount Drug Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 10-13 (June 2018), https://bit.ly/3kJ7eGa; GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, GAO-11-836, at 28 (Sept. 2011), https://bit.ly/2JvWKgJ. Making matters worse, the government has consistently found that "large numbers of low-income patients" do not receive ***any*** discounts when they acquire drugs through contract pharmacies. H.R. Rep. No. 102-384, at 10. Rather, "uninsured patients" typically "pay the full non-340B price for their prescription drugs at contract pharmacies," HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 2014), https://bit.ly/2LwZrzl, even when they are fully eligible for 340B discounts and even when the contract pharmacy is purporting to act as a covered entity's agent.

These abuses should surprise no one. The 340B Program is the rare federal program under which one private party directly obtains another's property (here, the manufacturer's drugs) below the market price. And decades of experience have proven that the discounts manufacturers must offer to covered entities far too often fail to translate into savings for the vulnerable and uninsured; instead, the discounts simply translate into profits for covered entities. *See* Sunita Desai & J.

Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 N. ENGL. J. MED. 539, 539 (Feb. 8, 2018) (concluding that covered entities' "[f]inancial gains have not been associated with clear evidence of expanded care … [for] low-income patients"). Adding contract pharmacies into the mix only makes things worse. After all, whereas covered entities are at least nominally non-profit, contract pharmacies are profit-maximizing enterprises with every incentive (and potentially even fiduciary obligations) to seize on all lawful opportunities to obtain other private parties' goods without paying full price for them. And, to be clear, contract pharmacies are under no legal obligation to pass on discounts to patients even when they purport to act as covered entity's dispensaries. Contract pharmacies can thus freely direct fungible money generated from the Program to any cause, including their own bottom lines, without accountability.

And they have: Since 2010, contract pharmacies have been "generat[ing] revenue" to the tune of hundreds of millions of dollars per year simply by "purchas[ing] covered outpatient drugs at the 340B Program price," charging full or nearly full price, but nonetheless "receiving reimbursement from patients' insurance that [ ] exceed the 340B prices paid for the drugs." GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108, at 5 (Dec. 2019), https://bit.ly/34Vj6zK. A program intended to benefit the needy has thus become a profit engine for big businesses—and, worse still, one funded by patients paying exorbitant markups on deeply discounted drugs.

In light of that experience, Defendants' decision to double down on the mistaken course they began back in 2010, and to now ***force*** manufacturers to offer 340B discounts to an unlimited number of contract pharmacies, will only exacerbate the problem and further distort the Program—and greatly increase the danger that, in practice, the Program will operate as a confiscatory regime.

II. The ADR Rule

A. Defendants Belatedly Propose, and then Withdraw, an ADR Regulation.

Defendants have compounded their substantive distortion and misinterpretation of the 340B Program by separately promulgating unconstitutional procedures to administer it. In 2010, Congress amended the 340B statute to require HHS to promulgate regulations within 180 days establishing an ADR process for resolving 340B price disputes between covered entities and manufacturers. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 826-27 (2010) (codified at 42 U.S.C. § 256b(d)(3)). HHS did not abide by the 180-day deadline; in fact, it took HHS nearly ***six years*** to even issue a Notice of Proposed Rulemaking suggesting ADR procedures. *See* Exh. A, 81 Fed. Reg. 53,381 (Aug. 12, 2016) ("NPRM").

The 2016 NPRM proposed to resolve ADR claims through three-member panels "chosen from a roster of eligible individuals alternating from claim to claim, and one ex-officio, non-voting member chosen from the staff of [HHS's Office of Pharmacy Affairs]." *Id.* at 53,382. ADR panel members would be "Federal employees … with demonstrated expertise or familiarity with the 340B Program," and would be appointed by the HHS Secretary. They also could be removed from a panel only "for cause," *id.*, by which the NPRM meant only a dispute-specific conflict of interest. *Id.* The NPRM also proposed how these panels would adjudicate 340B price disputes. ADR panel decisions would "be binding upon the parties involved," there would be no administrative appeal process for these binding decisions, and there would be no opportunity for the HHS Secretary to oversee, review, or otherwise alter panel decisions; instead, panel decisions would remain binding "unless invalidated by an order of a court of competent jurisdiction." *Id.* at 53,383. Importantly, however, the NPRM did not authorize ADR panels themselves to impose any specific remedies; it proposed only that ADR panel decisions "be submitted to [HRSA's Healthcare Systems Bureau] to take enforcement action or apply sanctions, as appropriate." *Id.*

In October 2016, several manufacturers, including Lilly, filed timely comments pointing out several fundamental defects with the proposed rule. *See, e.g.*, Am. Compl. Exh. M (Comment of Eli Lilly and Co. on Proposed 340B Drug Pricing Program: Administrative Dispute Resolution (ADR) Process, Office of Mgmt. & Budget RIN 0906-AA90 (Oct. 11, 2016)). Most relevant here, Lilly argued that, given their appointment by the HHS Secretary, the proposed ADR panelists would likely be driven by the desire to implement the agency's policy goals, rather than simply exercise independent expert judgment. Lilly thus recommended that HHS instead employ a neutral and disinterested adjudicator such as an administrative law judge ("ALJ"). *Id.* at 8-10.

After the close of the notice-and-comment period, the NPRM began appearing, with no changes made in response to manufacturer comments, on the Unified Agenda of Federal Regulatory and Deregulatory Actions ("Unified Agenda"), a semiannual compilation of information about federal regulations under agency development. On August 1, 2017, however, the NPRM was summarily withdrawn from the Unified Agenda without explanation. *See* Exh. B.

B. Defendants Unlawfully Resurrect and Alter the ADR Rule.

Three years passed, with no indication from HHS or HRSA that the ADR rulemaking remained pending. The NPRM never appeared again on the Unified Agenda, and no new NPRM ever appeared in the Federal Register. In fact, a HRSA official told a 340B-focused news publication in March 2020 that it had no plans to issue an ADR rule. According to the official, "[i]t would be challenging to put forth rulemaking on a dispute resolution process when many of the issues that would arise for dispute are only outlined in guidance" that Defendants understood to be legally unenforceable. Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B Report (Mar. 12, 2020), https://bit.ly/35kU6lw.

That all changed when groups of covered entities filed multiple lawsuits seeking to compel Defendants to promulgate the long-overdue ADR rules. *See, e.g.*, Compl., *Ryan White Clinics for*

340B Access v. Azar, No. 20-cv-2906 (D.D.C. Oct. 9, 2020), Dkt. 1. In the face of this mounting litigation pressure, Defendants abruptly published a final rule in December—without providing any advance notice or opportunity for public comment, including on any of the developments in the intervening six years. Exh. C, 85 Fed. Reg. 80,632 (Dec. 14, 2020) ("ADR Rule").

This hastily issued rule rectifies none of the defects in the NPRM, and in many cases exacerbates them. The ADR Rule creates panels of HHS employees whose work is not subject to supervision by any Senate-confirmed officer, rather than assign ALJs to adjudicate disputes. It establishes a Board of "at least six members appointed by the [HHS] Secretary"—two each from HRSA, the Centers for Medicare and Medicaid Services ("CMS"), and the HHS Office of the General Counsel ("OGC"), plus one non-voting, ex-officio Board member selected from the staff of the HRSA Office of Pharmacy Affairs ("OPA")—and provides that each panel will consist of one member drawn from each voting group. *Id.* at 80,634. It insulates these panels' judgments from review by any superior (much less Senate-confirmed) Executive Branch official. *Id.* at 80,640-41. It makes no provision for any Board member's removal from the Board, providing only that panelists can be removed ***from a panel*** "for cause," with "a conflict of interest" in a particular dispute listed as the only grounds for removal from a panel. And while it recognizes that commenters had raised concerns that such a system would result in biased decisionmaking, it cursorily brushes these concerns aside, simply noting that the panels "are uniquely situated to handle the complexities of the 340B Program and related disputes," and that the ex-officio Board member "would not exercise undue influence over the three voting members." *Id.* at 80,634-35.

The ADR Rule also grants each panel facsimiles of nearly every power enjoyed by federal judges. Panels may "determine, in [their] own discretion, the most efficient and practical form of the ADR proceeding." *Id.* at 80,645. They may require "submission of additional information,"

and they have discretion to choose from an array of formidable sanctions (including entry of judgment) if they conclude their instructions were not complied with. *Id.*; *see* 42 C.F.R. § 10.22(c). They also have "discretion in admitting evidence and testimony," and even apply the Federal Rules of Civil Procedure and Federal Rules of Evidence. 85 Fed. Reg. at 80,641; *see* 42 C.F.R. § 10.23. That said, while the ADR Rule permits covered entities to request discovery from covered entities and permits panels to issue requests to either side, it is one-sided; it does not include any express provision allowing discovery by manufacturers. *See* 42 C.F.R. § 10.22(a)-(b). Finally, the ADR Rule vests the panels with "jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim." 85 Fed. Reg. at 80,636.

Perhaps most striking of all, although the NPRM was silent on the issue, the ADR Rule provides that panels can resolve claims and issue self-executing judgments for "money damages," as well as other unspecified "equitable relief" sought by disgruntled litigants—not leaving it to the agency to take subsequent enforcement action, as contemplated by the NPRM. *Id.* at 80,633. That relief may or may not include injunctions, or even preliminary injunctions; yet one of the first "complaints" submitted to HHS purports to request preliminary injunctive relief, without any involvement whatsoever by an Article III court. *See* Exh. D. Despite the sweeping grant of authority, the Rule does not purport to authorize *de novo* review by an Article III court. Instead, it says only that review may be available under the APA and that "[t]he form of judicial review for 340B ADR Panel decisions is beyond the scope of this final rule." 85 Fed. Reg. at 80,642.

Predictably, the attempt to give HHS employees the powers of federal judges without plenary supervision from ***either*** an Article III court ***or*** any Senate-confirmed principal officer has

already led to fundamental unfairness. The ADR Rule states that it will be for a "panel" to decide "whether a pharmacy is part of a 'covered entity.'" *Id.* at 80,633. Yet HHS's OGC, a panel member, has already dictated the answer in its December 30 Decision obligating manufacturers to provide discounts to an unlimited number of contract pharmacies—and it did so before a single ADR petition was filed and before any manufacturer even had the opportunity to be heard. What is more, and not coincidentally, under the ADR Rule a panel decision requiring manufacturers to offer 340B discounts to contract pharmacies will carry binding force: In a striking departure from the NPRM, the final Rule provides that panel decisions are "binding" on the parties and "precedential" in future adjudications unless invalidated by a federal court. 85 Fed. Reg. at 80,641.

III. The ADR Floodgates Open, And Put Lilly In An Untenable Position

In light of the gross program abuses that gradually expanded after HHS's 2010 contract pharmacy guidance permitted an unlimited use of contract pharmacies, coupled with the potential for civil monetary penalties for each 340B transaction, Lilly ultimately announced that it was "discontinu[ing] [its] practice of voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products." Am. Compl. Exh. F (August 19, 2020 Ltr. from Lilly to HRSA); *see* Am. Compl. ¶¶ 77-97. Even though Lilly made clear that it will continue to honor contract pharmacy orders when a covered entity lacks an in-house pharmacy (and thus needs to partner with an outside contract pharmacy to dispense outpatient drugs) or wholly owns the outside pharmacy (and thus can assure compliance), Lilly immediately began receiving threats from covered entities upon making its announcement, including from some of the entities that ultimately filed suit against the government seeking to force the promulgation of a final ADR rule.

Now those chickens are about to come home to roost. On January 12, 2021—the day before the ADR Rule went into effect—HRSA posted a new webpage about the ADR process inviting "[s]takeholders" to "begin submitting petitions." Exh. E; *see also* 42 C.F.R. § 10.21(a).

Covered entities immediately began to do so, seeking all forms of relief—including ***preliminary injunctive relief*** nowhere contemplated in the statute—relying on the December 30 Decision as their central authority. *See, e.g.*, Exh. D. This is just the beginning: ***Hundreds*** of covered entities and their trade associations have threatened to take legal action against Lilly since it announced it would no longer provide 340B-discounted drugs to a limitless number of contract pharmacies. For example, by letter dated September 28, 2020, law firm Hall, Render, Killian, Heath & Lyman, P.C., threatened legal action on behalf of a list of 168 covered entities, a list the law firm soon expanded to include 226 covered entities. *See* Exhs. 1, 4 to Decl. of Derek L. Asay, hereto attached as Exh. G. Other covered entities have done the same. *See, e.g.*, Exh. 3 to Exh. G. ("It is UW Medicine Hospitals' intent to seek reimbursement of these losses through administrative action, including applicable fees and costs, should you not reverse your policy."). In addition, the President and CEO of 340B Health, a covered entity trade association, issued a public statement on Sept. 1, 2020, warning that "if the administration will not use its authority to enforce the law, we will pursue all legislative and legal avenues available to us to defend the safety net." Exh. F.

Lilly will therefore imminently be forced to expend considerable amounts of time and money litigating these numerous actions, every one of which will take place under Defendants' unconstitutional ADR process, against the backdrop of Defendants' unlawful decision that manufacturers must offer 340B discounts to for-profit contract pharmacies (lest they be exposed to crippling penalties), and in the shadow of the threat of binding and self-executing judgments for money damages and equitable relief. Making matters worse, none of the injuries Lilly will suffer pursuant to this unconstitutional regime are remediable. And because the ADR Rule is now in effect, all of this will be well underway while this case is pending, which is exactly why this

Court's immediate intervention is required and a preliminary injunction barring Defendants from implementing or enforcing the ADR Rule against Lilly in any manner should be granted forthwith.

ARGUMENT

"To obtain a preliminary injunction, a plaintiff must establish that it has some likelihood of success on the merits; that it has no adequate remedy at law; [and] that without relief it will suffer irreparable harm." *GEFT Outdoors, LLC v. City of Westfield*, 922 F.3d 357, 364 (7th Cir. 2019) (internal quotation marks omitted). "[I]f the plaintiff passes that threshold, the court must weigh the harm that the plaintiff will suffer absent an injunction against the harm to the defendant from an injunction, and consider whether an injunction is in the public interest." *Id.* (internal quotation marks omitted). Courts apply a "sliding scale" to the balance-of-harms analysis, meaning that "the more likely [the movant] is to win, the less the balance of harms must weigh in his favor." *Turnell v. CentiMark Corp.*, 796 F.3d 656, 662 (7th Cir. 2015). A likelihood of success on the merits "puts the heaviest weight on the scale" in favor of a preliminary injunction. *Planned Parenthood of Ind. & Ky., Inc. v. Comm'r of Ind. State Dep't of Health*, 896 F.3d 809, 832 (7th Cir. 2018). To make such a showing, a movant need only make out "a reasonable likelihood of success on the merits" on its claim. *NA Main Street LLC v. Cook*, 2020 WL 7624784, at *3 (S.D. Ind. Dec. 22, 2020). Lilly has done so here, and then some. Accordingly, given that Lilly will suffer irreparable harm absent an injunction and has no other "[]adequate remedy at law," *Foodcomm Int'l v. Barry*, 328 F.3d 300, 304 (7th Cir. 2003), the case for an injunction is clear.

I. Lilly Is Likely To Succeed On The Merits.

Lilly is likely to succeed on its claims that the ADR Rule is unlawful under both the Constitution and the APA. The Rule contravenes Article II by vesting powers reserved for "principal" officers in functionaries who are merely appointed by the Secretary of HHS, not the President with the advice and consent of the Senate. The Rule also runs afoul of Article III by

permitting HHS employees to adjudicate private rights, grant money damages, and order equitable relief—the hallmarks of the judicial power reserved to Article III courts. And the Rule violates the APA in at least three ways: (1) it exceeds HHS's statutory authority; (2) it was not subjected to the required notice-and-comment procedures; and (3) it is substantively arbitrary and capricious.

A. The ADR Rule Violates Article II of the Constitution.

Article II of the Constitution requires principal officers of the United States to be appointed by the President with the advice and consent of the Senate, and permits only "inferior officers" to be appointed by the heads of Executive departments. *See* U.S. Const. art. II, § 2, cl. 2. ADR panelists, by virtue of their sweeping powers and broad discretion in the use of those powers, are officers of the United States under the Appointments Clause. Because their decisions are unreviewable by any superior Executive Branch official and are protected by for-cause removal restrictions to boot, ADR panelists are also ***principal*** officers. Under the ADR Rule, however, ADR panelists can be appointed to that position by the HHS Secretary and then assigned to panels by the HRSA Administrator—*i.e.*, without Presidential appointment and without the Senate's advice and consent. *See* 42 C.F.R. § 10.20. Lilly is likely to succeed on the merits of its claim that this arrangement contravenes the Appointments Clause.

As an initial matter, there is no question that ADR panelists are "Officers of the United States" subject to the Appointments Clause. *See* U.S. Const. art. II, § 2, cl. 2. Officers have two defining characteristics: They "must occupy a 'continuing' position established by law," not an "occasional or temporary" one, *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018) (quoting *United States v. Germaine*, 99 U.S. 508, 511-12 (1878)), and they must exercise "significant authority pursuant to the laws of the United States." *Id.* (quoting *Buckley v. Valeo*, 424 U.S. 1, 126 (1976) (per curiam)). ADR panelists amply satisfy both requirements. First, the position they occupy is established by law and is permanent: Congress required the Secretary to promulgate regulations

designating "a decision-making official or decision-making body" to adjudicate claims between covered entities and manufacturers in 42 U.S.C. § 256b(d)(3)(B)(i), and the Secretary did just that in 42 C.F.R. § 10.20. Second, ADR panelists wield the precise suite of powers the Supreme Court has deemed "significant authority" in the agency adjudication context. *Lucia*, 138 S. Ct. at 2051. The ADR Rule affords "the 340B ADR Panel significant discretion in determining relevant material to consider and the manner to conduct its evaluation," "allow[s] the 340B ADR Panel discretion in admitting evidence and testimony during the course of a proceeding," authorizes ADR panelists to conduct "evidentiary hearing[s] when there are material facts in dispute" and to sanction failures to comply with discovery orders by "[e]xcluding evidence" or entering "[j]udgment in the proceeding or dismissal of proceeding," and provides that ADR panel rulings are "final agency decisions, binding on the parties, and precedential." 85 Fed. Reg. at 80,635-42; 42 C.F.R. §§ 10.22(c), 10.23, 10.24(d). ADR panelists thus have "all the authority needed to ensure fair and orderly adversarial hearings—indeed, nearly all the tools of federal trial judges," *Lucia*, 138 S. Ct. at 2048, just like the agency adjudicators deemed officers in *Lucia* and *Freytag v. Commissoner*, 501 U.S. 868 (1991). *See Lucia*, 138 S. Ct. at 2047-48 (deeming agency adjudicators who "take testimony, conduct trials, rule on the admissibility of evidence, and have the power to enforce compliance with discovery orders," and who exercise "'significant discretion' when carrying out" those functions, to be officers (quoting *Freytag*, 501 U.S. at 881-82)). In sum, it is plain that ADR panelists are officers of the United States.

It is equally plain that ADR panelists function as ***principal*** officers. Their decisions are unreviewable by any superior Executive Branch official and they cannot be removed except for cause. The Supreme Court has never concluded that an agency adjudicative officer was an inferior officer when—as here—no superior officer could review her decisions. That makes sense, as

"'inferior officers' are officers whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Edmond v. United States*, 520 U.S. 651, 663 (1997); *see, e.g.*, *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 510 (2010) (Board members are inferior officers in light of the SEC's "oversight authority" over their decisions); *Edmond*, 520 U.S. at 664-65 ("[Coast Guard] Court of Criminal Appeals Judges" are inferior officers because "another Executive Branch entity, the Court of Appeals for the Armed Forces," exercises "control over [them]," and they "have no power to render a final decision … unless permitted to do so by other Executive officers").

Unlike in *Edmond* and *Free Enterprise Fund*, the decisions of ADR panelists are not subject to review by any superior Executive Branch officer. Indeed, HHS actively rejected comments asking to "incorporate an [administrative] appeals process," instead choosing to promulgate a Rule under which an ADR panel's decision "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." 85 Fed. Reg. at 80,641; 42 C.F.R. § 10.24(d). This fact, standing alone, suffices to demonstrate ADR panelists' status as principal officers. *See, e.g.*, *Assoc. of Am. R.R. v. U.S. Dep't of Transp.*, 821 F.3d 19, 39 (D.C. Cir. 2016) (deeming "inescapable" the conclusion that Surface Transportation Board arbitrators were principal officers for the exclusive reason that the rule provided no "procedure by which the arbitrator's decision is reviewable by the [Board]").

But there is more. Although "[t]he power to remove officers" is a "powerful tool for control" that influences the Appointments Clause analysis, *Edmond*, 520 U.S. at 664, there is no such power here. The ADR Rule does not address whether or for what reason a panel member may be removed from the Board, as the Rule sets out no method of removal. More important, the Rule makes abundantly clear that, once appointed to an ADR panel, panelists may only "be

removed" from the panel "for cause," by which the Rule means having a conflict of interest. 85 Fed. Reg. at 80,634; *see* 42 C.F.R. § 10.20(a). This protection from removal further insulates ADR panelists from HHS control and confirms that they are functioning as principal officers. As a result, the only constitutional method for ADR panelists' appointment is nomination by the President with the advice and consent of the Senate. *See* U.S. Const. art. II, § 2, cl. 2. Because ADR panelists are not so appointed, Lilly has "a reasonable likelihood of success on the merits" on its Article II claim. *See NA Main Street LLC*, 2020 WL 7624784, at *3.

Any doubt on that score will soon be resolved. In *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), the Federal Circuit confronted an arrangement, much like the one here, where agency adjudicators lacked "any presidentially-appointed officer who can review, vacate, or correct [their] decisions … combined with [a] limited removal power." *Id.* at 1350. Even though the decisions of Administrative Patent Judges ("APJs") were subject to significant supervisory control by a duly-appointed principal officer (***unlike*** ADR panelists' decisions), *id.* at 1331-32, the Federal Circuit held that APJs were functioning as principal officers, and thus that their non-Presidential appointment was unconstitutional, *id.* at 1335. That conclusion is undoubtedly correct, and an injunction is warranted here for that reason alone.

To be sure, the Federal Circuit chose to remedy the Appointments Clause violation in *Arthrex* by severing the statute's removal provisions, concluding that doing so converted the APJs into inferior officers that were adequately supervised under the facts presented there. *Id.* at 1338. But even if that rationale were applicable here (and it is not due to the lack of supervision) there is serious reason to believe that *Arthrex*'s remedy was still constitutionally insufficient. That is for a simple reason: Even with the removal protections severed, there was still no means for a presidential appointee to review the decisions, which means that APJs—like ADR panelists—

remain improperly-appointed principal officers. *See Edmond*, 520 U.S. at 663, 665; *Dep't of Transp. v. Ass'n of Am. R.Rs.*, 575 U.S. 43, 64 (2015) (Alito, J., concurring); *see also Free Enter. Fund*, 561 U.S. at 544 (Breyer, J., dissenting) (doubting "that courts will always be able to cure such a constitutional defect merely by severing an offending removal provision"). That is likely why the Supreme Court granted certiorari to decide whether that quick-fix remedy actually solves the Article II problem, or whether when an official is designated by law to have the last word on an issue that official must be a properly-appointed principal officer. *See* 141 S. Ct. 551 (2020).

B. The ADR Rule Violates Article III of the Constitution.

The ADR Rule also unlawfully usurps the powers Article III assigns exclusively to a judiciary comprised of life-tenured judges. Article III vests the judicial power of the United States in "one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish," and mandates that those exercising the Judicial Power "shall hold their Offices during good Behaviour, and [who] shall, at stated Times, receive for their Services a Compensation, which shall not be diminished during their Continuance in Office." U.S. Const. art. III, § 1. This structural requirement is an indispensable means by which the Constitution guarantees individual liberty. By establishing "a body of judges insulated from majoritarian pressures and thus able to enforce [federal law] without fear of reprisal or public rebuke," *United States v. Raddatz*, 447 U.S. 667, 704 (1980) (Marshall, J., dissenting), Article III "preserves to litigants their interest in an impartial and independent federal adjudication of claims," *CFTC v. Schor*, 478 U.S. 833, 850 (1986). And because the Constitution "commands that the independence of the Judiciary be jealously guarded," *N. Pipeline Const. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 61 (1982) (plurality opinion), a statute or regulation is flatly unconstitutional if it "confer[s] the Government's 'judicial Power' on entities outside Article III," such as Executive Branch employees and officers, *Stern v. Marshall*, 564 U.S. 462, 484 (2011).

The ADR flagrantly violates these foundational principles. The Supreme Court has made clear that "[w]hen a suit is made of the stuff of the traditional actions at common law tried by the courts at Westminster in 1789, and is brought within the bounds of federal jurisdiction, the responsibility for deciding that suit rests with Article III judges in Article III courts," period. *Stern*, 564 U.S. at 484. There is no doubt that HHS employees infringe that bedrock constitutional requirement by issuing injunctions commanding one private party to convey its property to another without full payment, or that issuing self-executing damages judgments for failing to do so would likewise violate Article III—yet that is precisely what the ADR Rule purports to authorize.

The problem is that the ADR Rule permits Executive Branch adjudication of private-rights claims and remedies. To be sure, "Congress [has] significant latitude to assign adjudication of ***public*** rights," which are those which are collectively held by the entire community or which involve disputes between the government and a private party, "to entities other than Article III courts." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1373 (2018) (emphasis added). But Congress has no such latitude when it comes to ***private*** rights, which include the right to personal security, the right to freely contract, the rights to life and liberty, and—most relevant here—the right to private property. *See* 3 W. Blackstone, *Commentaries* *2, *138-39 (1765); *Ortiz v. United States*, 138 S. Ct. 2165, 2185 (2018) (Thomas, J., concurring); *see Newland v. Marsh*, 19 Ill. 376, 382 (1857) ("The legislative power … cannot directly reach the property or vested rights of the citizen, by providing for their forfeiture or transfer to another, without trial and judgment in the courts."). Since the earliest days of the Republic, courts have recognized that disputes over private rights "lie at the core of the historically recognized judicial power," *N. Pipeline*, 458 U.S. at 70, and thus that private rights disputes must be adjudicated by Article III courts and Article III courts alone. *See, e.g.*, *Murray's Lessee v. Hoboken Land &*

Improvement Co., 59 U.S. (18 How.) 272, 284 (1856); *see also* Caleb Nelson, *Adjudication in the Political Branches*, 107 COLUM. L. REV. 559, 604-05, 611 (2007) ("Historically, … if core private rights were at stake on one side of a dispute, the mere fact that public rights were at stake on the other side did not open the door to non-judicial adjudication"; still today, non-judicial adjudicators "cannot conclusively establish an individual's monetary liability (or otherwise dispose of his core private rights to property)" without running afoul of Article III.).

The right to sell a product at the seller's price arises from the right to private ownership—not government grace—and is at the core of the private rights that manufacturers hold at common law, making disputes over those prices "matter[s] which, from [their] nature, [are] the subject of a suit at the common law." *Murray's Lessee*, 59 U.S. at 284; *see also Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 55-56 (1989) (holding that a bankruptcy court could not adjudicate fraudulent conveyance claims between a bankrupt estate's trustee and a non-creditor because the claims were "quintessentially suits at common law that more nearly resembles state-law contract claims … to augment the bankruptcy estate than they do creditors' hierarchically ordered claims to a pro rata share of the bankruptcy res"). That is true, moreover, even though a covered entity's entitlement to 340B discounts may arise from a public right (given that it exists only as a matter of statute). *See, e.g.*, *Stern*, 564 U.S. at 488 (bankruptcy court cannot adjudicate state-law counterclaims arising out of federal bankruptcy); *see also* Nelson, *supra*, at 604-11.

But instead of assigning those claims to an Article III court, as precedent and history demand, the ADR Rule forces manufacturers like Lilly to submit to the judgment of Article II HHS employees who can supposedly issue self-executing judgments for money damages and/or equitable relief on those claims, and thus can exercise the core of the "judicial Power." *See Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 220 (1995). The ADR Rule thus violates Article III. To

be clear, ADR panels do not render decisions and then leave it to HHS to seek judicial enforcement and remedies; instead, by regulation (and ultimately statute), their remedies are self-executing.

It is no response to say that a manufacturer aggrieved by an ADR panel decision can go to court to try to get the panel's judgment overturned. For one thing, the ADR Rule expressly provides that ADR panel judgments will be binding and precedential, but does not expressly authorize federal court review—much less *de novo* review. That means that ADR panel decisions will (1) take immediate effect absent a federal court order commanding otherwise, and (2) receive some degree of fact-finding deference upon review in federal court if challenged under the APA. The role that scheme leaves for Article III courts is constitutionally insufficient. "'If the essential, constitutional role of the judiciary is to be maintained, there must be both the appearance and the reality of control by Article III judges over the interpretation, declaration, and application of federal law.' That control ***must be more than simple appellate review***." *United States v. Johnston*, 258 F.3d 361, 368 (5th Cir. 2001) (emphasis added) (quoting *Pacemaker Diagnostic Clinic, Inc. v. Instromedix, Inc.*, 725 F.2d 537 (9th Cir. 1984) (en banc) (Kennedy, J.)); *see also Schor*, 478 U.S. at 853 (noting that the "more deferential standard [of review] in *Northern Pipeline*" meant that the federal courts did not exert constitutionally sufficient control under that regime).

Moreover, ADR panels "exercise[] the range of jurisdiction and powers normally vested only in Article III courts," which further undermines federal courts' control and further underscores the Article III violation. *See Schor*, 478 U.S. at 851. As described above, ADR panels have authority to award money judgments, issue equitable remedies, take evidence and hear testimony, impose sanctions, issue precedential and binding decisions, and decide ancillary legal issues. And, again, ADR panels' binding and precedential money judgments are styled as self-executing. That makes the ADR process quite unlike most other administrative review schemes,

which require litigants to apply to a federal court for enforcement of an order. *See, e.g.*, 7 U.S.C. § 18(d)(1); 29 U.S.C. § 1401(b)(2). And it takes the ADR process well outside the realm of administrative review schemes the Supreme Court has been willing to accept. *See, e.g.*, *Schor*, 478 U.S. at 853 ("CFTC orders, like those of the agency in *Crowell*, but unlike those of the bankruptcy courts under the 1978 Act, are enforceable only by order of the district court."). Indeed, the fact that, in one of the first complaints filed with HHS, the petitioner asks the ADR panel to grant a ***preliminary injunction*** against various manufacturers (including Lilly) demonstrates just how extraordinary the usurpation of Article III authority appears to be.

Nor is it any response to say that manufacturers have agreed to the terms of the Program by entering into a PPA. To be sure, the Supreme Court recently held that "Article III is not violated when the parties knowingly and voluntarily consent[ed] to adjudication by a bankruptcy judge," a non–Article III officer. *Wellness Int'l Network, Ltd. v. Sharif*, 135 S. Ct. 1932, 1939 (2015). But, as an initial matter, *Wellness* made clear that consent can transform an otherwise-unconstitutional Executive adjudication into a permissible one only when "Article III courts retain supervisory authority over the process." *Id.* at 1944. And here, Article III courts ***do not*** retain sufficient supervisory authority over ADR panels. Consent therefore cannot cure the violation.

In all events, a manufacturer's decision to participate in the 340B Program, lest it lose the ability to participate in and receive reimbursements under Medicaid and Medicare altogether, is nowhere close to the sort of voluntary "consent" the Supreme Court has required in this context. *See, e.g.*, *Stern*, 564 U.S. at 493 ("Pierce did not truly consent to resolution of Vickie's claim in the bankruptcy court proceedings," because "[h]e had nowhere else to go if he wished to recover from Vickie's estate."). Nor can it be said that manufacturers like Lilly have consented to the 340B Program as it currently exists in the wake of the December 30 Decision obligating them to

offer full discounts to contract pharmacies; on the contrary, Lilly has filed suit challenging that (mis-)interpretation of the statute and unlawful exercise of agency authority. So even if the original decision to participate in the 340B Program were deemed sufficiently voluntary, that decision cannot be considered consent to allowing the government to force manufacturers to transfer their private property to other for-profit entities on pain of massive financial sanction, let alone consent to adjudication of such core private rights by an unconstitutionally constituted agency tribunal. That is clear as a legal matter, and it is equally clear as a factual matter. After all, ADR procedures were not proposed publicly until 2016 (which was more than two decades after most manufacturers signed their PPAs). And once those procedures were finally revealed, Lilly (and a host of others) ***specifically objected to them***. That can hardly be deemed implied consent.

In sum: By enabling ADR panels to (1) mandate that manufacturers like Lilly transfer their property to contract pharmacies often at an extreme financial loss, and (2) enforce such decisions through binding judgments for money damages and equitable relief, the ADR Rule empowers Article II HHS employees to determine "the liability of one individual to another under the law as defined." *N. Pipeline*, 458 U.S. at 69-70 (quoting *Crowell v. Benson*, 285 U.S. 22, 51 (1932)). And by simultaneously vesting ADR panels with Article III–like powers and insulating ADR panel decisions from meaningful Article III supervision, the ADR Rule unconstitutionally usurps and dilutes "the judicial Power of the United States." Lilly is therefore likely to succeed on this claim.

C. The ADR Rule Violates the APA's Notice-and-Comment Requirement.

Lilly is likely to succeed on its claim that Defendants did not comply with the APA's notice-and-comment procedures in hastily promulgating the ADR Rule. *See* 5 U.S.C. § 553(b). Indeed, they did not even try. Instead, they withdrew the NPRM on August 1, 2017, took no action on it for three years, and then abruptly announced that they were resurrecting the interred NPRM with significant (unconstitutional) changes. None of that is remotely consistent with the APA.

The decision to withdraw the NPRM put regulated parties on notice that, rather than continuing with the rulemaking process, they had "[chosen] the status quo" of non-regulation. *Ctr. for Auto Safety v. NHTSA*, 710 F.2d 842, 846-47 (D.C. Cir 1983); *cf. Cierco v. Lew*, 190 F. Supp. 3d 16, 25 (D.D.C. 2016) (determining that withdrawal of NPRM leaves challenger to notice with no relief), *aff'd on other grounds sub nom. Cierco v. Mnuchin*, 857 F.3d 407 (D.C. Cir. 2017). Put differently, if the purpose of the APA's notice-and-comment requirement is "to put interested parties on notice that Administrative rulemaking in certain areas is about to take place," *Nat'l Tour Brokers Ass'n v. United States*, 591 F.2d 896, 989 (D.C. Cir. 1978), then the August 2017 withdrawal of the NRPM put regulated parties on notice that rulemaking would ***not*** occur. Defendants thus needed to engage in notice-and-comment again to promulgate a valid ADR Rule.

The ADR Rule does not purport to invoke any statutory ground for excusing notice and comment—because there is none. Instead, it simply pretends that the agency had not withdrawn its NPRM. *See* 85 Fed. Reg. at 80,633 (claiming that its previous NPRM was not ***really*** withdrawn, just frozen by Presidential action"). That explanation is demonstrably false. For one thing, the Presidential memorandum to which the agency refers as providing the basis for its "freeze" argument plainly does not apply to the ADR Rule; ***on its face***, that memorandum excludes "regulations subject to statutory … deadlines," which plainly includes the ADR Rule. *See* Reince Priebus, Asst. to the President and Chief of Staff, *Memorandum for the Heads of Executive Departments and Agencies* (Jan. 20, 2017), https://bit.ly/2KIutnM. For another thing, the agency's contemporaneous actions demonstrate that it did not treat the memorandum as applicable to ADR at the time the memorandum was issued: The Presidential memorandum ordered agencies to remove pending regulations to which it ***did*** apply "immediately," *id.*, but Defendants did not remove the ADR NPRM from the Unified Agenda for another eight months. What is more,

although regulatory actions retain the same Regulatory Identification Number ("RIN") throughout the entire rulemaking process, the final ADR Rule was designated with a different RIN than the NPRM, *compare* 81 Fed. Reg. 53,381, *with* 85 Fed. Reg. 80,632, which means it is not the same.

In all events, even if the NPRM had not been withdrawn, the final Rule would still fail the APA's notice-and-comment requirement because it is not a logical outgrowth of the NPRM. A final rule is a "logical outgrowth" of a proposed rule only if interested parties "'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004); *see also Am. Med. Ass'n v. United States*, 887 F.2d 760, 767 (7th Cir. 1989). "If a 'final rule deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal,'" and the agency accordingly must undergo notice and comment again. *Public Citizen, Inc. v. Mineta*, 427 F. Supp. 2d 7 (D.D.C. 2006) (quoting *AFL-CIO v. Donovan*, 757 F.2d 330, 338 (D.C. Cir. 1985)). So it is here.

Multiple aspects of the ADR rule clearly are not a logical outgrowth of the NPRM because they are completely absent from the NPRM. Among other things, the NPRM did not mention, let alone elaborate upon, any suggestion that ADR panels would be given authority to issue binding judgments for money damages, or that those decisions would be "precedential." Because no manufacturer could "divine [Defendants'] unspoken thoughts" on this score, *Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C. Cir. 2000) (citation omitted), the ADR Rule is not a logical outgrowth of what preceded it. And because Defendants did not proceed through notice and comment after the NPRM's withdrawal on these new terms, the Rule must be set aside.

D. The ADR Rule Substantively Violates the APA.

Lilly is further likely to succeed in showing that the ADR Rule's substantive provisions violate the APA. *First*, the ADR Rule exceeds the clear terms of the 340B statute, and thus is "in

excess of" the scope of Defendants' "statutory [ ] authority." 5 U.S.C. § 706(2)(C). The statute allows HHS/HRSA to "promulgate regulations to establish and implement an administrative process … including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions." 42 U.S.C. § 256b(d)(3). The statutory term "appropriate procedures for the provision of remedies" is general and undefined; it does not specify which remedies are to be made available by the ADR regulations—only that they be "appropriate." *See id.* Allowing ADR panels to impose self-executing money judgments against manufacturers, as Defendants have done in the ADR Rule, cannot constitute "appropriate" remedial authority because, as explained, such an interpretation violates Article III. Private money judgments and equitable relief would not be "appropriate" under the statute—they would be illegal. Accordingly, the Rule is "in excess of statutory jurisdiction, authority, or limitations" and must be set aside. *See* 5 U.S.C. § 706(2)(C).[1]

Second, the Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and must be set aside on that basis too. *See* 5 U.S.C. § 706(2)(A). Agency action is arbitrary and capricious if the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Sparre v. U.S. Dep't of Labor*, 924 F.3d 398, 402 (7th Cir. 2019) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). In the ADR Rule, Defendants failed to acknowledge the relevant data in a number of respects, failed to articulate a satisfactory

[1] At the very least, allowing panels to issue such remedies raises grave constitutional concerns, and thus the canon of constitutional avoidance counsels strongly against adopting the ADR Rule's interpretation of the Statute. *See, e.g.*, *INS v. St. Cyr*, 533 U.S. 289, 299-300 (2001) (canon of constitutional avoidance); *United States v. Orona-Ibarra*, 831 F.3d 867, 875-76 (7th Cir. 2016).

explanation for many of its component parts—and, in some cases, offered no explanation at all. As outlined at Amended Complaint ¶¶ 251-63, Lilly is likely to succeed in showing that the ADR Rule is arbitrary and capricious in multiple respects. Three problems in particular stand out:

1. The Rule fails to account for changed legal circumstances in the years since it was withdrawn. An agency is "susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem" if it does not account for legal developments. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2384 (2020). That is precisely the case here: Not only has the Supreme Court brought significant clarity to its Appointments Clause jurisprudence since the NPRM was withdrawn, *see Lucia*, *supra*, but it recently granted certiorari to determine whether APJs, who are quite similar to ADR panelists in terms of their respective powers, are principal officers. *See Arthrex*, *supra*.

The same is true with respect to the Article III concerns. The ADR Rule does not even acknowledge, let alone attempt to justify, how a process that affords Executive Branch employees full adjudicative powers, including the ability to exercise common-law interpretive authority and the power to issue binding money judgments or equitable relief touching private property, without being subject to an Article III court's plenary control, could be constitutional. Rather, Defendants completely failed to grapple with this important aspect of the problem. Because they provided no explanation—let alone a reasoned one—the Rule cannot stand. *See, e.g.*, *Teva Pharm. USA, Inc. v. FDA*, 441 F.3d 1, 4 (D.C. Cir. 2006) ("We declined to evaluate the reasonableness of the FDA's statutory interpretation because the agency provided no explanation."); *Envtl. Def. Fund, Inc. v. EPA*, 898 F.2d 183, 189 (D.C. Cir. 1990) (courts cannot uphold an unexplained agency decision "on the basis of interpretive theories that the agency might have adopted and findings that (perhaps) it might have made" (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 92-95 (1943))).

2. Defendants also failed to adequately explain the reasons for choosing the structure for administrative dispute resolution established by the Rule. As multiple manufacturers explained in comment letters, the ADR panel would likely be staffed by many of the same individuals responsible for creation and implementation of HRSA policy. Because these individuals serve in other administrative functions, they are likely to hold biases, policy positions, or other objectives outside of the limited facts of the dispute at issue. The ex-officio OPA member only compounds these risks with its potential to exert undue influence over the panel. These concerns are legitimate, and stand in stark contrast to the independence and impartiality enjoyed by ALJs. *See, e.g.*, Kent H. Barnett, *Why Bias Challenges to Administrative Adjudication Should Succeed*, 81 MO. L. REV. 1023 (2016). Defendants' unsupported response that manufacturers should simply accept their say-so that no bias will exist is "not a statement of reasoning, but of conclusion," *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 737 (D.C. Cir. 2001), and thus is arbitrary and capricious. *See, e.g.*, *Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014).

The choice of ADR panelists instead of more independent ALJs is both unreasonable and unreasonably explained. The agency claims that the panel structure is reasonable because it allows relevant government officials to draw on their expertise. But the lion's share of what panelists do—*i.e.*, hearing evidence, making credibility determinations, applying and interpreting the Federal Rules of Evidence and Civil Procedure, and even imposing sanctions—is far more analogous to common-law judging and ***has nothing whatsoever to do*** with specialized agency expertise. These are the tasks of judges. Besides that, ADR panel rulings are "precedential" under the Rule, *see* 42 C.F.R. § 10.24(d), meaning that subsequent panels are supposed to uphold a body of existing administrative case law (again, a quintessentially judicial task) rather than adapt or alter decisionmaking based on accrued expertise. This gap between the agency's explanation and the

on-the-ground reality means that the agency has failed to provide "a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43.

3. The rule is further arbitrary and capricious because it fails to address Lilly's (and other manufacturers') concerns regarding Defendants' outdated and burdensome auditing guidelines. Though it acknowledges that numerous commenters had raised this issue, the final Rule gives those concerns short shrift, stating in a conclusory manner and without explanation or elaboration that "updated manufacturer audit guidelines" are not "needed to finalize the ADR process" and that ADR panels can "determine when there have been statutory violations concerning overcharges, diversion, and duplicate discounts." 85 Fed. Reg. at 80,633. Here, too, such conclusory explanations cannot stand. *See, e.g.*, *Dickson v. Sec'y of Def.*, 68 F.3d 1396, 1405 (D.C. Cir. 1995) (finding an agency explanation to be unreasoned because "[a]lthough the Board … briefly recited the facts alleged by petitioners, and then found that a waiver would not be in the interest of justice, it omitted the critical step—connecting the facts to the conclusion").

II. Absent A Preliminary Injunction, Lilly Will Suffer Irreparable Harm.

Although HHS has not given notice of their commencement, Lilly has already been named as a defendant in certain ADR petitions, with many, many more on the way. *See* pp. 13-14, *supra*. Without an order from this Court enjoining the ADR Rule, Lilly's subjection to an unlawful dispute resolution process will cause it irreparable injury. Indeed, as this Court has previously recognized, "[m]ost constitutional injury is presumed irreparable, with here-irrelevant exceptions for constitutional torts sufficiently analogous to common-law personal-injury claims." *Bernard v. Individual Members of Ind. Med. Licensing Bd.*, 392 F. Supp. 3d 935, 954-55 (S.D. Ind. 2019) (internal citations omitted); *see also, e.g.*, *Preston v. Thompson*, 589 F.2d 300, 303 n.3 (7th Cir.

1978) ("The existence of a continuing constitutional violation constitutes proof of an irreparable harm."); *Baskin v. Bogan*, 983 F. Supp. 2d 1021, 1028 (S.D. Ind. 2014) (same).[2]

The Seventh Circuit has already applied this principle in the preliminary injunction context where the plaintiff alleged that it was subjected to an unconstitutional decisionmaking body. In *United Church of the Medical Center v. Medical Center Commission*, 689 F.2d 693 (7th Cir. 1982), the court concluded that where (as here) "the precise violation claimed … is subjection to an unconstitutionally constituted decisionmaker," that "injury is irreparable" regardless of the availability of "judicial review" after the fact. *Id.* at 701. And the Seventh Circuit has since reiterated that subjection to an unconstitutionally constituted decisionmaker "is in itself a constitutional injury sufficient to warrant injunctive relief," *Tr. & Inv. Advisers, Inc. v. Hogsett*, 43 F.3d 290, 296 (7th Cir. 1994) (quoting *United Church*, 689 F.2d at 701), as subjection to unconstitutional procedures harms "intangible and unquantifiable interests" that "cannot be compensated by damages," *Ezell v. City of Chicago*, 651 F.3d 684, 699 (7th Cir. 2011); *see also, e.g.*, *Williams v. Bd. of Sch. Trs. of Metro. Sch. Dist. of Perry Twp.*, 2007 WL 1662337, at *3 (S.D. Ind. June 5, 2007) (granting a preliminary injunction to "avoid the risk that [plaintiff] would be subjected to an unconstitutional hearing, a deprivation that would have no remedy at law").

That should be the end of the matter, as Lilly's subjection to unconstitutionally constituted ADR panels is no different from the injury deemed constitutionally irreparable in *United Church* and its progeny. Regardless of whether it wins or loses a given ADR proceeding, Lilly is necessarily injured by its coerced participation in procedures that violate Article III overseen by

[2] Constitutional torts "analogous to a 'personal-injury' claim[s]" (*e.g.*, "a Fourth Amendment violation stemming from an illegal search or seizure") are exceptions to this rule because "money damages [can] be awarded" in such cases. *Exodus Refugee Immigr., Inc. v. Pence*, 165 F. Supp. 3d 718, 739 (S.D. Ind. 2016). But that is not the case here. *See infra* pp. 33-34.

panelists that violate Article II. *See United Church*, 689 F.2d at 701. And while Article III and the Appointments Clause are "structural" provisions, the Supreme Court has repeatedly emphasized that, because the Constitution's "structure in general … is ***designed*** to protect individual liberty," violation of structural provisions harms private entities as well and can form the basis for individual injury sufficient for legal and equitable remedies against the government. *Bond v. United States*, 572 U.S. 844, 880 (2014); *see, e.g.*, *Legal Servs. Corp. v. Velazquez*, 531 U.S. 533 (2001) (affirming grant of preliminary injunction to cure, *inter alia*, a separation-of-powers violation); *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952) (same); *see also Bond v. United States*, 564 U.S. 211, 222 (2011) ("Separation-of-powers principles … protect the individual."). Preliminary relief is thus necessary to prevent Lilly from suffering irreparable harm in the form of constitutional injuries that cannot be remedied once suffered as a matter of law.

That is all the more true in light of the United States' sovereign immunity. No matter what damages Lilly accrues or how vast the sums it is forced to expend complying with Defendants' unfairly burdensome audit requirements, responding to the deluge of ADR threats and incoming ADR petitions, and defending itself in the unconstitutional tribunals, Lilly will be precluded from recovering a cent as a matter of law. That harm is irreparable literally by definition: "[W]here, as here, the plaintiff in question cannot recover damages from the defendant due to the defendant's sovereign immunity[,] any loss of income suffered by a plaintiff is irreparable per se." *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008); *accord, e.g.*, *District of Columbia v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 34 (D.D.C. 2020) ("[E]conomic injury caused by federal agency action is unrecoverable because the APA's waiver of sovereign immunity does not extend to damages claims."); *see* 5 U.S.C. § 702 (permitting judicial review of agency action under the APA only where the plaintiff is "seeking relief other than money damages"). Indeed, the presence of

"irreparable injury because the government is immune from damage suits" makes preliminary relief "clearly appropriate" when, as here, it is "coupled with [a] strong showing of likelihood of success on the merits." *Woerner v. U.S. Small Bus. Admin.*, 739 F. Supp. 641, 650 (D.D.C. 1990).

In short, unless the ADR process is enjoined, Lilly will be forced to expend enormous resources, none of which it will be able to get back, all the while suffering personal constitutional harms that the Seventh Circuit has repeatedly recognize amount to irreparable injury on their own.

III. The Balance Of Harms And Public Interest Favor A Preliminary Injunction.

Lilly faces what could amount to hundreds of ADR petitions seeking damages and other relief imposed through unconstitutional administrative proceedings. *See, e.g.*, *Gov't Supp. Consolidating Servs., Inc. v. Bayh*, 734 F. Supp. 853, 865 (S.D. Ind. 1990) (granting preliminary injunction where irreparable economic harm and "possible violation of … constitutional rights" outweighed harms to the government). If allowed to proceed, the ADR panels could impose extra-statutory obligations on Lilly (and all other participating manufacturers) without providing Lilly a fair opportunity to defend itself and properly adjudicate the important federal questions raised in this case. That is more than enough to tilt the balance in Lilly's favor, particularly since Lilly is likely to prevail on the merits. *See Cook Cty. v. Wolf*, 962 F.3d 208, 234 (7th Cir. 2020) ("the more likely the plaintiff is to win, the less heavily need the balance of harms weigh in his favor").

By contrast, Defendants will not "be harmed by advancing the consideration of the constitutional questions" raised by HRSA's ADR rulemaking. *Kendall-Jackson Winery, Ltd. v. Branson*, 82 F. Supp. 2d 844, 878 (N.D. Ill. 2000) (granting preliminary injunction to enjoin administrative proceedings which raised constitutional questions). There is no harm to the government "when it is prevented from enforcing an unconstitutional [law]," *Joelner v. Vill. of Wash. Park*, 378 F.3d 613, 620 (7th Cir. 2004), and Defendants likewise will not be "harmed by having to conform to constitutional standards" related to rulemaking and statutory interpretation,

Does v. City of Indianapolis, 2006 WL 2927598, at *11 (S.D. Ind. Oct. 5, 2006). Nor will any covered entity suffer cognizable harm by virtue of an order enjoining the ADR process, given that the question of whether manufacturers must give discounts to contract pharmacies is dispositive of each ADR action filed thus far (and each likely to come). In any case, the potential harms to Lilly's constitutional rights far outweigh any private economic concerns related to Lilly's alleged "overcharges" of contract pharmacies for covered outpatient drugs—all of which (unlike Lilly's present and expanding injuries) can be remedied if Lilly does not ultimately prevail here. *See Tr. & Inv. Advisers*, 43 F.3d at 296-97 (deprivation of constitutional rights outweighs lost tax revenue).

Furthermore, Defendants have not yet even constituted the ADR panels, let alone assigned any cases to any specific ADR panel; in fact, the current Administration withdrew the prior Administration's notice of appointments. Any delay while this Court reviews the legality of their regime is thus minor compared to the ***years*** Defendants took to promulgate rules in the first place. The public interest is also served by a prompt adjudication of the questions at issue here ***in this Court***, not through piecemeal adjudication by administrative panels in a process that is both unfair and unconstitutional. Finally, "[i]t is always in the public interest to prevent the violation of a party's constitutional rights." *G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994); *accord ACLU v. Alvarez*, 679 F.3d 583, 590 (7th Cir. 2012).

CONCLUSION

For the foregoing reasons, the Court should grant Lilly's motion for preliminary injunction.

Dated: January 25, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on **January 25, 2021**, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system. I further certify that copies will be mailed by U.S. mail to the following addresses:

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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,
Lilly Corporate Center
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Indianapolis, IN 46225,

and

LILLY USA, LLC,
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Plaintiffs,

v.

NORRIS COCHRAN, in his official capacity as Acting Secretary of Health & Human Services,
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and

HEALTH RESOURCES AND SERVICES ADMINISTRATION
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Rockville, MD 20852,

Defendants.

No. 1:21-cv-81-SEB-MJD

Document Electronically Filed

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

INDEX OF EXHIBITS

EXHIBIT	DESCRIPTION
Exhibit A	81 Fed. Reg. 53,381, NPRM
Exhibit B	OMB RIN 0906-AA90
Exhibit C	85 Fed. Reg. 80,632, ADR Rule
Exhibit D	ADR Petition and PI Motion - complete B
Exhibit E	HRS A 340B (ADR) (posted Jan. 12, 2021)
Exhibit F	2020.09.01 Statement of CEO of 340B Health
Exhibit G	Declaration of Derek L. Asay

Exhibit A

81 FR 53381-01, 2016 WL 4240239(F.R.)
PROPOSED RULES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
42 CFR Part 10
RIN 0906-AA90

340B Drug Pricing Program; Administrative Dispute Resolution

Friday, August 12, 2016

AGENCY: Health Resources and Services Administration, HHS.

***53381** ACTION: Notice of proposed rulemaking.

SUMMARY: The Health Resources and Services Administration (HRSA) implements section 340B of the Public Health Service Act (PHSA), which is referred to as the "340B Drug Pricing Program" or the "340B Program." This proposed rule will apply to all drug manufacturers and covered entities that participate in the 340B Program. The proposed rule sets forth the requirements and procedures for the 340B Program's administrative dispute resolution process.

DATES: Submit written comments on or before October 11, 2016.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906-AA90, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions.
• Federal eRulemaking Portal: http://www.regulations.gov. Follow instructions for submitting comments. This is the preferred method for the submission of comments.

• Email: 340BNPRMADR@hrsa.gov. Include 0906-AA90 in the subject line of the message.

• Regular, express, or overnight mail: CAPT Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

All submitted comments will be available to the public in their entirety. All comments received may be posted without change to http://www.regulations.gov, including any personally identifiable or confidential business information that is included in a comment.

FOR FURTHER INFORMATION CONTACT: CAPT Krista Pedley, Director, OPA, HSB HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301-594-4353.

SUPPLEMENTARY INFORMATION: The President encourages Federal agencies through Executive Order 13563 to develop balanced regulations by encouraging broad public participation in the regulatory process and an open exchange of ideas. Accordingly, the Department of Health and Human Services (HHS or the Department) urges all interested parties to examine this regulatory proposal carefully and to share your views with us, including any data to support your positions. If you have questions before submitting comments, please see the FOR FURTHER INFORMATION CONTACT field above for the name and contact information of the subject-matter expert involved in the development of this proposal. We will consider all written comments received during the comment period before issuing a final rule.

If you are a person with a disability and/or a user of assistive technology who has difficulty accessing this document, please contact HRSA's Regulations Officer at: Room 13N82, 5600 Fishers Lane, Rockville, MD 20857; or by telephone at 301-443-1785, to obtain this information in an accessible format. This is not a toll free telephone number.

Please visit http://www.HHS.gov/regulations for more information on HHS rulemaking and opportunities to comment on proposed and existing rules.

I. Background

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the PHSA entitled "Limitation on Prices of Drugs Purchased by Covered Entities," which was codified at 42 U.S.C. 256b. The 340B Program permits covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. REP. No. 102-384(II), at 12 (1992). The Secretary of the HHS delegated the authority to operate section 340B of the PHSA to the Administrator of HRSA. Pursuant to this delegation of authority, HRSA established and administers the 340B Program. Operationally, the 340B Program is housed within HRSA's Healthcare Systems Bureau (HSB), Office of Pharmacy Affairs (OPA). Eligible covered entity types are defined in section 340B(a)(4) of the PHSA, as amended. Section 340B of the PHSA instructs HHS to enter into pharmaceutical pricing agreements (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS that comply with section 340B of the PHSA if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices, which are based on quarterly pricing data reported by manufacturers to the Centers for Medicare & Medicaid Services (CMS).

Section 7102 of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by section 2302 of the Health Care and Education Reconciliation Act (Pub. L. 111-152), hereinafter referred to as the "Affordable Care Act," added section 340B(d)(3) of the PHSA, which requires the Secretary of HHS (or the Secretary) to promulgate a regulation establishing ***53382** and implementing a binding administrative dispute resolution (ADR) process for certain disputes arising under the 340B Program. The purpose of the ADR process is to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers; and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion to ineligible patients or duplicate discounts. The 340B ADR process is not intended to be a trial-like proceeding governed by formal review of evidence and procedure. Rather, it is an administrative process that is designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts, or diversion. Historically, HHS has encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith. The ADR process as proposed in this rule is not intended to replace these good faith efforts, but should be considered as a last resort in the event good faith efforts to resolve disputes have not been successful. In addition, covered entities and manufacturers should carefully evaluate whether the ADR process is appropriate for de minimis claims given the investment of the time and resources required of the parties involved.

In 2010, HHS issued an advanced notice of proposed rulemaking (ANPRM) that requested comments on the development of an ADR process (75 FR 57233, September 20, 2010). The ANPRM specifically requested comments on: (1) Administrative procedures, (2) existing models, (3) threshold requirements, (4) hearings, (5) decision-making officials or bodies, (6) appropriate appeals procedures, (7) deadlines, (8) discovery procedures, (9) manufacturer audits, (10) consolidation of manufacturer claims, (11) covered entity consolidation of claims; (12) claims by organizations representing covered entities, and (13) integration of dispute resolution with other 340B requirements added by the Affordable Care Act. HHS received 14 comments on the ANPRM. The comments received were considered in the development of this proposed rule.

HHS encourages all stakeholders to provide written comments on this NPRM. This proposed regulation, when finalized, will replace the 340B Program's guidelines on the informal dispute resolution process developed to resolve disputes between covered entities and manufacturers, which was published on December 12, 1996 (61 FR 65406).

II. Summary of the Proposed Regulations

The proposed revisions to 42 CFR part 10 are described according to the applicable section of the regulations. The United States District Court for the District of Columbia vacated the 340B Program Regulations at 42 CFR part 10 relating to Orphan Drugs (subpart C). (PhRMA v. HHS, No. 13-01501 (D.D.C. May 23, 2014). This NPRM proposes to add new definitions to § 10.3 and retitle and replace the language in subpart C as set forth below.

§ 10.3 Definitions.

HHS is proposing to add the following definitions: "Administrative Dispute Resolution Process," "Administrative Dispute Resolution Panel (340B ADR Panel)," "claim," and "consolidated claim."

Subpart C—Administrative Dispute Resolution

§ 10.20 340B Administrative Dispute Resolution Panel

(a) Members of the 340B ADR Panel.

As required by section 340B(d)(3)(B)(i), regulations promulgated by the Secretary shall designate or establish a decision-making official or body within HHS to review and make a binding decision for claims filed by covered entities and manufacturers. HHS proposes to establish a decision-making body (referred to as the "340B ADR Panel" or "Panel") to review and resolve such claims.

The proposed 340B ADR Panel will ensure an unbiased and fair review of the claims, and reduce the individual burden associated with having a single decision-making official who is solely responsible for reviewing and resolving claims. The proposed 340B ADR Panel will include three members, chosen from a roster of eligible individuals alternating from claim to claim, and one ex-officio, non-voting member chosen from the staff of OPA to facilitate the review and resolution of claims within a reasonable time frame. The proposed roster of eligible individuals will be comprised of Federal employees (e.g., employees of CMS or the U.S. Department of Veterans Affairs) with demonstrated expertise or familiarity with the 340B Program. The ADR panel will not be compensated.

HHS proposes that for each filed claim that is reviewed, HSB will review the qualifications of individuals on the 340B ADR Panel roster and select those with expertise or familiarity with the appropriate aspects of the 340B Program. HHS also proposes that individuals serving on a 340B ADR Panel may be removed for cause. For example, if it is determined prior to or during the course of a Panel member's review of a claim that there is a conflict of interest, as described in subsection (b), with respect to that claim, the Panel member will be removed from the Panel and replaced by another individual from the 340B ADR Panel roster.

HHS is soliciting specific comments on the proposed size and composition of the 340B ADR Panel, in particular whether the 340B ADR Panel should be comprised of a set number of voting members to maintain consistency and transparency across each claim that is reviewed, whether HHS should retain the flexibility to appoint a requisite number of voting members based on the complexity of the claim and other factors, and whether the 340B ADR Panel should include at least one OPA staff member as a voting member or whether the inclusion of an OPA staff member as an ex-officio, non-voting member is sufficient to ensure adherence to 340B policies and procedures.

(b) Conflicts of interest.

To ensure fairness and objectiveness, HHS proposes that each 340B ADR Panel member be screened prior to reviewing a claim and not allowed to conduct a review if any conflicts of interest exist. For example, the individual would not review a claim if he or she has a conflict of interest with respect to the parties involved in the claim or the subject matter of the claim. HHS

proposes that individuals be screened for conflicts of interest in accordance with U.S. Office of Government Ethics policies and procedures applicable to Federal employees. Conflicts of interest may include the following: (1) Financial interest; (2) family or close relation to a party involved; and (3) current or former business or employment relation to a party. The specific procedures for screening members of the panel prior to their service on the 340B ADR Panel will be detailed in future guidance.

(c) Duties of the 340B ADR Panel.

In subsection (c), HHS proposes that once the 340B ADR Panel receives the claim, the 340B ADR Panel will consider all documentation provided by the parties and may request additional information or clarification from any party involved with the claim. HHS also proposes that the 340B ADR Panel review claims in a session closed to the parties involved, including any associations or organizations, or legal counsel representing the parties.

***53383** In this subsection, HHS also proposes that the 340B ADR Panel may consult with subject matter experts within OPA regarding 340B program requirements while reviewing a claim. The 340B ADR Panel will provide a final decision only with respect to the claim. HHS proposes that the 340B ADR Panel's final decision must represent the decision of a majority of the Panel members but need not be unanimous.

§ 10.21 Claims

(a) Claims permitted.

Section 7102 of the Affordable Care Act added section 340B(d)(3) of the PHSA, which instructs the Secretary to establish and implement a binding ADR process to resolve certain 340B Program statutory violations. Section 340B(d)(3)(A) of the PHSA specifies that the ADR process is to be used to resolve: (1) Claims by covered entities that they have been overcharged by manufacturers for drugs purchased under this section and (2) claims by manufacturers, after a manufacturer has conducted an audit of a covered entity, as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibitions against duplicate discounts and diversion (sections 340B(a)(5)(A) and (B) of the PHSA).

(b) Requirements for filing a claim.

In subsection (b), HHS proposes that the covered entity and the manufacturer meet certain requirements for filing a claim. These proposed requirements will ensure that a claim of the type specified in section 340B(d)(3)(A) of the PHSA is the subject of the dispute.

The Department is proposing that covered entities and manufacturers file a written claim, based on the facts available, to HSB within 3 years of the date of the sale (or payment) at issue in the alleged violation and that any claim not filed within 3 years shall be time barred. The proposed requirement that a claim be filed within 3 years is consistent with the record retention expectations for the 340B Program and will ensure that covered entities and manufacturers have access to relevant records needed to review and respond to claims. This proposal ensures documents must be submitted with each claim to verify that the alleged violation is not time barred. This proposed requirement will prevent a party from asserting a claim that is stale. HHS requests public comment concerning the 3 year limitation on claims submission.

HHS is also proposing that once a claim is submitted and the opposing party has been notified of the claim, any file, document, or record associated with a claim be maintained by the covered entity and/or manufacturer until the 340B ADR Panel's final agency decision is issued.

Covered Entity Claims

In section 10.21(b)(2), HHS proposes that to be eligible for the ADR process, each claim filed by a covered entity must include documents sufficient to demonstrate a covered entity's claim that it has been overcharged by a manufacturer, along with any

such documentation as may be requested by HSB to evaluate the veracity of the claim. Such documentation may include: (1) A 340B purchasing account invoice which shows the purchase price by national drug code (NDC), less any taxes and fees; (2) the 340B ceiling price for the drug during the quarter(s) corresponding to the time period(s) of the claim; and (3) documentation of the attempts made to purchase the drug via a 340B account at the ceiling price, which resulted in the instance of overcharging. HHS believes that these documents are readily available to a covered entity through the usual course of business and should not be overly burdensome to produce, however HHS requests public comment on the feasibility or producing the documentation as proposed. HHS may also request that the covered entity provide it with a written summary of attempts to work in good faith to resolve the instance of overcharging with the manufacturer at issue.

Pursuant to section 340B(d)(1)(B) of the PHSA, HHS is developing a system to verify the ceiling price of a 340B drug and allow covered entities to access and verify the ceiling price. Until such system is developed, HHS has access to ceiling price data and will ensure that the 340B ADR panel will also have access as they evaluate any particular claim. Covered entities will be able to access ceiling price information through this system, which may lessen the burden in submitting the information accompanying a claim.

Manufacturer Claims

In section 10.21(b)(3), HHS proposes that to be eligible for the 340B ADR process, each claim filed by a manufacturer must include documents sufficient to demonstrate a manufacturer's claim that a covered entity has violated the prohibition on diversion and/or duplicate discount, along with any such documentation as may be requested by HSB to evaluate the veracity of the claim. Such documentation may include: (1) A final audit report which indicates that the manufacturer audited the covered entity for compliance with the prohibition on diversion (section 340B(a)(5)(B) of the PHSA) and/or duplicate discounts (section 340B(a)(5)(A) of the PHSA) and (2) the covered entity's written response to the manufacturer's audit finding(s). HHS may also request that the manufacturer submit a written summary of attempts to work in good faith to resolve the claim with the covered entity.

(c) Consolidation of claims.

In subsection (c), HHS proposes that, if requested, covered entities or manufacturers may be permitted to consolidate their individual claims. Section 340B(d)(3)(B)(vi) of the PHSA permits "multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding. . . ." HHS proposes that for consolidated claims, the claim must list each covered entity and include documentation and/or information from each covered entity demonstrating that the covered entity meets all of the requirements for filing a claim with HHS and that a letter requesting consolidation of claims must also accompany the claim and must document that each covered entity consents to the consolidation of the claim.

Pursuant to section 340B(d)(3)(B)(vi) of the PHSA, consolidated claims are also permitted on behalf of covered entities by associations or organizations representing their interests. Therefore, HHS proposes that the covered entities must be members of the association or the organization representing them and that each covered entity must meet the requirements listed in subsection (b) for filing a claim with HSB. The proposed consolidated claim must assert overcharging by the same manufacturer for the same drug(s), and the organization or association will be responsible for filing the claim. HHS also proposes requiring that a letter requesting consolidation of claims must accompany the claim and must document that each covered entity consents to the organization or association asserting a claim on its behalf.

Similarly, at the request of two or more manufacturers, section 340B(d)(3)(B)(v) of the PHSA permits the consolidation of claims brought by more than one manufacturer against the same covered entity if consolidation is consistent with the statutory goals of fairness and economy of resources. This NPRM proposes that the claim must list each manufacturer and include documentation and/or information from each manufacturer demonstrating that the manufacturer meets the ***53384** requirements listed in subsection (b) for filing a claim with HSB. HHS also proposes that a letter requesting consolidation of claims must be submitted with the claim and must document that each manufacturer consents to the consolidation of the claims. The statutory authority

for implementing the 340B ADR process does not permit consolidated claims on behalf of manufacturers by associations or organizations representing their interests. Therefore, HHS is not proposing this option in this NPRM.

With regard to the consolidation of claims by manufacturers against a covered entity, HHS is seeking specific comment on the grounds under which consolidation would be consistent with the statutory goals of fairness and economy of resources, as required by section 340B(d)(3)(B)(v) of the PHSA. In addition, while HHS is proposing, as required by the 340B statute, an ADR process that allows manufacturers to consolidate claims against a covered entity, we recognize the operational challenges presented by the statutory requirement for a manufacturer to first audit the covered entity. HHS is, therefore, seeking comment on how manufacturers requesting a consolidated claim against a covered entity can satisfy the audit requirement.

(d) Deadlines and procedures for filing a claim.

In subsection (d), HHS proposes that covered entities and manufacturers file a claim with HSB demonstrating that they satisfy the requirements described in subsection (b) and that the party filing a claim must send written notice to the opposing party regarding the claim within 3 business days of submitting the claim and the party must submit confirmation of the opposing party's receipt or acknowledgement of receipt within 3 business days. HHS also proposes that the written notice to the opposing party must include a summary of the documents submitted as part of the claim.

HHS proposes that HSB will review the information submitted as part of the claim to verify that the requirements for filing a claim have been met. HSB would contact the initiating party once the claim has been received and may request additional information before accepting a claim for review by the 340B ADR Panel. If additional information is requested, the party filing the claim will have 20 business days of receipt of the request to respond. Claims will not move forward for review by the 340B ADR Panel if the initiating party does not respond to the request for additional information or if a party files a claim for any purpose other than those specified in the statute (i.e., overcharging, duplicate discount, or diversion), or if the alleged violation occurred more than 3 years before the date of filing the claim.

HHS proposes that HSB will make a determination as to whether all requirements are met and provide written notice to all parties within 20 business days after receiving the claim and any subsequently requested information, which will be transmitted via both hard copy and email. If HSB determines the claim includes all necessary documentation and meets the requirements for filing a claim, the claim will be forwarded to the 340B ADR Panel for review. HSB would provide additional information on the 340B ADR process to all parties at that time, including contact information for requested follow-up communications and an approximate timeframe for the 340B ADR Panel's review.

HHS proposes that if the claim does not move forward for review by the ADR Panel, written notice will be sent by HSB to the parties involved that includes the basis for the decision and will advise the party that they may revise and refile the claim if the party has new information to support the alleged statutory violation.

(e) Responding to a submitted claim.

In subsection (e), HHS proposes that once the parties have been notified by HSB that the claim has met the requirements in subsection (b) and will move forward for review by the 340B ADR Panel, the opposing party will have 20 business days to submit a written response to the allegation to the 340B ADR Panel and the party who filed the claim. Subsequent requests for information regarding the claim would be made by the 340B ADR Panel as needed, and the 340B ADR Panel will consider any additional information that was provided by the parties involved. However, if an opposing party does not respond to a request for information from HSB or the 340B ADR Panel or otherwise elects not to participate in the 340B ADR process, the 340B ADR Panel will make a decision on the claim based on the information submitted in the claim.

§ 10.22 Covered entity information requests.

Pursuant to section 340B(d)(3)(B)(iii) of the PHSA, regulations promulgated by the Secretary for the 340B ADR process will establish procedures by which a covered entity may discover or obtain information and documents from manufacturers and third parties relevant to a claim that the covered entity has been overcharged by the manufacturer. This NPRM proposes that such covered entity information requests be facilitated by the 340B ADR Panel. HHS proposes that a covered entity must submit a written request for information to the 340B ADR Panel no later than 20 business days after the entity was notified by HSB that the claim would move forward for the ADR Panel's review. The 340B ADR Panel will review the information/document request to ensure that it is reasonable and within the scope of the asserted claim. The 340B ADR Panel will notify the covered entity in writing if any request is deemed reasonable and within the scope of the asserted claim and permit the covered entity to submit a revised information/document request, if it is not.

In this section, HHS proposes that the 340B ADR Panel will consider relevant factors, such as the scope of the information/document request, whether there are consolidated claims, or the involvement of one or more third parties in distributing drugs on behalf of the manufacturer and that once reviewed, the 340B ADR Panel will submit the information/document request to the manufacturer, which must respond within 20 business days.

HHS also proposes that the manufacturer must fully respond in writing to the information request and submit its response to the 340B ADR Panel by the stated deadline and that the manufacturer is responsible for obtaining relevant information/documents from wholesalers or other third parties that may facilitate sales or distribution of its drugs to covered entities. HHS proposes that if a manufacturer anticipates it will not be able to fully respond by the deadline, the manufacturer may request one extension in writing within 15 business days. The extension request that is submitted to the 340B ADR Panel must include any available information, the reason why the deadline is not feasible, and outline a proposed timeline for fully responding to the information request. The 340B ADR Panel will review the extension request and notify both the manufacturer and the covered entity in writing as to whether the request for an extension is granted and the date of the new deadline. If a manufacturer does not respond to a request for information from HSB or the 340B ADR Panel, HHS proposes that the 340B ADR Panel will make a decision on the claim based on the information submitted in the claim package that moved forward for review.

***53385 § 10.23 Final agency decision**

In § 10.23, HHS proposes that the 340B ADR Panel review the documents submitted by the parties and determine if there is adequate support to conclude that a violation as described in subsection (a)(1) or (2) of § 10.21 has occurred. The 340B ADR Panel will prepare a draft agency decision letter, which includes the 340B ADR Panel's findings and conclusions regarding the alleged violation. HHS is proposing a process whereby the 340B ADR Panel's draft agency decision letter will be sent to all parties, and the parties involved will have 20 business days to respond to the 340 ADR Panel. HHS is seeking specific comments on this process and whether this proposed process will facilitate or hinder the fair, efficient, and timely resolution of claims.

HHS also proposes that once the parties have reviewed and submitted comments to the draft agency decision letter, the 340B ADR Panel will prepare and submit its final agency decision letter to all parties in the dispute, which may incorporate rebuttals from the parties that were considered by the 340B ADR Panel to help inform the final agency decision. The final agency decision made by 340B ADR Panel will conclude the administrative resolution process; however, HHS proposes that the final agency decision letter also be submitted to HSB to take enforcement action or apply sanctions, as appropriate. For example, if the 340B ADR Panel makes a decision that a covered entity has violated the prohibition against diversion, HSB may require, as a sanction, that the covered entity repay the affected manufacturer. If the 340B ADR Panel makes a decision that a manufacturer overcharged a covered entity, HSB may require, as a sanction, that the manufacturer refund or issue a credit to the affected covered entity. In both cases, HSB will work with the party in violation on any remedy and corrective action.

HHS proposes that the 340B ADR Panel's final agency decision letter will be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction in accordance with section 340B(d)(3)(C) of the PHSA. HHS may, at its sole discretion, publish a summary of the claims that have gone through the 340B ADR process on the HRSA Web site, including the names of the parties and the nature of the 340B ADR Panel's findings (e.g., overcharging, duplicate discount, or diversion). HHS will consider issuing future subregulatory guidance on this topic as necessary.

III. Regulatory Impact Analysis

HHS has examined the effects of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 8, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB).

This proposed rule is not likely to have economic impacts of $100 million or more in any one year; therefore, it has not been designated an "economically significant" rule under section 3(f)(1) of Executive Order 12866. This proposed rule creates a framework for the Department to resolve certain disputed claims regarding manufacturers overcharging covered entities and disputed claims of diversion and duplicate discounts by covered entities audited by manufacturers under the 340B Program. HHS does not anticipate the introduction of an administrative dispute resolution process to result in significant economic impacts.

The Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, HHS must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a 3 percent impact on at least 5 percent of small entities.

The proposed rule would affect drug manufacturers (North American Industry Classification System code 325412: Pharmaceutical Preparation Manufacturing). The small business size standard for drug manufacturers is 750 employees. Approximately 600 drug manufacturers participate in the 340B Program. While it is possible to estimate the impact of the proposed rule on the industry as a whole, the data necessary to project changes for specific manufacturers or groups of manufacturers is not available, as HRSA does not collect the information necessary to assess the size of an individual manufacturer that participates in the 340B Program. The proposed rule would also affect health care providers. For purposes of the RFA, HHS considers all health care providers to be small entities either by virtue of meeting the Small Business Administration (SBA) size standard for a small business, or for being a nonprofit organization that is not dominant in its market. The current SBA size standard for health care providers ranges from annual receipts of $7 million to $35.5 million. As of July 1, 2016, over 12,000 covered entities participate in the 340B Program, which represent safety-net healthcare providers across the country.

The proposed rule introduces an administrative mechanism to review claims by manufacturers that covered entities have violated certain statutory obligations and claims by covered entities that have been overcharged for ***53386** covered outpatient drugs by manufacturers. The documentation required as part of this administrative process are documents that manufacturers and covered entities are already required to maintain as part of their participation in the 340B Program. HHS expects that this documentation would be sufficiently available prior to submitting a claim. Therefore, the collection of this information would not result in an economic impact or create additional administrative burden on these businesses.

HHS believes the proposed administrative dispute resolution process will provide a cost-efficient option for resolving claims that would otherwise remain unresolved or require litigation. The proposed rule provides an option to consolidate claims by similar situated entities, and covered entities may have claims asserted on their behalf by associations or organizations which could reduce costs. HHS has determined, and the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small health care providers or a significant impact on the operations of a substantial number of small manufacturers; therefore we are not preparing an analysis of impact for the purposes of the RFA. HHS estimates that the economic impact on small entities and small manufacturers will be minimal and less than 3 percent. HHS welcomes comments concerning the impact of this proposed rule on small manufacturers and small health care providers.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year." In 2014, that threshold level was approximately $155 million. HHS does not expect this proposed rule to exceed the threshold.

Executive Order 13132—Federalism

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." This proposed rule would not "have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." The proposals in this notice of proposed rulemaking, if implemented, would not adversely affect the following family elements: family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income, or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999. HHS invites additional comments on the impact of this proposed rule from affected stakeholders.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. This proposed rule will not have a significant impact on the current reporting and recordkeeping burden for manufacturers or covered entities under the 340B Program. Based on current experience with the informal ADR process offered by the 340B Program, there have only been four requests for informal dispute resolution since the inception of the Program. Of the four dispute resolution requests, two were terminated by HRSA due to non-participation by one of the parties, another was dismissed due to lack of sufficient evidence, and the last was terminated because the parties disputed the existence of any attempt of good faith resolution. The relatively small number is attributed to the success of parties' attempts to resolve issues in good faith. Due to this very small number of informal dispute resolution requests, there has been very limited experience to date with dispute resolution record keeping. Changes proposed in this rulemaking would not result in significant reporting or recordkeeping burden. Comments are welcome on the accuracy of this statement.

Dated: May 24, 2016.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: June 7, 2016.

Sylvia M. Burwell,

Secretary. Department of Health and Human Services.

List of Subjects in 42 CFR Part 10

Biologics, Business and industry, Diseases, Drugs, Health, Health care, Health facilities, Hospitals, 340B drug pricing program.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 42 CFR part 10 as follows:

PART 10—340B DRUG PRICING PROGRAM

1. The authority citation for part 10 is revised to read as follows:

Authority: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b), as amended.

42 CFR § 10.3

2. Amend § 10.3 by adding definitions for “Administrative Dispute Resolution (ADR) process”,” Administrative Dispute Resolution Panel (340B ADR Panel)”, “Claim”, and “Consolidated claim” to read as follows:

42 CFR § 10.3

§ 10.3 Definitions.

* * * * *

Administrative Dispute Resolution (ADR) process means a process used to resolve claims by covered entities that may have been overcharged for 340B drugs purchased by manufacturers, and claims by manufacturers of 340B drugs, after a manufacturer has conducted an audit of a covered entity, that a covered entity may have violated the prohibitions against duplicate discounts or diversion.

Administrative Dispute Resolution Panel (340B ADR Panel) means a decision-making body within the Department that reviews and makes a binding decision for claims brought under the ADR Process.

* * * * *

Claim means an allegation made by or on behalf of a covered entity or by a manufacturer for purposes of the ADR Process.

Consolidated claim means the submittal of joint claims by covered entities (or their membership organization or association) or manufacturers to the 340B ADR Panel asserting the same allegation against the same party.

* * * * *

3. Revise subpart C to read as follows:

Subpart C—Administrative Dispute Resolution

Sec.

10.20 Administrative Dispute Resolution Panel.

10.21 Claims.

10.22 Covered entity information requests.

10.23 Final agency decision.
42 CFR § 10.20

§ 10.20 Administrative Dispute Resolution Panel.
The Secretary shall establish a decision-making body known as the Administrative Dispute Resolution Panel (340B ADR Panel) to review and make a binding final agency decision ***53387** regarding claims filed by covered entities and manufacturers.

(a) Members of the 340B ADR Panel. (1) The Health Resources and Services Administration (HRSA) shall:

(A) Select three voting members of the 340B ADR Panel from a roster of eligible individuals and one ex-officio, non-voting member from the staff of HRSA's Office of Pharmacy Affairs (OPA);

(B) Alternate the individuals on the 340B ADR Panel for each claim;

(C) Remove an individual from the 340B ADR Panel for cause; and

(D) Appoint replacement members should an individual be unable to complete his or her duties.

(2) No member of the 340B ADR Panel may have a conflict of interest, as defined in subsection (b) of this section.

(b) Conflicts of interest. All members of the 340B ADR Panel will be screened for conflicts of interest prior to reviewing a claim. Conflicts of interest may include:

(1) Financial interest in a party involved, a subsidiary of a party involved, or in the claim before the 340B ADR Panel;

(2) Family or close relation to a party involved; and

(3) Current or former business or employment relation to a party.

(c) Duties of the 340B ADR Panel. The 340B ADR Panel will:

(1) Review and evaluate documents or information submitted by covered entities and manufacturers;

(2) Request additional information or clarification of an issue from any or all parties to make a final decision;

(3) Evaluate a claim in a separate session from the parties involved;

(4) Consult with OPA regarding any inquiries or concerns while reviewing a claim; and

(5) Make a final agency decision on each claim that will be communicated to HRSA for appropriate enforcement.
42 CFR § 10.21

§ 10.21 Claims.
(a) Claims permitted. The ADR process is limited to the following:

(1) Claims by a covered entity that it has been overcharged, as defined in § 10.11(b), by a manufacturer for a covered outpatient drug; and

(2) Claims by a manufacturer, after it has conducted an audit of a covered entity pursuant to section 340B(a)(5)(C) of the PHSA, that the covered entity has violated section 340B(a)(5)(A) of the PHSA, regarding the prohibition of duplicate discounts, or section 340B(a)(5)(B) of the PHSA, regarding the prohibition of the resale or transfer of covered outpatient drugs to a person who is not a patient of the covered entity.

(b) Requirements for filing a claim. (1) A covered entity or manufacturer must file a claim for administrative dispute resolution in writing to HRSA within 3 years of the date of the alleged violation. Any file, document, or record associated with the claim that is the subject of a dispute must be maintained by the covered entity and manufacturer until the final agency decision letter is issued by the 340B ADR Panel.

(2) A covered entity filing a claim described in paragraph (a)(1) of this section must provide documents sufficient to demonstrate its claim that it has been overcharged by a manufacturer, along with any such other documentation as may be requested by HRSA.

(3) A manufacturer filing a claim under paragraph (a)(2) of this section must provide documents sufficient to demonstrate its claim that a covered entity has violated the prohibition on diversion and/or duplicate discount, along with any such documentation as may be requested by HRSA.

(c) Consolidation of claims. (1) Two or more covered entities may jointly file claims of overcharges by the same manufacturer for the same drug or drugs if each covered entity that could file a claim against the manufacturer consents to the jointly filed claim, and meets the minimum requirements, including submission of the required documentation, described in paragraph (b) of this section.

(2) An association or organization may file claims of overcharges by the same manufacturer for the same drug or drugs on behalf of multiple covered entities if each covered entity represented could file a claim against the manufacturer, is a member of the association or organization, meets the requirements described in paragraph (b) of this section, including submission of the required documentation, and each covered entity has agreed to representation by the association or organization on its behalf.

(3) A manufacturer or manufacturers may request to consolidate claims brought by more than one manufacturer against the same covered entity if each manufacturer could individually file a claim against the covered entity, consents to the jointly filed claim, meets the requirements described in paragraph (b) of this section for that claim, and the 340B ADR Panel determines that such consolidation is appropriate and consistent with the goals of fairness and economy of resources. The 340B ADR Panel will not permit joint claims filed on behalf of manufacturers by associations or organizations representing their interests.

(d) Deadlines and procedures for filing a claim. (1) Covered entities and manufacturers must file claims in writing to HRSA. A claim must include all of the requirements in paragraph (b) of this section. Additional information to substantiate a claim may be submitted.

(2) The party filing the claim must notify the opposing party in writing within 3 business days of the date the claim was filed and must provide documentation of such notification to HRSA. The written notice to the opposing party must include a summary of the documents submitted as part of the claim.

(3) HRSA will review all information submitted by the party filing the claim and will make a determination as to whether all requirements are met and provide written notice to all parties within 20 business days after receiving the claim and any subsequently requested information.

(A) Claims that move forward for review. If HRSA finds that the party filing the claim submitted all required documentation and thereby meets the requirements described in paragraph (b) of this section, written notification will be sent to both the manufacturer and covered entity advising that the claim will be forwarded to the 340B ADR Panel for review.

(B) Claims that do not move forward for review. If HRSA finds that the claim does not meet the requirements described in paragraph (b) of this section, written notification will be sent to both the manufacturer and covered entity detailing the reasons that the claim did not move forward. A claim will not move forward for review by the 340B ADR Panel if the claim does not meet the requirements in paragraph (b) of this section. That same claim may only be resubmitted if new information is presented to support the alleged statutory violation.

(e) Responding to a submitted claim. Upon receipt of notification that a claim will move forward to the 340B ADR Panel for review, the party in alleged violation will have 20 business days to submit a written response to the 340B ADR Panel. If an opposing party does not respond to a request for information from HRSA or the 340B ADR Panel, or elects not to participate in the 340B ADR process, the 340B ADR Panel will make a decision on the claim based on the information submitted in the claim. The 340B ADR Panel will consider any additional information that was provided by the parties involved.
42 CFR § 10.22

§ 10.22 Covered entity information requests.
***53388** (a) A covered entity must submit a written request for additional information necessary to support its claim to the 340B ADR Panel within 20 business days of the claim acceptance date. The 340B ADR Panel will review the information request and notify the covered entity if the information request is beyond the scope of the claim and will permit the covered entity to resubmit a revised information request if necessary.

(b) The 340B ADR Panel will submit the covered entity's information request to the manufacturer who must respond to the request within 20 business days.

(c) The manufacturer must fully respond, in writing, to an information request from the 340B ADR Panel by the response deadline.

(1) A manufacturer is responsible for obtaining relevant information from any wholesaler or other third party that may facilitate the sale or distribution of its drugs to covered entities.

(2) If a manufacturer anticipates that it will not be able to respond to the information request by the deadline, it can request one extension by notifying the 340B ADR Panel in writing within 15 business days of receipt of the request.

(3) A request to extend the deadline must include the reason why the current deadline is not feasible and must outline the proposed timeline for fully responding to the information request.

(4) The 340B ADR Panel may approve or disapprove the request for an extension of time and will notify all parties in writing of its decision.
42 CFR § 10.23

§ 10.23 Final agency decision.
(a) The 340B ADR Panel will review documents submitted by the parties and determine if there is adequate support to conclude that a violation as described in paragraph (a)(1) or (2) of § 10.21 has occurred.

(1) The 340B ADR Panel will prepare a draft agency decision letter based on its review and evaluation of all documents submitted by the parties, including documents provided as required in paragraph (b) of § 10.21, information requests in support of a claim, and responses to a claim.

(2) The draft agency decision letter will be sent to all parties and will include the 340B ADR Panel's preliminary findings regarding the alleged violation.

(3) All parties will have 20 business days to respond to the 340B ADR Panel's draft agency decision letter.

(b) The 340B ADR Panel will review the responses of all parties in producing the final agency decision letter.

(1) The final agency decision letter will represent the decision of a majority of the 340B ADR Panel's findings regarding the claim and discuss the findings supporting the decision.

(2) The 340B ADR Panel will submit the binding final agency decision letter to all parties, and to HRSA, as necessary, for appropriate enforcement action.

[FR Doc. 2016-18969 Filed 8-11-16; 8:45 am]

BILLING CODE 4165-15-P

Exhibit B

View Rule

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HHS/HRSA **RIN:** 0906-AA90 **Publication ID:** Spring 2017

Title: 340B Drug Pricing Program; Administrative Dispute Resolution Process

Abstract:

This proposed rule is required under the Affordable Care Act and would implement an enhancement to the 340B Program by establishing a required and binding administrative dispute resolution process to resolve claims raised by covered entities that they have been overcharged for drugs purchased under the 340B Program. This administrative dispute resolution process also is available to drug manufacturers.

Agency: Department of Health and Human Services(HHS)
Priority: Other Significant
RIN Status: Previously published in the Unified Agenda
Agenda Stage of Rulemaking: Completed Actions
Major: No
Unfunded Mandates: No
EO 13771 Designation: uncollected
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations.)
Legal Authority: sec. 7102 of the Affordable Care Act Pub. L. 111-148, amending subsec(d) of sec 340B of the PHS Act
Legal Deadline: None
Timetable:

Action	Date	FR Cite
ANPRM	09/20/2010	75 FR 57233
ANPRM Comment Period End	11/19/2010	
NPRM	08/12/2016	81 FR 53381
NPRM Comment Period End	10/11/2016	
NPRM Withdrawn	08/01/2017	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: None
Federalism: No
Included in the Regulatory Plan: No
RIN Data Printed in the FR: No
Agency Contact:
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Public Health Analyst/Health Care System Bureau
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Exhibit C

85 FR 80632-01, 2020 WL 7319758(F.R.)
RULES and REGULATIONS
DEPARTMENT OF HEALTH AND HUMAN SERVICES
42 CFR Part 10
RIN 0906-AB26

340B Drug Pricing Program; Administrative Dispute Resolution Regulation

Monday, December 14, 2020

AGENCY: Health Resources and Services Administration, HHS.

***80632** ACTION: Final rule.

SUMMARY: The Health Resources and Services Administration (HRSA) implements section 340B of the Public Health Service Act (PHSA), which is referred to as the "340B Drug Pricing Program" or the "340B Program." This final rule will apply to all drug manufacturers and covered entities that participate in the 340B Program. The final rule sets forth the requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process.

DATES: This final rule is effective January 13, 2021.

FOR FURTHER INFORMATION CONTACT: RADM Krista Pedley, Director, OPA, HRSA, 5600 Fishers Lane, Mail Stop 13N182, Rockville, MD 20857, or by telephone at 301-594-4353.

SUPPLEMENTARY INFORMATION:

I. Background

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the PHSA entitled "Limitation on Prices of Drugs Purchased by Covered Entities," which was codified at 42 U.S.C. 256b. The 340B Program permits covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). The Secretary of Health and Human Services (Secretary) delegated the authority to establish and administer the 340B Program to the Administrator of HRSA. Eligible covered entity types are defined in section 340B(a)(4) of the PHSA, as amended. Section 340B(a)(1) of the PHSA instructs HHS to enter into pharmaceutical pricing agreements (PPAs) with manufacturers of covered outpatient drugs. Under section 1927(a)(5)(A) of the Social Security Act, a manufacturer must enter into an agreement with the Secretary that complies with section 340B of the PHSA "[i]n order for payment to be available under section 1903(a) or under part B of title XVIII for covered outpatient drugs of a manufacturer." When a drug ***80633** manufacturer signs a PPA, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices. Those prices are based on quarterly pricing reports that manufacturers must provide to the Secretary through the Centers for Medicare & Medicaid Services (CMS).

Section 7102 of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by section 2302 of the Health Care and Education Reconciliation Act (Pub. L. 111-152), jointly referred to as the "Affordable Care Act," added section 340B(d)(3) to the PHSA, which requires the Secretary to promulgate regulations establishing and implementing a binding ADR process for certain disputes arising under the 340B Program. The purpose of the ADR process is to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts. The ADR process is an administrative process designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts, or diversion. To resolve these disputes, a panel charged with resolving the dispute may find it necessary to resolve related issues such as whether someone is

a "patient" or whether a pharmacy is part of a "covered entity." Historically, HHS has encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith. The ADR process is not intended to replace these good faith efforts, but should be considered as a last resort in the event good faith efforts to resolve disputes have failed. In addition, covered entities and manufacturers should carefully evaluate whether the ADR process is appropriate for minor claims given the investment of the time and resources required of the parties involved and the government.

In 2010, HHS issued an advanced notice of proposed rulemaking (ANPRM) that requested comments on the development of an ADR process (75 FR 57233, Sept. 20, 2010). HHS received 14 comments. In 2016, HHS issued a Notice of Proposed Rulemaking (NPRM) and received 31 comments. The NPRM was removed from the HHS Regulatory Agenda in accordance with a January 20, 2017, memorandum from the Assistant to the President and Chief of Staff, titled "Regulatory Freeze Pending Review," [FN1] which had the effect of pausing action on the proposed rule. The Secretary, however, did not formally withdraw the NPRM, but rather left it open as a viable option. HHS considered the comments received on the NPRM in the development of this final rule. This final rule will replace the 340B Program's guidelines on the informal dispute resolution process developed to resolve disputes between covered entities and manufacturers, which were published on December 12, 1996 (61 FR 65406). Finally, we note that in order to fairly, efficiently, and expeditiously resolve claims pursuant to the ADR process described in this final rule, the Secretary hereby delegates to each 340B ADR Panel, constituted from members of the 340B Administrative Dispute Resolution Board, the authority to make final agency decisions as set forth under 42 U.S.C. 256b(d)(3)(C) and codified in 42 CFR part 10, as amended by this final rule.

1 See https://www.whitehouse.gov/presidential-actions/memorandum-heads-executive-departments-agencies/.

II. Summary of Proposed Provisions and Analysis and Responses to Public Comments

Part 10 of title 42 of the Code of Federal Regulations has been amended to incorporate the ADR process, which is described below in conjunction with comments received to each such section.

General Comments

Comments received during the comment period addressed general issues. We have summarized those comments and have provided a response below.

Comment: Commenters recommend that, before HRSA develops the ADR process, HRSA should establish foundational guidance on key issues, as the conditions for creating such a process are not in place. Specifically, commenters suggest that HRSA reform its guidelines regarding manufacturer audits of covered entities as they are outdated and do not allow for a functioning ADR process; develop manufacturer refund procedures for cases where 340B ceiling prices change due to restated Medicaid rebate metrics; finalize the process for calculating 340B ceiling prices and imposing civil monetary penalties; and finalize the 340B mega-guidance.

Response: HHS finalized the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties (CMP) Regulation on January 5, 2017 (82 FR 1211). That regulation addressed the calculation of the 340B ceiling price, and imposition of CMPs on manufacturers who knowingly and intentionally overcharge a covered entity. Neither updated manufacturer audit guidelines nor the finalization of the 340B mega-guidance is needed to finalize the ADR process. The 340B statute empowers the 340B ADR Panel reviewing a claim, as set forth in this final rule, to determine when there have been statutory violations concerning overcharges, diversion, and duplicate discounts.

Comment: Several commenters urge HRSA to adopt those conventions for ascertaining deadlines that are commonly used by other administrative bodies and courts. Commenters suggested that HRSA should use calendar days for deadlines rather than business days as misunderstandings about correct deadlines and due dates can be avoided if HRSA were to adopt these commonly used conventions.

Response: HHS agrees with these comments. The ADR process will be governed, to the extent applicable, by the Federal Rules of Civil Procedure and Federal Rules of Evidence, unless the parties agree otherwise and the 340B ADR Panel concurs. Rule 6 of the Federal Rules of Civil Procedure sets out the rules for computing any time period specified in the Rules and that Rule will govern time computation under this regulation.

Comment: Commenters urge HRSA to clarify what would constitute a de minimis claim given the investment of time and resources required of the parties involved. Commenters argue that while the parties may be able to assess what would constitute a reasonable materiality threshold that would warrant pursuing the ADR process, having a standardized threshold could ensure a more uniform and judicious use of the ADR process. Commenters recommend that covered entities could use a threshold of 5 percent of total 340B savings for establishing a de minimis claim.

Response: HHS agrees that some disputes may be too small to warrant the expenditure necessary to conduct a hearing on the matter. Recognizing that petitioners can file jointly as warranted and that claims can be aggregated or consolidated, we do not believe that setting a jurisdictional threshold, whexwhex ere money damages are sought, should adversely affect any covered entity or manufacturer. We believe that an appropriate threshold for a claim or claims for money damages should be $25,000; where equitable relief is sought, however, there will be no threshold for past damages provided ***80634** that the relief sought will be the equivalent of $25,000 in the twelve months following the 340B ADR Panel's decision. HHS is finalizing the jurisdictional threshold for filing a claim in paragraph (b) of § 10.21.

Subpart C—Administrative Dispute Resolution

§ 10.20 Administrative Dispute Resolution Panel

In the proposed rule, HHS sought to establish a decision-making body to review and resolve claims in an unbiased and fair manner, ensure fairness and objectiveness by avoiding conflicts of interest, and set forth the duties of the panel. In this final rule, HHS is finalizing that proposal with some modifications. In this final rule, the Secretary shall establish a 340B Administrative Dispute Resolution Board (Board) consisting of at least six members appointed by the Secretary with equal numbers from the Health Resources and Service Administration (HRSA), the Centers for Medicare & Medicaid Services (CMS), and the HHS Office of the General Counsel (OGC). Administrative Dispute Resolution Panels (340B ADR Panel) of three Board members shall be selected by the HRSA Administrator to review claims and, pursuant to authority expressly delegated through this rule by the Secretary, make precedential and binding final agency decisions regarding claims filed by covered entities and manufacturers. HRSA and CMS Board members shall have relevant expertise and experience in drug pricing or drug distribution. OGC Board members shall have expertise and experience in handling complex litigation.

(a) Members of the 340B ADR Panel.

HHS proposed that HRSA select a 340B ADR Panel to include three members, chosen from a roster of eligible individuals, and one ex-officio, non-voting member chosen from the staff of the HRSA Office of Pharmacy Affairs (OPA) to facilitate the review and resolution of claims within a reasonable timeframe. HHS is modifying that proposal. In this final rule, the HRSA Administrator is empowered to select and convene three-member 340B ADR Panels, constituted from the above-referenced Board, with one member from HRSA, CMS, and OGC with relevant expertise to review claims and make final agency decisions. HHS proposed that individuals serving on a 340B ADR Panel may be removed for cause. HHS is finalizing that proposal. In this final rule, if there is a conflict of interest, as described in paragraph (b), with respect to a claim, the 340B ADR Panel member will be removed from the 340B ADR Panel and replaced by another individual from the Board.

Finally, HHS solicited specific comments on the proposed size and composition of the 340B ADR Panel, in particular whether the 340B ADR Panel should be comprised of a set number of voting members to maintain consistency and transparency across each claim that is reviewed, whether HHS should retain the flexibility to appoint a requisite number of voting members based on the complexity of the claim and other factors, and whether the 340B ADR Panel should include at least one OPA staff member

as a voting member or whether the inclusion of an OPA staff member as an ex-officio, non-voting member would be sufficient to ensure adherence to 340B policies and procedures.

HHS received comments related to the composition of the 340B ADR Panel and after consideration of the comments received, HHS has determined that each 340B ADR Panel must include one attorney from OGC with complex litigation expertise, along with one member from HRSA and one member CMS, each with drug pricing, drug distribution, and other relevant 340B expertise. A non-voting, ex-officio member from OPA will assist each three-member 340B ADR Panel.

Comment: Some commenters suggest that given that the 340B ADR Panel will likely review claims submitted by manufacturers that involve audits conducted of covered entities, the 340B ADR Panel members should also have demonstrated expertise or familiarity with the Government Audit Standards and expertise or familiarity with the 340B Program, in order to properly assess the quality of the audit conducted.

Response: HHS believes the requirements set forth in the final rule allow for 340B ADR Panels with a wide breadth of experience that will ensure an equitable review and fair outcome. In addition, each 340B ADR Panel will include a non-voting member of OPA who would bring additional 340B Program expertise to the ADR proceedings.

Comment: Several commenters support the 340B ADR Panel's composition as proposed, specifically with respect to limiting the 340B ADR Panel to three members to maintain consistency and transparency across each claim reviewed while asserting that a rotation of members will lead to conflicting decisions and inconsistency in dispute decisions. Some commenters recommend that the final rule establish a fixed pool of seven potential 340B ADR Panel members who would serve on the pool for a defined term. In addition, the commenters explain that 340B ADR Panel members would not develop expertise in the details of 340B policies if they only occasionally served on the 340B ADR Panel.

Response: HHS disagrees that appointing a permanent board rather than alternating individuals is the best course. The United States Courts of Appeals operate in panels of three and intra-circuit splits are rare. We are concerned that a single permanent panel may be unable to fairly, efficiently, and expeditiously hear and resolve cases.

Comment: Commenters support the inclusion of at least one OPA staff member as an ex-officio, non-voting member to ensure adherence to 340B policies and procedures. However, other commenters argue that OPA staff cannot be impartial due to their day-to-day involvement with the 340B Program. These commenters argue that even a non-voting member would exercise too much influence over the voting members, particularly if the voting members serve only part-time on the 340B ADR Panel.

Response: HHS appreciates the comments outlining both support and concern with OPA's participation in the process. HHS believes that participation of an OPA staff member as a non-voting, ex officio member is beneficial to the 340B ADR Panel to allow for quick and efficient responses to questions regarding the 340B statute, regulations, and policy and that an OPA staff member would not exercise undue influence over the three voting members. The OPA staff member or members, as the case may be, will be appointed by the Secretary to serve as a non-voting, ex officio member or members. See Federal Election Comm'n v. NRA Political Victory Fund, 6 F.3d 821 (D.C. Cir. 1993), cert. dismissed for want of jurisdiction, 513 U.S. 88 (1994).

Comment: Commenters opposing OPA staff being involved or participating on the 340B ADR Panel suggest that HRSA designate HHS Administrative Law Judges (ALJs) to decide 340B disputes. They argue that ALJs would be in the best position to resolve 340B disputes as ALJs have training to decide administrative law issues correctly, and using an ALJ would ensure an objective evaluation of each dispute by separating the dispute resolution function from HRSA's day-to-day activities and duties.

Response: The involvement of an OPA staff member as a non-voting, ex officio has been addressed above. HHS disagrees that ALJ's are best positioned to resolve 340B disputes. The ***80635** Department's established cadre of ALJs to resolve disputes between the Department and private entities involving federal funds whether through grants, contracts, or under benefit programs such as Medicare. Here, the 340B ADR Panels are more akin to an arbitration panel focusing on complex commercial

arrangements between private actors, where Federal funds may not be directly involved. In this final rule, HHS is establishing 340B ADR Panels, which are uniquely situated to handle the complexities of the 340B Program and related disputes.

Comment: Commenters recommend that the final rule include a provision that allows either party to object to a particular 340B ADR Panel member.

Response: HHS appreciates the comment but believes this is unnecessary as 340B ADR Panel members will be screened for conflicts of interest before reviewing a claim.

(b) Conflicts of interest.

To ensure fairness and objectiveness, HHS proposed that each 340B ADR Panel member be screened prior to reviewing a claim and not be allowed to conduct a review if any conflicts of interest exist. For example, the individual would not review a claim if he or she has a conflict of interest with respect to the parties involved in the claim or the subject matter of the claim. HHS proposed that individuals be screened for conflicts of interest in accordance with U.S. Office of Government Ethics policies and procedures applicable to Federal employees. Conflicts of interest may include the following: (1) Financial interest; (2) family or close relation to a party involved; and (3) current or former business or employment relation to a party. HHS received comments in support of the provision to review for conflicts of interest and is finalizing this section as proposed. Below is a summary of the comments received and HHS' responses.

Comment: Several commenters agree that the 340B ADR Panel members should have demonstrated expertise or familiarity with the 340B Program. These commenters also agree that the 340B ADR Panel members be screened for potential conflicts of interest. Commenters suggest that the final rule include flexibility to expand the 340B ADR Panel beyond the three members to ensure expeditious review of complex 340B claims.

Response: HHS appreciates the comments regarding the expansion of 340B ADR Panel members; however, it does not believe adding more members would expedite the review process.

(c) Duties of the 340B ADR Panel.

HHS proposed that once the 340B ADR Panel receives a claim, the 340B ADR Panel would consider all documentation provided by the parties and may request additional information or clarification from any party involved with the claim.

After further consideration, HHS has determined that a 340B ADR Panel reviewing a claim may consult with OPA subject matter experts regarding 340B program requirements, may entertain motions to dismiss pursuant to Rule 12 of the Federal Rules of Civil Procedure, may permit limited discovery, as necessary, may entertain motions for summary judgment (see Fed. R. Civ.P. 56), and may hold evidentiary hearings as necessary. The 340B ADR Panel's final agency decision must represent the decision of a majority of the 340B ADR Panel members, but need not be unanimous. The 340B ADR Panel's final agency decision shall be precedential and binding on the parties to the claim. HHS did not receive any comments related to the duties of the 340B ADR Panel. This final rule provides the 340B ADR Panel significant discretion in determining relevant material to consider and the manner to conduct its evaluation.

As with typical administrative hearings, the petitioner in an ADR proceeding would bear the burden of persuasion by a preponderance of the evidence. See Administrative Procedure Act, 5 U.S.C. 556(d) (“the proponent of a rule or order shall have the burden of proof.”); Director, OWCP v. Greenwich Collieries, 512 U.S. 267 (1994).

§ 10.21 Claims

(a) Initiating an action. In the NPRM, HHS proposed deadlines and procedures for filing a claim in § 10.21(f). To address some redundancies, HHS is consolidating and finalizing the requirements for initiating an ADR action in a new paragraph (a) of §

10.21. Correspondingly, the comments received on the proposals in the NPRM regarding deadlines and procedures for filing a claim are addressed here in paragraph (a).

In the NPRM, HHS proposed that covered entities and manufacturers file a claim demonstrating that they satisfy certain threshold requirements and that the party filing a claim must send written notice to the opposing party regarding the claim within 3 business days of submitting the claim and the party must submit confirmation of the opposing party's receipt or acknowledgement of receipt. HHS also proposed that the written notice to the opposing party must include a summary of the documents submitted as part of the claim. HHS proposed that information will be reviewed that is submitted as part of the claim to verify that the requirements for filing a claim have been met. The initiating party would then be contacted once the claim has been received and may request additional information before accepting a claim for review by the 340B ADR Panel. If HRSA requests additional information, the party filing the claim would have 20 business days of receipt of the request to respond. Claims would not move forward for review by the 340B ADR Panel if a party files a claim for any purpose other than those specified in the statute (i.e., overcharging, duplicate discount, or diversion), or if the alleged violation occurred more than 3 years before the date of filing the claim.

HHS proposed that a determination will be made as to whether all requirements are met and provide written notice to all parties within 20 business days after receiving the claim and any subsequently requested information. If it is determined the claim includes all necessary documentation and meets the requirements for filing a claim, the claim would be forwarded to the 340B ADR Panel for review. Additional information would be provided on the 340B ADR process to all parties at that time, including contact information for requested follow-up communications and an approximate timeframe for the 340B ADR Panel's review.

HHS proposed that if the claim does not move forward for review by the 340B ADR Panel, written notice would be sent to the parties involved that includes the basis for the determination and would advise the party that they may revise and refile the claim if the party had new information to support the alleged statutory violation.

HHS is finalizing these filing requirements with some changes. Any covered entity or manufacturer may initiate an action for monetary damages or equitable relief against a manufacturer or covered entity, as the case may be, by filing a written petition for relief with HRSA that satisfies all of the requirements set forth in this section. The parties may voluntarily submit additional information to substantiate a claim. In this final rule, HHS also clarifies that the party filing a claim must mail a copy of its petition, along with any attachments, to the General Counsel or other senior official (e.g., Executive Director) opposing party or legal counsel for the opposing party, if applicable, at its principal place of business by certified mail, return receipt requested, within three days of filing the ***80636** claim with HRSA. HHS intends for the 340B ADR Panel to have wide latitude to define the proper course of conduct, scope of the process, and any additional instructions necessary or desirable for the ADR proceedings. HHS underscores that the 340B ADR Panel may in its sole judgment request additional information from the parties to ensure that it will be able to conduct a fair, efficient, and expeditious review of a claim. Our summary of the comments and responses follow.

Comment: Some commenters request that just as covered entities have advance notice of potential claims due to a prior audit, manufacturers should also know about a potential covered entity's claim so that the parties can make good faith efforts to resolve the claim. These commenters explain that such an early notification requirement for covered entities would reinforce HHS' efforts to limit the ADR process to disputes that cannot be resolved informally and would be consistent with the requirement suggested earlier in this letter that any claim (whether asserted by a manufacturer or covered entity) must be accompanied by documentation of prior good faith efforts to resolve the dispute. Advance notification of potential claims and the opportunity to resolve them are crucial. Accordingly, manufacturers should have the same advance notice of potential claims as covered entities that learn of such claims due to a prior audit.

Response: While HHS appreciates the comments regarding advance notification to manufacturers of claims, it does not agree with the assertion that a manufacturer audit constitutes notification of a manufacturer filing an ADR claim. If a manufacturer engages in ADR after an audit of a covered entity, the manufacturer must provide written notice. Further, HHS believes there

is already a process in place for good faith negotiations between manufacturers and covered entities that occurs before filing an ADR claim.

Comment: When reviewing the sufficiency of a claim, HHS proposed that HRSA will decide whether a claim will move forward for review. Commenters request that HRSA include an additional safeguard clarifying that the individual or individuals who review the sufficiency of a claim should not be involved further in the process. The 340B ADR Panel should receive the claim (including any supporting documentation and response) as one complete package. That way, the 340B ADR Panel would be able to review the claim as a matter of first impression. The 340B ADR Panel could remain impartial, and would not be prejudiced by any claims that are initially deemed inadequate or that are further refined through additional documentation.

Response: HHS disagrees that the 340B ADR Panel could not remain impartial or would be prejudiced by claims that are initially deemed inadequate or that are further refined through additional documentation. In any event, HHS anticipates that the 340B ADR Panel will receive a complete package with all of the supporting documentation that is submitted by the parties for ADR review and resolution.

(b) 340B ADR Panel's jurisdiction. In response to comments received as discussed above (General Comments), HHS is finalizing this new paragraph (b), which provides that the 340B ADR Panel shall have jurisdiction to entertain any petition where the damages sought exceed $25,000 or where the equitable relief sought will likely have a value of more than $25,000 during the twelve-month period after the 340B ADR Panel's final agency decision, provided the petition asserts claims of the type set forth below.

(c) Claims permitted.

Section 7102 of the Affordable Care Act added section 340B(d)(3) of the PHSA, which instructs the Secretary to establish and implement a binding ADR process to resolve certain 340B Program statutory violations. Section 340B(d)(3)(A) of the PHSA specifies that the ADR process is to be used to resolve: (1) Claims by covered entities that they have been overcharged by manufacturers for drugs purchased under this section, and (2) claims by manufacturers, after a manufacturer has conducted an audit of a covered entity, as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibitions against duplicate discounts and diversion (sections 340B(a)(5)(A) and (B) of the PHSA). This includes covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim. Each 340B ADR Panel will necessarily have jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim in a fair, efficient, and expeditious manner.

Comment: Some commenters suggest that the proposed rule's requirement that permits claims by a manufacturer only after it has conducted an audit of a covered entity pursuant to section 340B(a)(5)(c) of the PHSA is overly burdensome. These commenters claim that in addition to audits being costly and time-consuming, there are instances where an audit of a covered entity is not possible, but a legitimate basis for a dispute exists. For example, a covered entity may reasonably or unreasonably withhold audit information or behave in a manner that would make an audit ineffective.

Response: HHS disagrees that the process for conducting an audit of a covered entity is improperly burdensome. More important, HHS does not have the authority to waive this statutory requirement. Section 340B(d)(3)(B)(iv) of the PHSA states that the ADR process requires “that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity.”

Comment: Some commenters recommend that HHS clarify that it is outside of the jurisdiction of the ADR process for a covered entity to pursue claims which challenge a manufacturer's Average Manufacturer Price (AMP) or best price (BP) calculations as

a covered entity's claims are limited to the allegation that they were overcharged relative to the statutory 340B ceiling price as calculated using the manufacturer's current "as submitted" AMP and BP data.

Response: Section 340B(d)(3)(A) of the PHSA states, in part, that the ADR process is to resolve claims of alleged 340B overcharges. HHS believes that to do so, the 340B ADR Panel may find it necessary to assess whether the manufacturer's claimed "ceiling price" is in fact accurate. Even though a challenge to the claimed ceiling price is within the 340B ADR Panel's jurisdiction and any potential overcharges that may have resulted from an incorrect ceiling price, a challenge to a manufacturer's AMP or BP calculations is beyond the scope of this jurisdiction.

Comment: A few commenters recommend that HRSA consider allowing the parties the opportunity to voluntarily select mediation, as opposed to arbitration, as a mechanism for resolving disputes. Only after the attempt at mediation proves unsuccessful or if the parties do not agree to meditation, then the process should move to binding arbitration before the 340B ADR Panel.

Response: HHS appreciates the comments regarding the ability of the parties to select mediation as opposed to ***80637** arbitration. HHS notes that there is already an informal process in place for good faith negotiations between covered entities and manufacturers to attempt to resolve 340B disputes before pursuing ADR.

(d) Limitations of actions.

In the NPRM, HHS proposed that the covered entity and the manufacturer meet certain requirements for filing an ADR claim set forth in proposed paragraph (d). The proposed requirements would ensure that a claim of the type specified in section 340B(d)(3)(A) of the PHSA is the subject of the dispute.

The Department proposed that covered entities and manufacturers file a written claim, based on the facts available, or that should have been available, within 3 years of the date of the sale at issue in the alleged violation and that any claim not filed within 3 years would be time barred. The proposed requirement that a claim be filed within 3 years is consistent with the record retention expectations for the 340B Program and would ensure that covered entities and manufacturers have access to relevant records needed to review and respond to claims. The party filing the ADR claim would need to submit documents with each claim to verify that the alleged violation is not time barred. This proposed requirement would prevent a party from asserting a claim that is stale.

HHS also proposed that any file, document, or record associated with a claim be maintained by the covered entity or manufacturer until the 340B ADR Panel's final agency decision is issued unless the 340B ADR Panel provides otherwise. HHS received comments both agreeing with and questioning the timeframe proposed. HHS is finalizing this provision of the rule as proposed, with some modifications, to ensure consistency with requirements set forth in 340B PPAs setting record retention for 3 years for both manufacturers and covered entities. Below is a summary of the comments received and HHS' responses.

Comment: While many commenters agree with the effort to establish a timeframe by which the parties should file a claim, many disagree with the proposed 3-year requirement and suggest a period of at least 5 years. Certain commenters urge HHS to extend the document retention period to take into account the length of manufacturer audits and the time it may take to work with manufacturers on potential solutions (e.g., which could include beginning the 3-year period on the date that the required covered entity audit is concluded, or other similar solutions). Other commenters urge HHS to adopt a different start date based on when a manufacturer restates the 340B ceiling price or when a covered entity discovers that the manufacturer should have restated the 340B ceiling price.

Response: HHS is changing the title of paragraph (d) to "Limitation of Actions" in this final rule. HHS appreciates comments regarding the requisite record retention period. HHS plans to finalize the 3-year period to be consistent with the PPA record retention requirements that apply to both covered entities and manufacturers. However, the three-year time limit would be

subject to normal rules governing statutes of limitations that are not jurisdictional, including the doctrine of equitable tolling. See United States v. Wong, 575 U.S. 402, No. 13-1074 (2015); United States v. June, 575 U.S. 402, No. 13-1075 (2015).

Covered Entity Claims

In the NPRM, HHS proposed that to be eligible for the ADR process, each claim filed by a covered entity must include documents sufficient to demonstrate a covered entity's claim that it has been overcharged by a manufacturer, along with any such documentation as may be requested to evaluate the veracity of the claim. Such documentation may include: (1) A 340B purchasing account invoice which shows the purchase price by national drug code (NDC), less any taxes and fees; (2) the 340B ceiling price for the drug during the quarter(s) corresponding to the time period(s) of the claim; and (3) documentation of the attempts made to purchase the drug via a 340B account at the ceiling price, which resulted in the instance of overcharging. HHS believes that these documents are readily available to a covered entity through the usual course of business and should not be overly burdensome to produce. HHS, however, recognizes that in some cases, a covered entity or manufacturer may not have access to all needed documentation. HHS may also request that a party in need of information provide it with a written summary of attempts to work in good faith to resolve issues with the other party. In cases where documents are essential to a case, but not in the possession of one party and are not provided voluntarily by the other party, the 340B ADR Panel may request the documents and ensure that they become a part of the administrative record and that in most cases, summary judgment would not be entertained where there are outstanding documents in the possession of the party seeking summary judgment but not in the possession of the other party. HHS received comments recommending additional instructions on how to file claims and the type of information requested, which are addressed below. HHS clarifies in this final rule that notwithstanding Rules 8 and 10 of the Federal Rules of Civil Procedure, a covered entity filing a claim described in paragraph (c)(1) of this section must provide documents sufficient to demonstrate in its claim that it has been overcharged by a manufacturer, along with any such other documentation as may be requested by the 340B ADR Panel.

Comment: Some commenters recommend that HHS should separate covered entity documentation requirements for the different types of illustrative overcharge claims: (1) Claims that the initial purchase price of a drug purchased by the covered entity exceeded the ceiling price at that time; and (2) claims that the purchase price of a drug should have been adjusted downward later and a refund should have been issued at a specified later point in time, but was not issued within the time period required under HRSA's yet-to-be-developed refund procedure.

Response: HHS disagrees and believes the documentation requirements set forth in this final rule will provide, in most cases, the necessary information to ascertain the type of overcharge a covered entity is alleging in its claim. Where that is not the case, the petitioner would be entitled to limited discovery, in the case of a covered entity, or an opportunity to make an information request to the 340B ADR Panel, in the case of a manufacturer.

Comment: Commenters object to the requirement that covered entities would need to submit 340B ceiling price information when initiating a claim. According to those commenters, the proposed rule did not consider that covered entities do not have access to 340B ceiling prices, and this information is central to proving that a manufacturer overcharged for a drug. These commenters suggest that HRSA fast-track the development of the ceiling price system that would ensure a level playing field in the ADR process.

Response: HHS has acted to ensure that covered entities have access to the 340B ceiling price, through its launch of the pricing component of the 340B Office of Pharmacy Affairs Information System in January 2019. Every active covered entity has access to the pricing component of 340B OPAIS and can view the prices of all active National Drug Codes (NDC) in the 340B Program. A covered entity's authorizing official and primary contact have secure access through an account and two-factor ***80638** authentication. A manufacturer's authorizing official and primary contact also have access to this secure, online system to view the prices of their company's NDCs.

Manufacturer Claims

In the NPRM, HHS proposed that, to be eligible for the 340B ADR process, each manufacturer claim must include documents sufficient to demonstrate that a covered entity has violated the prohibition on diversion or duplicate discount. After receiving such a claim, HRSA may request the following documentation for an initial screening of the claim: (1) A final audit report to indicate that the manufacturer audited the covered entity for compliance with the prohibition on diversion (section 340B(a)(5)(B) of the PHSA) or duplicate discounts (section 340B(a)(5)(A) of the PHSA), and (2) the covered entity's written response to the manufacturer's audit finding(s). HRSA may also request that the manufacturer submit a written summary of attempts to work in good faith to resolve the claim with the covered entity. In this final rule, HHS clarifies that it is the 340B ADR Panel that is reviewing a claim that is responsible for making a request for documents or other information from a party, and not HRSA. We further note that notwithstanding Rules 8 and 10 of the Federal Rules of Civil Procedure, a manufacturer filing a claim under paragraph (c)(2) of this section must provide documents sufficient to demonstrate its claim that a covered entity has violated the prohibition on diversion or duplicate discount, along with any such documentation as may be requested by the 340B ADR Panel.

Comment: Commenters express concern that the causes of actions for manufacturers to file a claim are limited to two instances (diversion and duplicate discounts) and recommend that they be broadened to include other legitimate claims, particularly for other unforeseen examples that may emerge. The commenters recommend an inclusion of “catch-all” language that would allow the 340B ADR Panel to accept other legitimate claims, such as a dispute of the covered entity's eligibility that led the manufacturer to grant the 340B ceiling price, or a dispute concerning the dollar amount attributable to a violation.

Response: HHS agrees that in adjudicating claims of duplicate discounts and diversion, it may be necessary for a 340B ADR Panel to address issues such as covered entity eligibility in making its decisions. HHS is clarifying in this final rule that a 340B ADR Panel's review of diversion and duplicate discounts may include a review of issues such as whether an individual does not qualify as a patient for 340B Program purposes and claims that a covered entity is not eligible for the 340B Program. These issues, although they may appear ancillary, would be entertained because they may determine the outcome of any claim by the manufacturer that the covered entity has engaged in diversion.

Comment: Commenters recommend that HHS exclude specific types of allegations involving duplicate discounts, including the following: (1) The allegation involves duplicate discounts on claims submitted to Medicaid managed care organizations (MCOs); (2) the covered entity incorrectly elected Medicaid carve-out status on the OPA database or failed to include state-mandated modifiers on its claims, but the state Medicaid agency did not claim rebates on the 340B drugs purchased by the covered entity; and (3) a covered entity has correctly listed its carve-in status on the OPA database and has included state-mandated modifiers on its claims, or otherwise followed state requirements to identify 340B drugs, but the state Medicaid agency claimed rebates on the 340B drugs purchased by the covered entity nonetheless.

Response: HHS appreciates these comments, and 340B ADR Panels will consider the first and third types of claims listed above as section 340B(d)(3)(B) of the PHSA states that the decision-making body or official shall be responsible for considering manufacturer duplicate discount claims (violations of section 340B(a)(5)(A) of the PHSA). 340B ADR Panels will not consider claims where the covered entity incorrectly elected Medicaid carve-out status on the OPA database or failed to include state-mandated modifiers on its claims, but the state Medicaid agency did not claim rebates on the 340B drugs purchased by the covered entity, as manufacturers would have not demonstrated that the drugs at issue were subject to duplicate discounts under the Medicaid Drug Rebate and the 340B Programs.

(e) Combining claims.

In the NPRM, HHS proposed that, if requested, covered entities or manufacturers may be permitted to combine their individual claims. Section 340B(d)(3)(B)(vi) of the PHSA permits “multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding . . . .” HHS proposed that for joint claims, the claim must list each covered entity and include documentation or information from each covered entity demonstrating that the covered entity meets all of the requirements for filing a claim with HHS and that a letter requesting consolidation of claims must also accompany the claim and must document that each covered entity consents to the consolidation of the claims.

Pursuant to section 340B(d)(3)(B)(vi) of the PHSA, joint claims are also permitted on behalf of covered entities by associations or organizations representing their interests. Therefore, HHS proposed that the covered entities must be members of the association or the organization representing them and that each covered entity must meet the requirements listed in paragraph (d) for filing a claim. The proposed joint claim must assert overcharging by the same manufacturer for the same drug(s), and the organization or association will be responsible for filing the claim. HHS also proposed requiring that a letter requesting consolidation of claims must accompany the claim and must document that each covered entity consents to the organization or association asserting a claim on its behalf.

Similarly, at the request of two or more manufacturers, section 340B(d)(3)(B)(v) of the PHSA permits the consolidation of claims brought by more than one manufacturer against the same covered entity if consolidation is appropriate and consistent with the statutory goals of fairness and economy of resources. HHS proposed that the claim must list each manufacturer and include documentation or information from each manufacturer demonstrating that the manufacturer meets the requirements listed in paragraph (d) for filing a claim. HHS also proposed that a letter requesting consolidation of claims must be submitted with the claim and must document that each manufacturer consents to the consolidation of the claims. The statutory authority for implementing the 340B ADR process does not permit consolidated claims on behalf of manufacturers by associations or organizations representing their interests. Therefore, HHS did not propose this option in the NPRM.

With regard to the consolidation of claims by manufacturers against a covered entity, HHS sought specific comment on the grounds under which consolidation would be consistent with the statutory goals of fairness and economy of resources, as required by section 340B(d)(3)(B)(v) of the PHSA. In addition, while HHS proposed, as required by the 340B statute, an ADR ***80639** process that allows manufacturers to consolidate claims against a covered entity, we recognized the operational challenges presented by the statutory requirement for a manufacturer to first audit the covered entity. HHS, therefore, sought comment on how manufacturers requesting a consolidated claim against a covered entity could satisfy the audit requirement. HHS received comments regarding the combining of claims for both manufacturers and covered entities. Both covered entities and manufacturers request the same drugs and alleged violations be present when making a request for combining claims and entering into the dispute process. HHS is finalizing this section as proposed as it did not receive specific comments on how to address the operational challenges set forth in the proposed rule and believes the process proposed to be sound, fair, and equitable to both parties. However, it should be noted that consolidation of claims by manufacturers against a single covered entity, or joint claims by multiple covered entities against one manufacturer shall be governed by this section guided by the relevant Rules of the Federal Rules of Civil Procedure (Rules), including Rules that contemplate multiple petitioners. Additionally, joinder, consolidation, and other third-party practice not referenced in this subsection (e) shall be governed by the Rules, as relevant, unless the parties and 340B ADR Panel agree otherwise. Below is a summary of the comments received and HHS' responses.

Comment: For consolidated manufacturer claims, commenters request that HHS should add a requirement that: (1) All manufacturers assert covered entity duplicate discount violations, diversion violations, or both arising out of the same policy or practice by the covered entity; and (2) all manufacturers assert these violations during the same time period. HHS must also recognize manufacturers' right to pursue claims (consolidated or otherwise) through a trade association or other agent of their choice.

Response: HHS disagrees. HHS believes that the above proposal would unnecessarily limit the scope of claims that could be brought against a covered entity, when the 340B statute provides only that the claim be based on a duplicate discount or diversion. The statutory ADR provisions allow associations to file joint ADR claims on behalf of covered entities; however, it does not include similar language for associations to file consolidated claims filed on behalf of manufacturers. Therefore, HHS will not alter the final rule to permit joint claims by associations representing manufacturers.

Comment: While the proposed rule outlines that covered entities must submit a letter requesting consolidation of claims, some commenters suggest that HHS further require covered entities to provide proof of consent of an organization or association

asserting a claim on the covered entities' behalf. These commenters argue that the proposed rule implies that a covered entity would have to request and be granted permission in order to combine claims, which is not consistent with the statute.

Response: Section 340B(d)(3)(vi) allows for the combining of claims by a covered entities and does require proof of consent. HHS has outlined a process for resolving 340B disputes and has given the 340B ADR Panels wide latitude to establish the proper course of conduct and scope of the process including any additional deadlines, procedures, or instructions that may be necessary or desirable for a fair, efficient, and expeditious ADR proceeding.

Comment: Commenters recommend that HHS clarify that multiple covered entities may combine claims as long as they have in common an overcharge allegation relating to at least one of the same NDCs. For example, if one covered entity alleges overcharges against a manufacturer for three NDCs and another covered entity alleges overcharges against the same manufacturer for two out of three of those NDCs (potentially because the second covered entity only purchased two of the three drugs), these commenters suggest that covered entities should be permitted to combine their claims.

Response: Section 10.21(e) allows for the combining of covered entities' overcharge claims against the same manufacturer for the same drug or drugs. The 340B statute does not require that joint claims contain overcharge claims for the identical set of NDCs. Section 340B(d)(3)(B)(vi) states that “multiple covered entities . . . (may) jointly assert claims of claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding[.]”

(f) Responding to a submitted claim.

In the NPRM, HHS proposed that once the parties have been notified that the claim has met the filing requirements (subsection (b) of the NPRM) and will move forward for review by the 340B ADR Panel, the opposing party will have 20 business days to submit a written response to the allegation to the 340B ADR Panel. The 340B ADR Panel may make subsequent requests for information regarding the claim as needed, and will consider any additional information provided by the named parties involved. However, if an opposing party does not respond to the ADR Panel's request for information or otherwise elects not to participate in the 340B ADR process, the 340B ADR Panel will issue its decision on the claim based on the information submitted in the claim. Commenters raised concerns regarding the lack of detail as it relates to timeframes and recommends set timeframes.

After consideration of the comments received, HHS is finalizing this section with some changes. In this final rule, HHS is extending the timeframe for responding to a claim. After an initiating party (or Petitioner) has received notification from HRSA that its claim will move forward to a 340B ADR Panel for review, the opposing party (or Respondent) will have 30 days to submit a written response to the 340B ADR Panel that may be of the type authorized by Rules 12, 13, or 56 of the Federal Rules of Civil Procedure. The 340B ADR Panel may issue additional instructions as may be necessary or desirable governing the conduct of ADR proceedings, including instructions pertaining to deadlines for submission of additional information that it may request. If the opposing party does not respond to the claim from the Petitioner, the 340B ADR Panel may enter a final agency decision by default in favor of the Petitioner. HHS believes that in a proceeding for damages, the Petitioner must still introduce evidence sufficient to support its claim for damages even though the merits have been resolved through default.

Comment: Several commenters raise concerns about the proposed rule's lack of detail regarding the timeframes for the 340B ADR Panel. They suggest that to better ensure predictability of the ADR process, HRSA should establish discreet timeframes for each of the steps in the ADR process for which HRSA is responsible. They explain that identifying these timeframes in the final rule will improve transparency of the process for all parties involved.

Response: HHS disagrees with the assertion that detailed timeframes must be established at this juncture for each step in the ADR process. Flexibility is needed as each dispute will be evaluated on its merits and the documents presented, and some disputes may take longer than others based on the level of complexity. The 340B ADR Panel is empowered to utilize the deadlines set forth in the ***80640** Federal Rules of Civil Procedure as necessary.

Comment: Some commenters recommend that HRSA change the period to respond to claims to 60 days as opposed to 20 business days, with potential extensions if needed. These commenters urge HRSA to provide more flexibility, especially as those involved in the process may not have had adequate prior notice of the subject of the claim. The commenters claim that the proposed 20 business day response time frame does not provide manufacturers sufficient time to review the data underlying a claim, assess the factual or legal questions raised by the claim, and prepare a response.

Response: HHS recognizes that there will be instances that require time beyond the stated deadlines. HHS has included in the final rule a provision that the "340B ADR Panel may issue additional instructions as may be necessary or desirable governing the conduct of ADR proceedings, including instructions pertaining to deadlines for submission of additional information."

§ 10.22 Information requests

Pursuant to section 340B(d)(3)(B)(iii) of the PHSA, regulations promulgated by the Secretary for the 340B ADR process will establish procedures by which a covered entity may discover and obtain information and documents from manufacturers and third parties as may be relevant to a claim that the manufacturer has overcharged the covered entity. The NPRM proposed that such covered entity information requests be facilitated by the 340B ADR Panel. HHS proposed that a covered entity must submit a written request for information to the 340B ADR Panel no later than 20 business days after the entity was notified that the claim would move forward for the 340B ADR Panel's review. The 340B ADR Panel will review the information/document request to ensure that it is reasonable and within the scope of the asserted claim. The 340B ADR Panel will notify the covered entity in writing if its request is deemed as such and permit the covered entity to submit a revised information/document request, if it is not.

In this section, HHS proposed that the 340B ADR Panel will consider relevant factors, such as the scope of the information/document request, whether there are consolidated claims, or the involvement of one or more third parties in distributing drugs on behalf of the manufacturer and that once reviewed, the 340B ADR Panel will submit the information/document request to the manufacturer, which must respond within 20 business days.

HHS also proposed that the manufacturer must fully respond in writing to the information request and submit its response to the 340B ADR Panel by the stated deadline and that the manufacturer is responsible for obtaining relevant information/documents from wholesalers or other third parties that may facilitate sales or distribution of its drugs to covered entities. HHS proposed that if a manufacturer anticipates it will not be able to fully respond by the deadline, the manufacturer may request one extension in writing within 15 business days. The extension request that is submitted to the 340B ADR Panel must include any available information, the reason why the deadline is not feasible, and outline a proposed timeline for fully responding to the information request. The 340B ADR Panel will review the extension request and notify both the manufacturer and the covered entity in writing as to whether the request for an extension is granted and the date of the new deadline. If a manufacturer does not respond to a request for information, HHS proposed that the 340B ADR Panel will issue its decision on the claim based on the information submitted in the submitted claim package. Many of the commenters recommended changes to the ability of parties to request and receive information during the course of the ADR proceedings including allowing a manufacturer to submit an information request, which was not addressed in the NPRM.

HHS has decided to broaden the scope of this section to include information requests from the 340B ADR Panel. To provide further guidance to the parties involved, HHS has also decided that covered entities' discovery shall be governed by the Federal Rules of Civil Procedure. While HHS limited the scope of these information requests to covered entities in the NPRM, consistent with the limited discovery requirements of the statute pertaining to covered entities, this final rule allows the 340B ADR Panel to request additional information from a party if deemed necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously. This leaves open the possibility that a drug manufacturer could petition the 340B ADR Panel to request further information from a covered entity. If the 340B ADR Panel determines that such a request would enhance its deliberations, the 340B ADR Panel could make the request to the covered entity. Based on comments received, HHS has also added (c) to this section to address actions the 340B ADR Panel may take if a party fails to fully respond to the information request.

Comment: Some commenters recommend that a covered entity should be afforded an opportunity to review the manufacturer's response before crafting and submitting its request for additional information. Once the covered entity has seen the manufacturer's position, it can better tailor its information request to the dispute, and request only those documents it needs to pursue its overcharge claim. HHS should allow covered entities 30 calendar days from the date on which it receives the manufacturer's response to submit an information request.

Response: The 340B ADR Panel is given wide latitude to determine the proper course of conduct in an ADR proceeding and may issue additional instructions as may be necessary or desirable governing the conduct of ADR proceedings including instructions pertaining to submission of additional information.

Comment: Some commenters recommend that HHS allow manufacturers to submit information requests regarding disputes just as covered entities can. They argue that manufacturers must have the right to submit information requests in the event that they are unable to obtain all relevant information during an audit or new information relevant to the dispute arises.

Response: Section 340B(d)(3)(B)(iii) of the PHSA expressly authorizes covered entities to "discover and obtain such information and documents from manufacturers" as may be relevant to their filed claims. As the statute does not provide similar authorization for manufacturer document requests, HHS declines to alter the final rule in this area. However, to the extent that a manufacturer believes an information request to a covered entity is necessary for the 340B ADR Panel's deliberations, it may petition the 340B ADR Panel to make the request to the covered entity.

Comment: The proposed rule allows 340B covered entities to request information relevant to their claim from manufacturers and third parties; however, commenters argue that the proposed rule does not hold a manufacturer accountable for actually producing the requested information. These commenters recommend that if a manufacturer fails to comply with the information request, the 340B ADR panel should rely on the information contained in the original submitted claim and issue a finding in favor of the covered entity due to lack of ***80641** information obtained from the manufacturer.

Response: HHS agrees. Section 10.22(c) has been added to address sanction for failure to respond or failure to respond fully to an information request.

Comment: Some commenters urge HHS to consider that the filing party should be required to share with the responding party all of the documents it has filed with HRSA to ensure that the ADR process benefits from the full and open exchange of information. These commenters explain that full disclosure of the filing documents also might prevent some parties from seeking judicial review of 340B ADR Panel final agency decisions. A party dissatisfied with a 340B ADR Panel final agency decision might be more prone to seek judicial review if it has not had the opportunity to review the evidence on which the 340B ADR Panel relied.

Response: HHS agrees. Section 10.22(b) allows the 340B ADR Panel to take into account the possibility that a manufacturer would need additional information in order to respond appropriately to the dispute in question. While it is expected that a manufacturer would have all the information needed through its audit of a covered entity, this section would allow the 340B ADR Panel to make an information request of any party and to share that information with the opposing party if necessary for the fair, efficient, and expeditious conduct of the ADR proceeding.

§ 10.23 Conduct of the ADR proceeding

HHS has added this section to address comments received regarding the needs of the parties as it relates to the conduct of these proceedings. HHS recognizes there are instances, sometimes beyond the control of the parties that warrant flexibility in how it conducts the proceedings and that may warrant additional instructions. This new section will allow for ADR proceedings to take place in the most fair, efficient, and expeditious manner, which could include video conference, in-person, or through other means. It will also allow the 340B ADR Panel discretion in admitting evidence and testimony during the course of a proceeding as well as provide the 340B ADR Panel with the additional flexibility to provide instructions during the proceeding in order to achieve a fair, efficient, and expeditious review. HHS has also decided that unless the parties agree

otherwise and the 340B ADR Panel concurs, the Federal Rules of Civil Procedure (https://www.uscourts.gov/sites/default/files/federal_rules_of_civil_procedure_-_dec_1_2019_0.pdf) and the Federal Rules of Evidence (https://www.uscourts.gov/sites/default/files/federal_rules_of_evidence_-_dec_1_2019_0.pdf), to the extent applicable, shall apply to proceedings. HHS has summarized and responded to comments received below.

Comment: Some commenters recommend HHS provide the parties with the opportunity to present evidence live in front of the 340B ADR Panel. The commenters explain that relying exclusively on a paper record could potentially lengthen the ADR process if the documents were interpreted differently by the parties and further clarification were needed before proceeding. A live process could allow for questions arising from paper records to be answered efficiently. These commenters explain that by enabling parties to present evidence and respond to questions from the 340B ADR Panel orally, HHS can provide a forum where information is shared among affected parties.

Response: HHS agrees that there may be instances where portions of the ADR may need to be conducted by telephone or video conference, or through other means. Therefore, HHS has clarified the means by which the process may be conducted in this final rule.

Comment: Several commenters suggest that HHS detail in the final rule how it plans to establish safeguards and protections to ensure that proprietary information submitted on behalf of either party is kept confidential by the 340B ADR Panel in order to minimize risk of harm.

Response: HHS appreciates the suggestion on addressing safeguards to ensure confidentiality and minimize disclosure risk. HHS believes adequate safeguards are in place to ensure that confidential, proprietary information is not disclosed.

§ 10.24 Final agency decision

In the NPRM, HHS proposed that the 340B ADR Panel would review the documents submitted by the parties to determine if there is adequate support to conclude that a violation occurred. HHS proposed a process whereby the 340B ADR Panel's draft agency decision letter would be sent to all parties, and the parties involved would have 20 business days to respond to the 340B ADR Panel. HHS sought specific comments on this process and whether this proposed process would facilitate or hinder the fair, efficient, and timely resolution of claims.

HHS also proposed that once the parties have reviewed and submitted comments in response to the draft agency decision letter, the 340B ADR Panel would prepare and submit its final agency decision letter to all parties in the dispute. In issuing a final agency decision letter, the 340B ADR Panel will be operating under an express, written delegation of authority from the Secretary of HHS to make such final agency decisions. This Regulation constitutes that ex officio delegation. The final agency decision made by the 340B ADR Panel would conclude the administrative resolution process; however, HHS proposed that the final agency decision letter also be submitted to HRSA to provide remedies and enforcement of determinations through mechanisms and sanctions as described section 340B(d)(1)(B) or (d)(2)(B), as appropriate.

HHS proposed that the 340B ADR Panel's final agency decision letter would be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction, acting under Section 10 of the Administrative Procedure Act (5 U.S.C. 706), and in accordance with section 340B(d)(3)(C) of the PHSA. HHS is finalizing the rule as proposed with modifications. First, in this final rule, HHS is replacing “HSB” with “HRSA Administrator,” in order to elevate the responsibilities conducted under the ADR process. Second, this final rule adds section 10.24(d), which states the final agency decision will be precedential and binding on the parties. Lastly, given that HHS has added procedural protections and more clearly defined the ADR process, HHS does not feel that it is necessary to provide the parties an opportunity to respond to a draft agency decision.

Comment: Commenters explain that the proposed rule does not incorporate an appeals process and recommend that an appeals process be made available to all parties. These commenters also suggest that HHS publish all findings and decisions by the

340B ADR Panel to enable all parties to be informed and more compliant. These commenters suggest that publication of the ADR's decisions will also prevent inconsistent decisions and unsupported rulings.

Response: HHS agrees, as these ADR decisions will be precedential. Therefore, HHS will ensure that the final agency decisions are publically available (e.g., by publication on the HRSA website). HHS does not believe that an appeals process is necessary given that an aggrieved party has a right to seek judicial review under section 10 of the Administrative Procedure Act (5 U.S.C. 706).

Comment: When deciding disputes, some commenters suggest that the 340B ADR Panel use a "preponderance of the ***80642** evidence" standard. Once the 340B ADR Panel reaches its decision, HHS should mandate the issuance of a summary that includes a transparent analysis of the reasons for the decision, without disclosing any proprietary or otherwise confidential information. HHS should also recognize that the 340B ADR Panel decision is binding on the parties involved in the dispute (unless otherwise overturned by a court acting pursuant to the Administrative Procedure Act), but is not binding on third parties.

Response: HHS agrees, as the final agency decisions will be precedential and binding on the named parties in the dispute. As such, HHS will ensure that all final agency decisions are publically available. HHS also agrees that the 340B ADR Panel use a "preponderance of the evidence" standard when making its determinations and has adjusted the final rule accordingly in section § 10.24(a).

Comment: Commenters suggest that HHS clarify that it will not impose sanctions on a party as a result of a 340B ADR Panel decision until the party has been given an opportunity to complete corrective action with respect to the 340B ADR Panel's findings.

Response: Section 340B(d)(3)(A) includes a requirement that the ADR process include the "appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B) (of 340B(d))" Therefore, when appropriate, the 340B ADR Panel may make recommendations to HRSA for sanctions, including referrals to the HHS Office of Inspector General for its consideration of civil monetary penalties, as appropriate. Whether sanctions or remedial action is appropriate will be dependent on the type of violation that occurred.

Comment: A few commenters were concerned that the proposed rule does not address how HRSA will enforce the findings of the 340B ADR panel or any underlying manufacturer audit. These commenters explain that the NPRM does not address if, or how, HRSA will go about enforcing the findings of the 340B ADR Panel or the underlying manufacturer audits. For example, if the 340B ADR Panel's final agency decision requires covered entities to make any applicable repayments to manufacturers, timeframes should be established around such payment and, at a minimum, HRSA should permit affected manufacturers to withhold future discounts until HRSA, the manufacturer, and the covered entity have resolved the findings noted in the manufacturer's audits.

Response: Wide varieties of covered entities participate in the 340B Program, from small, rural health care facilities to large academic medical centers. HHS expects that the 340B ADR Panel will review violations ranging from minor and inadvertent to systematic and intentional. Given the wide variety of 340B Program participants and varying types of violations, HHS believes that the form of enforcement should be left open to permit HHS maximum flexibility in determining what is appropriate given the specific facts of each situation.

Comment: Some commenters urge HRSA to incorporate a timeframe for the issuance of 340B ADR Panel's final agency decisions. They recommend that the final agency decision should be issued 30 business days from the date when the submission of all requested information is complete and in complex cases, the process should be extended 15 business days, so that the final agency decision would be issued within 45 business days. The commenters argue that this approach would be consistent with Medicare where the deadline for initial determination decisions is 45 days and for redetermination decisions is 60 days.

Response: HHS disagrees. The 340B ADR Panel has been given wide latitude to determine the scope of the process and should not be held to a timeframe that does not allow for thorough and thoughtful consideration of all materials presented.

Comment: Some commenters state that the ADR process should be governed by the Administrative Procedure Act (APA), 5 U.S.C. 551 et seq. They explain that a reviewing court should be authorized to hold unlawful and set aside ADR Panel decisions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law or unsupported by substantial evidence. The commenters request that HRSA clarify that the APA will apply to the ADR Process, including judicial review.

Response: The form of judicial review for 340B ADR Panel decisions is beyond the scope of this final rule.

Comment: Commenters support the proposal that HRSA has the sole authority to enforce the 340B ADR Panel's decision. The commenters explain that the 340B ADR Panel may not fully appreciate HRSA's historical enforcement practices, and the NPRM will ensure that HRSA retains responsibility for compliance with 340B statutory requirements.

Response: While HHS appreciates the support of HRSA having sole enforcement authority, this final rule contemplates and allows HRSA to take appropriate action, which could include enforcement action or referral to another HHS Operating Division or to another Federal agency. For example, if the 340B ADR Panel's final agency decision is that an overcharge did occur, HRSA could recommend the OIG review the overcharge to determine if it was knowing and intentional and should be assessed a civil monetary penalty.

Comment: Commenters express concern that HRSA should not use its enforcement authority to transform a 340B ADR Panel decision into a broad 340B policy decision. The commenters explain that enforcement should be limited to the parties to the ADR proceeding. 340B ADR Panel decisions should not have general applicability.

Response: As set forth in section 10.23(b)(2), 340B ADR Panel decisions will be final agency decisions, binding on the parties, and precedential.

III. Regulatory Impact Analysis

HHS has examined the effects of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 8, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, ***80643** productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact

analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB).

HHS does not believe that this final rule will have an economic impact of $100 million or more in any 1 year, and is therefore not designated as an "economically significant" final rule under section 3(f)(1) of Executive Order 12866. This rule creates a framework for the Department to resolve certain disputed claims regarding manufacturers overcharging covered entities and disputed claims of diversion and duplicate discounts by covered entities audited by manufacturers under the 340B Program. HHS does not anticipate the introduction of an ADR process to result in significant economic impacts.

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations "to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." This final rule is not expected to be an E.O. 13771 regulatory action because this final rule is not significant under E.O. 12866.

The Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a three percent impact on at least five percent of small entities.

The rule would affect drug manufacturers (North American Industry Classification System code 325412: Pharmaceutical Preparation Manufacturing). The small business size standard for drug manufacturers is 750 employees. Approximately 600 drug manufacturers participate in the 340B Program. While it is possible to estimate the impact of the final rule on the industry as a whole, the data necessary to project changes for specific manufacturers or groups of manufacturers is not available, as HRSA does not collect the information necessary to assess the size of an individual manufacturer that participates in the 340B Program. The rule would also affect health care providers. For purposes of the RFA, HHS considers all health care providers to be small entities either by virtue of meeting the Small Business Administration (SBA) size standard for a small business, or for being a nonprofit organization that is not dominant in its market. The current SBA size standard for health care providers ranges from annual receipts of $7.5 million to $38.5 million. Currently, in 2020,, 12,500 covered entities participate in the 340B Program, which represent safety-net healthcare providers across the country.

The final rule introduces an ADR mechanism to review manufacturer claims that covered entities have violated certain statutory obligations and covered entities claims that they have been overcharged for covered outpatient drugs by manufacturers. The documentation required as part of this administrative process are documents that manufacturers and covered entities are already required to maintain as part of their participation in the 340B Program. HHS expects that this documentation would be sufficiently available prior to submitting a claim. Therefore, the collection of this information would not result in an economic impact or create additional administrative burden on these businesses.

HHS believes the ADR process will provide a cost-effective option for resolving claims that would otherwise remain unresolved or prompt litigation. The final rule provides an option to consolidate claims by similar situated entities, and covered entities may have claims asserted on their behalf by associations or organizations, which could reduce costs. HHS has determined, and the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small health care providers or a significant impact on the operations of a substantial number of small manufacturers; therefore, it is not preparing an impact analysis for the purposes of the RFA. HHS estimates that the economic impact on small entities and small manufacturers will be minimal and less than 3 percent.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year." In 2020, that threshold is approximately $156 million. HHS does not expect this rule to exceed the $156 million threshold.

Executive Order 13132—Federalism

HHS has reviewed this final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." This rule would not "have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This rule would not adversely affect the following family elements: Family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under Section 654(c) of the Treasury and General Government Appropriations Act of 1999.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. Given the small number of requests for the informal dispute resolution process, HHS asserted in the proposed rule that the ADR process would not have a significant impact on the current reporting and recordkeeping burden for manufacturers or covered entities under the 340B Program. HHS solicited comments on the accuracy of this statement. No comments were received challenging the accuracy of this statement. Moreover, HHS believes that the 340B ADR Process is exempt from ***80644** the Paperwork Reduction Act requirements as it provides the mechanism and procedures for "an administrative action or investigation involving an agency against specific individuals or entities" pursuant to 44 U.S.C. 3518(c).

Dated: November 25, 2020.

Thomas J. Engels,

Administrator, Health Resources and Services Administration.

Dated: December 9, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

List of Subjects in 42 CFR Part 10

Biologics, Business and industry, Diseases, Drugs, Health, Health care, Health facilities, Hospitals, 340B Drug Pricing Program.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR part 10 as follows:

PART 10—340B DRUG PRICING PROGRAM

1. The authority citation for part 10 continues to read as follows:

Authority: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b), as amended.
42 CFR § 10.3
2. Amend § 10.3 by adding in alphabetical order definitions for "Administrative Dispute Resolution (ADR) Process", "Administrative Dispute Resolution Panel (340B ADR Panel)", "Claim", "Consolidated claim", and "Joint claim" to read as follows:
42 CFR § 10.3

§ 10.3 Definitions.
* * * * *
Administrative Dispute Resolution (ADR) Process means a process used to resolve the following types of claims, including any issues that assist the 340B ADR Panel in resolving claims:

(1) Claims by covered entities that may have been overcharged for covered outpatient drugs purchased from manufacturers; and

(2) Claims by manufacturers of 340B drugs, after a manufacturer has conducted an audit of a covered entity (pursuant to section 340B(a)(5)(C) of the Act), that a covered entity may have violated the prohibitions against duplicate discounts or diversion.

Administrative Dispute Resolution Panel (340B ADR Panel) means a decision-making body within the Department that, acting on an express, written delegation of authority from the Secretary of HHS, reviews and makes a precedential and binding decision for a claim brought under the ADR Process.
* * * * *
Claim means a written allegation filed by or on behalf of a covered entity or by a manufacturer for resolution under the ADR Process.
* * * * *
Consolidated claim means a claim resulting from combining multiple manufacturers' claims against the same covered entity;
* * * * *
Joint claim means a claim resulting from combining multiple covered entities' (or their membership organizations' or associations') claims against the same manufacturer for the same drug or drugs.
* * * * *
2. Add subpart C to read as follows:

Subpart C—Administrative Dispute Resolution

Sec.

10.20 Administrative Dispute Resolution Panel.

10.21 Claims.

10.22 Information requests.

10.23 Conduct of the ADR proceeding.

10.24 Final agency decision.
42 CFR § 10.20

§ 10.20 Administrative Dispute Resolution Panel.
The Secretary shall establish a 340B Administrative Dispute Resolution Board (Board) consisting of at least six members appointed by the Secretary with equal numbers from the Health Resources and Service Administration (HRSA), the Centers for Medicare & Medicaid Services (CMS), and the Office of the General Counsel (OGC) from which Administrative Dispute

Resolution Panels (340B ADR Panel) of three members shall be selected by the HRSA Administrator (to review claims and, pursuant to authority expressly delegated through this rule by the Secretary, and to make precedential and binding final agency decisions regarding claims filed by covered entities and manufacturers). There shall also be one ex-officio, non-voting member chosen from the staff of the HRSA Office of Pharmacy Affairs (OPA). HRSA and CMS Board members shall have relevant expertise and experience in drug pricing or drug distribution. OGC Board members shall have expertise and experience in handling complex litigation.

(a) Members of the 340B ADR Panel. (1) For each case, the HRSA Administrator shall:

(i) Select from the Board three voting members, one from each of the three HHS operating or staff divisions involved (i.e., CMS, HRSA, OGC) to form a 340B ADR Panel.

(ii) Remove an individual from a 340B ADR Panel for cause; and

(iii) Appoint replacement members from the Board should an individual be unable to complete his or her duties on a 340B ADR Panel.

(2) No member of a 340B ADR Panel may have a conflict of interest, as defined in paragraph (b) of this section.

(b) Conflicts of interest. All individuals who serve on a 340B ADR Panel will be screened for conflicts of interest prior to reviewing a claim. Conflicts of interest may include:

(1) Financial interest in a party involved, a subsidiary of a party involved, or in the claim before a 340B ADR Panel;

(2) Family or close relation to a party involved; and

(3) Current or former business or employment relation to a party.

(c) Duties of the 340B ADR Panel. The 340B ADR Panel will adjudicate each claim using the procedures described §§ 10.21, 10.22, 10.23, and 10.24.

(1) Review and evaluate documents and other information submitted by covered entities and manufacturers;

(2) Request additional information or clarification of an issue from any or all parties to make a final agency decision;

(3) When necessary, evaluate a claim in a separate session from the parties involved;

(4) Consult with OPA and the parties, as appropriate and necessary, regarding any inquiries or concerns while reviewing a claim; and

(5) Issue a final agency decision on each claim and submit the written decision to the parties, and to HRSA for appropriate action.
42 CFR § 10.21

§ 10.21 Claims.
(a) Initiating an action. Any covered entity or manufacturer may initiate an action for monetary damages or equitable relief against a manufacturer or covered entity, as the case may be, by filing a written petition for relief with HRSA and mailing a copy of the petition with any attachments to the General Counsel or other senior official of the opposing party at its principal place of business by certified mail, return receipt requested, within three days of filing the claim. The petition should satisfy the pleading requirements of Rules 8, 10, and 11 of the Federal Rules of Civil Procedure, including setting forth the factual basis

for invoking the 340B ADR Panel's jurisdiction. A claim must include all of the requirements in paragraph (d) of this section. Additional information to substantiate a claim may be submitted.

(b) 340B ADR Panel's jurisdiction. The 340B ADR Panel shall have jurisdiction to entertain any petition where the damages sought exceed ***80645** $25,000 or where the equitable relief sought will likely have a value of more than $25,000 during the twelve-month period after the 340B ADR Panel's final agency decision, provided the petition asserts claims of the type set forth below.

(c) Claims permitted. The ADR process is limited to the following:

(1) Claims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price; and

(2) Claims by a manufacturer, after it has conducted an audit of a covered entity pursuant to section 340B(a)(5)(C) of the PHSA, that the covered entity has violated section 340B(a)(5)(A) of the PHSA regarding the duplicate discount prohibition, or section 340B(a)(5)(B) of the PHSA regarding the diversion prohibition, including claims that an individual does not qualify as a patient for 340B Program purposes and claims that a covered entity is not eligible for the 340B Program.

(d) Limitation of actions. (1) A covered entity or manufacturer must file a written claim for administrative dispute resolution with HRSA within 3 years of the date of the alleged violation. Any file, document, or record associated with the claim that is the subject of the ADR process must be maintained by the covered entity and manufacturer until the final agency decision is issued by the 340B ADR Panel.

(2) Notwithstanding Rules 8 and 10 of the Federal Rules of Civil Procedure, a covered entity filing a claim described in paragraph (c)(1) of this section must provide documents sufficient to demonstrate its claim that it has been overcharged by a manufacturer, along with any such other documentation as may be requested by the 340B ADR Panel.

(3) Notwithstanding Rules 8 and 10 of the Federal Rules of Civil Procedure, a manufacturer filing a claim under paragraph (c)(2) of this section must provide documents sufficient to demonstrate its claim that a covered entity has violated the prohibition on diversion or duplicate discount, along with any such documentation as may be requested by the 340B ADR Panel.

(e) Combining claims. (1) Two or more covered entities may jointly file claims of overcharges by the same manufacturer for the same drug or drugs if each covered entity that could file a claim against the manufacturer consents to the jointly filed claim, including submission of the required documentation, described in paragraph (d) of this section.

(2) An association or organization may file claims of overcharges by the same manufacturer for the same drug or drugs on behalf of multiple covered entities if each covered entity represented could file a claim against the manufacturer, is a member of the association or organization, meets the requirements described in paragraph (d) of this section, including submission of the required documentation, and each covered entity has agreed to representation by the association or organization on its behalf.

(3) A manufacturer or manufacturers may request to consolidate claims brought by more than one manufacturer against the same covered entity if each manufacturer could individually file a claim against the covered entity, consents to the filing of the consolidated claim, meets the requirements described in paragraph (d) of this section for that claim, and the 340B ADR Panel determines that such consolidation is appropriate and consistent with the goals of fairness and economy of sources. The 340B ADR Panel will not permit consolidated claims filed on behalf of manufacturers by associations or organizations representing their interests.

(4) Joinder, consolidation, and other third-party practice not referenced in this paragraph (e) shall be governed by the Federal Rules of Civil Procedure, as relevant, unless the parties and 340B ADR Panel agree otherwise.

(f) Responding to a submitted claim. Upon receipt of service of petition, the respondent must file with the 340B ADR Panel a written response to the Petition as set forth in Rule 12 or 56. The 340B ADR Panel may issue additional instructions as may be necessary or desirable governing the conduct of ADR proceedings, including instructions pertaining to deadlines for submission of additional information. If an opposing party does not respond to the petition, the 340B ADR Panel may enter a final agency decision by default in favor of the Petitioner. In a proceeding for damages, the Petitioner must still introduce evidence sufficient to support its claim for damages even though the merits have been resolved through default.
42 CFR § 10.22

§ 10.22 Information requests.
(a) Discovery. The 340B ADR Panel may permit a covered entity limited discovery to obtain such information and documents as may be relevant to demonstrate the merits of a claim. Such discovery shall be governed, to the extent applicable, by the Federal Rules of Civil Procedure.

(b) 340B ADR Panel information requests. Taking into account any party's request for further information, the 340B ADR Panel may request additional information from either party.

(c) Failure to respond to information requests. If the 340B ADR Panel finds that a party has failed to respond or fully respond to an information request, the 340B ADR Panel make take the following actions, including:

(1) Holding facts to have been established in the proceeding;

(2) Precluding a party from presenting or contesting a particular issue;

(3) Excluding evidence; or

(4) Judgment in the proceeding or dismissal of proceeding.
42 CFR § 10.23

§ 10.23 Conduct of the ADR proceeding.
(a) The 340B ADR Panel will determine, in its own discretion, the most efficient and practical form of the ADR proceeding. Unless the matter is resolved through a motion to dismiss or summary judgment under Rule 56, the 340B ADR Panel shall conduct an evidentiary hearing when there are material facts in dispute. The ADR proceeding may be conducted by video conference, in-person, or through other means.

(b) The 340B ADR Panel will determine the proper course of conduct in an ADR proceeding. Unless the parties agree otherwise and the 340B ADR Panel concurs, the Federal Rules of Civil Procedure, to the extent applicable, shall govern the proceedings.

(c) Unless the parties agree otherwise and the 340B ADR Panel concurs, the Federal Rules of Evidence shall apply to the proceedings.

(d) The 340B ADR Panel may issue additional instructions or guidance as may be necessary or desirable governing the conduct of ADR proceedings.
42 CFR § 10.24

§ 10.24 Final agency decision.
(a) The 340B ADR Panel will review the evidence submitted by the parties and determine if the preponderance of the evidence supports the conclusion that a violation as described in § 10.21(c)(1) or (2) has occurred.

(b) The 340B ADR Panel will prepare an agency decision based on its review and evaluation of the evidence submitted by the parties, including documents provided as required in § 10.21(d), information requests in support of a claim, and responses to a claim.

(c) The agency decision will represent the decision of a majority of the 340B ***80646** ADR Panel's findings regarding the claim and discuss the findings supporting the decision.

(d) The agency decision constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction.

(e) The 340B ADR Panel will submit the final agency decision to all parties, and to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities.

[FR Doc. 2020-27440 Filed 12-10-20; 11:15 am]

BILLING CODE 4165-15-P

End of Document

Exhibit D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

Covered Entity Petition for the 340B Administrative Dispute Resolution Process

For use by Covered Entity or Covered Entities that may have been overcharged by manufacturers for covered outpatient drugs purchased

☐ Individual claim?

List 340B ID. Click or tap here to enter text.

Petitioner's contact information:

Name: Click or tap here to enter text.

Email address: Click or tap here to enter text.

Phone number:Click or tap here to enter text.

☒ Joint claim?

List all 340B IDs: See attached Complaint and exhibits, which identify the joint claimants

List membership organization or associations, if applicable: National Association for Community Health Centers

☒ Please attach a signed letter from all covered entities listed agreeing to be represented as part of this claim.

Point of contact information:

Name: Matthew Freedus

Email address: mfreedus@ftlf.com

Phone number:202.466.8960

Manufacturer name and labeler codes: See attached Complaint and exhibits

Narrative description of issue: See attached Complaint. Drug manufacturers Eli Lilly and Company, Sanofi-Aventis U.S. LLC, and AstraZeneca PLC (collectively, Respondents) have been restricting FQHC covered entity access to covered outpatient drugs at 340B discount pricing by refusing to make their covered outpatient drugs available for FQHC covered entity purchase at or below the applicable ceiling price where the FQHC covered entity drugs will be dispensed the drugs to its patients through contract pharmacy arrangements. Restricting FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices is overcharging in violation of 42 U.S.C. § 256b(a)(1).

Summary of attempts to work in good faith: Respondents unilaterally implemented the above-described and documented policies and have refused to rescind them despite public demands that they do so from Members of the U.S. Congress, trade associations, State Attorney Generals, and others.

Date of alleged violation: See attached Complaint and exhibits. The drug manufacturers' documented policies, which restrict FQHC covered entity access to covered outpatient drugs at 340B pricing, were released in or around the second half of 2020, and remain in effect to date.

General Counsel or other senior official of the opposing party contact information:

Name: Anat Hakim, Senior President, General Counsel & Secretary for Eli Lilly and Company

Email address: ahakim@lilly.com

Phone number:317-277-6066

General Counsel or other senior official of the opposing party contact information:

Name: Chan Lee, North America General Counsel for Sanofi-Aventis U.S. LLC

Email address: chan.lee@sanofi.com

Phone number:908-981-6600

General Counsel or other senior official of the opposing party contact information:

Name: Mariam Koohdary, U.S. General Counsel for AstraZenecca

Email address: mkoohdary@astrazenecca.com

Phone number:302-885-3891

Estimate of monetary damages: See attached Complaint. The joint claim is for equitable relief only and meets the prospective estimated value threshold.

List of NDCs in question: See attached Complaint and exhibits, which identify impacted NDCs

☐Attach a list of 340B ceiling prices listed on 340B OPAIS for sales quarters in question. N/A

☐ Attach all Invoices for purchases made on a 340B account that include purchase price that shows the overcharge or shows the covered entities' ability to purchase at the 340B price was limited. N/A

☒ Attach all communications with wholesalers, manufacturer, or both to resolve issue prior to filing claim.

☐ Attach copies of price unavailable/incorrect 340B price form submitted to HRSA prior to filing claim. N/A

☐ Attach all communications with HRSA, Office of Pharmacy Affairs prior to filing claim. N/A; any additional information: Please see attached Complaint and exhibits.

Please note: A copy of this petition with any attachments must be mailed to the General Counsel or other senior official of the opposing party at its principal place of business by certified mail, return receipt requested, within three days of filing the claim. Proof of that service will be required to be submitted to the secure workspace with the ADR supporting documentation.

BEFORE THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADMINISTRATIVE DISPUTE RESOLUTION PANEL

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS
7501 Wisconsin Ave Suite 1100W
Bethesda, MD 20814,

Petitioner,

v.

ELI LILLY AND COMPANY
Lilly Corporate Center
893 Delaware Street
Indianapolis, IN 46225,

and

SANOFI-AVENTIS U.S. LLC
55 Corporate Drive
Bridgewater, NJ 08807

and

ASTRAZENECA PLC
AstraZeneca
1800 Concord Pike
Wilmington, DE 19803,

Respondents.

Petition No: 210112-2

PETITION FOR DECLARATORY AND INJUNCTIVE RELIEF

Petitioner, National Association of Community Health Centers ("NACHC"), as an association and authorized representative of its Federally-qualified health center ("FQHC") members, brings this action for equitable relief under Section 340B of the Public Health Service ("PHS") Act, 42 U.S.C. § 256b, pursuant to and in compliance with the procedures set forth in 42

C.F.R. § 10.21, and alleges as follows:

NATURE OF ACTION

1. Petitioner seeks equitable relief to remedy ongoing and unlawful overcharging activity by drug manufacturers Eli Lilly and Company, Sanofi-Aventis U.S. LLC, and AstraZeneca PLC—collectively, "the drug manufacturers"—each of which, as described more fully below, recently restricted FQHC covered entity access to covered outpatient drugs at federal 340B drug discount program ("340B" or "340B Program") pricing by refusing to offer covered outpatient drugs for FQHC covered entity purchase at or below the applicable ceiling price whenever the FQHC covered entity will dispense the drugs to its patients through contract pharmacy arrangements.

2. The drug manufacturers' actions constitute unlawful overcharging and a clear violation of both the 340B statute and the binding pharmaceutical pricing agreements ("PPAs") between manufacturers and the United States Department of the Health and Human Services ("HHS") that statute requires. The 340B statute, codified at 42 U.S.C. § 256b, and the PPAs (which simply incorporate 340B statutory requirements) require that manufacturers "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). The drug manufacturers cannot impose their own unilateral conditions or restrictions on this unequivocal statutory requirement.

3. FQHC covered entities are statutorily required to provide "pharmaceutical services as may be appropriate for particular centers" and authorized to provide those services either through their own staff, through "contracts or cooperative arrangements" with other entities, or through a combination of the two approaches. 42 U.S.C. § 254b(a)(1), (b)(1)(A)(i)(V).

4. HHS has long recognized that FQHCs are statutorily afforded the flexibility to provide pharmacy services to their patients through contractual arrangements with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy owned by the health center. Indeed, in response to the recent, unilateral drug manufacturer actions underlying this claim, HHS—through its Office of General Counsel (OGC)—issued an advisory opinion which forcefully reiterates and reinforces the agency's longstanding position.

5. The drug manufacturers have acted strikingly similarly, if not in concert, to limit the FQHC covered entities' ability to purchase drugs at 340B pricing when those drugs will be dispensed to eligible FQHC patients via contracted pharmacies. The drug manufacturers' actions, taken close in time, form part of the same series of transactions or occurrences, and the ADR panel's resolution of Petitioner's joint claims against each manufacturer will involve common issues of law and fact—namely whether prohibited overcharging in violation of the 340B statute results from the drug manufacturers' refusal to provide covered outpatient drugs at the 340B ceiling price to FQHC covered entities for drugs dispensed to such entities' patients via contract pharmacies. Accordingly, joinder of the drug manufacturers in this single action is appropriate under Rule 20(a)(2) of the Federal Rules of Civil Procedure and the 340B statute, which provides that claims "shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii); 42 C.F.R. § 10.21(e)(4).

PARTIES

6. Petitioner is a national, nonprofit corporation whose primary objective is to further—through extensive education, training, and advocacy—the mission and purpose of FQHCs. The FQHCs represented herein play a vital role in our nation's health care safety-net by providing primary and other health care and related services—including pharmaceutical services—to

medically underserved populations throughout the nation and its territories, regardless of any individual patient's insurance status or ability to pay for such services. FQHCs have been recognized as 340B Program covered entities since the 340B Program's 1992 inception.

7. Petitioner brings this joint claim, as defined in 42 C.F.R. § 10.3 and authorized under 42 C.F.R. § 10.21(e), on behalf of its FQHC covered entity members listed in Exhibit A. Each FQHC covered entity so listed could, on its own, bring claims against one or more of the drug manufacturers for the equitable relief sought, has authorized NACHC to bring this joint claim on its behalf, and otherwise meets applicable regulatory requirements for bringing this joint claim.

8. Eli Lilly and Company ("Lilly") is a publicly traded pharmaceutical manufacturer and participant in the 340B Program. Lilly is organized under the laws of the State of Indiana and headquartered in Indianapolis, Indiana.

9. Sanofi-Aventis U.S. LLC ("Sanofi") is a pharmaceutical manufacturer and participant in the 340B Program. Sanofi is headquartered in Bridgewater Township, New Jersey.

10. AstraZeneca PLC ("AstraZeneca") is a limited partnership biopharmaceutical manufacturer and participant in the 340B Program. AstraZeneca is organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware.

JURISDICTION

11. This panel has jurisdiction over Petitioner's claims because, in accordance with the requirements of 42 C.F.R. §§ 10.3 and 10.21: (1) the claims are based on the drug manufacturers' unlawful overcharging activity, in particular their efforts to limit FQHC covered entities' ability to purchase covered outpatient drugs at or below 340B ceiling prices, and (2) the equitable relief sought will likely have a value of more than $25,000 for each joint claimant FQHC covered entity

member of NACHC during the twelve-month period after the 340B ADR Panel's final agency decision.

ALLEGATIONS

I. The 340B Program

12. The 340B Program exists to assist covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102–384(II), at 12 (1992). Under the 340B Program, drug manufacturers who wish to have their products covered by Medicare and Medicaid must provide covered outpatient drugs at a discount to covered entities.

13. Such covered entities, defined at 42 U.S.C. § 256b(a)(4), include, at subsection (a)(4)(1), "Federally-qualified health center[s] (as defined in section 1905(*l*)(2)(B) of the Social Security Act [42 U.S.C. 1396d(*l*)(2)(B)])."

14. For more than 20 years—from 1996 until mid-2020 when the prohibited overcharging activity leading to this Petition began—drug manufacturers, either directly or through wholesale distributors, have shipped FQHC-purchased covered outpatient drugs to FQHCs' contract pharmacies, i.e. third-party pharmacies with which FQHCs contract to dispense drugs to FQHC patients. All but a handful of the hundreds of manufacturers participating in the 340B Program under PPAs continue to do so.

15. Section 340B, at 42 U.S.C. § 256b(a)(1), requires HHS to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." Per that same statutory subsection, "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or

below the applicable ceiling price if such drug is made available to any other purchaser at any price." That agreement is the PPA.

16. As HHS recently made clear through its Office of General Counsel ("OGC"), the statute HHS is authorized to implement is unambiguous in obligating drug manufacturers to sell covered outpatient drugs to covered entities at or below applicable ceiling prices regardless of whether the drugs are distributed through a covered entity's in-house or contract pharmacies:

> [T]he core requirement of the 340B statute, as also reflected in the PPA and [PPA] Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity. In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute. . . . It is difficult to envision a less ambiguous phrase [than "purchased by"] and no amount of linguistic gymnastics can ordain otherwise. . . . The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant.

HHS Office of General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* at 2 (Dec. 30, 2020). This Advisory Opinion is attached as Exhibit B.

17. The December 30, 2020 OGC Advisory Opinion was written in response to the unlawful overcharging activity underlying this Petition.

18. The view espoused in that Advisory Opinion is not novel; it reiterates the longstanding and well-settled concept that covered entities, including FQHCs, have the common law right to contract with third-parties to provide services on their behalf, as HHS recognized in 1996, reiterated in 2010, and reaffirmed in the 2020 Advisory Opinion.

19. HHS has repeatedly made clear that contract pharmacy arrangements are a consistent and necessary outgrowth of the FQHC program's authorizing statute, Section 330 of the PHS Act, *codified at* 42 U.S.C. § 254b *et seq*., which requires FQHCs to provide pharmacy services and which permits the provision of such services through "contracts or cooperative

arrangements" with other entities. As HHS OGC noted in its 2020 Advisory Opinion: "the [340B] Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations. . . . These are the poster children of providers that one would expect to lack an in-house pharmacy." *Id.* at 4.

20. HHS is not alone in interpreting the plain language of a plainly written statue to obligate the drug manufacturers to offer covered entities drugs at 340B pricing regardless of whether those drugs are dispensed in-house or through a contract pharmacy arrangement. On September 14, 2020, numerous Members of Congress, weighing in on the drug manufacturer's "series of actions to restrict federally required 340B drug discounts for eligible health care organizations/covered entities"—i.e. the actions underlying this Petition—wrote:

> the 340B statute requires manufacturers wishing to participate in Medicaid and Medicare Part B to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." *There are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts.*

Letter from Members of Congress to Alex M. Azar II, Secretary, U.S. Dep't Health & Human Servs. at 1, Exhibit C (Sept. 14, 2020) (emphasis added). The letter, directed to the HHS Secretary, strongly condemned the unlawful overcharging activity at issue here, noting that "[t]he recent actions undermine the intended purpose of the 340B Drug Pricing Program. The Department of Health and Human Services (HHS) must take immediate action to stop these companies from either denying or limiting access to 340B pricing to hospitals, health centers, and clinics participating in 340B." *Id.* at 1.

II. FQHC Participation in the 340B Program

21. The FQHC covered entities on whose behalf Petitioner brings this action, as indicated in Exhibit A, purchase covered outpatient drugs from some or all of the drug manufacturers

named in this Petition. Certain of the covered entities regular purchases—where applicable provider and patient eligibility elements are satisfied—qualify for 340B discount pricing.

22. The FQHC covered entities represented herein utilize contract pharmacy arrangements to fulfill some or all of their patients' pharmaceutical dispensing needs, including the dispensing of drugs eligible for 340B discount pricing.

23. Under their agreements with contract pharmacies, the covered entities (either directly or through a third-party administrator) order and pay for the 340B drugs and direct the shipment of those drugs from the manufacturer (or wholesaler) to the contract pharmacy.

24. As Congress intended, the FQHC covered entities' participation in the 340B Program generates both savings and revenue at no cost to taxpayers: savings are realized when an FQHC covered entity pays the ceiling price for a particular drug provided to an uninsured or underinsured patient; revenue is generated on the spread between the ceiling price and any reimbursement at or above that price from third-party payers including the Medicare Program, Medicaid managed care organizations, or patients' private insurance carriers.

25. Section 330 of the PHS Act obligates the FQHC covered entities to use any non-grant or program income—e.g. revenue generated through public or private reimbursement for services—in furtherance of their health care safety-net mission. See 42 U.S.C. §§ 254b(e)(5)(A) (defining non-grant funds as "state, local, and other operational funding provided to the center" and "fees, premiums, and third-party reimbursements . . . the center may . . . receive for its operations"), (D) (mandating that non-grant funds be used to further center's project objectives).

III. The Drug Manufacturers' Unlawful Overcharging

A. Lilly

26. Beginning in or around the second half of 2020, the drug manufacturers threatened—and then imposed—significant limitations on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable 340B ceiling prices. The prohibited overcharging actions of each of the three named drug manufacturers are as follows:

27. On or about July 1, 2020, Lilly posted a notice on HHS's designated 340B Program webpage informing 340B covered entities that, effective immediately, it would no longer fulfill covered entities' purchases for multiple formulations of the drug Cialis at 340B pricing for dispensing through the covered entities' contract pharmacies. *See* Limited Distribution Plan Notice for Cialis, Exhibit D.

On or about September 2, 2020, Lilly disseminated another notice (which HHS declined to post on its webpage) informing the covered entities that, effective the day prior, it would no longer fulfill covered entities' purchases for *any* of its covered outpatient drugs at 340B pricing to be dispensed to FQHC patients through any contract pharmacies of a covered entity. Lilly's notice indicated it would provide an exception for certain insulin products. *See* Limited Distribution Plan Notice for Eli Lilly & Co. Prods., Exhibit F; *see also* Letter from Robert P. Charrow, General Counsel, U.S. Dep't of Health & Human Servs., to Anat Hakim, Senior Vice President and General Counsel, Eli Lilly & Co. (Sept. 21, 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf, Exhibit E (expressing grave concern and refusing to endorse Lilly's actions). The limited insulin exception has proved infeasible.

28. Lilly's near total restriction on the FQHC covered entities' ability to purchase Lilly drugs at 340B pricing is an overcharge as defined in 42 C.F.R. § 10.21(c)(1), i.e. a "limit[ation on]

the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." It is also exactly the sort of "knowing and intentional" overcharging HHS called out in its civil monetary penalty regulations at 42 CFR § 10.11(b).

29. A list of NDCs impacted by Lilly's overcharging is attached as Exhibit I.

B. Sanofi

30. On or around July, 2020 Sanofi announced that, effective October 1, 2020, Sanofi would no longer permit covered entities to purchase covered outpatient drugs at or below 340B ceiling prices for dispensing through the entities' contract pharmacies unless the covered entities submit claims data to Sanofi through third-party software vendor Second Sight Solutions. *See* Sanofi Letter Re: 340B Program Integrity Initiative, Exhibit H.

31. Sanofi claims publicly that it needs this data to identify and prevent duplicate discounts, but has no legal right to demand this information or condition its statutory obligation to offer covered outpatient drugs to covered entities at or below 340B ceiling prices on compliance with its demands. HHS has long made clear that the 340B statute does not permit manufacturers to impose any conditions on covered entities, including by, for example, conditioning the offer of 340B discounts on a covered entity's assurance of compliance with 340B Program requirements. *See, e.g.*, Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110 (May 13, 1994); HRSA, 340B Drug Pricing Program, Manufacturer Resources, https://www.hrsa.gov/opa/manufacturers/indExhibithtml (*last accessed* Jan. 13, 2021); HRSA, 340B Drug Pricing Program Notice No. 2011-1.1 (May 23, 2012), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf.

32. Sanofi's conditioning of the FQHC covered entities' ability to purchase its drugs at 340B pricing on participation in unsanctioned data sharing is an unlawful overcharge—i.e. a limitation on the covered entities' ability to purchase Sanofi drugs at or below applicable ceiling prices—as defined in 42 C.F.R. § 10.21(c)(1). Like Lilly's conduct, it too is the sort of overcharging HHS referenced in 42 CFR § 10.11(b).

33. A list of NDCs impacted by Sanofi's overcharging is attached as Exhibit K.

C. AstraZeneca

34. In or around August 2020, AstraZeneca informed the covered entities that, effective October 1, 2020, it would no longer ship covered entities' purchases of 340B discounted drugs to the entities' contract pharmacies. AstraZeneca followed through on its threat, with a limited exception for covered entities that lack any other pharmacy outlet to designate one single contract pharmacy per covered entity. *See* AstraZeneca Letter Re: 340B Contract Pharmacy Pricing (Aug. 17, 2020), Exhibit G.

35. AstraZeneca's "exception" concedes that it is refusing to make its covered outpatient drugs available to FQHC covered entities at or below 340B ceiling prices based on its unilateral decision as to whether a covered entity's use of contract pharmacies is permissible under the 340B Program. This documented action meets the definition of an overcharge included in 42 C.F.R. § 10.21(c)(1)—it is a "limit[ation on] the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." Like the other manufacturers' actions, it too is the sort of overcharging HHS referenced in 42 CFR § 10.11(b).

36. A list of NDCs impacted by AstraZeneca's overcharging is attached as Exhibit J.

IV. Harm to the FQHC Covered Entities

37. The drug manufacturers' ongoing and unlawful overcharging activities have caused and will continue to cause significant financial and other harms to the FQHC covered entities—and their patients—so long as the manufacturers' limitations on the entities' purchases continue.

38. The differential between the non-discounted "wholesale acquisition cost" ("WAC") and 340B ceiling price for affected drugs can be enormous, even for commonly prescribed drugs such as insulin, osteoporosis treatments, and asthma inhalers.

39. As just one example of the magnitude of the manufacturer's overcharging, the WAC for the Lilly osteoporosis treatment Forteo is approximately $3,663.39 per unit, while the 340B price is $0.02, resulting in an approximate overcharge of $3,663.37 for each unit of Forteo that Lilly refuses to offer the FQHC covered entities at 340B pricing. A sample of WAC/340B price comparisons is attached as Exhibit L to further illustrate the value of the drug manufacturers' sweeping restrictions on covered entity purchasing.

40. The cumulative financial harm to the FQHC covered entities caused by each drug manufacturer, taken separately, will far surpass the *de minimus* regulatory threshold for equitable relief—namely, an impact on the covered entity with an estimated value of $25,000 or more in the twelve months following the 340B ADR Panel's resolution of the claim.

41. Indeed, several of the FQHC covered entities on whose behalf Petitioner brings this joint claim anticipate that the equitable relief sought—i.e. the restoration of the covered entities' access to Lilly, Sanofi, and AstraZeneca drugs at applicable 340B pricing for dispensing to their patients at contract pharmacies—will have a far greater value than the estimated prospective threshold in 42 C.F.R. § 10.21(b).

42. Covered entity patients also stand to be harmed by cuts to non-reimbursable services that FQHCs currently support with funds generated through 340B Program participation.

These services—which may be drastically reduced or eliminated entirely due the drug manufacturers' refusal to offer their drugs at 340B pricing—include, for example, medication therapy management, behavioral health care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

COUNT ONE: LILLY

43. The allegations contained in paragraphs 1–44 above are re-alleged and incorporated by reference herein.

44. By refusing to allow the FQHC covered entities to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, Lilly has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS, it "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."

COUNT TWO: SANOFI

45. The allegations contained in paragraphs 1–44 above are re-alleged and incorporated by reference herein.

46. By placing restrictions and conditions on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, Sanofi has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS,

it "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."

COUNT THREE: ASTRAZENECA

47. The allegations contained in paragraphs 1–44 above are re-alleged and incorporated by reference herein.

48. By restricting the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, AstraZeneca has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS, it "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."

REQUEST FOR RELIEF

Petitioner respectfully requests equitable relief as follows:

1. Declare that each FQHC covered entity is entitled to purchase the drug manufacturers' covered outpatient drugs at 340B pricing to be dispensed to eligible patients through each covered entity's contract pharmacies.

2. Declare that Lilly, by restricting the FQHC covered entities' ability to purchase Lilly drugs at or below applicable ceiling prices, as described in paragraphs 27–28 herein, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

3. Declare that Sanofi, by restricting the covered entities' ability to purchase Sanofi drugs at or below 340B ceiling prices unless the covered entities' submit claims data to Sanofi

through a third-party vendor, as described in paragraphs 31–32 herein, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

4. Declare that AstraZeneca, by restricting the FQHC covered entities' ability to purchase Lilly drugs at or below applicable ceiling prices, as described in paragraphs 35–36 herein, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

5. Order the drug manufacturers to comply with 42 U.S.C. § 256b(a)(1) and the terms of their PPAs by removing all manufacturer-imposed qualifications, limitations, conditions, or restrictions on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices.

6. Order such other equitable relief as the Panel deems just and proper.

Dated: January 13, 2021

Respectfully submitted,

/s/ *Matthew S. Freedus*
Matthew S. Freedus (DC 475887)
Rosie Dawn Griffin (DC 1035462)
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Attorneys for Petitioner

Exhibit A

NATIONAL ASSOCIATION OF
Community Health Centers

January 13, 2021

VIA ELECTRONIC MAIL

Alternative Dispute Resolution Panel
U.S. Department of Health and Human Services
Health Resources and Services Administration
340BADR@hrsa.gov

RE: Request to Consolidate Claims

Dear ADR Panel:

The National Association of Community Health Centers ("NACHC") respectfully requests that the Alternative Dispute Resolution ("ADR") Panel consolidate the claims of its Federally-qualified health center ("FQHC") members listed in the attached document into a single joint claim pursuant to and in compliance with 42 C.F.R. §10.3. Each of the listed members is a covered entity under 340B of the Public Health Service Act.

The final rule for 42 C.F.R. Part 10, which was published December 14, 2020, requires associations to obtain authorization from each member to represent their interests but did not explicitly require that a signature from each member be included in the filing. Based on the language in the final rule counsel for NACHC prepared an electronic questionnaire to obtain authorization from interested members. A representative from each organization listed on the attached document completed an electronic authorization confirming that the organization: (1) holds NACHC membership; (2) has been limited in its ability to purchase covered outpatient drugs under the 340B program by Lilly, Sanofi, and/or AstraZeneca;[1] and (3) authorizes NACHC to bring ADR claims against the named drug manufacturers on its behalf.

In granting NACHC authorization to bring an ADR claim, each health center representative provided their name and email address along with the affirmative authorization for NACHC to bring the claim on their behalf along with the similar claims of other members. Both the member representatives and NACHC received a date and time-stamped copy of the authorization via email.

[1] For purposes of this question, those completing the questionnaire and authorization were informed that "limited" meant that the health center was unable to purchase drugs at or below the ceiling price through normal dispensing channels.

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HRSA later posted guidance on its website that included an additional explicit requirement that the association include a signature from each member in a petition brought on behalf of its membership. In response, counsel for NACHC updated the initial authorization to clarify that it would submit the names and email addresses of individual representatives as well as an explicit acknowledgement that the electronic authorization serves as the organization's signature for purposes of NACHC bringing consolidated claims.

The attached document is a summary of each of the electronic authorizations. The second portion of the list excludes the names and email addresses of the individual representatives because NACHC has not received explicit permission to include that information in the petition. We will supplement that information as it becomes available.

Sincerely,

Tom Van Coverden

Tom Van Coverden
President & CEO

Encl:

NACHC MEMBER AUTHORIZIATION

Datestamp	Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:	Authorize NACHC
1/13/21 18:17:04	bmiller@Jordanvalley.org	Advocates for a Healthy Community, Inc.	K. Brooks Miller, President/CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:24:42	nspencer@alconahc.org	Alcona Citizens for Health, Inc.	Nancy Spencer, CEO	Yes	AstraZeneca;Sanofi;Eli Lilly	Yes
1/13/21 16:02:56	Ed.Shanshala@ACHS-Inc.Org	Ammonoosuc Community Health Services, Inc.,	Edward D Shanshala II, MSHSA, MSEd, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:10:04	mparacha@ahsfhc.org	Asian Human Services Family Health Center, Inc	Muhammad Paracha, MD., MPH. - CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 19:29:51	david.mark@onechc.org	Bighorn Valley Health Center, Inc.	David Mark, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:15:46	blissbx@aol.com	BLISS Inc.	Saudah Muhammad, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:38:08	debbieackerson@bmrhc.net	Boston Mountain Rural Health Center, Inc.	Debbie Ackerson/CEO	Yes	Eli Lilly;AstraZeneca;	Yes
1/13/21 16:14:06	psgomez.bchc@tachc.org	Brownsville Community Health Clinic, Corp	Paula S. Gomez, Executive Director	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:10:38	sveer@carolinahealthcenters.org	Carolina Health Centers, Inc.	President and CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 15:56:12	mkaser@cfhinc.org	Center for Family Health	Molly Kaser, CEO	Yes	Eli Lilly	Yes
1/13/21 17:10:46	brenda.ware@cofmc.org	Central Oklahoma Family Medical Center	Brenda Ware, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:34:43	paulatomko@cvhsinc.org	Central Virginia Health Services, Inc.	Paula A. Tomko, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:51:32	jcywinski@chasebrexton.org	Chase Brexton Health Services	Jeffrey Cywinski, Director of	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:26:11	jmoldovan@chicagofamilyhealth.org	Chicago Family Health Center	Joseph Moldovan, Chief Financial Officer	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 18:45:11	simon.smith@clinica.org	Clinica Campesina/Family Health Services (Clinica Family Health	Simon Smith, President and CEO	Yes	AstraZeneca;Sanofi;Eli Lilly;	Yes
1/13/21 17:40:58	youngk@cdsdp.org	Clinicas de Salud del Pueblo, Inc.	Young C. Kwon, Executive Vice President & Chief Legal Officer	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes

NACHC MEMBER AUTHORIZIATION

Datestamp	Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:	Authorize NACHC
1/13/21 16:50:22	dbertsch@smcnd.org	Coal Country Community Health Center	Darrold Bertsch	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 19:06:08	cgillham@chanevada.org	Community Health Alliance	Casey Gillham, Chief Legal Officer	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:37:30	tbowman@chcqca.org	Community Health Care, Inc.	Tom Bowman, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 15:58:54	epkucher@hcnetwork.org	Community Health Centers of Pinellas	Edward Kucher, Chief Regulatory Officer	Yes	AstraZeneca	Yes
1/13/21 17:37:56	scannon@chcsi.org	Community Health Centers of Southern Iowa, Inc.	Samantha Cannon, CEO	Yes	Sanofi;AstraZeneca;	Yes
1/13/21 15:55:28	dpearce@chc-ut.org	Community Health Centers, Inc. (Salt Lake City, Utah)	Dexter A. Pearce ED	Yes	Eli Lilly	Yes
1/13/21 17:08:53	cdavis@chsofwi.org	Community Health Systems, Inc.	Caryn Davis, Director of Finance	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:17:02	kharvey@scenicrivershealth.org	Cook Area Health Services, Inc., dba Scenic Rivers Health Services	Keith Harvey, Chief Financial Officer	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 18:31:33	hrickertsen@crescentchc.org	Crescent Community Health Center	Director of Clinical Pharmacy Services	Yes	Eli Lilly;AstraZeneca;	Yes
1/13/21 18:29:38	mstaton@cfmcky.com	Cumberland Family Medical Center, Inc	Mona Staton, Director of 340B Services	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:15:44	agrandy@cvcphc.com	Curtis V. Cooper Primary Health Care, Inc.	Albert B. Grandy Jr. ---- CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 19:31:10	tmackey@arthurcenter.com	East Central Missouri Behavioral Health Services, Inc.	Terry Mackey, CEO	Yes	Eli Lilly;AstraZeneca;Sanofi;	Yes
1/13/21 16:52:00	jlock@eihc.co	Eastern Iowa Health Center	Joe Lock, President & CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:12:39	mclay@esrh.org	Eastern Shore Rural Health System, Inc.	Matthew Clay, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes

NACHC MEMBER AUTHORIZIATION

Datestamp	Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:	Authorize NACHC
1/13/21 18:19:20	rroden@call4hope.org	Ellis County Coalition for Health Options	Randy Roden, CFO	Yes	Eli Lilly;AstraZeneca;	Yes
1/13/21 17:40:46	lfrancis@eriefamilyhealth.org	Erie Family Health Ceners	Lee Francis, President and CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:18:26	rgadia@esperanzachicago.org	Esperanza Health Centers	Ryan Gadia, CFO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:58:12	ccarter@fairfaxclinic.com	Fairfax Medical Facilities, Inc.	COO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:35:49	jsmith@familyhealthnwo.org	Family Health Care of Northwest Ohio, Inc.	CEO	Yes	Sanofi;Eli Lilly;AstraZeneca;	Yes
1/13/21 16:47:13	kmcleod@fcpcga.org	First Choice Primary Care	Katherine McLeod, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:11:03	tstarkey@gsphealth.org	Great Salt Plains Health Center, Inc.	Tim Starkey, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:31:04	ctjonesjr@hhsi.us	Harbor Health Services, Inc.	Charles Jones, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 18:08:31	Joe.odom@hcpsc.org	Health Care Partners of SC Inc	Joe Odom Director of Pharmacy	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 18:00:30	stephanie.moore@whitehouseclinics.com	Health Help Inc d/b/a White House Clinics	Stephanie Moore, CEO	Yes	AstraZeneca;Sanofi;Eli Lilly;	Yes
1/13/21 17:02:16	jamie.ulmer@myhfhc.org	Heart of Florida Health Center	Jamie Ulmer, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 15:57:19	s.adams@hhsil.com	Heartland Health Services	Sharon Adams, CEO	Yes	Eli Lilly	Yes
1/13/21 16:07:50	kemi.alli@henryjaustin.org	Henry J. Austin Health Center	Kemi Alli, CEO	Yes	Eli Lilly;AstraZeneca	Yes
1/13/21 16:12:13	jay.breines@hhcinc.org	Holyoke Health Center	Jay Breines, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 15:57:15	Jgambino@hhchc.org	Hometown Health Centers	Joseph Gambino, CEO	Yes	AstraZeneca	Yes

NACHC MEMBER AUTHORIZIATION

Datestamp	Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:	Authorize NACHC
1/13/21 15:56:55	jmengenhausen@horizonhealthcare.org	Horizon Health Care, Inc.	John Mengenhausen, CEO	Yes	Eli Lilly	Yes
1/13/21 16:05:31	stsmith@intercare.org	InterCare Community Health Network	Stephanie Smith, Chief Financial Officer	Yes	AstraZeneca	Yes
1/13/21 16:55:32	dmarion@janepauleychc.org	Jane Pauley Community Health Center, Inc.	Dale Marion, Practice Manager and 340B Authorizing Official	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:52:20	kriben@keystoneruralhealth.com	Keystone Rural Health Consortia, Inc	Kristie Bennardi, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:45:23	kedwards@lamaestra.org	La Maestra Family Clinic Inc.	Keith Edwards, General Counsel	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:04:47	jenni.black@lanchc.org	Lancaster Health Center	Jenni Black Chief Quality and Compliance Officer	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 18:56:29	ktunghui@lifelongmedical.org	Lifelong Medical Care	Kyle Hui, Pharmacy Director	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:04:42	pdavis@lrmcenter.com	Little River Medical Center, Inc.	Pamela Davis, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:57:32	dnemirof@numc.edu	Long Island FQHC, Inc.	David Nemiroff, President/CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 18:07:27	brendaro@lchealth.org	Lowell Community Health Center	Brenda Rodriguez, Chief Strategy & Finance Officer	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:02:44	ckuntz@mhchealthcare.org	Marana Health Center, Inc.	Clint Kuntz, CEO	Yes	Eli Lilly	Yes
1/13/21 16:21:16	scott.riggs@meridianhs.org	Meridian Health Services Corp.	Scott Riggs, CFO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:13:32	ben.wiederholt@stridechc.org	Metro Community Provider Network (D/B/A STRIDE	Ben Wiederholt, President and CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:35:29	msilverberg@mfhcnj.org	Monmouth Family Health Center	Marta C. Silverberg, CEO	Yes	Eli Lilly;	Yes
1/13/21 16:26:52	diemnguyen.mqvncdc@gmail.com	MQVN Community Development Corp.	Diem Nguyen, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes

NACHC MEMBER AUTHORIZIATION

Datestamp	Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:	Authorize NACHC
1/13/21 16:05:44	jpolster@nfpmedcenter.org	Neighborhood Health Care, Inc. dba Neighborhood Family Practice	Jean Polster, President and CEO	Yes	Sanofi;Eli Lilly;AstraZeneca	Yes
1/13/21 17:51:19	jrrichards@mapbt.com	Neighborhood Improvement Project, Inc.	J.R. Richards, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 18:20:29	noel.twilbeck@crescentcare.org	NO/AIDS Task Force (d.b.a. CrescentCare)	Noel Twilbeck, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 15:57:48	ddey@connextcare.org	Northern Oswego County Health Services, Inc. dba ConnextCare	Daniel T. Dey, President/CEO	Yes	AstraZeneca	Yes
1/13/21 16:49:32	j.haefner@nwbchcc.org	Northwest Buffalo Community Healthcare Center d/b/a	Joanne Haefner, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:18:02	plogan@nwhumanservices.org	Northwest Human Services, Inc.	Paul Logan, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:52:55	admin.ncdv@tachc.org	Nuestra Clinica del Valle, Inc.	Lucy Ramirez Torres	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:14:37	bayars@opendoorhs.org	Open Door Health Services	Bryan Ayars, Chief Executive Officer	Yes	AstraZeneca;Sanofi;Eli Lilly	Yes
1/13/21 17:06:31	pam.mcmanus@peakvista.org	Peak Vista Community Health Centers	Pam McManus, President & CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:05:18	phillip.tatum@perrymedcenter.org	Perry County Medical Center, Inc.	CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 18:24:38	andersonb@prairiestarhealth.org	PrairieStar Health Center	Bryant Anderson, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:11:58	lynn.hopkins@primecarechi.org	PrimeCare Community Health	CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:50:25	tchase@telmedical.com	Project Health, Inc.	Thomas G. Chase, Chief Executive Officer	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:09:17	frank@phmc.org	Public Health Management Corporation	Frank Killian, Dir. of Finance and Regulatory Affairs	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:12:38	dmoore@pueblochc.org	Pueblo Community Health Center, Inc.	Donald Moore, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes

NACHC MEMBER AUTHORIZIATION

Datestamp	Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:	Authorize NACHC
1/13/21 16:54:10	gthrockmorton@riverhillshealth.org	River Hills Community Health Center	Gina Trhrockmorton, CFO/COO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 18:10:41	kschwartz@rcchc.org	Roanoke Chowan Community Health Center	Kim A. Schwartz	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:09:55	yvonne.long-gee@rhgnc.org	Rural Health Group Inc.,	Yvonne Long-Gee, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:50:09	scott.morgan@ryanhealth.org	Ryan Chelsea-Clinton Community Health Center, Inc.	Scott Morgan, Chief Financial Officer	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:43:19	cmurphy@svhc.org	Sacopee Valley Health Center	Carol Murphy Executive Director	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:01:46	brian.wallace@syhealth.org	San Ysidro Health	Brian Wallace, VP & CFO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:03:16	pjensen@shsdc.org	Shawnee Health Service and Development Corporation	Patsy R. Jensen, Executive Director	Yes	Eli Lilly	Yes
1/13/21 16:03:05	julie.schuller@sschc.org	Sixteenth Street Community Health Centers	Julie Schuller, MD, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:28:10	nfidanza@shchc.org	Southeast Community Health Systems	Nicole Fidanza, 340B Program Coordinator	Yes	Eli Lilly;	Yes
1/13/21 16:58:59	mperdue@stonemtn.org	St Charles Health Council, Inc / dba Stone Mountain Health	Malcolm Perdue, President and CEO	Yes	Eli Lilly;AstraZeneca;Sanofi;	Yes
1/13/21 16:54:04	golson@sterlinghealth.net	Sterling Area Health Center	George Olson - President and CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:00:10	mperdue@stonemtn.org	Stone Mountain Health Services / St Charles Health Council, Inc	Malcolm Perdue, CEO	Yes	Eli Lilly	Yes
1/13/21 17:37:54	mmoran.sunrise@nocoha.org	Sunrise Community Health	Mitzi Moran, CEO	Yes	AstraZeneca;	Yes
1/13/21 17:12:57	drogers@sunset-chc.org	Sunset Community Health Center, Inc.	David Rogers CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:22:24	mark.hall@schcny.com	Syracuse Community Health Center, Inc.	Mark Hall President, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes

NACHC MEMBER AUTHORIZIATION

Datestamp	Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:	Authorize NACHC
1/13/21 16:35:35	abrown@tandemhealthsc.org	Tandem Health SC	Annie Brown, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:52:51	robertsc@healthcare-connection.org	The Healthcare Connection, Inc.	Robert Schlanz, CFO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 15:56:51	mthomas@providencechc.org	The Providence Community Health Centers	Merrill R. Thomas, CEO	Yes	Eli Lilly	Yes
1/13/21 17:19:52	kboyd@triarea.org	Tri-Area Community Health	Kayla Boyd, Chief Financial Officer	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 18:10:32	jodi.joyce@ucnw.org	Unity Care NW	Jodi Joyce, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:44:03	Donald.simila@uglhealth.org	Upper Great Lakes	donald simila ceo	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 15:59:47	paloma.hernandez@urbanhealthplan.org	Urban Health Plan, Inc.	Paloma Hernandez, President/CEO	Yes	AstraZeneca	Yes
1/13/21 17:21:48	mbrubeck@valleyhealth.org	Valley Health Systems, Inc.	Mary-Beth Brubeck, Vice President of Finance/Chief Financial Officer	Yes	Eli Lilly;Sanofi;	Yes
1/13/21 19:09:53	fernando@vcc.org	Vista Community Clinic	Fernando Sanudo, CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:53:28	fortunerr@wmh.org	Wayne Memorial Community Health Centers, Inc	Robert J. Fortuner II, Finance Director	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 17:32:13	srollett@windrosehealth.net	Windrose Health Network, Inc.	Scott K. Rollett, Chief Executive Officer	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes
1/13/21 16:13:27	acroke@wrhsri.org	Wood River Health Services	Alison L Croke, President & CEO	Yes	Eli Lilly	Yes
1/13/21 16:13:11	eturbiner@zufallhealth.org	Zufall Health Centers Inc	Eva Turbiner, President & CEO	Yes	Eli Lilly;Sanofi;AstraZeneca	Yes

NACHC AUTHORIZATON
(Health Center Name Only)

Datestamp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
1/8/2021 16:56:41	1st Choice Healthcare, Inc.	Yes	Eli Lily, AstraZeneca	Yes
1/10/2021 17:43:18	Access Community Health Centers, Inc.	Yes	Sanofi	Yes
1/11/2021 17:57:42	Adelante Healthcare	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:32:04	Advance Community Health, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:13:43	Advantage Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 9:18:00	Advocates for a Healthy Community, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 17:13:33	AltaMed Health Services Corp.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:21:42	Anthony L Jordan Health Corporation, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/9/2021 11:34:17	Appalachian Mountain Community Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:11:54	Asian Health Services	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 7:31:52	Aspire Indiana Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 11:00:36	Atchison Community Health Clinic	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 19:07:31	Avenal community Health Center Avenal Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/10/2021 17:51:07	Baltimore Medical System, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:45:18	Barrio Comprehensive Family Health Care Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 17:05:02	Bay Area Community Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 9:50:05	Beaufort Jasper Hampton Comprehensive Health Services, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/10/2021 16:09:02	Berks Community Health Center	Yes	Eli Lily, Sanofi	Yes
1/11/2021 12:07:52	Betances Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 16:47:55	Bighorn Valley Health Center, Inc. DBA One Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 8:51:37	Black River Health Services, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:22:10	Blue Ridge Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:18:46	Bluestem Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 12:20:44	Board of Trustees of Southern Illinois University - SIU Center for Family Medicine	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 11:10:30	Broad Top Area Medical Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:26:49	Brockton Neighborhood Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 19:31:43	BROWARD COMMUNITY AND FAMILY HEALTH CENTERS	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:17:21	Butler County Community Health Consortium dba Primary Health Solutions	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:57:52	Cabarrus Rowan Community Health Centers, inc	Yes	Eli Lily, Sanofi, AstraZe	Yes

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Datestamp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
1/8/2021 16:33:28	CABUN Rural Health Services	Yes	Eli Lily, AstraZeneca	Yes
1/11/2021 14:45:33	Camarena Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:05:15	Care Resource Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/9/2021 13:32:19	Caring Hands Healthcare Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/12/2021 13:07:19	Caring Health Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 9:14:29	Cassopolis Family Clinic Network	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 11:34:31	Center for Family Health and Education	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:21:17	Central Counties Health Centers, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:24:19	Charles B. Wang Community Health Center	Yes	Eli Lily, Sanofi	Yes
1/11/2021 14:35:19	Charter Oak Health Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/10/2021 9:41:42	Cherokee Health Systems	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:07:18	Cherry Street Services	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/12/2021 8:20:50	Choptank Community Health System	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 18:51:28	Christ Community Health Services	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 18:54:48	Christ Community Health Services	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 9:53:36	CHRIST COMMUNITY HEALTH SERVICES AUGUSTA	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:40:05	Christopher Rural Health Planning Corporation	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 13:47:10	Clinicas del Camino Real, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:24:04	Coastal Community Health Services	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 18:19:23	Collier Health Services, Inc., d/b/a Healthcare Network	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:32:26	CommuniCare Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:35:52	Community Health Alliance	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:59:40	Community health and Wellness Center of Greater Torrington, inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 18:50:20	Community Health Center in Cowley County, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 13:41:30	Community Health Center of Buffalo, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/9/2021 0:22:53	Community Health Center of Richmond, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:26:47	Community Health Centers of Greater Dayton	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:07:08	Community Health Centers of the Central Coast, Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 20:46:45	Community Health Centers, Inc. (Salt Lake City)	Yes	Eli Lily, Sanofi, AstraZe	Yes

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Datestamp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
1/11/2021 13:03:19	Community Health of East TN, Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 17:57:49	Community HealthNet	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/10/2021 12:19:10	Coos County Family Health Services	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 8:49:32	Cornerstone Care, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:52:37	Cornerstone Family Healthcare	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:30:25	Crusaders Central Clinic Association	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:08:55	Damian Family Care Centers, Inc.	Yes	Eli Lily, Sanofi	Yes
1/9/2021 16:27:26	Dayspring Health	Yes	Eli Lily, AstraZeneca	Yes
1/10/2021 17:21:10	Diversity Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 12:39:16	East Arkansas Family Health Ctr, Inc	Yes	Eli Lily, AstraZeneca	Yes
1/11/2021 16:10:30	East Harlem Council for Human Services, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 16:39:38	East Jordan Family Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 20:08:21	East Valley Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:35:11	Eastern Shore Rural Health Systems, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:03:11	Eau Claire Cooperative Health Center, Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 23:32:14	Edward M. Kennedy Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:00:37	El Centro del Barrio, DBA CentroMed	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:22:06	El Rio Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 11:48:14	Erie Family Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/9/2021 19:41:44	Family Care Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 19:17:00	Family Health Care Centers of Greater Los Angeles	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:15:06	Family health Center of Worcester	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 11:31:41	Family Health Centers	Yes	Eli Lily	Yes
1/8/2021 18:59:34	Family Health Centers of San Diego	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:03:09	Family Health Network of Central New York, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:39:26	Family Medical Center of MI	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 16:28:23	Fetter Health Care Network	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:56:53	Finger Lakes Migrant Health Care Project, Inc. dba Finger Lakes Community Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:30:51	Florida Community Health Centers, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes

NACHC AUTHORIZATON
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Datestamp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
1/9/2021 9:17:09	Friend Family Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:40:38	Gardner Family Health Network, Inc. d.b.a. Gardner Health Services	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:15:44	Garfield Health Center	Yes	Sanofi, AstraZeneca	Yes
1/8/2021 14:57:53	Gateway Community Health Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:26:00	Generations Family Health Center, Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 18:32:58	Golden Valley Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:20:23	Goshen Medical Center Inc.	Yes	Eli Lily, AstraZeneca	Yes
1/8/2021 16:24:01	Grace Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 16:58:23	Great Lakes Bay Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:00:58	Greater Philadelphia Health Action	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 9:14:15	Greene County Health, Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:39:57	Gulf Coast Health Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:06:14	HAART, Inc. dba Open Health Care Clinic	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:18:20	Hackley Community Care Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:50:56	Harbor Health Services, Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:45:58	Hardin County Regional Health Center dba Lifespan Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 13:02:26	Health Care Partners of South Carolina Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 13:01:30	Health Partners of Western Ohio	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:33:31	Health West Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:27:29	HealthCore Clinic	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 11:29:57	HealthLinc, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/10/2021 16:25:59	HealthNet, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:39:35	HealthSource of Ohio	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:43:03	Heart City Health Center, Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 11:51:14	Heartland International Health Center	Yes	Eli Lily, Sanofi	Yes
1/11/2021 15:11:50	Hidalgo Medical Services	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:27:41	Holyoke Health Center, Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:36:46	HOPE Clinic	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:28:37	HopeHealth, Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes

NACHC AUTHORIZATON
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Datestamp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
1/8/2021 14:49:51	Hudson Headwaters Health Network	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:58:19	Jane Pauley Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:33:43	Jefferson Comprehensive Care System, Inc.	Yes	Eli Lily, AstraZeneca	Yes
1/11/2021 14:47:28	Johnson Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 8:45:51	Keystone Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:34:55	Kiamichi Family Medical Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:47:54	Kodiak Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/12/2021 12:59:03	Kyle Hui	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 17:11:01	La Clinica de Familia, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:35:15	La Clinica de La Raza, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:14:39	La Maestra Family Clinic Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 7:47:26	Lamprey Health Care	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:36:13	Legacy Community Health Services	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:36:46	Lewis Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:49:31	LifeSpring Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 13:41:07	Little River Medical Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 16:51:57	Lone Star Circle of Care	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:27:21	Lynn Community Health Center	Yes	Eli Lily, Sanofi	Yes
1/11/2021 12:16:54	Mainline Health Systems, Inc.	Yes	Eli Lily, AstraZeneca	Yes
1/11/2021 12:19:37	Marillac Community Health Centers dba DePaul Community Health Centers	Yes	Sanofi	Yes
1/11/2021 13:49:48	Marin Community Clinics	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:37:55	Mendocino Community Health Clinic	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 19:44:25	Mercy Medical Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:34:20	Metro Community Health Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:34:30	Metro Community Provider Network d/b/a STRIDE Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:35:49	Metro Health DC	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:10:16	MetroHealth DC	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:26:34	Mid-Delta Health Systems	Yes	Eli Lily, AstraZeneca	Yes
1/11/2021 15:59:15	Morris Heights Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes

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Datestamp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
1/8/2021 14:51:50	Morris Heights Health Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:40:51	Mosaic Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:53:54	Moses Lake Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:12:31	Mountain Comprehensive Health Corporation	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/12/2021 10:41:09	Mountain Park Health Center	Yes	Eli Lily, Sanofi	Yes
1/11/2021 8:29:48	Muskingum Valley Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:49:05	Near North Health Service Corporation	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:17:36	Neighborhood Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:35:09	Neighborhood Health Center of WNY Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 21:35:27	Neighborhood Healthcare	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 11:29:50	Neighborhood Outreach Access to Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:55:02	Newark Community Health Centers Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 12:32:40	North County Health Project, Inc.	Yes	Eli Lily, AstraZeneca	Yes
1/8/2021 16:42:50	North Olympic Healthcare Network	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/9/2021 10:22:04	Northern Counties Health Care	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:24:15	Northern Oswego County Health Services, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/12/2021 12:21:38	NorthShore Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:08:31	Oak Orchard Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 13:57:03	Oakhurst Medical Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:55:30	OCOEE REGIONAL HEALTH CORPORATION	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:35:04	OLE Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 18:31:50	Omni Family Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:54:12	Urban Health Plan	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:17:31	PanCare of Florida Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 18:01:44	People's Community Clinic	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/9/2021 9:53:34	Piedmont Access to Health Services, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:27:25	PrairieStar Health Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 22:07:24	PrairieStar Health Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:09:51	Premier Community Healthcare Group	Yes	Eli Lily, Sanofi, AstraZe	Yes

NACHC AUTHORIZATON
(Health Center Name Only)

Datestamp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
1/11/2021 12:20:17	Presbyterian Medical Services	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/12/2021 10:14:25	Primary Health Network	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/10/2021 18:19:21	PrimaryOne Healht	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 16:15:11	Pueblo Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:27:31	ReGenesis Organization Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 12:50:59	Resources for Human Development	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:25:47	Richford Health Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:04:44	Rocking Horse Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 18:29:59	Rural Health Group, Inc.,	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:01:50	Rural Health Medical Program	Yes	Eli Lily, AstraZeneca	Yes
1/11/2021 16:38:06	Rural Health Services Consortium, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:39:36	Rural Health Services, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:33:47	Rural Health Services, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 14:34:50	Salina Health Education Foundation (dba Salina Family Healthcare Center)	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 13:09:24	Salud Family Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 19:03:38	Santa Rosa Community Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:49:57	Sea Mar Community Health Centers	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:46:22	Settlement Health and Medical Services	Yes	Eli Lily, AstraZeneca	Yes
1/8/2021 13:58:45	Shasta Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/10/2021 16:02:45	Signature Health, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:32:40	Siouxland Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:45:11	Sixteenth Street Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:04:53	South County Community Health Center, Inc. dba. Ravenswood Family Health Center	Yes	Eli Lily, AstraZeneca	Yes
1/11/2021 11:28:19	Southeast Community Health Systemz	Yes	Eli Lily	Yes
1/11/2021 14:53:03	Southern Jersey Family Medical Centers, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 20:55:23	St Thomas CHC	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:05:37	staywellhealth center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/10/2021 22:20:54	Stigler Health and Wellness Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 15:06:39	Stony Creek Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes

NACHC AUTHORIZATON
(Health Center Name Only)

Datestamp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
1/11/2021 12:14:55	Su Clinica Familiar	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/12/2021 9:15:41	Sun River Health (Hudson River HealthCare)	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 12:13:50	Sunset Community Health Center Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 16:53:23	Sunset Park Health Council, Inc dba Family Health Centers @ NYU Langone	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:52:02	The Chautauqua Center, Inc.	Yes	Eli Lily	Yes
1/8/2021 13:54:32	The Providence Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 22:36:44	Tiburcio Vasquez Health Center	Yes	Eli Lily, Sanofi	Yes
1/11/2021 17:09:24	Treasure Coast Community Health, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/9/2021 16:12:37	Tri-Cities Community Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 15:58:54	Trillium Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 8:09:01	United Cerebral Palsy Association of the North Country, Inc., DBA Community Health Center of the North Country	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:16:03	United Community and Family Services, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 8:26:04	Valley Professionals Community Health Center	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:52:03	Valley-Wide Health Systems, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/10/2021 22:00:07	VIP Community Service, inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 23:42:22	Waikiki Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/12/2021 13:39:38	Wayne Memorial Community Heath Centers Inc	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 16:51:51	Westside Family Healthcare	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 14:44:01	Whiteside County Community Health Clinic	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 17:06:04	Whitney M. Young, Jr. Health Center, Inc.	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/8/2021 13:58:45	William F. Ryan Community Health Center, Inc. dba Ryan Health	Yes	Eli Lily, Sanofi, AstraZe	Yes
1/11/2021 10:58:05	Yakima Neighborhood Health Services	Yes	Eli Lily, AstraZeneca	Yes

Exhibit B

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

ADVISORY OPINION 20-06 ON CONTRACT PHARMACIES UNDER THE 340B PROGRAM DECEMBER 30, 2020

The 340B Program, established by section 340B of the Public Health Service Act ("PHSA"), 42 U.S.C. § 256b, imposes limitations on the prices manufacturers may charge for medications sold to specified health care facilities, referred to as "covered entities." Those facilities include public hospitals and community health centers, many of which provide safety-net services to the poor. The 340B Program requires drug manufacturers, as a condition of coverage of their products under Medicaid (*see* Social Security Act ("SSA") § 1902(a)(54)) and Medicare Part B (*see, e.g.*, SSA §§ 1842(o)(1), 1847A), to agree to sell their covered outpatient drugs to covered entities at no more than the statutorily-set "ceiling price." *See* SSA § 1927(a)(1).

Many covered entities enter into written agreements with pharmacies ("contract pharmacies") to distribute their covered outpatient drugs to the entities' patients. Under those agreements, the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy. Although the contact pharmacy has physical possession of the drug, it has been purchased by the covered entity.

Recently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price.

The Office of the General Counsel ("OGC") has received numerous requests from both manufacturers and covered entities to address whether it is proper for a drug manufacturer participating in the 340B Program to refuse to provide covered outpatient drugs at the 340B ceiling price to a covered entity for drugs distributed at the entity's contract pharmacies. For the reasons set forth below, we conclude that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs.

I. Analysis

A. The Plain Meaning of Section 340B Requires Manufacturers to Sell Covered Drugs to Covered Entities at or Below the Ceiling Price, Independent of Whether the Entity Opts to Use Contract Pharmacies to Dispense the Drugs

"[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004). Section 340B of the PHSA, entitled "Limitation on prices of drugs purchased by covered entities," states, in relevant part, that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1) (emphasis supplied). Furthermore, "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* As a result, the obligations placed on manufacturers by 340B are set out in a Pharmaceutical Pricing Agreement ("PPA") between the Secretary and the respective manufacturer. *See generally Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110 (2011) (describing role of PPAs in 340B Program). The exemplar PPA provides, in pertinent part, as follows:

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following: (a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to [the ceiling price].

PPA § II(a). The exemplar PPA Addendum provides that a "[m]anufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price." PPA Addendum ¶ 2.

Thus, the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity. In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute. *See Radovich v. Nat'l Football League*, 352 U.S. 445, 454 (1957) ("Congress itself has placed the private antitrust litigant in a most favorable position . . . . In the face of such a policy this Court should not add requirements to burden the private litigant beyond what is specifically set forth by Congress in those laws."); *Financial Planning Ass'n v. SEC,* 482 F.3d 481 (D.C. Cir. 2007); *Baker v. Bell Textron, Inc.*, 2020 WL 5513431, at *4 (N.D. Tex. 2020) ("The Court will not add requirements to the law that Congress could have included but did not.").

It is against this backdrop that we examine the 340B phrase "purchased by." It is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise. The Court recently cautioned against seeing ambiguity where none exists. For

example, a regulation must be "genuinely ambiguous" before resorting to deference. *Kisor v. Wilkie*, ___U.S.___, 139 S.Ct. 2400, 2415 (2019). Here, as we understand it, the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and the covered entity pays the manufacturer either directly or through the manufacturer's distributor. In either event, the arrangement between the manufacturer and covered entity is a straightforward "sale" which "consists of the passing of title from the seller [drug manufacturer] to the buyer [covered entity] for a price." Uniform Commercial Code (U.C.C.) § 2-106.[1] A "buyer" is, by definition, a "purchaser." BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "buyer" as "[s]omeone who makes a purchase"). The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant. *See* U.C.C. § 2-401(2) ("Unless otherwise explicitly agreed title passes to the buyer at the time and place at which the seller completes his performance with reference to the physical delivery of the goods . . . ").

Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive. *Bostock v. Clayton Cty.*, ___U.S.___, 140 S. Ct. 1731, 1739 (2020) ("[W]hen the meaning of the statute's terms is plain, our job is at an end."). This straightforward textual interpretation, aside from dutifully reflecting the plain meaning of the statute, has the added benefit of comporting with the statute's purpose and history.

B. The Purpose and History of the 340B Program Reflect the Provision's Plain Meaning

1. Contract Pharmacies Have Been an Integral Part of the 340B Program Since Its Outset

The 340B Program was created to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rept. No. 102–384(II), at 12 (1992). As the Health Resources and Services Administration ("HRSA")—the agency primarily responsible for administering the 340B Program—has explained in prior guidance, a substantial number of covered entities are practically constrained to rely on contract pharmacies to access the 340B Program; if manufacturers can simply shut off this means of access, the Program's effectiveness will be greatly diminished. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (proposed Feb. 6, 2019) (OIG proposed rule discussing distribution of pharmaceuticals).[2]

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[1] The U.C.C. can be used for statutory construction, even if it does not directly apply. *See Comm'r of Internal Revenue v. Brown*, 380 U.S. 563, 571 (1965) (interpreting provision of the Internal Revenue Code by pointing to U.C.C. as support for the "ordinary sense" of the word "sale").

[2] The argument that the statute also evinces a purpose to prevent drug diversion or duplicate discounting, and therefore prohibits contract-pharmacy arrangements, is not persuasive. That is like arguing that the main purpose of federal healthcare programs are their antifraud provisions. In the absence of the core 340B discount mechanism, there would be no need for the duplicate-discount or diversion provisions.

This is particularly pertinent given that at the outset of the 340B Program only approximately 500 out of 11,500 covered entities (less than 5 percent) used in-house pharmacies. *See* 61 Fed. Reg. at 43,550. This is not surprising: the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations. *See, e.g.*, 42 U.S.C. § 256b(a)(4) (defining covered entities); *Astra USA*, 563 U.S. at 113. These are the poster children of providers that one would expect to lack an in-house pharmacy. To champion a policy, ungrounded in the language of the statute, that would foreclose 340B discounts to 95 percent of covered entities and foreclose discounts to the neediest of this cohort is inconsistent with purpose of the Program and common sense. Had Congress intended to reach such a bizarre result, it would have used language affirmatively precluding the use of contract pharmacies as arms in the distribution channel, but it did not. *Doe v. Hesketh*, 828 F.3d 159, 167 (3d Cir. 2016) (the result is "so bizarre that Congress could not have intended it").

2. The Department's Longstanding Interpretation of Section 340B Reflects the Plain Language of the Section by Recognizing the Use of Contract Pharmacies

The Department's longstanding interpretation of the statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used. In 1996, HRSA issued the aforementioned guidance and stated, "[i]t has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price." 61 Fed. Reg. at 43,549. HRSA's assertion cannot be attacked as impermissible legislative rulemaking,[3] because the guidance only sought to "explain the statutory language by clarifying the meaning given by the Department to particular words or phrases"—it "create[d] no new law and create[d] no new rights or duties" not otherwise present in the statute. *See id.* at 43,550. HRSA reaffirmed its interpretation of the statute in guidance issued in 2010. *See* HRSA, *Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

The Department's consistent position over the past 24-plus years would factor into a court's interpretation of the statute. Courts defer to agency expertise in the interpretation of statutes, especially where they govern complex administrative regimes. *See, e.g.*, *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001). Conversely, a court would be skeptical of an abrupt about-face. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 577–81 (2009). Courts may also look to agency implementation and the actions of regulated parties to determine the meaning of a statute. *See, e.g.*, *S.D. Warren Co. v. Me. Bd. of Env't Prot.*, 547 U.S. 370, 377–78 (2006) (even though relevant agencies had not "formally settled the definition, or even set out agency reasoning," the "administrative usage of [the disputed term] in this way confirm[ed the Court's]

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[3] *See, generally, Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) ("Within section 340B, Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions."); *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 138 F. Supp. 3d 31, 39 (D.D.C. 2015) (even if "HHS lacks the authority to promulgate the rule as a binding statement of law, HHS is not forbidden altogether from proffering its interpretation of the statute").

understanding"); *Bd. of the Trs. of Leland Stanford Jr. Univ. v. Roche Molecular Sys.*, 563 U.S. 776, 792–93 (2011) ("[I]t is worth noting that our construction of the [statute in question] is reflected in the common practice among parties operating under the Act."). Here, contract-pharmacy arrangements have been utilized, and honored by manufacturers, since 1996 and earlier.[4]

C. Manufacturers' Rationale for Precluding the Use of Contract Pharmacies Is Not Supported by the Language of the Statute and Leads to Absurd Results

The primary rationale offered for cutting off contract pharmacies—that such arrangements lead to a heightened risk of diversion and duplicate discounts—makes clear that manufacturers are attempting to circumvent section 340B's procedures for resolving disputes between manufacturers and covered entities. *See, e.g., K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1984) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole.") (emphasis supplied). Not surprisingly, the manufacturers have been unable to point to any language in the statute that would support this hobbling interpretation. If a manufacturer is concerned that a covered entity has engaged in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must (1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ("ADR") process, *see* §256b(d)(3)(A). The PPA even provides that a covered entity's failure to comply with the audit requirement does not "relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of the Act and the Agreement." PPA § IV(d). Moreover, the Department specifically rejected this reasoning when issuing regulations regarding the calculation of the 340B ceiling price. In responding to a comment regarding perceived 340B violations, HRSA stated "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017). In addition, "[m]anufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly." *Id.* Certain manufacturers' newfound and unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute.[5]

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[4] The fact that Congress has not amended the 340B statute to expressly exclude contract-pharmacy arrangements from coverage can be read as supporting the agency's longstanding construction. *See* Valerie C. Brannon, Cong. Rsch. Serv., R45153, *Statutory Interpretation: Theories, Tools, and Trends* 63 (2018) (discussing "presumption of legislative acquiescence").

[5] For 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution. To the extent manufacturers now have sincere concerns about diversion or duplicate discounting, the 340B statute speaks directly to how they should proceed. *See also 340B Drug Pricing Program; Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) ("The purpose of the ADR process is to resolve . . . claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts."). Manufacturers who shut off contract-pharmacy access may have also skipped over any effort to resolve disputes with covered entities in "good faith." PPA § IV(a)(1) ("If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A) . . . [t]he Manufacturer shall attempt in good faith to resolve the matter with the covered entity."); 85 Fed. Reg. at 80,633 ("Historically, HHS has

Relatedly, it has also been argued that the use of contract pharmacies is inconsistent with the 340B statute's prohibition on diversion of discount drugs. We start with the basic proposition that subsection (a)(5)(B) was intended to prohibit the diversion of 340B drugs. *See* 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). According to one court, the 340B Program places a "ban on 'diversion,' *i.e.*, a requirement that covered entities refrain from reselling or otherwise transferring covered drugs to non–340B entities[.]" *Cty. of Santa Clara v. Astra USA, Inc.*, 257 F.R.D. 207, 211–12 (N.D. Cal. 2009), *vacated on other grounds*, *Astra USA*, 563 U.S. 110; *see also* 85 Fed. Reg. at 80,636 (subsection (a)(5)(B) prohibits diversion).

Diversion means that, on net, covered outpatient drugs end up in the hands of persons who are not patients of the covered entity. The movement of drugs purchased by the covered entity and ultimately dispensed to the patient by a contract pharmacy can involve complex inventory models. Whether diversion occurs, however, should be independent of the inventory-accounting model contemplated by the agreement between the contract pharmacy and the covered entity. *See Toyota Motor Sales, U.S.A., Inc. v. United States*, 35 Ct. Int'l Trade 1205 (2011) (noting that inventory-accounting methods are authorized to determine tariffs and drawbacks); *Sears, Roebuck & Co. v. King County*, 487 P.2d 221, 223, 5 Wash. App. 273, 276 (1971) (for tax purposes "identification by any reasonable and reliable [inventory-accounting] method [is proper], rather than by a strict tracing method.").

The notion that the legitimate transfer of drugs to contract pharmacies so that they can be dispensed to patients of the covered entity constitutes diversion not only ignores the realities of accounting, but also that the covered entity and contract pharmacy are not distinct, but function as principal-agent. As explained, the covered entity remains the purchaser whether it chooses to have discount drugs distributed through an in-house pharmacy or a contract pharmacy. *See also* 61 Fed. Reg. at 43,550 ("The mechanism does not in any way extend this pricing to entities which do not meet program eligibility."); *id.* (agreeing that "[a]s a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance") (citing Restatement (Second) of Agency § 17 (Am. L. Inst. 1995)); *id.* ("The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy."); *id.* at 43,552 (under "bill to/ship to" arrangement contemplated in guidance, "[t]he contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity" and "the manufacturer is still selling to the covered entities"); *cf. Abramski v. United States*, 573 U.S. 169, 186 (2014) ("[t]he individual who sends a straw [purchaser] to a gun store to buy a firearm is transacting with the dealer, in every way but the most formal" such that "straw arrangements are not a part of the secondary market, separate and apart from the dealer's sale") (emphasis in original).[6]

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encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith.").

[6] Similar reasoning still applies under the so-called "replenishment" model, where the contract pharmacy dispenses medications from a general inventory to the covered entity's patient and "replenishes" its general

In addition, the argument that use of contract pharmacies constitutes an illicit "transfer" leads to absurd results. For instance, if a covered entity uses a courier service to send discount drugs to its patient, this, too, would be appear to be an illegal "transfer" to the shipper. Any arrangement that did not involve a physical hand-off from the employee of a covered entity to the patient him or herself could be an unauthorized "transfer" under the 340B statute. To avoid such absurdities, and under the canon of *noscitur a sociis*,[7] the phrase "otherwise transfer" must be interpreted in conjunction with the word "resell" and the title of that specific provision ("Prohibiting resale of drugs") (emphasis supplied).[8]

This conclusion is reinforced by an understanding of the practical realities of drug distribution. Such distribution often functions through intermediaries. For example, covered entities often purchase 340B discounted drugs from wholesalers, not directly from manufacturers. And yet, the obligations of § 256b(a) are placed on manufacturers. If it were correct that distribution to any entity other than a covered entity freed the manufacturer from the obligation to charge no more than the ceiling price, then there would be no firm basis for the wholesalers to charge-back discounts to the manufacturer. Large portions of the current 340B Program would seem to turn on solely manufacturers' voluntary choice to offer the ceiling price,

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inventory with discount medications purchased by the covered entity. The inventory commingling (drugs purchased by covered entity(ies) under the auspices of 340B, commingled with what the contract pharmacy might otherwise have) does not change the analysis. *Cf. Martin Marietta Corp. v. N.J. Nat'l Bank*, 612 F.2d 745, 749 (3d Cir. 1979) ("identification" of goods for purposes of U.C.C. § 2-501 not broken even if "seller removes some of the fungibles and later replaces them . . . because such conduct is quite natural with fungibles and cannot be taken as an intent to negate the buyer's interest in the goods"); *Apex Oil Co. v. Belcher Co. of N.Y., Inc.*, 855 F.2d 997, 1,003–05 (2d Cir. 1988) ("[W]here fungible goods are concerned, identification is not always an irrevocable act and does not foreclose the possibility of substitution."); *Matter of Bevill, Bresler & Schulman Asset Mgmt. Corp.*, 67 B.R. 557, 588 (D.N.J. 1986) (under U.C.C. § 9-207, "a secured party is allowed to commingle fungible collateral, including certain types of securities, and may sell the collateral and replace it with instruments which are equivalent in kind and value without breaching his duty to exercise reasonable care in the custody and preservation of the pledged collateral"). Nor does the ordering of events. If the contract pharmacy's dispensing of the drugs is event "A" and the contract pharmacy's receipt of the drugs is event "B," the ordering of events does not matter if repeated over time. Whether the series looks like ...BABABA... or ...ABABAB... is simply a function of the reference timeframe. In sum, where the contract pharmacy is replenished by the covered entity and dispenses to the covered entity's patients on a rolling basis, it is still true that the covered entity's patients are receiving the covered entity's drugs—they are not re-sold or "otherwise transfer[red]" to the contract pharmacy.

It also bears mention that the replenishment inventory model is currently an integral part of many patient assistance programs operated by drug manufacturers. *See, e.g.*, *Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005); Merck & Co., Inc. *For Health Care Professionals*, MERCK HELPS, https://www.merckhelps.com/HCPs.aspx (last visited Dec. 21, 2020); Pfizer, Inc., *The Pfizer Institutional Patient Assistance Program (IPAP) At-a-Glance* (April 2019), https://www.pfizerrxpathways.com/sites/default/files/attachment/PP-PAT-USA1032%20RxPathways_IPAP_Factsheet%202019.pdf (last visited Dec. 21, 2020).

[7] "[W]e rely on the principle of *noscitur a sociis*—a word is known by the company it keeps—to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Yates v. United States*, 574 U.S. 528, 543 (2015) (plurality op.) (quotes omitted).

[8] An exact delineation of the scope of the phrase "otherwise transfer" is beyond the scope of the Advisory Opinion. The point here is simply that the phrase must have some limiting principle to avoid sweeping in innocuous conduct that is inevitable in the functioning of the 340B Program.

not a statutory mandate. Thus, manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies.

II. Conclusion and Limitations

For these reasons, the Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.[9]

This Advisory Opinion may be supplemented or modified by the Office of the General Counsel. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.[10] It is not a final agency action or a final order, and it does not have the force or effect of law.

Robert Charrow

Robert P. Charrow
General Counsel
December 30, 2020

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[9] This Advisory Opinion is limited to interpretation of the 340B statutory requirements in general and does not opine on the legality of any specific contract-pharmacy model, under either the 340B statute or other laws that may apply (such as the anti-kickback statute, 42 U.S.C. § 1320a-7b).

[10] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647–48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]"); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).

Exhibit C

Congress of the United States
Washington D.C. 20515

September 14, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Azar:

The 340B program plays an integral role in ensuring eligible health care organizations have access to vital lifesaving medications. As Members of Congress deeply committed to the important safety net mission of the 340B Drug Pricing Program, it is imperative that immediate action is taken to ensure covered entities continue to receive crucial 340B drug discounts.

Recently, several pharmaceutical companies have taken a series of actions to restrict federally required 340B drug discounts for eligible health care organizations/covered entities, which are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. These providers have always served as a critical part of our health care safety net, ensuring that our most vulnerable populations have access to the care they need. Right now, they are on the front lines of our national response to COVID-19. These providers rely on 340B savings to ensure access to care for low-income and rural patients. The recent actions undermine the intended purpose of the 340B Drug Pricing Program. The Department of Health and Human Services (HHS) must take immediate action to stop these companies from either denying or limiting access to 340B pricing to hospitals, health centers, and clinics participating in 340B.

Congress enacted 340B with strong bipartisan support more than 25 years ago to reduce drug costs for safety-net providers that care for vulnerable populations. Congress clearly stated the law's purpose: "To stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The savings created by 340B do not cost the American taxpayer a single dollar, as the savings come directly from discounts provided by the manufacturers. Specifically, the 340B statute requires manufacturers wishing to participate in Medicaid and Medicare Part B to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." There are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts.

Despite this statutory requirement, several major drug manufacturers have recently announced that they will limit or restrict 340B pricing based on where the safety-net provider elects to have its 340B drugs shipped. These actions are in violation of the statutory requirement that drug companies charge no more than the 340B ceiling price when selling their products to 340B providers. They establish a dangerous precedent for other manufacturers to follow if immediate action is not taken.

Additionally, within the past two months, other manufacturers have sent requests to covered entities demanding extensive claims data that goes far beyond the scope of the 340B statute. These demands are not only needlessly burdensome for providers but also raise issues related to patient privacy. These companies are also threatening to limit or deny 340B pricing if these covered entities do not comply.

The actions of these companies violate the 340B statute and must be rejected. A failure to act will serve as an invitation to other manufacturers to follow suit, leading to a wholesale increase in prescription drug costs for our safety-net providers during a public health emergency. We urge you to use your authority to address these troubling actions and require these companies to comply with the law.

Thank you for your attention to these matters. Should you have any questions please contact Kirsten Wing with Representative David B. McKinley's office at Kirsten.Wing@mail.house .gov or Sherie Lou Santos with Representative Diana DeGette's office at SherieLou.Santos@mail.house.gov.

Sincerely,

David B. McKinley P.E.
Member of Congress

Diana DeGette
Member of Congress

Greg Gianforte
Member of Congress

Peter Welch
Member of Congress

Dusty Johnson
Member of Congress

Doris Matsui
Member of Congress

_____/s/_____
Ralph Abraham
Member of Congress

_____/s/_____
Earl Blumenauer
Member of Congress

_____/s/_____
Tony Cardenas
Member of Congress

_____/s/_____
Alma S. Adams, Ph.D.
Member of Congress

_____/s/_____
Lisa Blunt Rochester
Member of Congress

_____/s/_____
André Carson
Member of Congress

_____/s/_____
Pete Aguilar
Member of Congress

_____/s/_____
Suzanne Bonamici
Member of Congress

_____/s/_____
Matt Cartwright
Member of Congress

_____/s/_____
Rick W. Allen
Member of Congress

_____/s/_____
Mike Bost
Member of Congress

_____/s/_____
Sean Casten
Member of Congress

_____/s/_____
Cindy Axne
Member of Congress

_____/s/_____
Brendan F. Boyle
Member of Congress

_____/s/_____
Kathy Castor
Member of Congress

_____/s/_____
Don Bacon
Member of Congress

_____/s/_____
Tim Burchett
Member of Congress

_____/s/_____
Judy Chu
Member of Congress

_____/s/_____
Nanette Diaz Barragan
Member of Congress

_____/s/_____
Cheri Bustos
Member of Congress

_____/s/_____
David N. Cicilline
Member of Congress

_____/s/_____
Joyce Beatty
Member of Congress

_____/s/_____
G.K. Butterfield
Member of Congress

_____/s/_____
Gilbert R. Cisneros, Jr.
Member of Congress

_____/s/_____
Jack Bergman
Member of Congress

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Bradley Byrne
Member of Congress

_____/s/_____
Katherine Clark
Member of Congress

_____/s/_____
Sanford D. Bishop, Jr.
Member of Congress

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Ken Calvert
Member of Congress

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Wm. Lacy Clay
Member of Congress

_____/s/_____
Emanuel Cleaver, II
Member of Congress

_____/s/_____
Charles J. Crist
Member of Congress

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Suzane DelBene
Member of Congress

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Ben Cline
Member of Congress

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Jason Crow
Member of Congress

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Antonio Delgado
Member of Congress

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Steve Cohen
Member of Congress

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John Curtis
Member of Congress

_____/s/_____
Val Demings
Member of Congress

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Paul Cook
Member of Congress

_____/s/_____
Sharice L. Davids
Member of Congress

_____/s/_____
Mark DeSaulnier
Member of Congress

_____/s/_____
J. Luis Correa
Member of Congress

_____/s/_____
Susan A. Davis
Member of Congress

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Ted Deutch
Member of Congress

_____/s/_____
Jim Costa
Member of Congress

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Rodney Davis
Member of Congress

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Debbie Dingell
Member of Congress

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Joe Courtney
Member of Congress

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Danny K Davis
Member of Congress

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Mike Doyle
Member of Congress

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TJ Cox
Member of Congress

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Madeleine Dean
Member of Congress

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Veronica Escobar
Member of Congress

_____/s/_____
Angie Craig
Member of Congress

_____/s/_____
Peter A. DeFazio
Member of Congress

_____/s/_____
Adriano Espaillat
Member of Congress

_____/s/_____
Rick Crawford
Member of Congress

_____/s/_____
Rosa DeLauro
Member of Congress

_____/s/_____
Dwight Evans
Member of Congress

_____/s/_____ Abby Finkenauer Member of Congress	_____/s/_____ Louie Gohmert Member of Congress	_____/s/_____ Michael Guest Member of Congress
_____/s/_____ Brian Fitzpatrick Member of Congress	_____/s/_____ Jared Golden Member of Congress	_____/s/_____ Deb Haaland Member of Congress
_____/s/_____ Lizzie Fletcher Member of Congress	_____/s/_____ Jimmy Gomez Member of Congress	_____/s/_____ Vicky Hartzler Member of Congress
_____/s/_____ Bill Foster Member of Congress	_____/s/_____ Vicente Gonzalez Member of Congress	_____/s/_____ Alcee Hastings Member of Congress
_____/s/_____ Marcia L. Fudge Member of Congress	_____/s/_____ Lance Gooden Member of Congress	_____/s/_____ Jahana Hayes Member of Congress
_____/s/_____ Russ Fulcher Member of Congress	_____/s/_____ Josh Gottheimer Member of Congress	_____/s/_____ Denny Heck Member of Congress
_____/s/_____ Mike Gallagher Member of Congress	_____/s/_____ Sam Graves Member of Congress	_____/s/_____ Jaime Herrera Beutler Member of Congress
_____/s/_____ Ruben Gallego Member of Congress	_____/s/_____ Garrett Graves Member of Congress	_____/s/_____ Brian Higgins Member of Congress
_____/s/_____ John Garamendi Member of Congress	_____/s/_____ Raúl M. Grijalva Member of Congress	_____/s/_____ Clay Higgins Member of Congress
_____/s/_____ Jesús G. "Chuy" García Member of Congress	_____/s/_____ Glenn S. Grothman Member of Congress	_____/s/_____ French Hill Member of Congress

_____/s/_____
Jim Himes
Member of Congress

_____/s/_____
William Keating
Member of Congress

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Peter King
Member of Congress

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Kendra S. Horn
Member of Congress

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Fred Keller
Member of Congress

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Ann Kirkpatrick
Member of Congress

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Steven Horsford
Member of Congress

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Trent Kelly
Member of Congress

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Raja Krishnamoorthi
Member of Congress

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Chrissy Houlahan
Member of Congress

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Mike Kelly
Member of Congress

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Ann McLane Kuster
Member of Congress

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Will Hurd
Member of Congress

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Joseph P. Kennedy, III
Member of Congress

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Connor Lamb
Member of Congress

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Chris Jacobs
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Ro Khanna
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James R. Langevin
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Hakeem Jeffries
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Daniel T. Kildee
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Rick Larsen
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Eddie Bernice Johnson
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Derek Kilmer
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Ron Kind
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Brenda L. Lawrence
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John Katko
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Steve King
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Al Lawson
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Barbara Lee
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Ben Ray Luján
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Jerry McNerney
Member of Congress

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Mike Levin
Member of Congress

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Stephen F. Lynch
Member of Congress

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Gregory W. Meeks
Member of Congress

/s/
Andy Levin
Member of Congress

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Tom Malinowski
Member of Congress

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Grace Meng
Member of Congress

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Ted W. Lieu
Member of Congress

/s/
Carolyn B. Maloney
Member of Congress

/s/
Carol D. Miller
Member of Congress

/s/
Daniel W. Lipinski
Member of Congress

/s/
Sean Patrick Maloney
Member of Congress

/s/
John Moolenaar
Member of Congress

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Dave Loebsack
Member of Congress

/s/
Ben McAdams
Member of Congress

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Alex X. Mooney
Member of Congress

/s/
Zoe Lofgren
Member of Congress

/s/
Lucy McBath
Member of Congress

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Gwen Moore
Member of Congress

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Alan Lowenthal
Member of Congress

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Betty McCollum
Member of Congress

/s/
Joseph D. Morelle
Member of Congress

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Nita M. Lowey
Member of Congress

/s/
A. Donald McEachin
Member of Congress

/s/
Seth Moulton
Member of Congress

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Blaine Luetkemeyer
Member of Congress

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James P. McGovern
Member of Congress

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Stephanie Murphy
Member of Congress

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Jerrold Nadler
Member of Congress

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Collin C. Peterson
Member of Congress

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Kathleen M. Rice
Member of Congress

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Grace F. Napolitano
Member of Congress

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Chellie Pingree
Member of Congress

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Cedric Richmond
Member of Congress

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Dan Newhouse
Member of Congress

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Mark Pocan
Member of Congress

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Denver Riggleman
Member of Congress

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Eleanor Holmes Norton
Member of Congress

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Katie Porter
Member of Congress

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Martha Roby
Member of Congress

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Tom O'Halleran
Member of Congress

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Ayanna Pressley
Member of Congress

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Hal Rogers
Member of Congress

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Ilhan Omar
Member of Congress

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David E. Price
Member of Congress

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Max Rose
Member of Congress

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Steve Palazzo
Member of Congress

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Mike Quigley
Member of Congress

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John Rose
Member of Congress

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Jimmy Panetta
Member of Congress

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Jamie Raskin
Member of Congress

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Harley Rouda
Member of Congress

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Chris Pappas
Member of Congress

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Tom Reed
Member of Congress

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David Rouzer
Member of Congress

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Ed Perlmutter
Member of Congress

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Guy Reschenthaler
Member of Congress

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Lucille Roybal-Allard
Member of Congress

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Raul Ruiz. M.D.
Member of Congress

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Kim Schrier, M.D.
Member of Congress

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Darren Soto
Member of Congress

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Dutch Ruppersberger
Member of Congress

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Austin Scott
Member of Congress

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Abigail D. Spanberger
Member of Congress

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Bobby L. Rush
Member of Congress

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David Scott
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Ross Spano
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John H. Rutherford
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José E. Serrano
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Greg Stanton
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Tim Ryan
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Brad Sherman
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Pete Stauber
Member of Congress

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Linda T. Sanchez
Member of Congress

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Mikie Sherrill
Member of Congress

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Elise Stefanik
Member of Congress

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John P. Sarbanes
Member of Congress

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Mike Simpson
Member of Congress

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Bryan Steil
Member of Congress

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Mary Gay Scanlon
Member of Congress

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Elissa Slotkin
Member of Congress

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Haley Stevens
Member of Congress

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Jan Schakowsky
Member of Congress

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Jason Smith
Member of Congress

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Chris Stewart
Member of Congress

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Adam B. Schiff
Member of Congress

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Adam Smith
Member of Congress

_____/s/_____
Thomas R. Suozzi
Member of Congress

_____/s/_____
Eric M. Swalell
Member of Congress

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Lori Trahan
Member of Congress

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Bonnie Watson Coleman
Member of Congress

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Bennie G. Thompson
Member of Congress

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David Trone
Member of Congress

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Jennifer Wexton
Member of Congress

_____/s/_____
Mike Thompson
Member of Congress

_____/s/_____
Michael Turner
Member of Congress

_____/s/_____
Susan A. Wild
Member of Congress

_____/s/_____
Glen "GT" Thompson
Member of Congress

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Lauren Underwood
Member of Congress

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Robert J. Wittman
Member of Congress

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Mac Thornberry
Member of Congress

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Fred Upton
Member of Congress

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Steve Womack
Member of Congress

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Scott Tipton
Member of Congress

_____/s/_____
Jeff Van Drew
Member of Congress

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John Yarmuth
Member of Congress

_____/s/_____
Dina Titus
Member of Congress

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Juan Vargas
Member of Congress

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Ted Yoho
Member of Congress

_____/s/_____
Paul D. Tonko
Member of Congress

_____/s/_____
Nydia M. Velázquez
Member of Congress

_____/s/_____
Norma J. Torres
Member of Congress

_____/s/_____
Peter J. Visclosky
Member of Congress

_____/s/_____
Xochitl Torres Small
Member of Congress

_____/s/_____
Ann Wagner
Member of Congress

Exhibit D

Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs

This notice provides information to 340B eligible covered entities seeking to purchase Cialis® (tadalafil) tablets indicated only for erectile dysfunction, specifically:

00002-4463-30: 10 mg 30 tablet bottle
00002-4464-30: 20 mg 30 tablet bottle
00002-4465-34: 2.5 mg 2x15 blister pack

These formulations of Cialis are approved exclusively for use in patients with erectile dysfunction. Since October 2018, generic versions of Cialis have been widely available, and currently more than a dozen generic manufacturers offer low-priced versions of these medicines.

Effective, July 1, 2020, Lilly is limiting distribution of 340B ceiling price product of these Cialis formulations directly to covered entities and their child sites only. Contract pharmacies will not be eligible to receive these formulations of Cialis at the 340B ceiling price. Any contract pharmacy orders placed with a wholesaler as of June 30 will be honored. Covered entities that do not have an in-house pharmacy may contact 340B@lilly.com regarding the exception process to designate a contract pharmacy location.

Lilly is committed to compliance with the 340B statute and to responsible distribution of its products. If you have any questions regarding how to acquire Cialis please contact Lilly at 340B@lilly.com.

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Exhibit E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

September 21, 2020

Anat Hakim
Senior Vice President and General Counsel
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Ms. Hakim:

I am responding to your September 8, 2020 letter to the Deputy Secretary and me. In that letter, you requested a pre-enforcement advisory opinion ("AO") as to whether Lilly's new unilateral policy involving the 340B program would subject Lilly to sanctions. Under that policy, Lilly will cease extending 340B pricing to pharmacies under contract with covered entities, unless the covered entity lacks an in-house pharmacy.[1] In such a case, Lilly will extend 340B pricing to only one designated contract pharmacy. As we understand it, Lilly has already implemented that policy for Cialis and has since extended the same policy for its other covered outpatient drugs.

As we have indicated in earlier correspondence, although the Health Resources and Services Administration ("HRSA") has significant initial concerns with Lilly's new policy, it continues to review that policy and has yet to make a final determination as to any potential action. Correspondingly, Lilly cannot and should not view the absence of any questions from the government as somehow endorsing Lilly's policy especially when this Department is leading the government's response to the COVID-19 pandemic.

In the interim, we have four concerns with your letters that do not relate to the legal propriety of your unilateral price increases.

First, Lilly sought to unilaterally impose an artificial deadline on HRSA's decision-making when it asserted in its May 18, 2020, letter to HRSA that unless it heard from HRSA to the contrary by June 30, 2020, it would assume that HRSA had no objections to its price restructuring for Cialis and would implement the same on July 1. Lilly imposed a similar set of deadlines for the rest of its drugs, indicating in its August 19, 2020 letter to HRSA that unless Lilly heard to the contrary by August 31, 2020, it would begin charging higher prices to pharmacies under contract with covered entities serving the disadvantaged on September 1. Lilly cannot and should not seek to impose such deadlines on the government's deliberations—especially when HRSA is playing a pivotal role in responding to an unprecedented pandemic. Nor is Lilly entitled to know the substance of those ongoing deliberations.

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[1] In addition to the September 8 letter from you, Lilly has submitted four other letters with respect to its proposal to scrap 340B pricing to contract pharmacies—dated August 27, 2020, August 19, 2020, July 17, 2020, and May 18, 2020.

Second, Lilly's decision to interpret HRSA's responses as tantamount to definitive agency agreement with Lilly's position is incorrect. As noted above, HRSA is still evaluating how to proceed.

Third, Lilly's designation of its letters of September 8 and May 18 as exempt from disclosure under FOIA Exemptions 4, 6, and 7 and containing trade secrets under 18 U.S.C. § 1905 is fundamentally in error. Exemption 4 covers trade secrets and commercial confidential information. Lilly's legal position is neither. Moreover, we could find nothing in any of your letters that qualifies as either a trade secret or commercial confidential information. Exemption 6 relates to "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." We could find nothing in any of the Lilly letters that would qualify for this exemption. Exemption 7 relates to law-enforcement records. It is unclear why Lilly believes that Exemption 7 applies.

Fourth, we believe that the timing of your pricing changes is, at the very least, insensitive to the recent state of the economy. Although the economy is rebounding at a record rate, the unemployment and under-employment rates are still temporarily higher than at the beginning of the year due to COVID-19. Many Americans and many small businesses have had difficulty making ends meet. Lilly, on the other hand, seems to be enjoying an outstanding year. The price of Lilly's stock has increased by more than 11 percent since January 1, 2020, reflecting, among other things, the fact that your company's comprehensive income jumped from $1.414 billion during the second quarter of 2019 to $1.615 billion for the second quarter of 2020, an increase of more than 14 percent.

In contrast, during this same period, most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance. It is against this backdrop that you are effectively increasing the prices of 10 mg and 20 mg Cialis by more than 500,000 percent and have done the same for other drugs in your portfolio.

In your letter, you noted that at least one covered entity has been the subject of a *qui tam* False Claims Act suit arising, in part, out of the 340B program. *See* Letter to the Deputy Secretary from Ms. Hakim (Lilly) at 2 n.6 (July 17, 2020); Letter to Rear Admiral Pedley from Mr. Asay (Lilly) at 11 n.36 (May 18, 2020). Please bear in mind that a similar suit against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors.

Sincerely yours,

Robert P. Charrow
General Counsel

Exhibit F

Limited Distribution Plan Notice for Eli Lilly and Company Products

This notice provides information to 340B eligible covered entities seeking to purchase any product manufactured or distributed by Eli Lilly and Company or its subsidiaries and affiliates (labeler codes 00002, 00077, and 66713). Effective September 1, 2020, Lilly is limiting distribution of all 340B ceiling priced product directly to covered entities and their child sites only. Covered entities will not be eligible to purchase Eli Lilly and Company products at the 340B ceiling price for shipment to a contract pharmacy.

Covered entities that do not have an in-house pharmacy may contact 340B@lilly.com regarding the exception process to designate a contract pharmacy location.

Special Exception for Insulins: Contract Pharmacies that Pass on 340B Discounts

Consistent with the spirit of Executive Order 13,937, "Access to Affordable Life-saving Medications" (July 24, 2020), Lilly will grant an exception to the limited distribution program described above for Lilly insulin products (NDCs attached) subject to a 340B covered entity and their contract pharmacies' ability to ensure that the following conditions are met:

- Any and all 340B eligible patients will be able to acquire their Lilly insulins through the contract pharmacy at the 340B price (typically $.03 per 3 mL pen or $.10 per 10 mL vial) at the point-of-sale;

- Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin;

- No insurer or payer is billed for the Lilly insulin dispensed; and,

- The covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions.

Lilly shares the goal of ensuring that 340B patients directly benefit from the significant 340B discounts on Lilly insulins.

To take advantage of this exception for insulins contact 340B@lilly.com. Please be prepared to submit documentation demonstrating that the conditions set forth above will be satisfied.

Lilly is committed to compliance with the 340B statute and to responsible distribution of its products. If you have any questions regarding this notice please contact Lilly at 340B@lilly.com.

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Special Exception for Insulins:
Contract Pharmacies that Pass on 340B Discounts to patients
Applicable NDCs

NDC	Brand Name	Product Description
00002-7510-01	HUMALOG	HUMALOG 100UCD 10.000000 MML
00002-7510-17	HUMALOG	HUMALOG 100UCD 3 MILLILITER
00002-7516-59	HUMALOG	HUMALOG CARTRIDGE 100UCD 15.000000 MML
00002-7714-59	HUMALOG	HUMALOG JR KWIKPEN 100UCD 15 MILLILITER
00002-8799-59	HUMALOG	HUMALOG KWIKPEN 100UCD 15 MILLILITER
00002-7511-01	HUMALOG	HUMALOG MIX 75/25 100UCD 10 MILLILITER
00002-7512-01	HUMALOG	HUMALOG MIX50/50 100UCD 10 MILLILITER
00002-8798-59	HUMALOG	HUMALOG MIX50/50 KWIKPEN 100UCD 15 MILLILITER
00002-8797-59	HUMALOG	HUMALOG MIX75/25 KWIKPEN 100UCD 15 MILLILITER
00002-8824-27	HUMULIN R U500	HUMULIN 500 UCD 6.000000 MILLILITER
00002-8501-01	HUMULIN R U500	HUMULIN R 500UCD 20 MILLILITER
00002-7737-01	INSULIN LISPRO	INSULIN LISPRO 100 UCD 10.000000MILLILITER
00002-7752-05	INSULIN LISPRO	INSULIN LISPRO KWIKPEN JR 100UCD 15 MILLILITER
00002-8222-59	INSULIN LISPRO	INSULIN LISPRO KWIKPEN 100UCD 15.000000 MILLILITER
00002-8233-05	INSULIN LISPRO	INSULIN LISPROMIX75/25 KWIKPEN 100UCD 15 MILLILITER
66733-0773-01	INSULIN LISPRO	INSULIN LISPRO 100 UCD 10.000000 MILLILITER
66733-0822-59	INSULIN LISPRO	INSULIN LISPRO 100 UCD 15.000000 MILLILITER

Exhibit G

AstraZeneca

Date: August 17, 2020

Re: 340B Contract Pharmacy Pricing

Dear Valued Partner,

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

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

Pricing will be honored on all chargeback invoices prior to this date consistent with AstraZeneca's historic approach, but AstraZeneca asks for the removal of Contract Pharmacy eligibility prior to or by the end of business September 30, 2020.

For additional information or questions, please contact your AstraZeneca Account Director.

Sincerely,

DocuSigned by:

0781790EE5034A7...

Odalys Caprisecca
Executive Director, Strategic Pricing & Operations

Exhibit H

To Whom It May Concern:

I am writing to inform you that Sanofi is implementing a new 340B program integrity initiative to address duplicate discounts. Sanofi supports the 340B Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to maintaining and strengthening its mission. However, we are concerned about the rate of duplicate discounting on Medicaid prescriptions filled with 340B-purchased drugs. Similarly, manufacturers pay ineligible rebates on Medicare Part D and commercial utilization due to the lack of transparency in the 340B program.

To resolve these issues, Sanofi will require 340B covered entities to submit claims data for 340B prescriptions of Sanofi products filled through its contract pharmacies. Sanofi will use this data to match against rebate claims it receives to ensure it isn't paying ineligible discounts. This initiative is enabled through 340B ESP™, a Second Sight Solutions technology. Sanofi is requiring 340B covered entities to register at www.340BESP.com by October 1, 2020.

Sanofi has maintained a strong commitment to the 340B program since its inception. We also recognize that for the 340B program to continue in its mission, serious program integrity and transparency challenges must be addressed. That is why we are adopting the 340B ESP™ platform and we look forward to working with 340B covered entities to further strengthen the 340B program.

Best regards,

Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes ~15 minutes.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP and submit your 340B contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520. To learn more about how Sanofi is working to improve program integrity through 340B ESP™, please contact Sanofi directly at Sanofi340BOperations@sanofi.com.

Q: How will Sanofi use the 340B claims data that we provide through 340B ESP™?

A: Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means no actual protected health information (PHI) is collected and the data cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: Is Sanofi requesting data for all Sanofi products?

A: No. Sanofi is only requesting data for Sanofi drugs commonly dispensed through retail, specialty and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: What happens if my organization does not provide 340B contract pharmacy claims data?

A: Sanofi is requiring 340B covered entities to register with 340B ESP™ and begin providing 340B claims data by October 1, 2020. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.

Q: Is Sanofi requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Sanofi is only requesting data for 340B claims that originates from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: What benefit does the 340B covered entity realize by using 340B ESP™?

A: By providing 340B claims data that originate from contract pharmacies, you will enable Sanofi to definitively identify duplicate Medicaid rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA encourages 340B covered entities to work with pharmaceutical manufacturers in good faith to resolve issues of non-compliance in the 340B program. Although neither HRSA nor Apexus has commented publicly on this specific initiative, Sanofi believes 340B ESP™ provides a simple platform for Sanofi and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts.

Q: How often will I need to upload 340B contract pharmacy claims data to 340B ESP™?

A: The 340B ESP™ platform requires claims uploads every two weeks. The actual upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology requirements exist to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, FireFox and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.

Exhibit I

EXHIBIT I

NDCs Impacted by Lilly Overcharging

**Note that NDCs are displayed in XXXX-XXXX or XXXXX-XXXX form, without the final two-digit product size code or labeler code leading zero.*

Labeler Code 00002

NDC*	Brand Name	Generic Name	Dosage Form
0002-6145	Baqsimi	Glucagon	Powder
0002-7715	Basaglar KwikPen	Insulin Glargine	Injection, Solution
0002-8214	Basaglar Tempo Pen	Insulin Glargine	Injection, Solution
0002-4462	Cialis	Tadalafil	Tablet, Film Coated
0002-4463	Cialis	Tadalafil	Tablet, Film Coated
0002-4464	Cialis	Tadalafil	Tablet, Film Coated
0002-4465	Cialis	Tadalafil	Tablet, Film Coated
0002-3235	Cymbalta	Duloxetine Hydrochloride	Capsule, Delayed Release
0002-3240	Cymbalta	Duloxetine Hydrochloride	Capsule, Delayed Release
0002-3270	Cymbalta	Duloxetine Hydrochloride	Capsule, Delayed Release
0002-5121	Effient	Prasugrel Hydrochloride	Tablet, Film Coated
0002-5123	Effient	Prasugrel Hydrochloride	Tablet, Film Coated
0002-1436	Emgality	Galcanezumab-gnlm	Injection, Solution
0002-2377	Emgality	Galcanezumab-gnlm	Injection, Solution
0002-3115	Emgality	Galcanezumab-gnlm	Injection, Solution
0002-4184	Evista	Raloxifene Hydrochloride	Tablet
0002-8400	Forteo	Teriparatide	Injection, Solution

0002-8031	Glucagon	Glucagon	Kit
0002-7510	Humalog	Insulin Lispro	Injection, Solution
0002-7516	Humalog	Insulin Lispro	Injection, Solution
0002-7714	Humalog Junior KwikPen	Insulin Lispro	Injection, Solution
0002-7712	Humalog KwikPen	Insulin Lispro	Injection, Solution
0002-8799	Humalog KwikPen	Insulin Lispro	Injection, Solution
0002-7512	Humalog Mix50/50	Insulin Lispro	Injection, Suspension
0002-8798	Humalog Mix50/50 KwikPen	Insulin Lispro	Injection, Suspension
0002-7511	Humalog Mix75/25	Insulin Lispro	Injection, Suspension
0002-8797	Humalog Mix75/25 KwikPen	Insulin Lispro	Injection, Suspension
0002-8213	Humalog Tempo Pen	Insulin Lispro	Injection, Solution
0002-7335	Humatrope	Somatropin	Kit
0002-8147	Humatrope	Somatropin	Kit
0002-8148	Humatrope	Somatropin	Kit
0002-8149	Humatrope	Somatropin	Kit
0002-8715	Humulin 70/30	Insulin Human	Injection, Suspension
0002-8803	Humulin 70/30 KwikPen	Insulin Human	Injection, Suspension
0002-8315	Humulin N	Insulin Human	Injection, Suspension
0002-8805	Humulin N	Insulin Human	Injection, Suspension
0002-8215	Humulin R	Insulin Human	Injection, Solution
0002-8501	Humulin R U-500	Insulin Human	Injection, Solution
0002-8824	Humulin R U-500 KwikPen	Insulin Human	Injection, Solution

0002-7737	Insulin Lispro	Insulin Lispro	Injection, Solution
0002-7752	Insulin Lispro Junior KwikPen	Insulin Lispro	Injection, Solution
0002-8222	Insulin Lispro KwikPen	Insulin Lispro	Injection, Solution
0002-8233	Insulin Lispro Protamine And Insulin Lispro Injectable Suspension Mix75/25 KwikPen	Insulin Lispro	Injection, Suspension
0002-7726	Lyumjev	Insulin Lispro-aabc	Injection, Solution
0002-7728	Lyumjev	Insulin Lispro-aabc	Injection, Solution
0002-8351	Lyumjev Junior KwikPen	Insulin Lispro-aabc	Injection, Solution
0002-8207	Lyumjev KwikPen	Insulin Lispro-aabc	Injection, Solution
0002-8228	Lyumjev KwikPen	Insulin Lispro-aabc	Injection, Solution
0002-8235	Lyumjev Tempo Pen	Insulin Lispro-aabc	Injection, Solution
0002-4182	Olumiant	Baricitinib	Tablet, Film Coated
0002-4732	Olumiant	Baricitinib	Tablet, Film Coated
0002-2980	Retevmo	Selpercatinib	Capsule
0002-3977	Retevmo	Selpercatinib	Capsule
0002-4312	Reyvow	Lasmiditan	Tablet
0002-4491	Reyvow	Lasmiditan	Tablet
0002-4736	Reyvow	Lasmiditan	Tablet
0002-3227	Strattera	Atomoxetine Hydrochloride	Capsule
0002-3228	Strattera	Atomoxetine Hydrochloride	Capsule
0002-3229	Strattera	Atomoxetine Hydrochloride	Capsule
0002-3238	Strattera	Atomoxetine Hydrochloride	Capsule

0002-3239	Strattera	Atomoxetine Hydrochloride	Capsule
0002-3250	Strattera	Atomoxetine Hydrochloride	Capsule
0002-3251	Strattera	Atomoxetine Hydrochloride	Capsule
0002-3230	Symbyax	Olanzapine And Fluoxetine Hydrochloride	Capsule
0002-3231	Symbyax	Olanzapine And Fluoxetine Hydrochloride	Capsule
0002-3233	Symbyax	Olanzapine And Fluoxetine Hydrochloride	Capsule
0002-3234	Symbyax	Olanzapine And Fluoxetine Hydrochloride	Capsule
0002-1445	Taltz	Ixekizumab	Injection, Solution
0002-7724	Taltz	Ixekizumab	Injection, Solution
0002-1433	Trulicity	Dulaglutide	Injection, Solution
0002-1434	Trulicity	Dulaglutide	Injection, Solution
0002-2236	Trulicity	Dulaglutide	Injection, Solution
0002-3182	Trulicity	Dulaglutide	Injection, Solution
0002-4483	Verzenio	Abemaciclib	Tablet
0002-4815	Verzenio	Abemaciclib	Tablet
0002-5337	Verzenio	Abemaciclib	Tablet
0002-6216	Verzenio	Abemaciclib	Tablet
0002-4112	Zyprexa	Olanzapine	Tablet
0002-4115	Zyprexa	Olanzapine	Tablet
0002-4116	Zyprexa	Olanzapine	Tablet
0002-4117	Zyprexa	Olanzapine	Tablet
0002-4415	Zyprexa	Olanzapine	Tablet

0002-4420	Zyprexa	Olanzapine	Tablet
0002-7597	Zyprexa Intramuscular	Olanzapine	Injection, Powder, For Solution
0002-7635	Zyprexa Relprevv	Olanzapine Pamoate	Kit
0002-7636	Zyprexa Relprevv	Olanzapine Pamoate	Kit
0002-7637	Zyprexa Relprevv	Olanzapine Pamoate	Kit
0002-4453	Zyprexa Zydis	Olanzapine	Tablet, Orally Disintegrating
0002-4454	Zyprexa Zydis	Olanzapine	Tablet, Orally Disintegrating
0002-4455	Zyprexa Zydis	Olanzapine	Tablet, Orally Disintegrating
0002-4456	Zyprexa Zydis	Olanzapine	Tablet, Orally Disintegrating

Labeler Code 00777

NDC*	Brand Name	Generic Name	Dosage Form
0777-3104	Prozac	Fluoxetine Hydrochloride	Capsule
0777-3105	Prozac	Fluoxetine Hydrochloride	Capsule
0777-3107	Prozac	Fluoxetine Hydrochloride	Capsule

Labeler Code 66733

NDC*	Brand Name	Generic Name	Dosage Form
66733-773	Insulin Lispro	Insulin Lispro	Injection, Solution
66733-822	Insulin Lispro KwikPen	Insulin Lispro	Injection, Solution

Exhibit J

EXHIBIT J

NDCs Impacted by AstraZeneca Overcharging

**Note that NDCs are displayed in XXXX-XXXX form, without the final two-digit product size code or labeler code leading zero.*

Labeler Codes 00186 and 00310

NDC*	Brand Name	Generic Name	Dosage Form
0310-4600	Bevespi Aerosphere	Glycopyrrolate And Formoterol Fumarate	Aerosol, Metered
0310-4616	Breztri	Budesonide, Glycopyrrolate, And Formoterol Fumarate	Aerosol, Metered
0186-0776	Brilinta	Ticagrelor	Tablet
0186-0777	Brilinta	Ticagrelor	Tablet
0310-7370	Budesonide And Formoterol Fumarate Dihydrate	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0310-7372	Budesonide And Formoterol Fumarate Dihydrate	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0310-6530	Bydureon	Exenatide	Injection, Suspension, Extended Release
0310-6540	Bydureon Bcise	Exenatide	Injection, Suspension, Extended Release
0310-6512	Byetta	Exenatide	Injection
0310-6524	Byetta	Exenatide	Injection
0310-0512	Calquence	Acalabrutinib	Capsule, Gelatin Coated
0310-0751	Crestor	Rosuvastatin Calcium	Tablet, Film Coated

0310-0752	Crestor	Rosuvastatin Calcium	Tablet, Film Coated
0310-0754	Crestor	Rosuvastatin Calcium	Tablet, Film Coated
0310-0755	Crestor	Rosuvastatin Calcium	Tablet, Film Coated
0310-0088	Daliresp	Roflumilast	Tablet
0310-0095	Daliresp	Roflumilast	Tablet
0186-0382	Esomeprazole Magnesium	Esomeprazole Magnesium	Capsule, Delayed Release
0186-0384	Esomeprazole Magnesium	Esomeprazole Magnesium	Capsule, Delayed Release
0310-6205	Farxiga	Dapagliflozin	Tablet, Film Coated
0310-6210	Farxiga	Dapagliflozin	Tablet, Film Coated
0310-1730	Fasenra	Benralizumab	Injection, Solution
0310-1830	Fasenra	Benralizumab	Injection, Solution
0310-0720	Faslodex	Fulvestrant	Injection
0310-7720	Fulvestrant	Fulvestrant	Injection
0310-0482	Iressa	Gefitinib	Tablet, Coated
0310-6125	Kombiglyze XR	Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6135	Kombiglyze XR	Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6145	Kombiglyze XR	Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-0610	Koselugo	Selumetinib	Capsule

0310-0625	Koselugo	Selumetinib	Capsule
0310-1105	Lokelma	Sodium Zirconium Cyclosilicate	Powder, For Suspension
0310-1110	Lokelma	Sodium Zirconium Cyclosilicate	Powder, For Suspension
0310-0668	Lynparza	Olaparib	Tablet, Film Coated
0310-0679	Lynparza	Olaparib	Tablet, Film Coated
0310-1969	Movantik	Naloxegol Oxalate	Tablet, Film Coated
0310-1970	Movantik	Naloxegol Oxalate	Tablet, Film Coated
0186-4010	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4020	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4025	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4040	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4050	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-5020	Nexium	Esomeprazole Magnesium	Capsule, Delayed Release
0186-5040	Nexium	Esomeprazole Magnesium	Capsule, Delayed Release
0310-6100	Onglyza	Saxagliptin	Tablet, Film Coated
0310-6105	Onglyza	Saxagliptin	Tablet, Film Coated
0186-0916	Pulmicort FLEXHALER	Budesonide	Aerosol, Powder

0186-0917	Pulmicort FLEXHALER	Budesonide	Aerosol, Powder
0186-1988	Pulmicort Respules	Budesonide	Suspension
0186-1989	Pulmicort Respules	Budesonide	Suspension
0186-1990	Pulmicort Respules	Budesonide	Suspension
0310-6770	Qtern	Dapagliflozin And Saxagliptin	Tablet, Film Coated
0310-6780	Qtern	Dapagliflozin And Saxagliptin	Tablet, Film Coated
0310-6925	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-6950	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-6975	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-6990	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-8284	Quetiapine Fumarate Extended Release	Quetiapine Fumarate	Tablet, Film Coated, Extended Release
0310-0271	Seroquel	Quetiapine	Tablet, Film Coated
0310-0272	Seroquel	Quetiapine	Tablet, Film Coated
0310-0274	Seroquel	Quetiapine	Tablet, Film Coated
0310-0275	Seroquel	Quetiapine	Tablet, Film Coated
0310-0278	Seroquel	Quetiapine	Tablet, Film Coated

0310-0279	Seroquel	Quetiapine	Tablet, Film Coated
0310-0280	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0281	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0282	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0283	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0284	Seroquel XR	Quetiapine	Tablet, Extended Release
0186-0370	Symbicort	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0186-0372	Symbicort	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0310-6615	Symlinpen	Pramlintide Acetate	Injection
0310-6627	Symlinpen	Pramlintide Acetate	Injection
0310-1349	Tagrisso	Osimertinib	Tablet, Film Coated
0310-1350	Tagrisso	Osimertinib	Tablet, Film Coated
0186-1088	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0186-1090	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0186-1092	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0186-1094	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0310-0800	Tudorza Pressair	Aclidinium Bromide	Powder, Metered

0310-6225	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6250	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6260	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6270	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6280	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release

Exhibit K

EXHIBIT K

NDCs Impacted by Sanofi Overcharging

**Note that NDCs are displayed in XXXX-XXXX or XXXXX-XXXX form, without the final two-digit product size code or labeler code leading zero.*

Labeler Codes 00024, 00039, 00068, 00075, and 00088

NDC*	Brand Name	Generic Name	Dosage Form
0024-5745	Adlyxin	Lixisenatide	Kit
0024-5747	Adlyxin	Lixisenatide	Injection, Solution
0024-5924	Admelog	Insulin Lispro	Injection, Solution
0024-5925	Admelog	Insulin Lispro	Injection, Solution
0024-5926	Admelog	Insulin Lispro	Injection, Solution
0039-0221	Amaryl	Glimepiride	Tablet
0039-0222	Amaryl	Glimepiride	Tablet
0039-0223	Amaryl	Glimepiride	Tablet
0024-5401	Ambien	Zolpidem Tartrate	Tablet, Film Coated
0024-5421	Ambien	Zolpidem Tartrate	Tablet, Film Coated
0024-5501	Ambien CR	Zolpidem Tartrate	Tablet, Coated
0024-5521	Ambien CR	Zolpidem Tartrate	Tablet, Coated
0088-2500	Apidra	Insulin Glulisine	Injection, Solution
0088-2502	Apidra Solostar	Insulin Glulisine	Injection, Solution
0088-2160	Arava	Leflunomide	Tablet, Film Coated
0088-2161	Arava	Leflunomide	Tablet, Film Coated
0088-2162	Arava	Leflunomide	Tablet, Film Coated
0024-5855	Avalide	Irbesartan And Hydrochlorothiazide	Tablet, Film Coated

0024-5856	Avalide	Irbesartan And Hydrochlorothiazide	Tablet, Film Coated
0024-5850	Avapro	Irbesartan	Tablet, Film Coated
0024-5851	Avapro	Irbesartan	Tablet, Film Coated
0024-5852	Avapro	Irbesartan	Tablet, Film Coated
0024-5914	Dupixent	Dupilumab	Injection, Solution
0024-5915	Dupixent	Dupilumab	Injection, Solution
0024-5916	Dupixent	Dupilumab	Injection, Solution
0024-5918	Dupixent	Dupilumab	Injection, Solution
0024-5150	Elitek	Rasburicase	Kit
0024-5151	Elitek	Rasburicase	Kit
0024-5837	Flomax	Tamsulosin Hydrochloride	Capsule
0024-5824	Jevtana	Cabazitaxel	Kit
0024-5908	Kevzara	Sarilumab	Injection, Solution
0024-5910	Kevzara	Sarilumab	Injection, Solution
0024-5920	Kevzara	Sarilumab	Injection, Solution
0024-5922	Kevzara	Sarilumab	Injection, Solution
0088-2220	Lantus	Insulin Glargine	Injection, Solution
0088-5021	Lantus	Insulin Glargine	Injection, Solution
0088-2219	Lantus Solostar	Insulin Glargine	Injection, Solution
0088-5020	Lantus Solostar	Insulin Glargine	Injection, Solution
0024-5843	Leukine	Sargramostim	Injection, Powder, For Solution
0024-5844	Leukine	Sargramostim	Liquid
0075-0620	Lovenox	Enoxaparin Sodium	Injection

0075-0621	Lovenox	Enoxaparin Sodium	Injection
0075-0622	Lovenox	Enoxaparin Sodium	Injection
0075-0623	Lovenox	Enoxaparin Sodium	Injection
0075-0624	Lovenox	Enoxaparin Sodium	Injection
0075-0626	Lovenox	Enoxaparin Sodium	Injection
0075-2912	Lovenox	Enoxaparin Sodium	Injection
0075-2915	Lovenox	Enoxaparin Sodium	Injection
0075-8013	Lovenox	Enoxaparin Sodium	Injection
0075-8014	Lovenox	Enoxaparin Sodium	Injection
0075-8016	Lovenox	Enoxaparin Sodium	Injection
0075-8018	Lovenox	Enoxaparin Sodium	Injection
0075-8020	Lovenox	Enoxaparin Sodium	Injection
0075-8022	Lovenox	Enoxaparin Sodium	Injection
0075-8025	Lovenox	Enoxaparin Sodium	Injection
0075-8030	Lovenox	Enoxaparin Sodium	Injection
0024-5862	Mozobil	Plerixafor	Solution
0024-4142	Multaq	Dronedarone	Tablet, Film Coated
0024-1171	Plavix	Clopidogrel	Tablet, Film Coated
0024-1332	Plavix	Clopidogrel	Tablet, Film Coated
0024-5901	Praluent	Alirocumab	Injection, Solution
0024-5902	Praluent	Alirocumab	Injection, Solution
0024-5903	Praluent	Alirocumab	Injection, Solution
0024-5904	Praluent	Alirocumab	Injection, Solution
0088-2102	Priftin	Rifapentine	Tablet, Film Coated

0024-1596	Primaquine Phosphate	Primaquine Phosphate	Tablet, Film Coated
0024-5761	Soliqua 100/33	Insulin Glargine And Lixisenatide	Injection, Solution
0024-5869	Toujeo	Insulin Glargine	Injection, Solution
0024-5871	Toujeo Max	Insulin Glargine	Injection, Solution
0024-5803	Xyzal	Levocetirizine Dihydrochloride	Tablet, Film Coated
0024-5804	Xyzal	Levocetirizine Dihydrochloride	Solution

Labeler Code 00955

NDC*	Brand Name	Generic Name	Dosage Form
0955-1720	Doxercalciferol	Doxercalciferol	Capsule
0955-1721	Doxercalciferol	Doxercalciferol	Capsule
0955-1722	Doxercalciferol	Doxercalciferol	Capsule
0955-1003	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1004	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1006	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1008	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1010	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1012	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1015	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1016	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1040	Irbesartan	Irbesartan	Tablet, Film Coated
0955-1041	Irbesartan	Irbesartan	Tablet, Film Coated
0955-1042	Irbesartan	Irbesartan	Tablet, Film Coated

0955-1045	Irbesartan And Hydrochlorothiazide	Irbesartan And Hydrochlorothiazide	Tablet, Film Coated
0955-1046	Irbesartan And Hydrochlorothiazide	Irbesartan And Hydrochlorothiazide	Tablet, Film Coated
0955-1735	Leflunomide	Leflunomide	Tablet, Film Coated
0955-1737	Leflunomide	Leflunomide	Tablet, Film Coated
0955-1050	Sevelamer Carbonate	Sevelamer Carbonate	Tablet, Film Coated
0955-1052	Sevelamer Carbonate	Sevelamer Carbonate	Powder, For Suspension
0955-1054	Sevelamer Carbonate	Sevelamer Carbonate	Powder, For Suspension
0955-1048	Sevelamer Hydrochloride	Sevelamer Hydrochloride	Tablet, Film Coated
0955-1702	Zolpidem Tartrate	Zolpidem Tartrate	Tablet, Film Coated, Extended Release
0955-1703	Zolpidem Tartrate	Zolpidem Tartrate	Tablet, Film Coated, Extended Release

Labeler Code 72733

NDC*	Brand Name	Generic Name	Dosage Form
72733-5901	Praluent	Alirocumab	Injection, Solution
72733-5902	Praluent	Alirocumab	Injection, Solution

Exhibit L

EXHIBIT L

WAC/340B Price Differentials

Manufacturer	Product	NDC	340B	WAC	Difference
Eli Lilly	Humalog Vial	00002-7510-01	$0.10	$266.46	$266.36
	Humalog Pen	00002-8799-59	$0.15	$514.49	$514.34
	Basaglar	00002-7715-59	$244.29	$316.57	$72.28
	Forteo	00002-8400-01	$0.02	$3,663.39	$3,663.37
	Trulicity	00002-1434-80	$294.30	$819.03	$524.73
Astra-Zeneca	Byetta	00310-6512-01	$0.01	$754.49	$754.48
	Farxiga	00310-6205-30	$0.29	$516.85	$516.56
	Pulmicort	00186-0917-06	$0.01	$186.08	$186.07
	Symbicort	00186-0370-20	$0.10	$360.51	$360.41
	Onglyza	00310-6100-30	$0.29	$443.51	$443.22
Sanofi	Lantus	00088-2220-33	$0.10	$275.05	$274.95
	Admelog	00024-5924-10	$97.88	$126.84	$28.96
	Apidra Solostar	00088-2502-05	$0.15	$532.06	$531.91
	Dupixent	00024-5918-01	$2,229.04	$3,107.29	$878.25
	Multaq	00024-4142-60	$96.14	$638.66	$542.52

BEFORE THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADMINISTRATIVE DISPUTE RESOLUTION PANEL

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS *Petitioner,* v. ELI LILLY AND COMPANY and SANOFI-AVENTIS U.S. LLC and ASTRAZENECA PLC *Respondents.*	Petition No: 210112-2

PETITIONER'S MOTION FOR PRELIMINARY INJUNCTION

Petitioner National Association of Community Health Centers ("NACHC"), on behalf of its joint claimant Federally-qualified health center ("FQHC") covered entity members, hereby moves the Administrative Dispute Resolution Panel ("Panel") to employ its equitable authority under 42 C.F.R. § 10.21(a) to compel drug manufacturers Eli Lilly and Company ("Lilly"), Sanofi-Aventis U.S. LLC ("Sanofi"), and AstraZeneca PLLC ("AstraZeneca") (collectively, the "drug manufacturers") to immediately make their covered outpatient drugs available to FQHC covered entities at or below 340B ceiling prices when shipped to a contract pharmacy, pending the Panel's final resolution of this claim.

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

The joint claimants—FQHC covered entities who are required by statute to care for some of the country's most vulnerable and medically underserved patients—participate in the 340B Program as Congress intended. NACHC Pet. ¶¶ 6, 24 (Jan. 13, 2021).

In recent months, pharmaceutical manufacturers Lilly, Sanofi, and AstraZeneca (the "drug manufacturers" or "manufacturers") have unlawfully restricted the joint claimants' ability to purchase covered outpatient drugs at 340B discount pricing by ceasing such sales to covered entities where the drugs at issue will be dispensed to covered entity patients via contract pharmacies. *See* Pet.. ¶¶ 1, 26–28, 30–32, 34–35. As alleged in the joint claimants' Petition, such limitations on access are unlawful overcharges in violation of 42 U.S.C. § 256b(a)(1) and 42 C.F.R. § 10.21(c)(1).

The factual record is clear and no material facts are in dispute. In addition to the public notices and correspondence the joint claimants cite in their Petition, several federal district court filings document and describe the drug manufacturers' unlawful actions in the manufacturers' own words. *See, e.g.,* Mem. in Supp. of Eli Lilly and Co's Mot. to Intervene, ECF No. 12-1 at 19–21, *Ryan White Clinics for 340B Access v. Azar*, Case No. 1:20-cv-02906 (D.D.C. filed Oct. 9, 2020); Mem. in Supp. Of Sanofi-Aventis U.S. LLC's Mot. to Intervene, ECF No. 13-1 at 3, *Ryan White Clinics v. Azar*, Case No. 1:20-cv-02906; Mem. in Supp. of AstraZeneca's Mot. to Intervene, ECF No. 29-1 at 15, *Ryan White Clinics*, No. 1:20-cv-02906-KBJ (Nov. 24, 2020); Compl. at 16–20, *AstraZeneca Pharmaceuticals v. Azar*, Case No. 1:21-cv-00027 (D. Del. Jan. 12, 2021); Compl. at 2, 15–17, *Sanofi-Aventis U.S. v. Azar*, Case No. 3:21-cv-00634 (D. N.J. Jan. 12, 2021); Compl. at 27–28, *Eli Lilly and Co. v. Azar*, Case No. 1:21-cv-00081 (S.D. Ind. Jan.

12, 2021); *see also* Pet. ¶¶26–36. The drug manufacturers' federal court filings cited in this paragraph are attached as Exhibits A, B, C, D, E, and F, respectively.

The manufacturers' public justifications for their unlawful actions are meritless. The 340B statute imposes a clear duty on the drug manufacturers to offer covered outpatient drugs at 340B discount pricing for covered entities to purchase regardless of a particular covered entity's chosen dispensing mechanism. Equally clear is the unwavering interpretation given to that statute by the U.S. Department of Health and Human Services (HHS), the agency entrusted with overseeing the 340B Program, including by adjudicating disputes like this one.

Preliminary injunctive relief is not only appropriate here, where the joint claimants are all but guaranteed to prevail on the merits of their overcharging claims, but also necessary to prevent further irreparable harm to the joint claimants and their patients while the Panel adjudicates this matter. The 340B statute guarantees "that claims shall be resolved fairly, efficiently, and expeditiously" through the ADR process. 42 U.S.C. § 256b(d)(3)(B)(ii). Because of the absence—until yesterday—of an ADR process, the joint claimants have already been detrimentally delayed in obtaining relief. *See* Compl. ¶¶ 75–86, *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar,* No. 1:20-cv-03032-KBJ (D.D.C. Oct. 21, 2020), attached as Exhibit G. Now, having successfully secured the regulatory implementation of that process through litigation in federal court, the joint claimants implore the Panel to use its equitable authority to compel a return to status quo 340B sales and purchasing through a grant of preliminary injunctive relief.[1]

[1] Before its district court litigation was stayed, Petitioner was poised to seek preliminary injunctive relief to alleviate the harm caused by the drug manufacturers' refusal to allow the joint claimants to purchase covered outpatient drugs at 340B pricing for dispensing through contract pharmacies. Indeed, the declarations attached to this filing—originally prepared and executed for filing in the D.C. District Court—demonstrate the urgent need for equitable relief.

II. BACKGROUND

The 340B Program, *codified at* 42 U.S.C. § 256b *et seq*., requires drug manufacturers, as a condition of having their drugs covered by Medicare and Medicaid, to enter into pharmaceutical pricing agreements (PPAs) with HHS, under the terms of which they must make certain outpatient drugs available to covered entities at prices that do not exceed a statutorily-set ceiling price. 42 U.S.C. § 256b(a)(1). By reducing drug costs to covered entities—which are predominantly safety-net providers serving poor, underserved, and either uninsured or underinsured populations—the 340B Program furthers its legislative objective to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), 12 (1992).

Petitioner's FQHC covered entity members receive, or are deemed eligible to receive, federal grant funds under Section 330 of the Public Health Service ("PHS") Act to provide certain required health care and related services to medically underserved populations regardless of patient insurance status or ability to pay for such services. 42 U.S.C. §§ 254b(a), (e), (k); Pet. ¶ 6. As alleged in the Petition, these statutorily required services include pharmacy services, and FQHCs are permitted to meet their patients' pharmaceutical needs either directly or through contracts or similar arrangements. Pet. ¶¶ 3, 19 (citing 42 U.S.C. § 254b(a), (b)(1)(A)(i)(V)).

Although FQHC covered entities have flexibility in determining how best to meet the needs of their patient population and communities, any operational savings or revenue an FQHC generates—through 340B Program participation or otherwise—must be used to further the health center's project. *See* 42 U.S.C. §§ 254b(e)(5)(A) (defining non-grant funds as "state, local, and other operational funding provided to the center" and "fees, premiums, and third-party reimbursements . . . the center may . . . receive for its operations"), (D) (mandating that non-

grant funds be used to further center's project objectives). As Congress intended, FQHC covered entities use 340B Program savings and revenue to provide additional services within their federally-designated service areas. *See* H.R. Rep. No. 102-384(II), at 12 (1992). For example, FQHCs use their 340B savings to cover the cost of medication for uninsured or underinsured patients who could not otherwise afford such costs. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549-01, 43549 (Aug. 23, 1996) (noting that covered entities can use 340B savings to subsidize patients' prescriptions). FQHC covered entities also use these funds to expand and increase access to necessary medical and crucial enabling services. *See id.* at 43549, 43551 (noting that covered entities can also use 340B savings to increase the number of patients they serve, increase the number of services they provide, and offer more comprehensive services).

As alleged in the Petition and reflected in the drug manufacturers' own public statements and legal filings, the drug manufacturers recently threatened—and then imposed—significant (unlawful) limitations on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable 340B ceiling prices. *See* Pet. ¶¶ 27, 30, 34.

On October 21, 2020, Petitioner, on behalf of the joint claimants, brought suit in federal court to compel the implementation of the statutorily-required ADR process of which Petitioner now avails itself. *See* Ex. G (NACHC Compl.) at 1–2. The final rule establishing that process was published on December 14, 2020, with an effective date of January 13, 2021. Given the publication of the final rule, Petitioner and HHS Secretary jointly moved to stay that matter pending the establishment of this Panel and its adjudication of Petitioner's joint claim. *See* Joint Mot. for Stay, ECF No. 12, *Nat'l Ass'n of Cmty. Health Ctrs.*, No. 1:20-cv-03032, (D.D.C. Dec. 17, 2020) (stay granted Jan. 7, 2021), attached as Exhibit H.

III. ARGUMENT

This Panel should grant Petitioner's request for immediate equitable relief pending final adjudication of the joint claim asserted in its Petition. The joint claimants are almost certain to succeed on the merits of this joint claim, and such interim equitable relief will prevent further irreparable harm to the joint claimants and their patients while their first-of-its-kind claim is pending in this newly established process. Additionally, the delay in the ADR rulemaking and implementation of this process—for which Petitioner bears no blame—renders Petitioner's request for relief all the more pressing.

Preliminary injunctive relief is appropriate where the movant shows it "is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). In the D.C. Circuit—where Petitioner, on behalf of its covered entity members, filed suit seeking the creation of this ADR process—a preliminary injunction is warranted where a movant demonstrates (1) a substantial likelihood of success on the merits, (2) that they will suffer irreparable injury if injunctive relief is not granted, (3) that the injunction would not substantially injure other interested parties, and (4) that the public interest is furthered by the injunction. *See Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006); *see also Sherley v. Sebelius*, 644 F.3d 388, 393 (D.C. Cir. 2011) (indicating likelihood of success on the merits is key factor).

A. Petitioner is Substantially Likely to Succeed on the Merits.

Petitioner is all but guaranteed to succeed on the merits of its joint claim. The drug manufacturers' refusal to allow the joint claimants to purchase covered outpatient drugs at or

below the drugs' applicable ceiling prices is not only an abrupt departure from decades of past practice and a repudiation of previously accepted agency policies, but also amounts to a prohibited overcharge as defined in 42 C.F.R. § 10.21(c)(1) (defining prohibited overcharging activity to include any "limit[ation on] the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price").

In longstanding, well-reasoned, and persuasive agency issuances—that are squarely on point and date back nearly twenty-five years—HHS has consistently and repeatedly stated that covered entities may contract with third parties to provide pharmaceutical services to their patients. For instance, in an August 23, 2006 final notice published in the Federal Register, HHS wrote: "[e]ach covered entity should conduct its own business review and patient assessment to determine what level of pharmacy services is needed, and the appropriate delivery mechanism for those services." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. at 43549–50. (Aug. 23, 1996). The Agency also provided, in its "Contract Pharmacy Services Revised Final Mechanism" included in that Notice that "[u]nder section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drugs at the discounted price." *Id.* At that time, HHS, considering a situation in which a covered entity directs a drug shipment to its contract pharmacy, saw "no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance." *Id.*

HHS reiterated its unwavering interpretation of the 340B statute in a March 2010 final notice published to "inform interested parties of final guidelines regarding the utilization of multiple contract pharmacies" without individualized Agency approval. Notice Regarding 340B

Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10272-01, 10272–73 (Mar. 5, 2010) (replacing all previous 340B Program guidance, including 61 Fed. Reg. 43549). The notice informed all stakeholders that covered entities were free to use contract pharmacies for dispensing "as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." *Id.* at 10273.

Roughly a decade after the March 2010 final notice was published, on September 21, 2020, HHS General Counsel Robert P. Charrow responded to a September 8, 2020 request from Lilly for an advisory opinion as to whether Lilly's "new unilateral policy" on 340B contract pharmacies "would subject Lilly to sanctions." *See* Pet. Exhibit E (Sept. 21, 2020 Letter from Robert P. Charrow, General Counsel, U.S. Dep't of Health & Human Servs., to Anat Hakim, Senior Vice President and General Counsel, Eli Lilly & Co.). In that letter, General Counsel Charrow indicated that HHS "ha[d] significant initial concerns" with Lilly's limitations on covered entities' ability to purchase Lilly drugs at 340B discount pricing, advised Lilly that it could not and should not "view the absence of any questions from the government as somehow endorsing Lilly's policy," and warned Lilly that "a [False Claims Act] suit against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the [340B] program that results in over-charges to grantees and contractors." *Id.* at 1–2; *Cf.* 42 C.F.R § 10.11(a) (providing that a manufacturers' "knowing[] and intentional[]" refusal to offer covered outpatient drugs at 340B pricing is an example of prohibited overcharging subject to civil monetary penalties); *see also* Letter from Krista M. Pedley, Director, Office of Pharmacy Affairs, Health Res. & Servs. Admin., to Derek L. Asay, Senior Director, Government Strategy, Eli Lilly & Co. (Aug. 26, 2020) at 1 (noting "[u]nder 42 U.S.C. 256b(a)(1), manufacturers must offer covered entities outpatient drugs at specified prices"), attached as Exhibit I; Letter from

Krista Pedley to Christie Bloomquist (Sept. 2, 2020) at 1-2 (asserting AstraZeneca's actions "could have the effect of severely limiting access" to 340B drugs during the COVID-19 pandemic, which "would undermine the 340B Program and the Congressional intent behind enactment of the 340B statute"), attached as Exhibit J. The manufacturer-imposed limitations on purchasing considered in the cited letters from HHS are the same as those at the heart of the joint claimants' Petition.

Finally, as the joint claimants explain in their Petition, a December 30, 2020 HHS Office of General Counsel Advisory Opinion, also written to address the very conduct at issue here, is a particularly persuasive and forceful reiteration of HHS' prior interpretive guidance:

> 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.

Pet. Exhibit B (HHS Office of General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* at 1 (Dec. 30, 2020)). As HHS further notes in that Advisory Opinion, the 340B statute, in plain language, requires manufacturers to offer covered outpatient drugs at or below the ceiling price for "purchase by" covered entities and neither qualifies, restricts, nor otherwise conditions this requirement on the mechanism through which a covered entity *distributes* its covered outpatient drugs so long as the covered entity *purchases* the drugs. *Id.* at 2.

The Panel is not only bound by the plain language of the 340B statute, there is no legally justifiable reason for it to depart from HHS's longstanding interpretation of that statute as permitting covered entities to purchase covered outpatient drugs at 340B discount pricing for dispensing to covered entity patients either directly or through contract pharmacies. *See Fed. Commc'ns Comm'n v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (agency generally

may not depart from prior policies without reasoned basis, including acknowledgment of changed position); *Barnhart v. Walton*, 535 U.S. 212, 220 (2002) (noting courts "normally accord particular deference to an agency interpretation of 'longstanding' duration") (*quoting North Haven Bd. of Ed. v. Bell*, 456 U.S. 512, 522 n.12 (1982)); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988) (deference inappropriate for agency interpretation initially adopted in litigation, particularly where interpretation departs from prior agency position). The drug manufacturers effectively conceded that the Panel must adhere to its prior interpretive guidance in three separate—but strikingly similar— lawsuits, each filed just the day before the ADR process became available. One of those suits, initiated by Lilly, characterizes HHS's December 30, 2020 Advisory Opinion as a "binding decision under which manufacturers like Lilly must offer full 340B discounts to contract pharmacies on all covered drugs." Ex. F (Eli Lilly Compl.) at 4–5; *see also* Ex. D (AstraZeneca Compl.); Ex. E (Sanofi Compl.).

B. The Joint Claimants Will Continue to Suffer Irreparable Harm Absent Preliminary Injunctive Relief

The joint claimants will be irreparably harmed if the Panel does not grant preliminary injunctive relief. A movant seeking a preliminary injunction demonstrates irreparable harm by showing two things: (1) the harm that will result in the absence of injunctive relief "must be 'certain and great,' 'actual and not theoretical,' and so 'imminen[t] that there is a clear and present need for equitable relief to prevent irreparable harm;'" and (2) that harm cannot be remediated. *See League of Women Voters of the United States v. Newby*, 838 F.3d 1, 7–8 (D.C. Cir. 2016) (*quoting Chaplaincy of Full Gospel Churches*, 454 F.3d at 297).

FQHCs currently provide numerous non-reimbursable services in part through 340B savings and program income. These services include, for example, medication therapy management, behavioral health care, dental services, case management and care coordination

services, translation/interpretation services for patients with limited English language ability, and transportation assistance. *See, e.g.,* Declaration of J.R. Richards ¶ 14 (indicating covered entity's "behavioral health, dental, mobile van services, patient assistance program, and free prescription delivery" are funded in part through 340B savings and revenue), attached as Exhibit K; Declaration of Donald A. Simila ¶¶ 15, 16, 17, and 19 (indicating substance abuse, dental, and OB/GYN services supported by 340B funds), attached as Exhibit L; Declaration of Patricia DeShields ¶ 16 (indicating uninsured patients' prescription drug costs, transportation, medical supplies, lab fees, and vaccinations supported by 340B funds), attached as Exhibit M.

If drug manufacturers continue to refuse to provide 340B discounts for contract pharmacies, FQHCs will be forced to drastically reduce or even eliminate these services. Ex. K (Richards Decl.) ¶¶ 24, 25 (estimating that covered entity will lose approximately $350,000 annually—41 percent of its annual budget—as result of 340B restrictions, forcing reduction in services); Declaration of Heather Rickertsen ¶¶ 34, 36 (estimating annual loss of approximately $1 million in revenue and $500,000 to $2 million increase in cost of goods sold, forcing reduction in coverage of patient copays, clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health program), attached as Exhibit N; Ex. L (Simila Decl.) ¶¶ 28–30 (estimating annual revenue loss of approximately $600,000 from Lilly's actions alone, resulting in "major reductions in services" and "significant reduction in access to comprehensive care for an elderly, impoverished, and underserved rural community"); *see also* Declaration of Lee Francis ¶ 30 ("We already know that critical patient programs will need to be reduced or eliminated because of the decline in 340B savings and revenue."), attached as Exhibit O.

Reductions in 340B savings and revenue resulting from the drug manufacturer's unlawful overcharging will also result in many covered entities needing to reduce the size of their clinical

staffs, further restricting the amount and scope of care they provide to patients. For example, Upper Great Lakes Family Health Center, an FQHC covered entity which serves approximately 25,000 patients annually in Michigan's remote Upper Peninsula, reports that 340B reductions have already forced it to reduce staffing for OB/GYN services and that it is currently planning other major reductions in services—including closure of service delivery sites, termination of employees, reductions in health care providers, and likely closure of OB/GYN, dental, and mental health services. Ex. L (Simila Decl.) ¶ 29; *see also* Ex. K (Richards Decl.) ¶ 25; Declaration of Kiame Jackson Mahaniah ¶ 20 (currently preparing to permanently layoff 5 percent of its employees due to loss of 340B revenue), attached as Exhibit P; Declaration of Kimberly Christine Chen ¶ 42 (indicating likely elimination of clinical pharmacists and closure of one or more rural clinic locations due to manufacturers' restrictions), attached as Exhibit Q.

These harms are also incapable of remediation, especially given the 340B program's purpose. Covered entities cannot retroactively provide, and their patients cannot retroactively benefit from, critical health care and enabling services that must be reduced or eliminated due to manufacturers' noncompliance with 340B pricing requirements.

C. Other Interested Parties Will Not be Substantially Harmed by the Preliminary Injunction

The drug manufacturers will not be substantially harmed by a preliminary injunction that, in effect, restores the status quo ante. First, as a threshold matter, enforcement of a pre-existing federal obligation causes no cognizable harm at all. *See Newsom v. Albemarle Cnty. School Bd.*, 354 F.3d 259, 261 (4th Cir. 2003).

Second, the requested relief would restore the 340B program's status quo as it existed for decades—*i.e.*, drug manufacturer compliance with both the 340B statute's plain language and HHS interpretive rules recognizing the propriety of the contract pharmacy model to dispense

drugs to patients of FQHC covered entities. That longstanding state of affairs changed mere months ago by virtue of the drug manufacturers' own unilateral actions.

From 1996 to late 2020, drug manufacturers honored covered entity's purchases at 340B discount pricing where the purchased drugs are shipped to and dispensed by covered entities' contract pharmacies. While covered entities (and their patients) will suffer irreparable harm in the absence of injunctive relief, *see* Section III.B, *supra*, there is no reason to believe that the drug manufacturers will be substantially, much less irreparably, harmed by continuing to do what they did for more than 20 years during the period it takes the ADR panel to "expeditiously" resolve this dispute. *See*, *e.g.*, Pet. Ex. E at 2 (noting "[t]he price of Lilly's stock has increased by more than 11 percent since January 1, 2020" reflecting jump in comprehensive income "from $1.414 billion during the second quarter of 2019 to $1.615 billion for the second quarter of 2020"). Further, given the substantial public equities at stake in providing affordable medications and health care services to vulnerable communities, any private interest asserted by the drug manufacturers should be given little weight. Unlike the deprivation of medical care or the restriction of services to an underserved population, drug manufacturers could only conceivably complain of economic harm, for which they would have a damages remedy in this ADR process. 42 U.S.C. § 256b(d)(3)(A).

D. The Requested Relief is in the Public Interest

Requiring the drug manufacturers to provide 340B-priced drugs to covered entities' contract pharmacies pending the resolution of the ADR proceedings is in the public interest. First, the public interest is not served by the drug manufacturer's continued violation of their statutory obligations. *See Washington Post Guild Majority v. Washington-Baltimore Newspaper Guild, Local 35 (ANG)*, No. 76-0009, 1976 WL 1547 at *4 (D.D.C. 1976) ("the public interest is

served by preventing the violation of a federal statute"); *Laborers' Int'l Union of N. Am. v. Nat'l Post Office Mail Handlers, Watchmen, Messengers & Grp. Leaders Div. of Laborers Int'l Union of N. Am.*, Case No. 88-1731-OG, 1989 WL 251211, at *12 (D.D.C. Jan. 17, 1989) ("The public interest lies in seeing that the statute is complied with.").

Second, the public interest favors a preliminary injunction because it will prevent the substantial direct and indirect harm to covered entities patients' currently resulting from the drug manufacturers' violations of the 340B statute. Due to the drug manufacturers' practical elimination of the joint claimants' ability to purchase the manufacturers' drugs at or below applicable ceiling prices for dispensing through contract pharmacies, the joint complainants' patients have experienced dramatic increases in the price of life-sustaining medications used to treat common, chronic conditions such as diabetes, cardiovascular disease, and respiratory diseases. *See, e.g.,* Declaration of Ludwig M. Spinelli ¶ 21 (asthma and diabetes medication), attached as Exhibit R; Ex. N (Rickertsen Decl.) ¶ 30 (medications treating diabetes, heart disease, hypertension, and asthma/COPD). For instance, a joint claimant FQHC health center located in Connecticut and serving approximately 50,000 patients in the Bridgeport and Stamford regions reports that uninsured health center patients receiving insulin or asthma medication through their health center's contract pharmacy now have to either pay up to $1800 for medication which previously cost them less than $16 for the same amount or, if a substitution is possible, coordinate with and wait for their providers to approve the substitution of a cheaper alternative medication. *See* Ex. R (Spinelli Decl.) ¶ 21 (noting change to $300–600 for a month's supply of medication which previously cost $12–15 per three months' supply); *see also* Declaration of Daniel Fulwiler ¶ 14a (noting change in price for month's supply of insulin from less than $17 to $700), attached as Exhibit S.

Other joint claimants, including those with existing in-house pharmacy capabilities that could theoretically be leveraged to provide discounted medications to needy patients, report that patients would have to travel prohibitive distances to reach such a pharmacy. For example, North Country HealthCare, located in Flagstaff, Arizona, indicates that some of its patients previously served by its contract pharmacies would have to travel up to 180 miles to reach the FQHC's nearest in-house pharmacy. *See* Ex. Q (Chen Decl.) ¶ 21; *see also* Declaration of Ronald E. Castle ¶ 15 (declaring that health center's single in-house pharmacy is located roughly at mid-point of 110-mile service area), attached as Exhibit T. A delay in obtaining life-sustaining and health maintenance medications caused by these sorts of practical barriers to access can result in significant adverse health effects for the joint claimants' patients—including death. Great Salt Plains Health Center, located in northwestern Oklahoma, reports that its "patients will be denied access to medications that are critical to their survival, such as rescue inhalers, blood pressure medications, and insulin." Declaration of Timothy E. Starkey ¶ 16, attached as Exhibit U; *see also* (Declaration of David Steven Taylor ¶ 18 (reporting that numerous patients are already forgoing insulin treatments because of increased cost and/or difficulty in traveling to the FQHC's in-house pharmacy), attached as Exhibit V; Ex. R (Spinelli Decl.) ¶¶ 23–25 (reporting that diabetic and asthmatic patients have been forced to forego medication and/or switch to less effective substitute medication).

A shift to clinical alternative medications—when such alternatives exist—may result in reduced health outcomes due to lower efficacy, serious side effects, or decreased medication compliance as a result of patient confusion or difficulty in adapting to a new regimen. *See e.g.* Ex. Q (Chen Decl.) ¶ 38 (reporting that switching stable diabetic patients to substitute medications reduces adherence to medication regimens and increases weight gain and the risk of

hypoglycemia "which can lead to seizures, coma, and even death"); Ex. K (Richards Decl.) ¶ 23 (reporting that patients whose diabetes is controlled with one medication may develop uncontrolled diabetes or suffer other adverse effects when switching to a substitute medication).

The public interest is served by ensuring the continued viability of the nation's health care safety-net and the health of its most vulnerable patients. *See Lopez v. Heckler*, 713 F.2d 1432, 1437 (9th Cir. 1983) ("Our society as a whole suffers when we neglect the poor, the hungry, the disabled, or when we deprive them of their rights or privileges."). Indeed, the existence of the PHS Act programs at issue here evidences a significant public interest in safeguarding access to health care for those who are medically underserved.

IV. CONCLUSION

For the foregoing reasons a preliminary injunction should issue compelling the drug manufacturers to comply with their statutory obligation to offer the joint claimants' covered outpatient drugs at or below 340B ceiling prices, regardless of whether those drugs are to be dispensed in-house or through a contract pharmacy, until the Panel resolves the merits of Petitioner's joint claim.

Dated: January 14, 2021

Respectfully submitted,

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Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RYAN WHITE CLINICS FOR 340B ACCESS
1501 M Street NW, Suite 700
Washington, DC 20005,

MATTHEW 25 AIDS SERVICES, INC.
452 Old Corydon Road
Henderson, KY 42420,

CHATTANOOGA C.A.R.E.S.,
DBA CEMPA COMMUNITY CARE
1000 E. 3rd Street, Suite 300
Chattanooga, TN 37403,

Plaintiffs,

- vs. -

Case No. 20-cv-2906

ALEX M. AZAR II,
in his official capacity as Secretary of the U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, DC 20201,

THOMAS J. ENGELS,
in his official capacity as Administrator for the Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857,

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20857,

Defendants.

MEMORANDUM OF LAW IN SUPPORT OF ELI LILLY AND COMPANY'S MOTION TO INTERVENE AS DEFENDANT

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This is a textbook case for intervention. Plaintiffs contend that Section 340B of the Public Health Services Act requires prescription drug manufacturers like Eli Lilly and Company ("Lilly") to provide steep discounts to an unlimited number of for-profit, commercial "contract pharmacies." They call out Lilly by name in their pleadings. And they seek a court order compelling the Health Resources and Services Administration ("HRSA") to punish Lilly with draconian penalties—including ***exclusion from participation in Medicaid and Medicare Part B altogether***—if Lilly refuses to comply with this purported obligation. Rule 24(a) was made for cases such as this one. "[T]he subject of the action" is Lilly's obligations under federal law, and the "existing parties" (namely, the governmental defendants) cannot adequately represent Lilly interests. Fed. R. Civ. P. 24(a). The Court should grant Lilly's motion to intervene as a defendant as of right, or in the alternative permit Lilly to intervene pursuant to Rule 24(b).

Congress established the 340B Program to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 WM. & MARY L. REV. 637, 638 (2015); *see also* H.R. Rep. No. 102-384 (II) at 12 (1992) (the statute "provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans"). The Program requires participating manufacturers such as Lilly to offer outpatient drugs to eligible "covered entities" at deeply discounted prices. The 340B Statute painstakingly enumerates 15—***and only 15***—classes of entities entitled to participate in the program (and thus entitled to receive medications at discounted prices). Large commercial entities like contract pharmacies did not make Congress's list. The statute also forbids covered entities from transferring 340B-discounted products to other entities or persons, a practice known as "diversion." These provisions of the 340B Statute work together

not just to limit the universe of entities eligible to receive discounted pharmaceutical products under the program, but to ensure the program functions as intended.

Despite these express limits, HRSA has issued nonbinding guidance permitting covered entities to contract with an unlimited number of third-party, for-profit "contract pharmacies" to fill prescriptions for their 340B patients. Plaintiffs here have now gone further, seeking a declaratory judgment that the 340B Statute ***requires*** participating manufacturers like Lilly to provide 340B discounts via contract pharmacies. They also seek to compel HRSA to punish Lilly and others if they refuse to extend those discounts beyond covered entities, to all contract pharmacies as well.

Accepting Plaintiffs' theory would allow large, for-profit commercial entities to generate substantial revenue on 340B-eligible prescriptions without accountability and without conferring benefits to patients—none of which is remotely consistent with the carefully articulated scheme Congress enacted in the 340B Statute. Contract pharmacies reap hundreds of millions of dollars in profit ***each year*** from 340B discounts, but they rarely, if ever, pass along savings to the patients who purchase 340B drugs. Indeed, government reports repeatedly caution against the contract pharmacy model, which "creates more opportunities for drug diversion compared to in-house pharmacies," GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, GAO-11-836 (2011), at 28, and "has led to concerns about whether the money is truly devoted to improving patient care," House Energy & Commerce Committee, *Review of the 340B Drug Pricing Program*, at 75 (Jan. 20, 2018).

Against this backdrop, and consistent with the plain text and purpose of the 340B Statute, Lilly announced earlier this year that it would cease extending 340B discounts to contract pharmacies, as opposed to the covered entities themselves. Notwithstanding that announcement, ***Lilly at all times has continued to provide 340B discounts to all eligible covered entities***. Lilly

has also permitted covered entities without an in-house pharmacy to designate one contract pharmacy to dispense drugs to patients, and it continues to offer 340B prices to contract pharmacies wholly owned by covered entities. Moreover, consistent with its commitment to providing affordable insulin, Lilly has agreed to provide 340B-discounted prices to contract pharmacies that pass along the entire discount to patients purchasing certain formulations of Lilly insulin products. Every step of the way, Lilly has explained the reasoning behind its distribution plan to both HRSA and its parent agency, the Department of Health and Human Services ("HHS"). Tellingly, HRSA and HHS have ***never disputed Lilly's legal right to proceed this way***, let alone cited a provision that forbids it. That is because Lilly's plan is consistent with both the letter and spirit of the law.

Plaintiffs' extraordinary request against Lilly, a non-party, for financial penalties and the unwarranted exclusion from federal healthcare programs undeniably requires Lilly to protect its interests in this lawsuit—which no government defendant can do—and vindicate the correct interpretation of the 340B Statute. Lilly plainly meets the standard for intervention as of right. Timely motions to intervene should be granted under Rule 24(a) where (1) the party claims an interest relating to the subject of the lawsuit, (2) an existing party cannot adequately represent its interests, and (3) the disposition could impair the party's ability to protect that interest. *See, e.g.*, *The Wilderness Soc'y v. Babbitt*, 104 F. Supp. 2d 10, 18 (D.D.C. 2000). Each prong is readily satisfied here. First, Lilly obviously has a direct stake in the outcome: Not only do Plaintiffs identify Lilly by name throughout the complaint, *see, e.g.*, Compl. ¶¶ 2, 59, they also seek a court order compelling HRSA to impose massive financial penalties on Lilly, including ordering refunds on certain drugs already dispensed to contract pharmacies and additional civil monetary penalties of up to $5,883 ***per drug sold to contract pharmacies***. Plaintiffs even request that HRSA cancel Lilly's Pharmaceutical Pricing Agreement ("PPA"), "thereby excluding [its] drugs from coverage

under the Medicaid and Medicare Part B insurance programs." *Id.* at 36. Second, HRSA and HHS cannot adequatley defend Lilly's interests. There is always a conflict between governmental defendants and private parties, but that conflict is particularly stark here: Although HRSA has never identified any provision of the 340B Statute that Lilly's distribution plan violates—and, indeed, conceded that the guidance at issue in this suit is "not legally enforceable"—it has since threatened Lilly with massive penalties should it change its mind, thus effectively hanging a Sword of Damocles over Lilly's head. Finally, there is no question that an adverse outcome could impair Lilly's interests—not just in its continuing ability to participate in Medicaid and Medicare, but in the correct interpretation and application of federal law. In sum, all considerations point in the same direction: The Court should grant Lilly's motion to intervene.

BACKGROUND

I. Legal And Factual Background

A. Without Statutory Authority, HRSA Expands the 340B Program to Contract Pharmacies, Unleashing Abuses and Program Integrity Concerns, and Compounding Civil Monetary Penalty Risk and Manufacturer Burdens.

Pharmaceutical manufacturers participate in the 340B Program as a condition of receiving coverage and reimbursement under Medicaid and Medicare Part B, 42 U.S.C. § 1396r-8(a)(1), (5), and they must "offer" outpatient drugs at substantial discounts to "each covered entity," *id.* § 256b(a)(1). The resulting 340B "ceiling prices" are significantly lower than what other purchasers would pay for the same product, and can even be as low as one penny per pill or per milligram. Covered entities thus pay significantly discounted prices for "covered outpatient drugs" according to a prescribed statutory formula. *Id.* § 256b(a)(1), (a)(4), (b)(1).

Consistent with the 340B Program's focus on "creat[ing] a low-cost source of pharmaceutical medication for the indigent patients themselves," Baer, *supra*, at 638, only the covered entities specifically enumerated in the statute—nearly all of which serve predominantly

low-income and vulnerable populations—are eligible to participate in the 340B Program. *See* 42 U.S.C. § 256b(a)(4). And to help ensure that covered entities and others do not inappropriately benefit from the opportunity of 340B price arbitrage, the 340B Statute expressly forbids "diversion": A "covered entity" may not "resell or otherwise transfer" a covered drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

HHS delegated 340B oversight and enforcement to HRSA, one of the defendants in this suit. The statute authorizes HHS to monitor unlawful drug diversion by covered entities, audit covered entities and manufacturers, and (as part of the Affordable Care Act) assess civil monetary penalties when manufacturers knowingly "overcharge" a covered entity for eligible drugs. *See id.* § 256b(d)(1)(B)(vi); 42 C.F.R. § 10.11(a); 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020) (authorizing penalties up to $5,883 "for each instance" of overcharging). Nothing in the statute, however, authorizes HHS or its affiliated agencies to expand (or contract) the list of entities eligible to participate in, and thus eligible to benefit financially from, the 340B Program.

Nevertheless, HRSA issued guidance in 1996 allowing "contract pharmacies"—typically large, commercial, for-profit entities—to sign agreements with covered entities to dispense covered outpatient drugs in connection with the 340B Program. 61 Fed. Reg. 43,549 (Aug. 23, 1996). That initial guidance permitted covered entities that lacked an in-house pharmacy to contract with a single outside pharmacy to dispense drugs to the covered entity's patients. In 2010, however, HRSA issued new guidance that expanded the contract pharmacy option to ***all*** covered entities, not just those without an in-house pharmacy, without any numeric or geographic limitations.

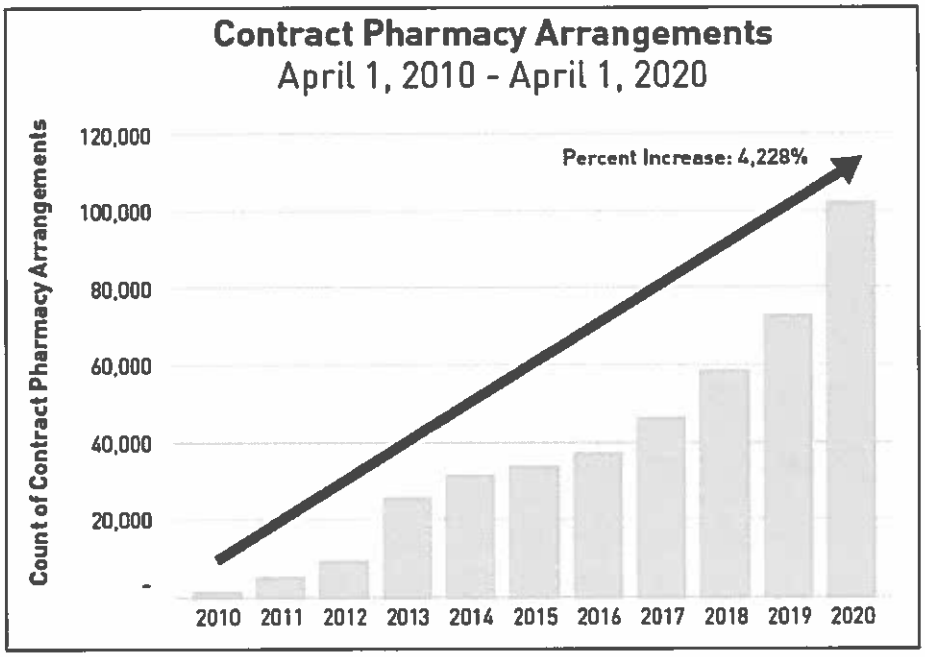
When HRSA issued the 2010 guidance, numerous stakeholders expressed concern that it violated the statute to permit an unlimited number of contract pharmacies—entities never

mentioned in the Act. Indeed, one commenter stated that the new guidance represented "new obligations and burdens on manufacturers … [and] create[d] new rights for covered entities under the law." 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). Yet HRSA did not engage in notice-and-comment rulemaking when issuing the guidance. In fact, it disclaimed any intention of issuing rules binding on manufacturers, perhaps recognizing the tenuousness of its position. *See id.*

Unfortunately, the 2010 guidance has worked a sea change in the industry. In addition to allowing covered entities with in-house pharmacies to enter into contractual arrangements with contract pharmacies, the 2010 guidance also jettisoned the single-pharmacy limitation, permitting all eligible 340B covered entities to use an ***unlimited*** number of outside contract pharmacies to dispense covered outpatient drugs. *Id.* at 10,277. And because it placed no limits on covered entities' ability to contract with for-profit pharmacies, the 2010 guidance has allowed covered entities to contract with pharmacies that are hundreds or even thousands of miles away, far away from any of the covered entity's actual patients. For example, Plaintiff Chattanooga C.A.R.E.S., DBA Cempa Community Care ("Cempa"), which is located only in Tennessee, has relationships with more than 200 contract pharmacies (most of which are large commercial chains such as Walgreens and CVS) spread across 18 different states, including Hawaii, Massachusetts, and California.

Cempa is far from alone. As one recent report concluded, "[t]he 2010 guidance created an opportunity for sophisticated, for-profit pharmacy chains to realize larger margins than they otherwise could." Aaron Vandervelde, Kevin Erb, & Lauren Hurley, *For-Profit Pharmacy Participation in the 340B Program*, at 5 (Oct. 2020), https://bit.ly/3l4Jb5f (hereinafter "BRG Report"). It is thus little surprise that more than 100,000 arrangements now exist between contract pharmacies and covered entities—more than double the number of covered entity locations in the

entire Program, and many times more than the number of covered entity locations that lack an in-house pharmacy (and thus could plausibly claim to be using contract pharmacies to benefit their patients rather than simply to line their own pockets). *See* HRSA, *Office of Pharmacy Affairs, 340B OPAIS*, https://bit.ly/35IQHOb. Indeed, the Government Accountability Office ("GAO") recently reported a ***1,438% increase*** in the number of contract pharmacies distributing 340B outpatient drugs in the first seven years following HRSA's 2010 expansion. GAO, *Discount Drug Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480 (June 2018), https://bit.ly/3nAVVS3 (hereinafter "GAO Report").



This explosion of contract pharmacy arrangements is not a small matter. Nor is it remotely beneficial to patients, or indeed anyone other than the covered entities and contract pharmacies. Contract pharmacy arrangements are increasingly untethered to the original objectives of the 340B Program, allowing for-profit entities all over the country to generate "[o]utsized profit margins on 340B purchased medicines." BRG Report at 5. For example, the GAO reported that a single covered entity used as many as 439 distinct contract pharmacies—meaning each of those 439

pharmacies would seek drugs from manufacturers at the 340B prices. GAO Report at 18. Covered entities also used contract pharmacies up to 5,000 miles away. *Id.* at 22. Most remarkably, contract pharmacy arrangements benefit the five biggest for-profit retail chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—which now operate more than 60% of 340B contract pharmacies, despite accounting for only a third of pharmacies nationwide. *Id.* at 20, 22. These for-profit chains now operate at least 14,000 locations receiving 340B discounts.

HRSA's approach to contract pharmacies has not only unleashed abuses and program integrity concerns; it has also left manufacturers in an uncertain limbo, compounding the risk that they will face crippling sanctions. As noted, HRSA has statutory authority not only to assess manufacturer compliance with the 340B Program, but also to impose sweeping civil monetary penalties as high as $5,883 ***for each instance*** of knowingly and intentionally overcharging a covered entity. 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. § 10.11(a); 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020). That means a manufacturer that overcharges for a 340B drug by even one cent may be subject to massive penalties. By allowing contract pharmacies to participate in the 340B Program as though they were covered entities, HRSA has vastly increased the possibility that manufacturers may "overcharge" contract pharmacies and find themselves subject to sanctions.

B. The 340B Statute Does Not Contemplate Contract Pharmacies, Let Alone Require Manufacturers to Go Along with the Co-opting of the Program.

Notwithstanding HRSA's nonbinding guidance documents, the 340B Statute emphatically does not require manufacturers to provide 340B discounts to contract pharmacies. That is clear from the plain language of the statute. The 340B Statute expressly limits manufacturers' obligation to offer 340B prices to "each covered entity." 42 U.S.C. § 256b(a)(1); *see also id.* (authorizing HHS Secretary to "require that the manufacturer offer each ***covered entity*** covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other

purchaser at any price" (emphasis added)). And, crucially, the statute defines the term "covered entity" in exhaustive detail. Under the provision titled "'Covered entity' defined," the term is defined to mean "an entity that meets the requirements described in paragraph (5)" (which prohibits diversion and duplicate discounts) "and ***is*** one of the following":

> (A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).
>
> (B) An entity receiving a grant under section 256a of this title.
>
> (C) A family planning project receiving a grant or contract under section 300 of this title.
>
> (D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).
>
> (E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.
>
> (F) A black lung clinic receiving funds under section 937(a) of title 30.
>
> (G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.
>
> (H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.
>
> (I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.
>
> (J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).
>
> (K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).
>
> (L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act that—

> (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;
>
> (ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and
>
> (iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.
>
> (M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.
>
> (N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).
>
> (O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

42 U.S.C. § 256b(a)(4) (emphasis added). The statute thus lists 15 types of eligible entities, specifically designated because they potentially provide safety-net care, in painstaking detail. The list does not include commercial or retail pharmacies, as one would expect given Congress's focus on ensuring that savings flow to vulnerable patients through the medical facilities that serve them.

The 340B Statute does not have a process for creating "exceptions" to that exclusive list, either; nor does it authorize HHS or HRSA to expand the distribution functions to so-called "agents" of covered entities. In fact, it expressly prohibits "reselling" or "transferring" drugs to ***any person*** that is not a patient of the covered entity. *See id.* § 256b(a)(5)(B) (forbidding the "resell[ing]" or transfer[ing]" of 340B-discounted product to any person that is not a "patient" of the covered entity). Thus, contract pharmacy arrangements, which instruct wholesalers to honor 340B prices to for-profit commercial pharmacies, result in 340B-discounted product being diverted—*i.e.*, "otherwise transfer[red]" to another person or entity in violation of the statute. In other words, a covered entity may not transfer or sell 340B-discounted drugs to patients who are not eligible to receive them, and likewise not transfer or sell 340B-discounted drugs to any person or entity who is not its own patients—*e.g.*, to contract pharmacies.

C. Contract Pharmacies Flout Prohibitions on Drug Diversion and Duplicate Discounts, And Often Do Not Pass Along 340B Discounts to Patients.

There is a good reason that Congress did not include contract pharmacies in the list of covered entities: Contract pharmacies are not required to "pass along" to patients the spread between the discounted acquisition prices from manufacturers and the reimbursement paid by an insurer (or the price charged to the uninsured patient), and they rarely, if ever, do so. Nor are there any restrictions or reporting requirements related to how or even if the contract pharmacy redirects this 340B savings to benefit low-income or underserved patients in other ways.

Unsurprisingly, for-profit contract pharmacies typically take a portion of the savings on each drug dispensed and pocket the difference as pure profit, instead of reinvesting those revenues to expand access to affordable prescription drugs or other health care. Indeed, the 2018 GAO Report cited above concluded that, far from assisting low-income patients, ***45 percent*** of covered entities admitted they do not pass along ***any*** discount to ***any*** patients that use contract pharmacies.

GAO Report at 30; *see also* HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 2014), https://bit.ly/2UNDgWK (In most cases, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies," ***even though the contract pharmacies obtained the drugs at 340B-discounted prices***.). Nor is there any reason to believe that the remaining 55 percent pass meaningful savings on to patients. On the contrary, the GAO specifically noted that the remaining surveyed entities rarely pass on discounts. GAO Report at 10. What is more, a recent industry analysis found that "[t]he ***average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent***, compared with just 22 percent for non-340B medicines dispensed through independent pharmacies." BRG Report at 3; *see also id.* at 7 ("[I]ncome from the program is now being captured by some of the largest corporations in the world."). In short, permitting an unlimited number of contract pharmacy arrangements distorts the basic objectives of the 340B Program—to benefit vulnerable patients whose lives often depend on medicines they cannot afford.

Making matters worse, contract pharmacy arrangements have also led to unlawful drug diversions to ineligible persons and a practice known as duplicate discounts—*i.e.*, a situation in which the manufacturer pays ***both*** a 340B discount ***and*** a Medicaid rebate on the same utilization. 42 U.S.C. § 256b(a)(5)(A). Tellingly, multiple agencies have reported that "operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in house pharmacies." *E.g.*, GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 at 28 (Sept. 2011), https://bit.ly/3pFGwBR. That is because contract pharmacies often dispense 340B-covered outpatient drugs from the ***same inventory*** as drugs dispensed to all other customers, creating

opportunities for unlawful distributions to ineligible patients (and more ways for the contract pharmacies to profit). The GAO likewise has found that approximately two-thirds of diversion violations "involved drugs distributed at contract pharmacies." GAO Report at 44. Audits published on HRSA's own website also reveal that dozens of covered entities using contract pharmacies engage in drug diversion every year, and have for nearly a decade. *See, e.g.*, HRSA, 340B Program Integrity, *Audits of Covered Entity Results* (Apr. 2020), https://bit.ly/3fcAALF (83 out of 199 total audited entities had an adverse finding at a contract pharmacy in 2017).

Even members of Congress have raised concerns about retail pharmacy chains taking advantage of the 340B Program to turn enormous profits. In July 2013, for example, U.S. Senator Chuck Grassley sent a letter to Walgreens CEO Gregory Wasson detailing concerns about Walgreens' 5,400 contract pharmacy locations and demanding information such as a "summary of all profits generated as a result of participating in the 340B program as a contract pharmacy." *See* C. Grassley Ltr. to G. Wasson (July 31, 2013), https://bit.ly/3p2mAc0. The letter reported that Walgreens projected that dispensing 340B-discounted drugs through contract pharmacies would "add a ***minimum of $250 million***" in revenue over a 5-year period. *Id* (emphasis added). Those projections were accurate. A September 2020 analysis by an investment bank confirmed that Walgreens generated profits through 340B contract pharmacy arrangements "***in the hundreds of millions***." Raymond James, *340B Pharmacy Follow Up—Less Than $1.4B but Still Yuge* (Sept. 9, 2020) (emphasis added). Tellingly, in Walgreens' October 2020 10-K filing with the SEC, the company reported that any pricing changes "in connection with the federal 340B drug pricing program[] could ***significantly reduce [its] profitability***." Walgreens Boots Alliance, Inc. Form 10-K (Oct. 15, 2020), https://bit.ly/3p4rRQw (emphasis added).

D. Lilly's Distribution Program Curbs Unchecked Expansion and Abuses.

Against this backdrop, effective July 1, 2020, Lilly instructed its wholesalers to provide 340B discounts exclusively to covered entities and their child sites—and not to contract pharmacies—for certain formulations of Cialis®. Mindful of maintaining access to discounted drugs for all patients, Lilly permitted covered entities that do not operate an in-house pharmacy to designate an off-site contract pharmacy to fill 340B outpatient prescriptions. HRSA reviewed and posted Lilly's notice to covered entities on its 340B Program website. *See* HHS/HRSA/OPA 340B Program, Manufacturer Notices to Covered Entities, https://bit.ly/3p75xpp; *Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs*, https://bit.ly/3exsz3E. Shortly thereafter, Lilly extended its distribution plan to all covered outpatient drugs, effective September 1, 2020.

In addition to retaining its policy for covered entities without a contract pharmacy, Lilly announced that it would also allow contract pharmacies wholly owned by a covered entity to access 340B-priced product. It also agreed to offer 340B prices to contract pharmacies for certain insulin products, provided the contract pharmacy passed the ***entire 340B discount*** to the patient rather than pocketing the profits. Lilly's insulin exception is based on an Executive Order issued on July 24, 2020, which conditions future grants to Federally Qualified Health Centers (FQHCs) on making insulin and injectable epinephrine available to patients at the 340B-discounted price. *See* Executive Order on Access to Affordable Life-saving Medications (July 24, 2020), https://bit.ly/2IeWYYK. The insulin exception is also consistent with other Lilly programs dedicated to reducing out-of-pocket expenses. For instance, Lilly provides automatic discounts at retail pharmacies for any patient with commercial insurance to cap monthly insulin costs at $95. Moreover, in April 2020, Lilly announced that both uninsured and commercial-insurance patients can purchase a monthly prescription of Lilly insulin for $35 through the Lilly Insulin Value

Program. Lilly also distributes three non-branded insulins with a list price 50 percent lower than brand name alternatives and donates insulin for distribution at free clinics for qualifying patients with demonstrated financial need.

E. HRSA Initially Gave Lilly's Distribution Program a Green Light, But It Later—And Abruptly—Changed Course.

Lilly was transparent with HRSA and HHS throughout the entire process of unveiling its distribution plans. Over five months ago, in response to Lilly's initial outreach in May 2020 describing its distribution plan, HRSA responded that its 2010 Contract Pharmacy Guidance did not contain "binding regulations." HRSA then publicly confirmed that the guidance was "not legally enforceable." And after exchanging other written communications during June 2020, HRSA not only stated two days before Lilly's distribution plan took effect for Cialis® that it did "not have any further questions at this time," but posted Lilly's announcement of the plan to its agency website. Lilly then sent one further letter to HHS on July 17, outlining its communications with HRSA and explaining that its distribution plan complied with all obligations under the 340B Statute. In sum, HRSA gave no indication that it believed Lilly's proposed plan violated the 340B Statute, and gave every indication of the contrary.

With no negative response from HHS, Lilly told HRSA a month later on August 19 that it planned to expand its distribution plan beyond Cialis®. HRSA responded on August 26—five days before Lilly's plan took effect—surprisingly asserting that it "is considering whether [Lilly's] new proposed policy constitutes a violation of section 340B and whether sanctions apply," including, but "not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256(d)(1)(B)(vi)." Lilly immediately issued a follow-up letter, asking HRSA to clarify which provision of the 340B Statute Lilly's plan potentially violated and highlighting the imminent harm resulting from HRSA's "threats of sanctions" designed to force Lilly to acquiesce to HRSA's position. Instead

of responding to Lilly, HRSA released a public statement to the *340B Report* publication on September 2 repeating its threat that it is "considering whether manufacturer policies, ***including Lilly's***, violate the 340B statute and whether sanctions may apply." Bronwyn Mixter, *BREAKING: HRSA Is Investigating Whether Manufacturer Policies to Restrict 340B Pricing at Contract Pharmacies Violates Statute*, 340B Report (Sept. 2, 2020), https://bit.ly/2GzoZtk. HRSA has still not responded directly to the letter.

Meanwhile, Lilly corresponded further with HHS, seeking "confirmation that HHS is not considering, and will not consider, sanctions against Lilly in response to Lilly's stated plan to discontinue providing 340B discounts to contract pharmacies." HHS responded nearly two weeks later, on September 21, declining to say whether the policy "would subject Lilly to sanctions."

II. Plaintiffs' Lawsuit

Plaintiffs filed this lawsuit on October 9, 2020 against HRSA, the Administrator of HRSA, HHS, and the Secretary of HHS (collectively, "Defendants"). Plaintiffs seek to compel Defendants to take action against Lilly (and others) "to enforce the Plaintiff Covered Entities' right to purchase and dispense covered outpatient drugs via contract pharmacies at 340B discounts." Compl. at 35. In particular, Plaintiffs seek "an order from this Court directing the [HHS] Secretary to act now against the Drug Companies," *id.* ¶ 5, and "a writ of mandamus requiring the Secretary … to enforce the Plaintiff Covered Entities' rights to purchase covered outpatient drugs at 340B discounts via contract pharmacy arrangements," *id.* ¶ 6.

Defendants have never once told Lilly its distribution plan violates any provision of the 340B Statute. On the contrary, HRSA has consistently affirmed that its guidance authorizing such discounts is non-binding and "not legally enforceable." Relying on that position, Lilly offers discounts only to covered entities, and not generally to contract pharmacies, because it firmly believes the statute does not require discounts to highly profitable contract pharmacies. Yet

Plaintiffs seek relief that would reject HRSA's position, require manufacturers such as Lilly to provide 340B discounts to contract pharmacies, and declare that a manufacturer charging a contract pharmacy more than the 340B ceiling price "has overcharged the covered entity in violation of the 340B Statute." *Id.* ¶ 90. They also seek to impose massive financial penalties on Lilly (by name) and to exclude it from the Medicaid and Medicare Part B programs altogether.[1]

Indeed, despite acknowledging that "covered entities do not have a private right of action" against participating manufacturers, *id.* ¶ 50, and that "only the Secretary may enforce the manufacturer's obligation to charge at or below the 340B ceiling price," *id.* ¶ 48, Plaintiffs seek a judicial order compelling HRSA "to order Lilly … to refund overpayments owed to the Plaintiff Covered Entities" and "impose [civil monetary penalties] upon … Lilly … unless and until [it complies] with the requirements of the 340B statute and honor[s] contract pharmacy arrangements," *id.* at 35-36. Plaintiffs also seek to compel HRSA to "revoke the PPA" between Lilly and HRSA, "thereby excluding drugs produced by such manufacturer from coverage under the Medicaid and Medicare Part B insurance programs." *Id.* at 36.

As a result, if Plaintiffs succeed—despite the 340B Statute's clear limitation with regard to who is a covered entity and who is not—Lilly would find itself facing the prospect of massive civil monetary penalties and even the potential "loss of Medicaid and Medicare Part B reimbursement for all of [its] products." *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 46 (D.D.C. 2015).

[1] Plaintiffs "request a writ of mandamus requiring the Secretary to implement ADR regulations" as well. Compl. ¶ 6.

ARGUMENT

I. Lilly Has A Right To Intervene Under Rule 24(a).

Lilly's direct financial and legal stake in the outcome of this lawsuit warrants intervention. Rule 24(a) provides that on "timely motion," a court "must permit anyone to intervene" who "claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2). The D.C. Circuit takes a "liberal approach to intervention," *The Wilderness Soc'y v. Babbitt*, 104 F. Supp. 2d 10, 18 (D.D.C. 2000), and has "distilled" Rule 24(a) into "four factors":

> (1) the timeliness of the motion; (2) whether the applicant claims an interest relating to the property or transaction which is the subject of the action; (3) whether the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest; and (4) whether the applicant's interest is adequately represented by existing parties.

Wash. All. of Tech. Workers v. DHS, 395 F. Supp. 3d 1, 9-10 (D.D.C. 2019) (quoting *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 731 (D.C. Cir. 2003)). A putative intervenor must also establish that it has standing under Article III. *Id.* at 10. Plaintiffs' lawsuit threatens massive financial penalties and other punitive action against Lilly for lawfully restricting discounts to commercial pharmacies not listed in the statute. With no party to protect its legal and financial interests at stake, the Court should permit Lilly to intervene in this lawsuit.

First, Lilly's motion is timely. Timeliness "is to be judged in consideration of all the circumstances," including "time elapsed since the inception of the suit" and "the probability of prejudice to those already parties in the case." *United States v. British Am. Tobacco Australia Servs., Ltd.*, 437 F.3d 1235, 1238 (D.C. Cir. 2006). A Rule 24 motion brought at the early stages of the litigation is thus generally deemed timely. Such is the case here. Lilly filed its motion to intervene a mere five weeks after Plaintiffs filed their complaint. That is comfortably within what

is routinely deemed timely. *See, e.g., Karsner v. Lothian*, 532 F.3d 876, 886 (D.C. Cir. 2008) (one month); *Fund for Animals*, 322 F.3d at 735 (two months after case began, before agency answered).

Furthermore, Lilly's intervention will not prejudice any party in the case. *See Ute Indian Tribe of Uintah & Ouray Indian Reservation v. U.S. Dep't of the Interior*, No. 1:18-CV-00547 (CJN), 2020 WL 1465886, at *1 (D.D.C. Feb. 5, 2020) (deeming "'whether any delay in moving for intervention will prejudice the existing parties to the case'" the 'critical factor'" (quoting *Akiachak Native Cmty. v. U.S. Dep't of Interior*, 584 F. Supp. 2d 1, 5 (D.D.C. 2008))). No briefing schedule has yet been set; in fact, Defendants have not even appeared, let alone filed a responsive pleading, and nothing else has occurred since Plaintiffs filed their complaint. Lilly is also prepared to participate in the case on whatever schedule the Court establishes and to work with Defendants (and any other potential intervenor) to avoid unnecessary delay and duplication of efforts.

Second, Lilly undeniably has an "interest relating to the property or transaction that is the subject of" Plaintiffs' claims, and therefore likewise has standing under Article III. Fed. R. Civ. P. 24(a)(2); *see Fund for Animals*, 322 F.3d at 735 (standards for Rule 24(a) and Article III standing interest are the same). Courts routinely find the interest and standing requirements met where, as here, "a party benefits from agency action, the action is then challenged in court, and an unfavorable decision would remove the party's benefit." *Crossroads Grassroots Policy Strategies v. FEC*, 788 F.3d 312, 317 (D.C. Cir. 2015); *see also, e.g., Fund for Animals*, 322 F.3d at 733; *Military Toxics Project v. EPA*, 146 F.3d 948 (D.C. Cir. 1998). Plaintiffs have challenged agency (in)action by HRSA and HHS, and "an unfavorable decision" would directly harm Lilly's interests. Indeed, Lilly stands to suffer financial injury directly traceable to this case and redressable only by a decision rejecting Plaintiffs' claims. *See generally Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992); *see also, e.g., Fund for Animals*, 322 F.3d at 733, 735 (putative intervenor's threatened

loss of tourist dollars from plaintiff's challenge to agency action satisfied standing and interest requirements); *Crossroads Grassroots Policy Strategies*, 788 F.3d at 318, 320 (putative intervenor's threatened exposure to enforcement proceedings satisfied standing and interest requirements). That is more than enough under Rule 24(a)(2) and Article III.

Third, disposition of this action will impair Lilly's ability to protect its interests. In analyzing this factor, courts must look "to the practical consequences of denying intervention." *Fund for Animals*, 322 F.3d at 735 (internal quotations omitted). The practical consequences here are severe, and they are apparent on the face of Plaintiffs' complaint. Again, if Plaintiffs secure a declaration "that they are entitled to purchase and dispense drugs at 340B discounts through arrangements with contract pharmacies," Compl. ¶ 84, then Lilly will be legally obligated to provide drugs to commercial contract pharmacies at heavily discounted prices, at great financial cost. Even if Lilly were to urge its own interpretation of the statute in another proceeding—whether in its own affirmative declaratory judgment action or in response to an enforcement proceeding initiated by the government—this Court's ruling "would have persuasive weight with a new court." *Crossroads Grassroots Policy Strategies*, 788 F.3d at 320. Put differently, an adverse judgment in this case would impair Lilly's interest because "a judicial pronouncement" that Lilly's position on the 340B Statute is "contrary to law" would "make the task of reestablishing the status quo" much more "difficult and burdensome." *Id.*; *see also Nat. Res. Def. Council v. Costle*, 561 F.2d 904, 910 (D.C. Cir. 1977) (It "is not enough to deny intervention under 24(a)(2) because applicants may vindicate their interests in some later, albeit more burdensome, litigation."). Moreover, Lilly's financial losses in the interim "would be substantial and likely irreparable." *Fund For Animals*, 322 F.3d at 735. If denied the right to intervene, Lilly could be

ordered "to refund overpayments" to contract pharmacies and pay a $5,883 penalty for each drug dispensed without any opportunity to vindicate its legal position. *See* Compl. at 35-36.

Fourth, none of the current defendants in this lawsuit (or other manufacturers if permitted to intervene) adequately represent Lilly's interest. The D.C. Circuit has described this requirement as "not onerous," *Fund for Animals*, 322 F.3d at 735; a movant "ordinarily should be allowed to intervene unless it is clear" that existing parties "will provide adequate representation," *United States v. AT&T*, 642 F.2d 1285, 1293 (D.C. Cir. 1980). The only parties besides Plaintiffs (who seek a court order compelling the government to penalize Lilly) are government agencies and officials: HRSA and its Administrator, plus HHS and its Secretary. These defendants cannot adequately represent Lilly's financial interests while also representing the interests of the public at large. The government "would face a potential conflict of interest were it to represent both the general interests of its citizens and the financial interests of" the proposed intervenor. *Dimond v. District of Columbia*, 792 F.2d 179, 193 (D.C. Cir. 1986). Indeed, the government "would be shirking its duty" to the public "were it to advance [Lilly's] narrower interest at the expense of its representation of the general public interest." *Id.* at 192-93.

That is true as a general matter: Courts "look skeptically on government entities serving as adequate advocates for private parties," *Crossroads Grassroots Policy Strategies*, 788 F.3d at 321, and the already-low adequate-representation bar is particularly low when the would-be intervenor is a private party asserting a "'financial stake in the outcome' of the suit" and the defendant is a government, *Alphapointe v. Dep't of Veterans Affairs*, No. 19-cv-02465, 2019 WL 7290853, at *1 (D.D.C. Aug. 26. 2019) (quoting *Crossroads*, 788 F.3d at 321); *see also Fund for Animals*, 322 F.3d at 736 & n.9 (collecting cases supporting proposition that "governmental entities do not adequately represent the interests of aspiring intervenors").

It is also particularly true here: HRSA has publicly stated it "is considering whether manufacturer policies, including Lilly's, violate the 340B statute and whether sanctions may apply." Compl. ¶ 58 (quoting Mixter, *supra*). In fact, HRSA has vacillated in its responses to Lilly's distribution program, further demonstrating that neither HRSA nor its Administrator nor HHS could possibly represent Lilly's interest in an adequate manner.

Finally, the other manufacturers named in the Complaint could not adequately represent Lilly's interests. The other manufacturers have different 340B policies, *see* Compl. ¶¶ 57, 60, 63, 64, and "might have strategic reasons not to press certain arguments available to" Lilly, *see Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1070 (D.C. Cir. 1998), or interests that "might diverge during the course of litigation," *Fund for Animals*, 322 F.3d at 736.

In sum, Lilly satisfies the requirements of Rule 24(a) and should be allowed to intervene as of right.

II. In The Alternative, The Court Should Allow Lilly To Intervene Under Rule 24(b).

Rule 24(b) provides that on "timely motion" a court "may permit anyone to intervene" who "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). Factors include (1) whether there is an independent basis for subject matter jurisdiction over the intervenor's claims, (2) whether the motion is timely, and (3) whether a claim or defense has a question of law or fact in common with the main action. *EEOC v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1046-47 (D.C. Cir. 1998). Each factor supports intervention here.

First, the Court has subject matter jurisdiction over Lilly's defenses, which arise under federal law and concern the interpretation of the federal 340B Statute. ***Second***, Lilly's motion is timely and will not "unduly delay or prejudice the adjudication of any original party's rights." Fed. R. Civ. P. 24(b)(3). Absent the ability to intervene, Lilly's rights would be seriously impaired. ***Third***, Lilly's anticipated defenses all relate to the question at the heart of this proceeding—

namely, whether the 340B Statute requires pharmaceutical manufacturers to provide 340B discounts to contract pharmacies. At a minimum, then, Lilly should be permitted to intervene.

CONCLUSION

For the foregoing reasons, the Court should grant the motion to intervene as of right under Rule 24(a), or in the alternative should allow Lilly to intervene under Rule 24(b).

Respectfully submitted,

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November 20, 2020

CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States District Court for the District of Columbia by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ *Daniel T. Donovan*
Daniel T. Donovan

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RYAN WHITE CLINICS FOR 340B ACCESS,

MATTHEW 25 AIDS SERVICES, INC.,

CHATTANOOGA C.A.R.E.S., DBA CEMPA COMMUNITY CARE,

Plaintiffs,

v.

ALEX M. AZAR II,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

THOMAS J. ENGELS,

HEALTH RESOURCES AND SERVICES ADMINISTRATION,

Defendants,

SANOFI-AVENTIS U.S. LLC,

Proposed Intervenor-Defendant.

Civil Action No. 20-cv-2906 (KBJ)

MEMORANDUM OF LAW IN SUPPORT OF SANOFI-AVENTIS U.S. LLC'S MOTION TO INTERVENE

Plaintiffs ask this Court to direct the government to take a series of significant enforcement actions against Sanofi-Aventis U.S. LLC ("Sanofi") and other pharmaceutical manufacturers, on the theory that the manufacturers have not provided discounted drug pricing to which Plaintiffs claim they are statutorily entitled. Plaintiffs' claims are replete with problems—but if Plaintiffs obtain their requested relief, Sanofi will be exposed to significant harms. Federal

Rule of Civil Procedure 24 entitles Sanofi to intervene in this matter to defend its interests, which no other party adequately represents.

BACKGROUND

This case concerns Section 340B of the Public Health Service Act, which requires pharmaceutical manufacturers participating in Medicare and Medicaid to offer outpatient drugs at discounted prices to certain "covered entities" that provide care for many uninsured or low-income patients (the "340B Program"). *See* 42 U.S.C. § 256b. Covered entities that claim to have been overcharged under the 340B Program cannot sue manufacturers directly. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113–14 (2011). But Congress authorized the imposition of civil monetary penalties on manufacturers that "knowingly and intentionally" overcharge covered entities. *See* 42 U.S.C. § 256b(d)(1)(B)(vi). Congress also directed HHS to promulgate regulations "to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged." *Id.* § 256b(d)(3)(A).

Plaintiffs are several covered entities and a covered-entity trade association that participate in the 340B Program. *See* Dkt. 1 ("Compl.") ¶ 1. They allegedly participate in the 340B Program "primarily, or exclusively," through their relationships with third-party pharmacies known as "contract pharmacies." *Id.* Under this alleged arrangement, Plaintiffs' orders for discounted drugs are shipped to contract pharmacies and billed to Plaintiffs. *Id.* But Plaintiffs contend that they have not received discounted prices from four drug companies: Eli Lilly and Company ("Lilly"), AstraZeneca PLC ("AstraZeneca"), Sanofi, and Novartis Pharmaceuticals Corporation ("Novartis"). According to the Complaint, Lilly and AstraZeneca have declined to provide discounted drugs through contract-pharmacy arrangements, and instead offered to provide discounted drugs only to covered entities directly. *See id.* ¶¶ 53–59, 62–63.

As alleged, Sanofi and Novartis will provide discounted drugs to contract pharmacies, but only on conditions that Plaintiffs refuse to accept. *See id.* ¶¶ 60–61, 64.

For Sanofi, Plaintiffs complain that the company requires covered entities to provide claims data to a third-party vendor, Second Sight Solutions, for 340B Program drugs purchased through contract pharmacies. *See id.* ¶¶ 60–61. As Sanofi explained when announcing this integrity initiative, Sanofi was "concerned about the rate of duplicate discounting on Medicaid prescriptions filled with 340B-purchased drugs." Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services (July 2020) (cited by Compl. ¶ 60) ("Gleeson Letter"). Duplicate discounting, which can occur when the same claims are submitted both for 340B discounts and for Medicaid rebates, is impermissible. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(A). Sanofi also noted that manufacturers can "pay ineligible rebates . . . due to the lack of transparency in the 340B program." Gleeson Letter, *supra*, at 1. With the data requested, Sanofi can "match against rebate claims it receives to ensure it isn't paying ineligible discounts." *Id.* But Plaintiffs contend that Sanofi's integrity initiative improperly deprives them of 340B discounts.

Notably, however, Plaintiffs do not allege that Sanofi has refused to participate in the 340B Program. Nor do Plaintiffs allege that Sanofi has refused to supply 340B-discounted drugs to covered entities through contract pharmacies. Nor, for that matter, do Plaintiffs allege that Sanofi has failed to "*offer* [them] covered outpatient drugs for purchase at or below" the discounted price, which is what the statute governing the 340B Program requires. 42 U.S.C. § 256b(a)(1) (emphasis added).

Nonetheless, Plaintiffs filed this action against the government—specifically, the Department of Health and Human Services ("HHS"), its Secretary, the Health Resources and

Services Administration ("HRSA") (which administers the 340B Program), and its Administrator, *see* Compl. ¶¶ 15–18—asking for a declaratory judgment stating that Sanofi and other drug manufacturers must supply 340B-discounted drugs to contract pharmacies. *Id.* at 35 ¶ 1. Plaintiffs also ask for an order "directing the Secretary" to enforce their alleged "right to purchase and dispense covered outpatient drugs via contract pharmacies at 340B discounts." *Id.* at 35 ¶ 3. And Plaintiffs ask for an order "directing the Secretary" to take several specific enforcement actions against Sanofi and the other three manufacturers named in the Complaint—to order the manufacturers "to refund overpayments owed to" Plaintiffs, *id.* at 35 ¶ 4; to "impose CMPs [civil monetary penalties]" on the manufacturers "unless and until they . . . honor contract pharmacy arrangements," *id.* at 36 ¶ 5; and to "exclud[e] drugs produced by [each] manufacturer from coverage under the Medicaid and Medicare Part B insurance programs," by "revok[ing]" each manufacturer's participation agreement for the programs, *id.* at 36 ¶ 6. Finally, Plaintiffs ask this Court to direct the Secretary "to promulgate ADR regulations" as § 256b(d)(3)(A) requires, but as has not yet happened. *Id.* at 35 ¶ 2. Plaintiffs seek their requested relief through four counts, asserting claims under the Declaratory Judgment Act (Count I), *see id.* ¶¶ 83–90, the Fifth Amendment's Due Process Clause (Count II), *see id.* ¶¶ 91–97, the Administrative Procedure Act (Count III), *see id.* ¶¶ 98–103, and for a writ of mandamus (Count IV), *see id.* ¶¶ 104–107.

Plaintiffs filed their Complaint on October 9, 2020. The government's response to the Complaint is currently due on December 12, 2020. Sanofi now moves to intervene, so that it may defend its interests that are explicitly implicated by Plaintiffs' claims. Sanofi understands that Lilly is also moving to intervene in this action. If this motion is granted, Sanofi intends to file a motion to dismiss the Complaint.

ARGUMENT

I. Sanofi Can Intervene as of Right Under Rule 24(a).

Sanofi is entitled to intervene in this matter as of right under Federal Rule of Civil Procedure 24(a). Rule 24(a) provides that "[o]n timely motion," a court "*must* permit anyone to intervene" who "claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2) (emphasis added). The D.C. Circuit takes a "liberal approach to intervention," *The Wilderness Soc'y v. Babbitt*, 104 F. Supp. 2d 10, 18 (D.D.C. 2000), and has "distilled" Rule 24(a) into "four factors":

> (1) the timeliness of the motion;
> (2) whether the applicant claims an interest relating to the property or transaction which is the subject of the action;
> (3) whether the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest; and
> (4) whether the applicant's interest is adequately represented by existing parties.

Wash. All. of Tech. Workers v. DHS, 395 F. Supp. 3d 1, 9–10 (D.D.C. 2019) (quoting *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 731 (D.C. Cir. 2003)). A putative intervenor must also demonstrate its Article III standing. *Id.* at 10. Sanofi's request to intervene satisfies these factors with ease.

First, Sanofi's motion is timely. Timeliness is "judged in consideration of all the circumstances," including "time elapsed since the inception of the suit" and the "probability of prejudice to those already parties in the case." *United States v. British Am. Tobacco Australia Servs., Ltd.*, 437 F.3d 1235, 1238 (D.C. Cir. 2006). Sanofi moves to intervene less than two months after Plaintiffs filed suit. Intervention motions filed this quickly are routinely granted as

timely. *See, e.g., Karsner v. Lothian*, 532 F.3d 876, 886 (D.C. Cir. 2008) (one month after case began); *Fund for Animals*, 322 F.3d at 735 (less than two months after case began).

Nor will Sanofi's intervention prejudice any party already in the case. Defendants have not even appeared yet, much less filed a responsive pleading, and Sanofi's intervention thus should not cause any delay. *See Friends of Animals v. Ashe*, 2015 WL 13672460, at *3 (D.D.C. July 10, 2015) (noting intervention "before the deadline for the federal defendants to answer" would not prejudice existing parties).

Second, Sanofi's interest in this action satisfies Rule 24(a) and establishes its Article III standing. *See* Fed. R. Civ. P. 24(a)(2); *Fund for Animals*, 322 F.3d at 735 (standards for Rule 24(a) interest and Article III standing are the same). These requirements are met when a proposed intervenor "would suffer concrete injury if the court were to grant the relief the plaintiffs seek." *Fund for Animals*, 322 F.3d at 733. And there is "little question" that complained-of government "action or inaction" injures a party that would be the "object of the action (or forgone action) at issue." *Id.* at 733–34 (internal quotation marks and citations omitted); *see also, e.g., Crossroads Grassroots Policy Strategies v. FEC*, 788 F.3d 312, 317 (D.C. Cir. 2015); *Military Toxics Project v. EPA*, 146 F.3d 948 (D.C. Cir. 1998). That is unquestionably the case here, where Plaintiffs want the government to take enforcement actions against Sanofi—and expressly seek an order that would require Sanofi to pay "refunds" to Plaintiffs as well as significant civil monetary penalties to the government. *See* Compl. at 35–36, ¶¶ 4–5. These financial injuries for Sanofi would be directly traceable to Plaintiffs' claims and redressable by this Court's rejection of those claims. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992); *see also, e.g., Fund for Animals*, 322 F.3d at 733, 735 (proposed intervenor's threatened financial loss from challenge to agency action satisfied standing and interest

requirements); *Crossroads Grassroots Policy Strategies*, 788 F.3d at 318, 320 (proposed intervenor's threatened exposure to enforcement proceedings satisfied standing and interest requirements).

Third, the resolution of this matter will plainly affect Sanofi's ability to protect its interests. The "practical consequences" of denying Sanofi's motion to intervene would be serious, when granting Plaintiffs' requested relief would cause a government order that levies financial penalties upon Sanofi and also disqualifies Sanofi from participating in Medicare and Medicaid. *Fund for Animals*, 322 F.3d at 735. Nor does it matter that Sanofi could theoretically challenge such an order "in some later, albeit more burdensome, litigation." *Nat. Res. Def. Council v. Costle*, 561 F.2d 904, 910 (D.C. Cir. 1977). To the contrary, undoing such "a judicial pronouncement"—and thus restoring the current status quo—would be unduly "difficult and burdensome." *Crossroads Grassroots Policy Strategies*, 788 F.3d at 320.

Fourth, the current defendants in this lawsuit—all federal agencies and officials—do not adequately represent Sanofi's interests. This requirement is "not onerous," *Fund for Animals*, 322 F.3d at 735, and a movant "ordinarily should be allowed to intervene unless it is clear" that existing parties "will provide adequate representation," *United States v. AT&T*, 642 F.2d 1285, 1293 (D.C. Cir. 1980). Moreover, courts "look skeptically on government entities serving as adequate advocates for private parties." *Crossroads Grassroots Policy Strategies*, 788 F.3d at 321; *see also Fund for Animals*, 322 F.3d at 736 & n.9 (collecting cases). This reflects that the government's "obligation is to represent the interests of the American people," not the "narrower interest[s]" of particular private parties. *Fund for Animals*, 322 F.3d at 736–37. Indeed, the government "would face a potential conflict of interest were it to represent both the general interests of its citizens and the financial interests of" a proposed intervenor. *Dimond v. District*

of Columbia, 792 F.2d 179, 193 (D.C. Cir. 1986). That is particularly true where, as here, Plaintiffs seek to compel government enforcement action *against* Sanofi. *See* Compl. at 35–36, ¶¶ 4–5. As government parties, Defendants thus cannot adequately represent Sanofi's interests while also representing the interests of the public.

Nor could the other manufacturers named in the Complaint, if permitted to intervene, adequately represent Sanofi's interests. For one thing, the different manufacturers have taken different approaches to contract pharmacies under the 340B Program. *See id.* ¶¶ 57, 60, 63, 64. A manufacturer whose practices differ from Sanofi's practices "might have strategic reasons not to press certain arguments available to" Sanofi. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998). And even if the manufacturers share "a partial congruence of interests, that does not guarantee the adequacy of representation." *Fund for Animals*, 322 F.3d at 737.

In short, Sanofi easily meets the requirements for intervention as of right under Rule 24(a). The motion should thus be granted.

II. Alternatively, Sanofi Should Be Permitted to Intervene Under Rule 24(b).

Alternatively, the Court should permit Sanofi to intervene under Rule 24(b). Under that rule, on "timely motion," the court "may permit anyone to intervene" who "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b). Courts "liberally" assess (1) whether there is an independent basis for subject matter jurisdiction over an intervenor's claims or defenses, (2) whether the motion is timely, and (3) whether a claim or defense has a question of law or fact in common with the main action. *EEOC v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1046–47 (D.C. Cir. 1998); *In re Vitamins Antitrust Litig.*, 2001 WL 34088808, at *3 (D.D.C. Mar. 19, 2001). Moreover, courts have "eschewed

strict readings of the phrase 'claim or defense,' allowing intervention even in 'situations where the existence of any nominate "claim" or "defense" is difficult to find.'" *Nat'l Children's Ctr.*, 146 F.3d at 1046 (quoting *Nuesse v. Camp*, 385 F.2d 694, 704 (D.C. Cir. 1967)).

Each of these factors supports Sanofi's intervention. *First*, the Court has subject matter jurisdiction over the defenses Sanofi may assert in response to the relief sought by Plaintiffs. *See* Compl. at 35–36, ¶¶ 4–5. Those defenses arise under federal law and concern the meaning and force of federal statutes and regulations. *Second*, as explained, Sanofi's motion is timely and will not "unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3). *Third*, the defenses Sanofi may assert against the imposition of fines or other enforcement actions plainly relate to Plaintiffs' claims and the relief they seek. *See* Compl. at 35–36, ¶¶ 4–5.

CONCLUSION

For the reasons explained, the Court should grant Sanofi's motion to intervene.

Dated: November 20, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States District Court for the District of Columbia by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

November 20, 2020

s/ Brett A. Shumate
Brett A. Shumate

Exhibit C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RYAN WHITE CLINICS FOR 340B ACCESS, et al., *Plaintiffs*, v. ALEX M. AZAR II, et al., *Defendants*.	Case Number 1:20-cv-2906

MEMORANDUM IN SUPPORT OF ASTRAZENECA'S MOTION TO INTERVENE

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November 24, 2020

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INTRODUCTION

The 340B Drug Pricing Program, 42 U.S.C. § 256b, caps the prices that drug manufacturers can charge for out-patient medications sold to certain healthcare facilities, called "covered entities," that cater to underserved populations. Because the program is targeted at assisting these vulnerable populations—not providing windfalls to for-profit corporations—Congress included safeguards against the fraud and abuse that can occur when covered entities divert discounted 340B drugs to non-covered entities or persons. Congress also carefully circumscribed the types of covered entities that may participate in the program, specifically identifying by statute fifteen eligible categories. *Id.* § 256b(a)(4)(A)-(*O*). Off-site, for-profit pharmacies (like CVS or Walgreens) conspicuously were *not* included on the list of covered entities. That much is undisputed.

In 2010, however, the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) that administers the 340B program, issued nonbinding "interpretive" guidance that has transformed the scheme that Congress created. The guidance purports to authorize covered entities to enter into contracts with an unlimited number of off-site, for-profit pharmacies—called "contract pharmacies"—under which these pharmacies can directly purchase drugs at deeply discounted 340B prices. Over the decade that followed HRSA's guidance, use of contract pharmacies has increased exponentially, to more than 100,000 documented contract pharmacy arrangements. That sharp increase has been directly followed by the very abuses and diversion that Congress feared: Ample evidence demonstrates that 340B discounts are now rarely passed on to patients, going instead to intermediaries (including contract pharmacies themselves).

In response to these systemic problems, some drug manufacturers, including proposed intervenor AstraZeneca LP, have begun to limit the number of contract pharmacy arrangements they will recognize. Consistent with its statutory obligations, AstraZeneca has continued to offer

340B drugs to each covered entity on non-discriminatory terms at the 340B price; AstraZeneca has also permitted covered entities that lack on-site pharmacies to use an off-site contract pharmacy arrangement. But AstraZeneca has announced that, effective October 1, it would no longer recognize an *unlimited* number of contract pharmacy arrangements. Instead, it will recognize one such arrangement per covered entity that does not maintain its own on-site pharmacy.

AstraZeneca's policy is intended to bring balance back to the 340B program, by limiting the potential for abuse while also ensuring that all patients served by 340B covered entities have access to 340B drugs at 340B prices. And in the short time since it went into effect, more than 1,200 covered entities that lack an on-site pharmacy have already registered a contract pharmacy with AstraZeneca, and AstraZeneca has continued offering 340B pricing on 340B drugs dispensed at those contract pharmacies.

Plaintiffs (a trade association and two covered entities) are not satisfied with these new arrangements. They sued the government, arguing that HRSA's nonbinding "interpretive" guidance is actually mandatory. They seek a court order declaring that they are entitled to enter into as many contract pharmacy arrangements as they want—even with pharmacies located thousands of miles away in other states—and that manufacturers are required to honor those agreements. What is more, Plaintiffs ask this Court to force HRSA to levy substantial legal and monetary sanctions against non-party drug manufacturers (including AstraZeneca) whom they falsely accuse of denying them access to 340B pricing. Plaintiffs seek to exclude these manufacturers altogether from participation in Medicaid and Medicare Part B.

Given these stakes, AstraZeneca must be allowed to intervene in this lawsuit to set the record straight and defend its interests. Although Plaintiffs' suit is nominally against the government—the only named Defendants are governmental agencies and their officials—it is plain

from the face of the Amended Complaint that this suit directly implicates the interests of AstraZeneca. Plaintiffs call into question the lawfulness of specific contract pharmacy policies adopted by manufacturers, including AstraZeneca; they blatantly mischaracterize AstraZeneca's 340B policy; and they seek relief that targets non-party drug manufacturers, including AstraZeneca, for serious sanctions. Indeed, Plaintiffs practically admit that they *would have* sued the manufacturers directly, if only such a suit were not foreclosed by Supreme Court precedent.

Nor can AstraZeneca rely on the governmental Defendants to adequately represent AstraZeneca's interests. HRSA has already threatened to take legal positions that are directly adverse to AstraZeneca and that contradict its reading of the 340B statute: Despite HRSA's repeated concessions that its "interpretive" guidance is unenforceable, HRSA has nevertheless asserted that it is "considering" imposing civil penalties on AstraZeneca for noncompliance.

In light of these circumstances, only AstraZeneca can protect its interests in demonstrating the lawfulness of its policy. The Court should grant AstraZeneca's motion to intervene as a defendant in this lawsuit.

BACKGROUND

I. Statutory and Regulatory Background

A. The 340B Program

Section 340B of the Public Health Services Act "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as covered entities, that provide healthcare to certain underserved populations. *Pharmaceutical Research & Manufacturers of Am. v. HHS*, 43 F. Supp. 3d 28, 31 (D.D.C. 2014) (*PhRMA*) (quoting *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011)). As a condition of receiving coverage and reimbursement for its drugs under Medicaid and Medicare Part B, a pharmaceutical manufacturer must enter into a pharmaceutical pricing agreement with HHS. *See* 42 U.S.C.

§ 256b(a)(1). In that agreement, the manufacturer must "offer each covered entity covered outpatient drugs for purchase" at a specified discount price "if such drug is made available to any other purchaser at any price." *Id.* This is known as the 340B program's must-offer requirement. Manufacturers that "knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the [340B discount price]" are subject to civil monetary penalties. *Id.* § 256b(d)(1)(B)(vi)(III).

Congress enacted the 340B program "to enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Balanced against its goal of increasing access, however, Congress also recognized the need to "assure the integrity of the drug price limitation program." *Id.* at 16. To that end, Congress imposed three requirements on covered entities. *Id.* at 16-17. First, it prohibited covered entities that receive 340B discounted drugs from *also* obtaining payment under Medicaid for dispensing those same drugs (known as "duplicate discounts"). 42 U.S.C. § 256b(a)(5)(A). Second, it forbade covered entities from reselling or otherwise transferring such drugs to persons other than their patients (known as "diversion"). *Id.* § 256b(a)(5)(B). Third, it subjected covered entities to audit to verify compliance with these requirements. *Id.* § 256b(a)(5)(C).

Consistent with the purpose of benefiting underserved patients, covered entities under the original 340B statute were "generally disproportionate share hospitals—hospitals that serve indigent populations." *PhRMA*, 43 F. Supp. 3d at 31. Congress has added to the list of 340B covered entities over time, and today there are fifteen statutorily defined categories, including: federally qualified health centers; certain healthcare providers that receive federal grants (such as black lung clinics, hemophilia treatment centers, and urban Indian health organizations); and

certain types of hospitals (critical access hospitals, disproportionate share hospitals, children's hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals). *See* 42 U.S.C. § 256b(a)(4)(A)-(*O*).

Notably, Congress has *never* included contract pharmacies in the statutorily defined list of facilities that qualify as covered entities. Indeed, in drafting what would become the 340B statute, Congress considered proposed language that would have permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services. *See* S. Rep. No. 102-259 at 1-2 (1992) (requiring manufacturer to provide a discounted price for drugs that are "purchased and dispensed by, or under a contract entered into for *on-site pharmacy services* with" certain enumerated covered entities) (emphasis added). This on-site pharmacy language was dropped from subsequent bills, however, and never enacted.

B. HRSA Issues Non-Binding Guidance Permitting Contract Pharmacy Arrangements

As noted, Section 340B itself does not require manufacturers to provide discounts to contract pharmacies—even to on-site contract pharmacies—or, indeed, to *any* entity not specifically enumerated in § 256b(a)(4). But over the last three decades, HRSA has issued two "guidance" documents—considered "interpretive" rules—purporting to authorize covered entities to enter into agreements with contract pharmacies to dispense outpatient drugs under the 340B program. HRSA issued this guidance despite the fact that Congress did not grant HHS general rulemaking authority, authority to promulgate regulations with respect to Section 340B(a), or authority to expand the list of 340B covered entities. *See PhRMA*, 43 F. Supp. 3d at 41 (identifying the specific, limited grants of rulemaking authority in Section 340B).

In 1996, HRSA issued guidance asserting that "eligible covered entities that do not have access to appropriate 'in-house' pharmacy services" could now enter into an agreement with a

single outside pharmacy of its choice to provide such services for 340B drugs. 61 Fed. Reg. 43,555 (1996 Guidance). HRSA explained that "only a very small number of the 11,500 covered entities used in-house pharmacies." *Id.* at 43,500. HRSA accordingly justified allowing a covered entity without its own in-house pharmacies to use a single affiliated outside pharmacy on the ground that the arrangement would enable such entities to access the 340B program without having to "expend precious resources to develop their own in-house pharmacies (which for many would be impossible)." *Id.*

In response to questions about HRSA's authority to expand the 340B program in this manner, the 1996 Guidance acknowledged that "[t]he statute is silent as to permissible drug distribution systems." *Id.* at 43,549. HRSA thus asserted that it was "creat[ing] no new law and . . . no new rights or duties," but instead that "[i]nterpretive rules and statements of policy were developed to provide necessary program guidance" in view of "many gaps in the legislation." *Id.* at 43,550. HRSA recognized that some manufacturers had raised concerns that its new approach would lead to drug diversion. HRSA thus cautioned that it "intend[ed] to study the use of contracted pharmacy services for accessing 340B drugs to determine if there is evidence of drug diversion" and "w[ould] consider whether additional safeguards are necessary." *Id.* at 43,549.

In 2010, HRSA issued new guidelines designed to supersede the 1996 Guidance and to greatly expand the use of contract pharmacies under the 340B Program—though again, HRSA denied that it was creating any new rights or obligations, and instead insisted that it was only issuing "interpretive guidance." 75 Fed. Reg. 10,273 (2010 Guidance). The relevant statutory language, including the exhaustive list of covered entities to which the must-offer requirement applies, had not changed. HRSA nevertheless announced that covered entities must now be permitted to "use multiple pharmacy arrangements"—that is, an *unlimited* number of contract

pharmacies and without any geographic limits—"as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." *Id.* at 10,273. To take advantage of this new set of arrangements, HRSA announced, a covered entity merely must have a written contract in place with each contract pharmacy through which it intends to dispense 340B drugs; the covered entity need not submit these contracts to HRSA. *Id.* at 10,277; *see* Government Accountability Office, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 1, GAO-18-480 (June 2018) (2018 GAO Report), https://www.gao.gov/assets/700/692697.pdf.

Numerous 340B stakeholders expressed serious concerns that allowing covered entities to use an unlimited number of contract pharmacies would exacerbate the problems of diversion and duplicate discounts. The 2010 Guidance rejected these concerns, asserting that "there are appropriate safeguards in place" to protect program integrity, though it also emphasized that "it is the responsibility of the covered entity to ensure against diversion and duplicate discounts." 75 Fed. Reg. 10,274; *see id.* at 10,275. HRSA further rejected the suggestion from stakeholders that it should place reasonable limits on the number of contract pharmacies that a single covered entity could use, or should impose restrictions on the geographic location of contract pharmacies in relation to the covered entity they serve (such as preventing the use of pharmacies "over State lines"). *Id.* at 10,276. As a result of its categorical stance, the 2010 Guidance purports to authorize a covered entity to enter into an unlimited number of contract pharmacy arrangements anywhere in the United States, even hundreds or thousands of miles away.

II. Factual Background

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

HRSA's 2010 Guidance immediately triggered a massive surge in the number of contract pharmacies receiving and distributing 340B drugs. In 2018, the Government Accountability Office reported that the number of contract pharmacies had ballooned from 1,300 in 2010, to nearly 20,000 by 2017. 2018 GAO Report at 2. These numbers have continued to escalate. Today, more than 27,000 individual pharmacies participate in the 340B program, with a total of well over 100,000 individual contracts.[1] Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program* 4 (Oct. 2020) (BRG Report), https://bit.ly/3owtUwa. A large majority of these contract pharmacies (75% as of 2018) are national, for-profit retail pharmacies; and the five largest national pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—accounted for a combined 60% of all 340B contract pharmacies, even though these chains represent only 35% of all pharmacies nationwide. 2018 GAO Report at 20-21.

The boom in contract pharmacies has been fueled by the prospect of outsized profit margins on 340B discounted drugs. The determination whether a medicine is eligible for a 340B discount is not made until *after* the medicine is dispensed to the patient and paid for at a non-discounted price by the patient and his or her health plan; even when a drug is later found to be eligible for a discount, that discount is usually not passed along to the patient. The difference between the drug's non-discounted price and the 340B discounted price accordingly gives rise to a massive potential profit margin—which may be claimed by hospitals, pharmacies, and other intermediaries. As

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

Senator Chuck Grassley put it in a letter to HRSA, these entities "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Letter from Sen. Chuck Grassley, S. Comm. on the Judiciary, to Mary K. Wakefield, Administrator, Health Resources and Servs. Admin. (March 27, 2013), https://bit.ly/3kFquVS.

One recent study estimated that, due to the steep discounts mandated under the 340B program, "340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines"—a margin more than triple that ordinarily available to independent pharmacies. BRG Report at 7. The study found that "340B covered entities and their contract pharmacies generated over $13 billion in profits from 340B purchased medicines in 2018, which represents over 25 percent of the total $48 billion in profits realized by all providers that dispensed or administered brand medicines in 2018." *Id.* Most of these profits are not going to federally qualified health centers or other federal grantees that provide services to underserved populations, but instead to 340B hospitals and contract pharmacies, which are responsible for nearly 90% of all 340B purchases. *Id.*

At the same time, the proliferation of contract pharmacy arrangements has facilitated increased diversion and duplicate discounts—the very risks that Congress sought to avoid when it created the 340B program. A 2011 report from the Government Accountability Office warned that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies. For example, contract pharmacies are more likely to serve both patients of covered entities and others in the community; in these cases more sophisticated inventory tracking systems must be in place to ensure that 340B drugs are not diverted—intentionally or unintentionally—to non-340B patients." Gov. Accountability Office,

Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement 28, GAO-11-836 (Sept. 23, 2011), https://www.gao.gov/assets/330/323702.pdf. The report further found that "HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance." *Id.* at 21.

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

Indeed, HRSA's own audits of covered entities continue to identify numerous instances of abuse. The 2018 GAO Report observed that "66 percent of the 380 diversion findings in HRSA audits [between 2012 and 2017] involved drugs distributed at contract pharmacies." *Id.* at 44. And based on information from the HRSA website, over 25% of covered entities audited since 2017 have had at least one finding related to contract pharmacy noncompliance. Indeed, out of 199

audits conducted in 2019, HRSA discovered dozens of instances of duplicate discounts, as well as evidence that at least 19 covered entities had permitted diversion of 340B drugs through contract pharmacies. *See Program Integrity: FY19 Audit Results*, Health Resources & Services Administration, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results (last visited Nov. 19, 2020).

B. AstraZeneca Updates Its Contract Pharmacy Policy to Remedy Abuse of the 340B Program

Against this legal and factual backdrop, AstraZeneca announced that, effective October 1, 2020, it would no longer permit covered entities to enter into an unlimited number of contract pharmacy arrangements, but rather "only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy." Am. Compl. ¶ 65 (quoting Letter from Odalys Caprisecca dated Aug. 17, 2020, *available at* http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf). In other words, AstraZeneca would reinstate the procedures that governed effectively in the 340B program from 1996 through 2010.

From the outset, AstraZeneca was open and transparent with HRSA about this policy change. AstraZeneca first explained its new policy to HRSA in a letter dated July 24, 2020. *See* Letter from Christie Bloomquist to Krista Pedley dated July 24, 2020 (attached as Exhibit A). In that letter, AstraZeneca explained that the 340B statute refers only to outpatient drugs that are "***purchased by*** a covered entity," and provides that such drugs must be offered at the discounted price, but "does not mention 'contract pharmacies.'" *Id.* at 2. Its policy of recognizing one contract pharmacy per covered entity that does not maintain an on-site pharmacy thus "complies with operative 340B statutory provisions," AstraZeneca explained, because "AstraZeneca will make its products available to all covered entities at or below the applicable ceiling price." *Id.*

AstraZeneca also cited to substantial evidence, drawn from HRSA's own audits, that the unlimited use of contract pharmacies had caused "significant increases in covered entity violations of the statutory prohibitions against product diversion and duplicate discounting." *Id.* at 3. AstraZeneca closed its letter to HRSA by proposing to meet to discuss its policy change. *Id.*

After nearly a month had passed without any response from HRSA, AstraZeneca began informing its wholesalers and distributors directly of its new policy. *See, e.g.*, Am. Compl. ¶ 65 (quoting Letter from Odalys Caprisecca dated Aug. 17, 2020). Then, on August 20, AstraZeneca provided HRSA with a notice for distribution to covered entities regarding the changed policy and requested that HRSA post it on HRSA's website. *See* Notice to Covered Entities Regarding 340B Pricing (attached as Exhibit B). Consistent with AstraZeneca's prior letter to HRSA, the notice explained that, effective October 1, "AstraZeneca will recognize one Contract Pharmacy per Covered Entity for those Covered Entities that do not maintain an on-site dispensing pharmacy." *Id.* at 1. The notice emphasized that the new policy would not disrupt any covered entity's access to 340B drugs at 340B prices, explaining that "Covered Entities will continue to be able to purchase our products at the statutory ceiling price from either their designated single Contract Pharmacy or the Covered Entity's on-site dispensing pharmacy." *Id.* The notice also provided covered entities with information about how to designate a contract pharmacy under the policy. *Id.* In its cover email to HRSA, AstraZeneca reiterated its offer to meet with HRSA to explain these changes in more detail.

HRSA finally responded to AstraZeneca's July letter and August email on September 2. *See* Letter from Krista Pedley to Christie Bloomquist dated Sept. 2, 2020 (attached as Exhibit C). HRSA indicated that it was "considering whether AstraZeneca's proposed policy constitutes a violation of the 340B statute and whether sanctions would apply," including "civil monetary

penalties pursuant to 42 U.S.C. § 256(d)(1)(B)(vi)." *Id.* at 1. HRSA further asserted that it believed AstraZeneca's new policy "could have the effect of severely limiting access" to 340B drugs during the COVID-19 pandemic, which "would undermine the 340B Program and the Congressional intent behind enactment of the 340B statute." *Id.* at 1-2.

HRSA did not respond to AstraZeneca's discussion of the text of the 340B statute. Nor did HRSA acknowledge the HRSA reports that AstraZeneca cited as evidence that distribution to unlimited contract pharmacies has led to duplicate discounts and diversion. Instead, HRSA asked AstraZeneca to submit "evidence of specific duplicate discount and diversion violations, . . . including the alleged covered entities and drugs involved." *Id.* at 1. Finally, HRSA refused to post AstraZeneca's notice, thus depriving 340B covered entities of information on how to access AstraZeneca medicines: as the agency "continues to evaluate this issue, it will not be posting AstraZeneca's 'Notice to Covered Entities Regarding 340B Pricing' until this matter is resolved." *Id.* at 2.

AstraZeneca replied to HRSA's response letter on September 15. *See* Letter from Christie Bloomquist to Krista Pedley dated Sept. 15, 2020 (attached as Exhibit D). AstraZeneca expressed surprise that HRSA would threaten sanctions, such as civil monetary penalties, given that its policy was fully consistent with the 340B statute and guidance that HRSA itself had endorsed for fourteen years. AstraZeneca also expressed disappointment that HRSA chose to convey this threat by letter, rather than taking AstraZeneca up on its two separate offers to meet with HRSA to discuss its new approach. *Id.* at 1. As to the merits, AstraZeneca reiterated that its "planned approach complies fully with the 340B statute" because "[u]nder [AstraZeneca's] new structure, each covered entity will be offered 340B drugs at the 340B price on non-discriminatory terms." *Id.* AstraZeneca further explained that its new policy in fact "will go beyond the statute's requirements by assuring

access to 340B pricing through a contract pharmacy arrangement if a covered entity is unable to dispense 340B drugs from its own facilities." *Id.*

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

Regarding the notice that AstraZeneca had asked HRSA to post, AstraZeneca explained that "HRSA's refusal to post our notice to covered entities is causing very real and tangible harm, as it is denying covered entities access to vital information on how to register their designated pharmacy." *Id.* at 2. AstraZeneca again requested "that HRSA immediately post our notice on its website so that covered entities can learn how they may enroll and designate their pharmacy to receive AstraZeneca medicines." *Id.* And AstraZeneca further requested that "HRSA confirm to us promptly in writing that it will not seek civil monetary penalties against AstraZeneca related to our impending change to contract pharmacy designation, which fully complies with applicable law." *Id.* Finally, AstraZeneca reiterated for a third time its offer to meet with HRSA "to discuss this critically important issue for 340B program integrity and to correct any misunderstandings that HRSA may have about our approach." *Id.* at 3.

In light of HRSA's failure to respond to its letters, or to honor AstraZeneca's request to post notice to covered entities on the agency's website, AstraZeneca sent a letter to approximately 8,000 covered entities informing them of the new policy. *See* Letter from Odalys Caprisecca,

Re: 340B Contract Pharmacy Pricing, dated Sept. 14, 2020 (attached as Exhibit E). The letter explained that "AstraZeneca will continue to provide [its] products directly to all Covered Entities . . . at the required statutory ceiling price," and it encouraged "any Covered Entity that does not have an outpatient, on-site dispensing pharmacy [to] contact AstraZeneca" by email "to identify a single Contract Pharmacy of its choice." *Id.*

On November 2, AstraZeneca sent another letter to HRSA, specifically addressing this litigation. *See* Letter from Odalys Caprisecca to Krista Pedley dated Nov. 2, 2020 (attached as Exhibit F). As in its previous correspondence, AstraZeneca explained that, under its new policy "all covered entities will continue to have access to AstraZeneca medicines at the 340B price," and that the policy "is fully compliant with the 340B statute." *Id.* at 2. AstraZeneca noted that the original complaint in this case—like the Amended Complaint—misstates AstraZeneca's approach to contract pharmacies by selectively quoting from letters, and reaffirmed that "[t]he change that AstraZeneca has implemented makes its products available to covered entities either through their own in-house pharmacy or through a designated contract pharmacy." *Id.* at 2. AstraZeneca also reiterated its request for a meeting with HRSA and asked the agency to advise whether it was "accepting or rejecting our formal meeting request." *Id.*

To this day, HRSA has neither responded to AstraZeneca's letters nor posted AstraZeneca's notice to covered entities on its website. *See* HRSA, Manufacturer Notices to Covered Entities, https://www.hrsa.gov/opa/manufacturer-notices/index.html (database of manufacturer notices posted by HRSA). Nor has HRSA taken up AstraZeneca on its multiple offers to meet to discuss this issue in more detail or to correct the erroneous public record regarding AstraZeneca's approach to contract pharmacies.

III. Procedural Background

On October 9, 2020, Plaintiffs Ryan White Clinics for 340B Access, a trade association representing 340B covered entities, and two covered entities, Matthew 25 Aids Services, Inc. and Cempa Community Care, filed this lawsuit. Matthew 25, which is located in Kentucky, uses three contract pharmacies, all of which are located in other states (Georgia, Florida, and Pennsylvania). Cempa uses more than 200 contract pharmacies, most of them large commercial chains such as Walgreens and CVS. And although Cempa is located in Chattanooga, Tennessee, its contract pharmacies are spread across eighteen different states, including Hawaii, Massachusetts, and California. On November 23, Plaintiffs filed an Amended Complaint naming three new Plaintiffs: Little Rivers Health Care, Inc. and WomenCare, Inc. (both federally qualified health centers), and Springhill Medical Center, a sole community hospital in Louisiana. Like the original Plaintiffs, these new Plaintiffs have engaged in numerous contract pharmacy arrangements in far-flung States: WomenCare (located in West Virginia) has 79 contract pharmacies, including one in Florida and one in Texas. Little Rivers (located in Vermont) has four contract pharmacies in Vermont, New Hampshire, Texas, and Florida. And Springhill has 14 contract pharmacies in Louisiana, Texas, and Florida.

The Amended Complaint names four governmental Defendants: HHS, HHS Secretary Alex Azar, HRSA, and HRSA Administrator Thomas Engels. *See* Am. Compl. ¶¶ 18-21. But the substance of the Amended Complaint—and the relief that it seeks—are directed at recent 340B policy changes adopted by four drug manufacturers: AstraZeneca, Eli Lilly and Company (Lilly), Sanofi-Aventis U.S. LLC (Sanofi), and Novartis Pharmaceuticals Corporation (Novartis). *See, e.g.*, Am. Compl. ¶ 2.

With regard to AstraZeneca, the Amended Complaint selectively quotes from AstraZeneca's August letter to covered entities regarding changes in AstraZeneca's approach to

contract pharmacies. The Amended Complaint then asserts that "AstraZeneca ceased offering 340B pricing on drugs dispensed at contract pharmacies on October 1, 2020." *Id.* ¶ 66. But that allegation is false, and is contradicted by the August 17 letter itself, which specifically provides that "[a]ny 340B Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca to arrange for a Contract Pharmacy of its choice to be eligible to receive 340B pricing on behalf of the Covered Entity." *Id.* ¶ 65 (quoting Letter from Odalys Caprisecca dated Aug. 17, 2020). In fact, more than 1,200 covered entities have *already* registered a contract pharmacy with AstraZeneca consistent with the instructions in the August letter, and AstraZeneca has continued offering 340B pricing on 340B drugs dispensed at those contract pharmacies.

The Amended Complaint further asserts that AstraZeneca has "denied 340B discounts to the Plaintiff Covered Entities." *Id.* ¶ 2. In particular, the Amended Complaint alleges that "[s]ince October 1, 2020, Matthew 25 has not been able to purchase 340B discounted drugs from AstraZeneca." *Id.* ¶ 82. These allegations are also false. Based on AstraZeneca's investigations to date, Matthew 25 continues to access AstraZeneca's medicines at the statutory ceiling price through their on-site pharmacies.

Plaintiffs seek to compel HRSA to take action against the four drug companies named in the Amended Complaint, purportedly "to enforce the Plaintiff Covered Entities' rights to purchase and dispense covered outpatient drugs via contract pharmacies at 340B discounts." Am. Compl. at 42. To that end, Plaintiffs seek "an order from this Court directing the Secretary to act now against the Drug Companies," *id.* ¶ 5, as well as "a writ of mandamus requiring the Secretary . .

. to enforce the Plaintiff Covered Entities' rights to purchase covered outpatient drugs at 340B discounts via contract pharmacy arrangements," *id.* ¶ 6.[2]

Plaintiffs concede, as they must, that under the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110 (2011), "covered entities do not have a private right of action" under the 340B Statute, Am. Compl. ¶ 52, such that "only the Secretary may enforce the manufacturer's obligation to charge at or below the 340B ceiling price," *id.* ¶ 51. Plaintiffs nonetheless attempt to circumvent HRSA's exclusive enforcement authority by asking this Court to enjoin HRSA "to order Lilly, Sanofi, AstraZeneca, and Novartis to refund overpayments owed to the Plaintiff Covered Entities," and to "impose [civil monetary penalties] upon drug manufacturers Lilly, Sanofi, AstraZeneca, and Novartis unless and until they comply with the requirements of the 340B statute and honor contract pharmacy arrangements." *Id.* at 36. Plaintiffs also ask this Court to order HRSA to "revoke the [pharmaceutical pricing agreement] of any pharmaceutical manufacturer that does not offer drugs at 340B discounts when ordered via contract pharmacy arrangements, thereby excluding drugs produced by such manufacturer from coverage under the Medicaid and Medicare Part B insurance programs." *Id.* at p. 36. If Plaintiffs' requests for relief were granted, drug manufacturers, including AstraZeneca (and potentially many others), could be threatened with civil monetary penalties and even the potential "loss of Medicaid and Medicare Part B reimbursement for all of [their] products." *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 46 (D.D.C. 2015) (citation omitted).

On November 20, Lilly and Sanofi filed motions to intervene as defendants in this lawsuit. Dkt. 12, 13. The government's answer to the original complaint was not due until December 14,

[2] Plaintiffs also "request a writ of mandamus requiring the Secretary to implement [Alternative Dispute Resolution] regulations." *Id.* ¶ 6.

Dkt. 4, and the Court has yet to set a deadline for the government to respond to the Amended Complaint.

ARGUMENT

For the same reasons stated by Lilly and Sanofi in their motions to intervene, AstraZeneca has a right to intervene under Rule 24(a) and, alternatively, should be permitted to intervene under Rule 24(b). AstraZeneca's motion is timely, *see* Lilly Mem. 18-19 (Dkt. 12-1); Plaintiffs' lawsuit threatens to impair AstraZeneca's interests, *see id.* at 19-21; and none of the governmental Defendants will adequately represent AstraZeneca's interests, *see id.* at 21-22. In the interests of judicial economy, AstraZeneca hereby adopts and incorporates Lilly's arguments, which are discussed below only as necessary to confirm their applicability to AstraZeneca.

I. AstraZeneca Has a Right to Intervene under Rule 24(a)

Rule 24(a) provides that on "timely motion," a court "must permit anyone to intervene" who "claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a). AstraZeneca readily meets all four factors that courts in the D.C. Circuit consider under Rule 24(a): (1) its motion is timely; (2) it has an interest in the subject of the action; (3) Plaintiffs' lawsuit threatens to impair its ability to protect its interest; and (4) the governmental Defendants will not adequately represent its interest. *See Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 731 (D.C. Cir. 2003).

First, AstraZeneca's motion is timely. There is no set number of days within which a proposed intervenor must move to intervene; rather, timeliness is evaluated based on "all the circumstances," including "time elapsed since the inception of the suit" and "the probability of prejudice to those already parties in the case." *United States v. British Am. Tobacco Australia*

Servs., Ltd., 437 F.3d 1235, 1238 (D.C. Cir. 2006) (citation omitted). Here, AstraZeneca filed its motion to intervene only 45 days after Plaintiffs filed their original complaint—only a day after Plaintiffs filed their Amended Complaint. That is well before the governmental Defendants will be required to respond to the Amended Complaint. Neither Plaintiffs nor Defendants will suffer any prejudice from AstraZeneca's intervention at this early stage of the proceedings. And AstraZeneca is prepared to proceed on whatever schedule the Court establishes, and will work with the governmental Defendants and any other parties to avoid undue delay or redundant filings. Under these circumstances, AstraZeneca has easily satisfied the timeliness requirement.

Second, AstraZeneca has a strong "interest relating to the property or transaction that is the subject of" Plaintiffs' claims, Fed. R. Civ. P. 24(a)(2), and thus also has Article III standing. *See Fund for Animals*, 322 F.3d at 735. The core legal question in this litigation is whether Plaintiffs are correct that the 340B statute, which says nothing about contract pharmacies, nevertheless requires pharmaceutical manufacturers (like AstraZeneca) to provide 340B discounts to an unlimited number of contract pharmacies. AstraZeneca disagrees with Plaintiffs' interpretation of the statute and has organized its business accordingly, including by informing covered entities that it will recognize *one* contract pharmacy per covered entity that does not maintain an on-site pharmacy. Beyond that, the relief Plaintiffs seek directly targets AstraZeneca by name for substantial legal and monetary sanctions. Plaintiffs ask the Court to enjoin HRSA to (1) order AstraZeneca to refund overpayments allegedly caused by this policy, (2) impose civil monetary penalties on AstraZeneca, and (3) revoke AstraZeneca's pharmaceutical pricing agreement, thus excluding AstraZeneca's products from reimbursement under Medicaid and Medicare Part B. *See* Am. Compl. at pp. 42-43. Any one of those serious potential remedies would be more than enough to satisfy Rule 24(a)(2) and Article III.

Third, for related reasons, a judgment in Plaintiffs' favor would directly impair AstraZeneca's ability to protect its interests. As stated, the relief that Plaintiffs seek directly targets AstraZeneca, exposing it to potentially millions of dollars in overpayment refunds and civil monetary penalties, as well as to the potentially devastating exclusion of its products from reimbursement under Medicaid and Medicare Part B altogether. Indeed, Plaintiffs essentially admit that the only reason they have not sued AstraZeneca directly is because Supreme Court precedent forecloses such a suit. *See* Am. Compl. ¶¶ 51-52.

Fourth, none of the current Defendants—who are all governmental agencies or officials—adequately represents AstraZeneca's interests.[3] As Lilly explained in support of its intervention motion (at 21), courts in the D.C. Circuit "look skeptically on government entities serving as adequate advocates for private parties," *Crossroads Grassroots Policy Strategies v. FEC*, 788 F.3d 312, 321 (D.C. Cir. 2015), including because the government "would face a potential conflict of interest were it to represent both the general interests of its citizens and the financial interests of" the proposed intervenor, *Dimond v. District of Columbia*, 792 F.2d 179, 193 (D.C. Cir. 1986). *See Fund for Animals*, 322 F.3d at 736 & n.9 (collecting cases).

Beyond that presumption of inadequacy, there is good reason to think that governmental Defendants will not represent AstraZeneca's interests here. The agency has told AstraZeneca that it believes AstraZeneca's new policy "could have the effect of severely limiting access" to 340B drugs during the COVID-19 pandemic, which "would undermine the 340B Program and the Congressional intent behind enactment of the 340B statute." Exhibit C at 1-2. As noted, AstraZeneca strongly disputes the accuracy of that assertion. HRSA also threatened that the

[3] Even if the Court grants Lilly's and Sanofi's motions to intervene, those other manufacturers would not adequately represent AstraZeneca's interests. AstraZeneca has its own unique history of interactions with HRSA and potential differences in approach to contract pharmacies that may bear on the proper outcome.

agency "is considering whether AstraZeneca's proposed policy constitutes a violation of the 340B statute and whether sanctions would apply," including "civil monetary penalties pursuant to 42 U.S.C. § 256(d)(1)(B)(vi)." *Id.* at 1. And HRSA *still* has not responded to AstraZeneca's repeated requests for a meeting to discuss the matter further or agreed to post AstraZeneca's proposed notice to covered entities. *See supra* Section II.B. This conduct raises the very real possibility that HRSA will take positions in this litigation that not only fail to represent AstraZeneca's interests but are, in fact, directly adverse to them.

II. Alternatively, the Court Should Permit AstraZeneca to Intervene under Rule 24(b)

In the alternative, the Court should exercise its broad discretion to grant permissive intervention under Rule 24(b), which provides that on "timely motion" a court "may permit anyone to intervene" who "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1). As Lilly explained in support of its motion (at 22-23), each of the factors that courts consider under Rule 24(b) is met here. *See EEOC v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1046-47 (D.C. Cir. 1998).

First, the Court has subject matter jurisdiction over AstraZeneca's defenses, which arise under federal law and concern the interpretation of the federal 340B Statute. *Second*, as explained, AstraZeneca's motion is timely and will not "unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3). *Third*, AstraZeneca's anticipated defenses all relate to the core legal question presented by Plaintiffs' lawsuit: whether the 340B statute requires pharmaceutical manufacturers to provide 340B discounts to an unlimited number of contract pharmacies. Accordingly, even if the Court determines that intervention as of right under Rule 24(a) is not warranted under the circumstances, the Court should nonetheless permit AstraZeneca to intervene under Rule 24(b).

CONCLUSION

For the foregoing reasons, AstraZeneca respectfully requests that the Court grant its motion to intervene.

Dated: November 24, 2020

By: */s/ Allon Kedem*

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Exhibit D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

COMES NOW Plaintiff AstraZeneca Pharmaceuticals LP and alleges as follows:

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

JURISDICTION AND VENUE

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

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

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

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

PARTIES TO THE ACTION

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

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

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

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

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

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

FACTUAL ALLEGATIONS

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

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

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

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

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

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

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

HRSA Issues Non-Binding Guidance Permitting Contract Pharmacy Arrangements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

62. As relevant here, the statute provides that a manufacturer must enter into an agreement with the HHS Secretary that "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). Section 340B(a)(4), in turn, enumerates fifteen types of healthcare providers that qualify as "covered entities." *Id.* § 256b(a)(4). This exhaustive list does *not* include "contract pharmacies," a term that appears nowhere in Section 340B.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

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

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

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

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

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

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

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

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

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

SECOND CLAIM FOR RELIEF

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

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

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

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

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

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

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

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

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

THIRD CLAIM FOR RELIEF

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

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

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

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

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

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

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

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

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

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

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

FOURTH CLAIM FOR RELIEF

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

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

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

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

PRAYER FOR RELIEF

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

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

B. Set aside and vacate the Advisory Opinion;

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

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

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

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

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

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

Dated: January 12, 2021

Respectfully submitted,

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Exhibit E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services,

ROBERT P. CHARROW, in his official capacity as General Counsel of the United States Department of Health and Human Services,

HEALTH RESOURCES AND SERVICES ADMINISTRATION,

THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration,

Defendants.

Civil Action No. 3:21-cv-634

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi"), by and through its undersigned attorneys, alleges as follows:

INTRODUCTION

1. This Administrative Procedure Act ("APA") case challenges a new rule governing the 340B drug-discounting program (the "340B Program") issued by the U.S. Department of Health and Human Services ("HHS") without statutory authority and without complying with the requirements for issuing rules having the force and effect of law.

2. Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to discount their drugs (often quite significantly) for fifteen types of "covered entities" that are enumerated in the statute—governmental and non-profit entities that mostly provide care for underserved areas or populations. Manufacturers that overcharge covered entities can face enforcement actions, significant civil monetary penalties, and revocation of their ability to participate in the Medicare and Medicaid programs.

3. Instead of dispensing 340B-priced drugs themselves, many covered entities have entered into agreements with for-profit contract pharmacies (such as commercial chain pharmacies like Walgreens and CVS), under which contract pharmacies acquire and dispense the discounted drugs to the covered entities' patients, with the covered entities writing the underlying prescriptions.

4. These contract pharmacy arrangements have made it much harder for drug manufacturers to detect "duplicate discounting," which occurs when the same prescription is subject to both a 340B discount and a Medicaid rebate. Section 340B expressly prohibits duplicate discounting, which—if unaddressed—can result in manufacturers being forced to sell their drugs for below cost. As the use of contract pharmacies has exploded in recent years, duplicate discounting has also increased.

5. In July 2020, to address these concerns about duplicate discounting, Sanofi announced an integrity initiative that took effect on October 1, 2020. Under this initiative, Sanofi continues to offer discounted pricing to all covered entities, but (with limited exceptions) Sanofi now requires covered entities to submit minimal claims data for 340B-priced drugs acquired and dispensed by contract pharmacies. Using this data, Sanofi can

better identify and prevent duplicate discounts. To be clear, Sanofi still offers 340B discounts on all of its drugs to all covered entities without this condition. But Sanofi currently offers 340B pricing through contract pharmacy arrangements only if a covered entity provides the data requested (unless an exception applies).

6. In a new rule entitled Advisory Opinion 20-06 (the "Advisory Opinion"), however, HHS imposed new legal obligations on drug manufacturers that effectively outlaw Sanofi's integrity initiative. HHS's new rule expands the list of entities entitled to acquire 340B-priced drugs—now to include for-profit contract pharmacies—and limits manufacturers' ability to detect waste and abuse in the 340B Program (such as through the integrity initiative adopted by Sanofi). In particular, the Advisory Opinion interprets Section 340B to require drug manufacturers to provide 340B discounts to contract pharmacies and to prohibit manufacturers from imposing conditions on such sales. As a result, the Advisory Opinion exposes Sanofi to enforcement actions, severe monetary penalties, and revocation of its ability to participate in the Medicare and Medicaid programs for operating its integrity initiative.

7. The Court should hold unlawful and set aside the Advisory Opinion for at least the following four reasons.

8. *First*, HHS failed to comply with the APA's notice-and-comment requirement before issuing the Advisory Opinion. The APA requires agencies to provide advance notice and an opportunity to comment on legislative rules having the force and effect of law. The Advisory Opinion contains a legislative rule having the force and effect of law—namely, that manufacturers *shall* provide 340B discounts to contract pharmacies and *shall not* impose

conditions on these sales—that effectively dooms Sanofi's integrity initiative. HHS's failure to comply with the APA's notice-and-comment requirement means the Advisory Opinion is procedurally unlawful and must be vacated.

9. *Second*, HHS also failed to comply with its own procedural regulations when issuing the Advisory Opinion. In addition to the APA's notice-and-comment requirement, HHS has adopted regulations governing the issuance of guidance documents such as the Advisory Opinion, yet the agency skirted these procedural requirements, too. The Advisory Opinion is contrary to law and arbitrary and capricious as a result.

10. *Third*, the Advisory Opinion's interpretation of Section 340B is wrong. Section 340B does not require drug manufacturers to provide 340B-priced drugs to contract pharmacies. Nor does Section 340B prohibit manufacturers from imposing conditions on doing so, particularly where those conditions are designed to aid compliance with the statute's other provisions and are reasonable. Even if manufacturers must provide 340B-priced drugs to contract pharmacies, Sanofi's integrity initiative complies with Section 340B because Sanofi ships discounted drugs to contract pharmacies—and, moreover, will do so for all covered entities under reasonable conditions that are not burdensome and that do not discriminate against covered entities as compared to commercial customers. The Advisory Opinion thus exceeds HHS's statutory authority, and Sanofi's integrity initiative is fully consistent with Section 340B.

11. *Fourth*, both of the Advisory Opinion's key conclusions—that Section 340B requires manufacturers to provide discounted drugs to contract pharmacies, and that

manufacturers may not impose conditions on doing so—are arbitrary and capricious because the agency failed to reasonably explain its interpretation of the statute.

12. For these reasons, the Court should set aside the Advisory Opinion, declare that Section 340B does not require manufacturers to provide discounted covered outpatient drugs to contract pharmacies or prohibit manufacturers from imposing conditions on doing so, confirm that Sanofi's integrity initiative comports with the statute, and enjoin HHS from enforcing the Advisory Opinion in any administrative proceeding.

JURISDICTION AND VENUE

13. This Court has jurisdiction over this case under 28 U.S.C. § 1331 because Sanofi's claims arise under the APA. *See* 5 U.S.C. § 702.

14. This Court has the authority to grant declaratory relief and to vacate and set aside the Advisory Opinion under the Declaratory Judgment Act, the APA, and this Court's inherent equitable powers. *See* 28 U.S.C. §§ 2201, 2202; 5 U.S.C. §§ 702, 706.

15. Venue is proper in this district under 28 U.S.C. § 1391(e)(1)(C) and 5 U.S.C. § 703.

PARTIES

16. Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi") is a global healthcare leader that produces extensive lines of prescription medicines, vaccines, and other consumer health products. Sanofi's headquarters are located in Bridgewater, New Jersey.

17. Defendant HHS is an agency of the United States government.

18. Defendant Alex M. Azar II is the Secretary of HHS (the "Secretary") and is sued in his official capacity.

19. Defendant Robert P. Charrow is General Counsel of HHS and is sued in his official capacity.

20. Defendant Health Resources and Services Administration ("HRSA") is an HHS agency.

21. Defendant Thomas J. Engels is Administrator of HRSA and is sued in his official capacity.

STATEMENT OF FACTS

I. The 340B Program

22. Congress established the 340B Program in 1992 to reduce pharmaceutical costs for "public hospitals and community health centers, many of which provide safety-net services to the poor." HHS Office of the General Counsel, Advisory Opinion 20-06: On Contract Pharmacies Under the 340B Program ("Advisory Opinion"), at 1 (Dec. 30, 2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

23. Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires drug manufacturers participating in the 340B Program to offer certain drugs at a significant discount to a list of entities (known as "covered entities") defined by statute. While manufacturers are not formally required to participate in the 340B Program, they have little practical choice but to do so. Their participation in Medicare and Medicaid, which together contribute a significant portion of manufacturers' annual revenues, "is conditioned on their entry into [Pharmaceutical Pricing Agreements] for covered drugs purchased by 340B entities." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

24. In particular, Section 340B requires that the Secretary "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed" a discounted price calculated according to a prescribed statutory formula. 42 U.S.C. § 256b(a)(1). This agreement is known as the Pharmaceutical Pricing Agreement ("PPA"). Section 340B further provides that "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below" the discounted price. *Id.*

25. Failure to comply with the 340B statute exposes a manufacturer to termination of the PPA (and, correspondingly, the manufacturer's ability to participate in Medicare and Medicaid) as well as enforcement actions and civil monetary penalties.

26. Section 340B defines "covered entities" in an enumerated list of 15 discrete types of entities, such as children's hospitals and rural hospitals. *Id.* § 256b(a)(4)(A)–(O). In full, that list is:

> (A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).
>
> (B) An entity receiving a grant under section 256a of this title.
>
> (C) A family planning project receiving a grant or contract under section 300 of this title.
>
> (D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).
>
> (E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that—

> (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;
>
> (ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and
>
> (iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

> (M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.
>
> (N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).
>
> (O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

27. Notably, the list of covered entities does not include contract pharmacies, which are for-profit third-party pharmacies that fill prescriptions written by other healthcare providers.

28. In order to prevent waste and abuse, Section 340B prohibits "duplicate discounts or rebates," which occur when the same prescription receives both a 340B discount and a Medicaid rebate. *Id.* § 256b(a)(5)(A).

29. Section 340B also prohibits "diversion," by barring covered entities from reselling or otherwise transferring discounted drugs to persons other than their patients. *See id.* § 256b(a)(5)(B).

30. Section 340B authorizes not just the Secretary but also manufacturers themselves to audit a covered entity's compliance with these twin requirements. *See id.*

§ 256b(a)(5)(C). The Secretary can sanction covered entities that fail to comply with these requirements. *See id.* § 256b(a)(5)(D).

31. Section 340B directs the Secretary to promulgate regulations establishing an administrative process for resolving (i) claims by covered entities that they have been overcharged for drugs purchased under the 340B Program and (ii) claims by manufacturers, after conducting an audit, that a covered entity has violated the prohibitions on duplicate discounts and diversion. *See id.* § 256b(d)(3)(A).

32. The Secretary promulgated such regulations on December 14, 2020, and they are scheduled to take effect on January 13, 2021. *See* 340B Drug Pricing Program: Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,632 (Dec. 14, 2020) (to be codified at 42 C.F.R. pt. 10) (the "ADR Rule").

33. Claims brought under the ADR Rule are to be adjudicated by a panel (the "ADR Panel") consisting of representatives in equal numbers from the HHS Office of General Counsel, HRSA, and the Centers for Medicare & Medicaid Services ("CMS"). *Id.* at 80,634.

34. CMS, like HRSA, is an HHS agency. The HHS Office of General Counsel "supervises all legal activities of the Department and its operating agencies," including HRSA and CMS, and furnishes "all legal services and advice to the Secretary, Deputy Secretary, and all offices, branches, or units of the Department in connection with the operations and administration of the Department and its programs." Statement of Organization, Functions, and Delegations of Authority ("Statement of Organization"), 85 Fed. Reg. 47,228, 47,230 (Aug. 4, 2020).

35. Under the ADR Rule, the ADR Panel is charged with reviewing "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 85 Fed. Reg. at 80,645; 42 C.F.R. § 10.21(c)(1).

II. Covered Entities' Use of Contract Pharmacies

36. Even though Congress did not include contract pharmacies as covered entities, define a role for contract pharmacies in the 340B Program, or otherwise mention them in the 340B statute, HHS and its agency HRSA have issued guidance on whether covered entities can use contract pharmacies.

37. In 1996, four years after the 340B Program was created, HRSA issued guidance purporting to allow contract pharmacies to dispense 340B-priced drugs by signing agreements with covered entities. *See* 61 Fed. Reg. 43,549 (Aug. 23, 1996). HRSA provided in this guidance that a covered entity could enter into such an arrangement with a maximum of one contract pharmacy. *Id.* at 43,555. But HRSA recognized that it lacked authority to expand the list of covered entities. *Id.* at 43,549. It also maintained that this guidance was merely an interpretive rule that created "no new law" and "no new rights or duties." *Id.* at 43,550. This guidance did not address whether manufacturers could impose conditions on the provision of 340B-priced drugs to contract pharmacies.

38. In 2010, HRSA issued guidance that sought to expand the participation of contract pharmacies in the 340B Program. *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010). This guidance purported to allow covered entities to contract with an *unlimited* number of

pharmacies, without any geographical restrictions. *See id.* at 10,272–73. But HRSA once more denied that it was creating any new rights or obligations, characterizing the 2010 guidance as "interpretive guidance." *Id.* at 10,273. And again, this guidance did not address whether manufacturers could impose conditions on providing 340B-priced drugs to contract pharmacies.

39. Since HRSA issued its 2010 guidance, covered entities' use of contract pharmacies has exploded. For-profit contract pharmacies participating in the 340B Program increased in number from 1,300 in 2010, to nearly 20,000 by 2017. *See* U.S. Government Accountability Office ("GAO"), Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 39, 40 (June 2018), https://www.gao.gov/assets/700/692697.pdf ("GAO Report"). Last year, the number of participating contract pharmacies reached 28,000—almost half of the U.S. pharmacy industry. *See* Adam J. Fein, Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?, Drug Channels (July 14, 2020), https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html. And in total, there are currently more than 100,000 arrangements between contract pharmacies and covered entities. *See* PhRMA, 340B Contract Pharmacy 101 (Sept. 2020), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/340B-Contract-Pharmacy-101-Deck_Sept-2020.pdf.

40. But the expansion of contract pharmacy arrangements has undermined the 340B Program's goals in several ways. For one thing, contract pharmacies can and typically do capture significant amounts of the discounts that Congress intended for covered entities

and their patients. Generally, under contract pharmacy arrangements, drugs are provided to the contract pharmacy, who dispenses the drugs and, in turn, collects payment from the patients and/or patients' insurance. Often, contract pharmacies will not pass on the 340B discount to covered entities' patients when billing them. *See* GAO Report, *supra*, at 30; HHS Office of Inspector General, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431, at 2 (Feb. 2014) ("HHS Report"), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. And contract pharmacies typically earn significant profits from the difference between what the insurer or patient pays and what they paid to acquire the drug. *See* PhRMA, New Analysis Shows Contract Pharmacies Financially Gain From 340B Program With No Clear Benefit to Patients (Oct. 8, 2020), https://phrma.org/Press-Release/New-Analysis-Shows-Contract-Pharmacies-Financially-Gain-From-340B-Program-With-No-Clear-Benefit-to-Patients; PhRMA, For-Profit Pharmacies Make Billions Off 340B Program Without Clear Benefit to Patients (Oct. 7, 2020), https://phrma.org/Graphic/For-Profit-Pharmacies-Make-Billions-Off-340B-Program-Without-Clear-Benefit-to-Patients. The contract pharmacy often pockets much of the difference between the 340B price and the higher reimbursement value of the drug, while also paying a typically pre-negotiated amount to the covered entity for each discounted drug it dispenses. Congress never, however, intended for 340B discounts to be corporate largesse. *See* 42 U.S.C. § 256b(a)(4)(A)–(O) (entitling only governmental and non-profit entities to receive 340B discounts).

41. In addition, the expansion of contract pharmacy arrangements has been accompanied by widespread diversion and duplicate discounting, as numerous government

reports attest. As noted, Congress explicitly prohibited these practices when enacting Section 340B.

42. For example, HHS has found that contract pharmacy arrangements "create complications in preventing diversion." HHS Report, *supra*, at 1. Similarly, the GAO has warned that "[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion." GAO, Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement, GAO-11-836, at 28 (Sept. 2011), https://www.gao.gov/assets/330/323702.pdf. Bearing out these concerns, a 2018 GAO report determined that approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies. GAO Report, *supra*, at 44.

43. HHS has also found that contract pharmacy arrangements "create complications in preventing duplicate discounts." HHS Report, *supra*, at 2. According to a 2014 HHS investigation, some covered entities "did not report a method to avoid duplicate discounts," "most covered entities . . . d[id] not conduct all of the oversight activities recommended by HRSA," and "[f]ew covered entities reported retaining independent auditors for their contract pharmacy arrangements." *Id.* It is therefore unsurprising that a limited HRSA audit in 2019 uncovered widespread duplicate discounting at contract pharmacies. *See* HRSA, Program Integrity: FY19 Audit Results (Dec. 3, 2020), https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results. Sanofi has discovered similar violations of Section 340B. In a limited analysis of three years of Medicaid rebates from five states for three Sanofi drugs, for example, the company identified over $16 million in duplicate discounts.

44. These duplicate-discounting problems stem in part from an information gap. Whereas 340B discounts are provided to the covered entity, requests for Medicaid reimbursement are made by the pharmacy that fills the prescription. But HRSA has only partial insight into which covered entities use which contract pharmacies, and only incomplete information on which covered entities use 340B-priced drugs for Medicaid-insured patients. *See* GAO Report, *supra*, at 36; HRSA OPA Policy Release, Clarification on Use of the Medicaid Exclusion File (Dec. 12, 2014), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/clarification-medicaid-exclusion.pdf. As a result, based on publicly available information, there is no effective or comprehensive way to know whether a contract pharmacy's prescriptions are being submitted for duplicate discounts—*i.e.*, for both a 340B discount (under the covered entity's name) and a Medicaid rebate (under the contract pharmacy's name). Instead, according to CMS, "duplicate discounts can often best be identified from a review of claims level data by the manufacturers." CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid (Jan. 8, 2020), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf.

III. Sanofi's Integrity Initiative

45. Sanofi shares HHS's concerns about duplicate discounting when prescriptions are filled at contract pharmacies. Accordingly, on July 28, 2020, Sanofi announced an integrity initiative to prevent duplicate discounting. Under the integrity initiative, Sanofi continues to offer discounted pricing to all covered entities, and Sanofi continues to ship discounted drugs to all contract pharmacies. The only change is that Sanofi now requires

covered entities to submit minimal claims data for 340B-priced drugs dispensed by contract pharmacies, subject to limited exceptions. *See* Ex. 1, Letter from G. Gleeson, Vice President & Head, Sanofi US Market Access Shared Services (July 2020); Ex. 2, Letter from A. Gluck to Secretary Azar (August 13, 2020).

46. Specifically, Sanofi asks covered entities to periodically submit anonymized, de-identified claims data for any 340B-priced prescriptions dispensed by contract pharmacies. *See* Ex. 3, Sanofi's New Initiative Combats Waste and Abuse in the 340B Program; Ex. 4, Understanding Sanofi's 340B Data Reporting Requirements. Sanofi requests only eight categories of information—the prescription number, prescribed date, fill date, NDC, quantity, pharmacy ID, prescriber ID, and 340B covered entity ID—which are to be submitted to a third-party vendor that administers the program. Sanofi's request is fully compliant with the Health Insurance Portability and Accountability Act ("HIPAA") and imposes no burden on covered entities. Nor does Sanofi discriminate against covered entities as compared to commercial customers. Indeed, this information is just a subset of what third-party payors already require for insurance reimbursement and is included in the data elements that drug manufacturers require of insurance companies when paying rebates on prescriptions. Any additional claims information that might be submitted by covered entities is automatically scrubbed during the submission process and not uploaded to Sanofi's or its vendor's systems.

47. The collected information enables Sanofi to identify and halt impermissible duplicate discounts that would otherwise go undetected. For example, by comparing the information to Medicaid payor data, Sanofi can detect duplicate discounts for drugs

dispensed to Medicaid patients. And the information also enables Sanofi to flag when Medicare Part D and commercial rebates are being sought for 340B-priced drugs.

48. Under Sanofi's integrity initiative, covered entities have no obligation to provide the requested claims data. If a covered entity declines to provide the claims data, Sanofi continues to offer its drugs at 340B prices for shipment to the covered entity's own facilities; the entity simply may not order discounted drugs for shipment to contract pharmacies. If a covered entity provides the requested claims data, the entity remains able to pay the discounted price for drugs shipped to contract pharmacies or its own facilities.

49. Since announcing the integrity initiative, Sanofi has continued to provide discounted drugs to contract pharmacies for the many covered entities that are providing the requested claims data. Sanofi has also excepted certain covered entities from this integrity initiative.

IV. The Advisory Opinion

50. In recent months, various covered entities and state officials asked HHS to take enforcement actions, including the assessment of civil monetary penalties, against Sanofi and other drug manufacturers that had implemented policies to combat duplicate discounts and diversion at contract pharmacies. *See* Ex. 5, Letter from California Attorney General Becerra to Secretary Azar (Dec. 14, 2020); Ex. 2, Letter from A. Gluck to Secretary Azar (Aug. 13, 2020); Ex. 6, Letter from A. Gluck to American Hospital Association (Aug. 28, 2020); Ex. 7, Letter from American Hospital Association, et al. to Secretary Azar (Aug. 26, 2020). Various covered entities also filed lawsuits seeking to require HHS to take such action. *See Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906 (D.D.C.); *Am. Hosp.*

Ass'n v. HHS, No. 4:20-cv-8806 (N.D. Cal.). (Sanofi has filed motions to intervene in both suits; both motions remain pending.)

51. On December 30, 2020, HHS took action against drug manufacturers such as Sanofi when HHS's General Counsel published the Advisory Opinion, concluding (for the first time) that drug manufacturers are legally obligated to provide 340B-priced drugs to contract pharmacies—notwithstanding the widespread recognition (including by HHS itself) of waste and abuse at contract pharmacies. In particular, HHS "conclude[d] 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 340B-priced drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." Advisory Opinion at 1, 8.

52. In addition, the Advisory Opinion prohibits manufacturers from imposing conditions on the delivery of discounted drugs to contract pharmacies based on concerns about duplicate discounting or diversion. In particular, HHS determined that "private actor[s]" are not "authorized by section 340B to add requirements to the statute." *Id.* at 2. Thus, according to the Advisory Opinion, "'[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity.'" *Id.* at 5 (quoting 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017)). As per the Advisory Opinion, "[i]f a manufacturer is concerned that a covered entity has engaged in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must

(1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ('ADR') process, *see* §256b(d)(3)(A)." *Id.* & n.5.

53. Under the Advisory Opinion, because of its integrity initiative, Sanofi is exposed to government enforcement actions for noncompliance, including civil monetary penalties in the amount of $5,000 for each instance of noncompliance, *see* 42 U.S.C. § 256b(d)(1)(B)(vi)(II), and the revocation of its ability to participate in Medicare and Medicaid.

54. Third parties have already recognized that the Advisory Opinion requires Sanofi to provide 340B-priced drugs to contract pharmacies without any conditions. For example, certain covered entities recently notified Sanofi that the Advisory Opinion requires "drug companies to provide 340B entities covered outpatient drugs . . . when those covered entities use contract pharmacies to dispense the drugs." *See* Ex. 8, Letter From W. Schultz to C. Lee (Jan. 7, 2021). These covered entities contend that the Advisory Opinion requires Sanofi to pay them reimbursements and justifies imposition of civil monetary penalties for Sanofi's integrity initiative. *Id.* at 2.

55. Given their repeated threats against Sanofi, covered entities will almost certainly file ADR claims against Sanofi challenging the integrity initiative once the ADR Rule takes effect on January 13, 2021. As noted, the ADR Panel will consist of representatives from the HHS Office of General Counsel (which issued the Advisory Opinion) and from HRSA and CMS, both of which are HHS agencies and subject to the Office of General Counsel's legal advice and supervision. Given this composition, the ADR Panel will treat the Advisory Opinion as binding in any ADR proceeding, almost certainly

find that Sanofi's integrity initiative violates Section 340B as interpreted by HHS, and potentially impose crippling sanctions.

STANDING

56. Sanofi is injured by the Advisory Opinion because Sanofi now must provide its drugs to contract pharmacies at discounted prices, cannot impose conditions on the delivery of 340B-priced drugs to contract pharmacies, and is exposed to sanctions (including enforcement actions, civil monetary penalties, and revocation of its participation in the Medicare and Medicaid programs) that are certainly impending if Sanofi fails to comply with HHS's new rule.

57. Sanofi's injuries are fairly traceable to the Advisory Opinion because the Advisory Opinion contains binding legal requirements that drug manufactures must provide discounted drugs to contract pharmacies and that manufacturers cannot impose conditions on the delivery of 340B-priced drugs to contract pharmacies. Neither Section 340B nor any existing regulation contains these binding legal requirements. Through the Advisory Opinion, HHS has effectively outlawed Sanofi's integrity initiative for imposing a condition on the delivery of 340B-priced drugs to contract pharmacies. As a result of the Advisory Opinion, Sanofi is exposed to enforcement actions and civil monetary penalties, as well as the revocation of its participation in the Medicare and Medicaid programs, if it fails to comply with the Advisory Opinion by continuing to operate the integrity initiative.

58. A favorable ruling is likely to redress Sanofi's injuries. Vacating the Advisory Opinion would redress Sanofi's injury because Sanofi would not be required to provide 340B-priced drugs to contract pharmacies, and Sanofi could impose conditions on the

delivery of such drugs to contract pharmacies (such as through its integrity initiative). Likewise, a declaratory judgment that Sanofi's integrity initiative complies with Section 340B would redress Sanofi's injuries because Sanofi would not be exposed to enforcement actions, civil monetary penalties, or revocation of its participation in Medicare and Medicaid for continuing to operate the integrity initiative.

FINAL AGENCY ACTION

59. Although the Advisory Opinion self-servingly claims that it "is not a final agency action" and "does not have the force or effect of law," Advisory Opinion at 8, the Advisory Opinion is in fact "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

60. The Advisory Opinion represents the consummation of HHS's decision-making process, through which HHS concluded that drug manufacturers must provide drugs discounted under the 340B Program to contract pharmacies. *See* Advisory Opinion at 1–4. HHS also concluded that drug manufacturers cannot impose conditions on the delivery of discounted covered outpatient drugs to contract pharmacies. *See id.* at 5. Indeed, the Secretary recently admitted that these conclusions have "been set forth *conclusively* in the recently issued advisory opinion." Dkt. 64, Defs.' Mot to Dismiss, at 9, No. 4:20-cv-8806 (N.D. Cal.) (filed Jan. 11, 2021) (emphasis added). HHS reached these conclusions after years of study and after reviewing complaints from covered entities and government officials about Sanofi's integrity initiative and other drug manufacturers' compliance with Section 340B. The Advisory Opinion was issued by HHS's chief legal officer, who "supervises all legal activities of the Department and its operating agencies," *see* Statement of Organization,

85 Fed. Reg. at 47,230, and the Advisory Opinion is not subject to further review or appeal within HHS. And because the Advisory Opinion will be treated as binding in any ADR proceeding against Sanofi, any attempt to contest the Advisory Opinion's determinations before an ADR Panel would be futile.

61. The Advisory Opinion determines Sanofi's rights and legal obligations under Section 340B, and legal consequences will inevitably flow from the Advisory Opinion. Sanofi must now provide 340B-priced drugs to contract pharmacies. Sanofi is now forbidden from imposing conditions on the delivery of 340B-priced drugs to contract pharmacies. And Sanofi is now exposed to enforcement actions and civil monetary penalties if it fails to comply with the Advisory Opinion by continuing with the integrity initiative, even though neither Section 340B nor any existing regulation contains these binding legal requirements. Indeed, as the Secretary recently stated, the Advisory Opinion sets forth the agency's "legal interpretation that the statute *requires* manufacturers to make discounts available regardless whether covered entities choose to disburse drugs through contract pharmacies." Dkt. 64, Defs.' Mot to Dismiss, at 16, No. 4:20-cv-8806 (N.D. Cal.) (filed Jan. 11, 2021) (emphasis added). Noncompliance with the Advisory Opinion—which will be treated as binding in any ADR proceeding against Sanofi—also jeopardizes Sanofi's participation in Medicare and Medicaid by risking termination of Sanofi's PPA.

62. Sanofi is thus now put to a painful choice: either comply with the unlawful obligations in the Advisory Opinion by abandoning a reasonable integrity initiative which Sanofi believes fully complies with Section 340B, or risk devastating financial penalties by

continuing to operate the integrity initiative in the face of the Advisory Opinion and repeated threats of enforcement.

CLAIMS FOR RELIEF

Count I—Violation of Administrative Procedure Act
HHS Failed to Observe the Notice and Comment Procedure Required by Law

63. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

64. A court must "hold unlawful and set aside agency action, findings, and conclusions found to be … without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

65. The APA requires agencies to issue rules through a notice-and-comment process. *See id.* § 553.

66. The APA defines a "rule" as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4).

67. The Advisory Opinion is a rule within the meaning of the APA because it is an agency statement of general applicability to all drug manufacturers, applies prospectively, and implements, interprets, or prescribes HHS's law or policy with respect to drug manufacturers' obligations under Section 340B.

68. In particular, the Advisory Opinion requires drug manufacturers to provide drugs discounted under the 340B Program to contract pharmacies. It also prohibits drug

manufacturers from imposing conditions on the delivery of 340B-priced drugs to contract pharmacies.

69. The Advisory Opinion has the force and effect of law because it imposes binding obligations that exceed existing law. Neither Section 340B nor any regulation requires drug manufactures to provide discounted drugs to contract pharmacies or restricts the ability of manufacturers to impose conditions on the delivery of drugs to contract pharmacies. But the Advisory Opinion does both. *See* Advisory Opinion at 1–5. Sanofi is exposed to enforcement actions and civil monetary penalties if it fails to comply with the Advisory Opinion and continues to operate the integrity initiative. Noncompliance with the Advisory Opinion also puts at risk Sanofi's participation in Medicare and Medicaid.

70. HHS issued the Advisory Opinion without engaging in the notice-and-comment process. 5 U.S.C. § 553.

71. This Court should hold unlawful and set aside the Advisory Opinion because it violates the APA's notice-and-comment requirement. *Id.* § 706(2)(D).

Count II—Violation of Administrative Procedure Act
HHS Failed to Follow Its Good Guidance Rule

72. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

73. A court must "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" as well as agency action "found to be without observance of procedure required by law." *Id.* § 706(2)(A), (D).

74. Through the "Good Guidance Rule," HHS regulations subject guidance documents to various requirements. *See* Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 78,770 (Dec. 7, 2020) (to be codified at 45 C.F.R. pt. 1).

75. The Good Guidance Rule defines a "guidance document" as "any Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation." *Id.* at 78,785, 45 C.F.R. § 1.2.

76. The Good Guidance Rule defines "a significant guidance document" as "a guidance document that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more." *Id.* A guidance document can also be a "significant guidance document" if it "raise[s] novel legal or policy issues arising out of legal mandates." *Id.*

77. The Advisory Opinion is a guidance document within the meaning of the Good Guidance Rule because it interprets Section 340B to require manufacturers to provide 340B-priced drugs to contract pharmacies and because it prohibits manufacturers from imposing conditions on such delivery. It is generally applicable to manufacturers participating in the 340B Program and is intended to have future effect on the behavior of participants in the 340B Program because it exposes them to the potential for enforcement actions, the imposition of civil monetary penalties, and other consequences of non-compliance.

78. The Advisory Opinion is a significant guidance document within the meaning of the Good Guidance Rule because it "raise[s] novel legal or policy issues arising out of legal mandates." *Id.* In particular, the Advisory Opinion raises a novel legal issue relating to the meaning of Section 340B arising out of its mandates that manufacturers participating in the 340B Program provide 340B-priced drugs to contract pharmacies and that they not impose conditions on such delivery.

79. The Advisory Opinion is also a significant guidance document within the meaning of the Good Guidance Rule because it "may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more." *Id.*

80. The Advisory Opinion violates the Good Guidance Rule because it "establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute." *Id.* at 78,786, 45 C.F.R. § 1.3(a)(1). In particular, the Advisory Opinion requires drug manufacturers to provide drugs covered under the 340B Program to contract pharmacies. It also prohibits drug manufacturers from imposing conditions on the delivery of 340B-priced drugs to contract pharmacies.

81. The Advisory Opinion violates the Good Guidance Rule because it "requir[es] a person or entity outside of the Department to take an[] action, or refrain from taking an[] action, beyond what is required by the terms of an applicable statute or regulation." *Id.* 78,785–86, 45 C.F.R. § 1.3(a)(2). In particular, the Advisory Opinion's requirement that manufacturers provide discounted covered outpatient drugs under the 340B Program to contract pharmacies is "beyond what is required by the terms" of Section 340B. *Id.* In addition, the Advisory Opinion's determination that manufacturers participating in the 340B

Program may not impose conditions on the delivery of discounted covered outpatient drugs to contract pharmacies requires those manufacturers to "refrain from taking an[] action" when Section 340B imposes no such limit.

82. The Advisory Opinion violates the Good Guidance Rule because it does not "identify itself as 'guidance.'" *Id.* at 78,786, 45 C.F.R. § 1.3(a)(3)(i).

83. The Advisory Opinion violates the Good Guidance Rule because it "directs parties outside the federal government to take or refrain from taking action." *Id.* at 78,786, 45 C.F.R. § 1.3(a)(3)(ii). In particular, the Advisory Opinion directs drug manufacturers to provide covered outpatient drugs to contract pharmacies at discounted prices under Section 340B. The Advisory Opinion also directs drug manufacturers to refrain from imposing conditions on deliveries of covered outpatient drugs to contract pharmacies at discounted prices under Section 340B.

84. The Advisory Opinion violates the Good Guidance Rule because HHS did not follow the procedures required by the Good Guidance Rule for significant guidance documents. *Id.* at 85 Fed. Reg. at 78,785, 45 C.F.R. § 1.3(b)(2). Specifically, the Advisory Opinion was not subject to "at least a 30-day public notice and comment period" or "approved, on a non-delegable basis, by the Secretary." *Id.*

85. This Court should hold unlawful and set aside the Advisory Opinion as contrary to law and arbitrary and capricious in light of these violations of the Good Guidance Rule. *See* 5 U.S.C. § 706(2)(A), (D).

Count III—Violation of Administrative Procedure Act
The Advisory Opinion Is Contrary to Law and in Excess of Statutory Authority

86. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

87. A court must "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" as well as agency action "in excess of statutory authority." 5 U.S.C. § 706(2)(A), (C).

88. The Advisory Opinion's conclusion that drug manufacturers must provide discounted covered outpatient drugs to contract pharmacies is contrary to law and in excess of statutory authority because Section 340B does not require drug manufacturers to provide discounted covered outpatient drugs to contract pharmacies. *See* 42 U.S.C. § 256b.

89. The Advisory Opinion's conclusion that drug manufacturers cannot impose conditions on the use of contract pharmacies is contrary to law and in excess of statutory authority because Section 340B does not prohibit manufacturers from imposing conditions on the use of contract pharmacies—particularly when such conditions are reasonable. *See id.*

90. Even if the Advisory Opinion is correct that manufacturers must provide 340B-priced drugs to contract pharmacies, Sanofi's integrity initiative complies with Section 340B because it imposes a permissible condition on the delivery of discounted covered outpatient drugs to contract pharmacies. Sanofi ships discounted drugs to contract pharmacies—and, moreover, will do so for all covered entities. So long as a covered entity provides the claims data requested by Sanofi, Sanofi provides discounted pricing wherever

the prescriptions are filled. This request for claims data is a reasonable condition that is not burdensome and that does not discriminate against covered entities as compared to commercial customers.

91. The Advisory Opinion is not entitled to *Chevron* or *Skidmore* deference. *See generally Chevron USA, Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

92. This Court should hold unlawful and set aside the Advisory Opinion because it is contrary to law and in excess of statutory authority. 5 U.S.C. § 706(2)(A).

Count IV—Violation of Administrative Procedure Act
The Advisory Opinion Is Arbitrary and Capricious

93. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

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

95. The Advisory Opinion's conclusion that drug manufacturers must provide discounted covered outpatient drugs to contract pharmacies is arbitrary and capricious because HHS failed to reasonably explain this aspect of the Advisory Opinion.

96. The Advisory Opinion's conclusion that drug manufacturers cannot impose conditions on the use of contract pharmacies is arbitrary and capricious because HHS failed to reasonably explain this aspect of the Advisory Opinion.

97. This Court should hold unlawful and set aside the Advisory Opinion because it is arbitrary and capricious. *Id.* § 706(2)(A).

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for the following relief:

1. A declaration, order, and judgment holding unlawful, enjoining, and setting aside the Advisory Opinion;

2. A declaration, order, and judgment holding that Section 340B does not require drug manufacturers to provide discounted covered outpatient drugs to contract pharmacies;

3. A declaration, order, and judgment holding that Section 340B does not prohibit drug manufacturers from imposing conditions on the provision of discounted covered outpatient drugs to contract pharmacies;

4. A declaration, order, and judgment holding that Sanofi's integrity initiative complies with Section 340B because it imposes a permissible condition on the provision of discounted covered outpatient drugs to contract pharmacies;

5. A preliminary and permanent injunction enjoining Defendants from enforcing the Advisory Opinion in any administrative proceeding;

6. An award of all costs and attorneys' fees pursuant to any applicable statute or authority; and

7. Any other relief this Court deems just and proper.

Dated: January 12, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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Counsel for Plaintiff
Sanofi-Aventis U.S. LLC

Exhibit F

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware Street
Indianapolis, IN 46225,

and

LILLY USA, LLC,
1500 South Harding Street
Indianapolis, IN 46221,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services,
Office of the Secretary
200 Independence Avenue, S.W.
Washington, D.C. 20201,

ROBERT P. CHARROW, in his official capacity as General Counsel of Health & Human Services
Office of the General Counsel
200 Independence Avenue, S.W.
Washington, D.C. 20201,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington D.C. 20201,

THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration
5600 Fishers Lane,
Rockville, MD 20852,

and

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane,
Rockville, MD 20852,

Defendants.

Civil Action No. 1:21-cv-81

Document Electronically Filed

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

At issue in this case is the lawful scope of the 340B Drug Pricing Program ("340B Program"), which Congress created in 1992 to expand low-income Americans' access to affordable prescription medicines. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act) ("340B Statute"). Under the 340B Statute, pharmaceutical manufacturers "must" offer steep discounts on their products to certain "covered entities." 42 U.S.C. § 256b(a)(1); *see also id.* § 256b(a)(4), (b)(1); *id.* § 1396r-8(a)(1), (5). And while manufacturers are not formally required to participate in the 340B Program, they have little practical choice but to "opt in[]": "Manufacturers' eligibility to participate in State Medicaid [and federal Medicare] programs," which "touch[] the lives of nearly all Americans," *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019), and contribute a significant portion of manufacturers' annual revenues, "is conditioned on their" participation in the 340B Program and "entry into [Pharmaceutical Pricing Agreements] for covered drugs purchased by 340B entities." *Astra U.S.A., Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

Under the original terms of the 340B Program, and cognizant of the constitutional limits on forcing private parties to effectively subsidize other private parties, Congress provided that only "covered entities"—a narrowly circumscribed class of non-profit healthcare providers that Congress defined to be limited to 15 discrete and specifically enumerated types of entities that serve low-income and/or vulnerable populations—could demand these steep discounts. Entities not included on Congress's list of covered entities—such as for-profit hospitals or big businesses like Walgreens and CVS, the latter of which are referred to as "contract pharmacies"—had no legal basis to demand to receive medications from manufacturers at 340B discounted prices. *See* 42 U.S.C. § 256b(a)(4).

But that has all changed now. On December 30, 2020, the U.S. Department of Health and Human Services ("HHS") Office of the General Counsel "released an advisory opinion concluding that drug manufacturers are required to deliver discounts under the 340B Drug Pricing Program (340B Program) on covered outpatient drugs when contract pharmacies are acting as agents of 340B covered entities." U.S. Dep't of Health and Human Servs., *HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies* (Dec. 30, 2020), https://bit.ly/38Qh0lB; *see* U.S. Dep't of Health & Human Servs. Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 1 (Dec. 30, 2020) ("December 30 Decision") ("We conclude" that "a drug manufacturer in the 340B Program is ***obligated*** to deliver its covered outpatient drugs to those contract pharmacies ***and to charge the covered entity no more than the 340B ceiling price for those drugs***" whenever a contract pharmacy acts as a covered entity's "agent." (emphasis added)), https://bit.ly/357nqfk.

That is no small matter. Unlike the 15 types of entities Congress enumerated in the statute, contract pharmacies do not predominantly serve vulnerable populations, and they rarely pass along any 340B price savings to the patients who purchase 340B drugs. *See* U.S. Gov't Accountability Office ("GAO"), *Discount Drug Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480 ("2018 GAO Report"), at 10-13 (June 2018), https://bit.ly/3kJ7eGa; Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, at 3 (Oct. 2020), https://bit.ly/2XryAY5. When Defendants HHS and the Health Resources and Services Administration ("HRSA") first allowed covered entities to enter into an unlimited number of contract pharmacy arrangements for 340B drugs back in 2010 (but did not require manufacturers to honor those arrangements), contract pharmacies began "generat[ing] revenue" ***to the tune of hundreds of millions of dollars per year*** by perverting the 340B Program

simply by "purchas[ing] covered outpatient drugs at the 340B Program price for all eligible patients regardless of the patients' income or insurance status" and "receiving reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs." GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108, at 5 (Dec. 2019), https://bit.ly/34Vj6zK.

Against this backdrop, and consistent with the plain text and clear purpose of the statute, Plaintiffs Eli Lilly and Company and Lilly USA, LLC (together, "Lilly") announced last summer that it would cease to offer 340B discounts to contract pharmacies on three formulations of its drug Cialis®. Lilly later expanded this new distribution model to include all of its products—except when a covered entity lacks an in-house pharmacy, in which case an outside pharmacy is necessary to dispense covered drugs, and in which case Lilly will permit the covered entity to designate one contract pharmacy to receive and dispense 340B product.

To be clear: Lilly still offers full 340B discounts to all entities eligible for them. And Lilly will continue to ensure that patients are able to receive 340B product even when a covered entity cannot dispense drugs itself. Lilly's new distribution plan is thus not only a necessary bulwark against contract pharmacy abuses of the 340B Program, but is consistent with the plain text and the original intent of the 340B Statute. Yet when Lilly announced that it would no longer allow an unlimited number of contract pharmacies to demand discounts, Defendants first threatened Lilly with sanctions and now have made good on those threats: They have jettisoned their prior nonbinding guidance that contract pharmacy arrangements are permissible but not enforceable and replaced that guidance with a new, binding decision under which manufacturers like Lilly must offer full 340B discounts to contract pharmacies on all covered drugs, lest they face massive penalties of up to $5,000 per occurrence, plus the potential revocation of the manufacturer's ability

to participate in and receive reimbursements under the pervasive Medicare and Medicaid programs.

Lilly therefore brings this action seeking an order (1) declaring that the December 30 Decision violates the Administrative Procedure Act because it was issued without following proper procedure, is in excess of statutory authority, violates the Constitution, and is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law; (2) declaring that Lilly is not required to offer 340B discounts to contract pharmacies; and (3) enjoining enforcement of the December 30 Decision and all actions by Defendants inconsistent with that declaratory relief.

THE PARTIES

1. Plaintiff Eli Lilly and Company is a publicly traded pharmaceutical company organized and existing under the laws of the State of Indiana and headquartered in Indianapolis, Indiana. Eli Lilly and Company participates in the 340B Program.

2. Plaintiff Lilly USA, LLC is a wholly owned subsidiary of Eli Lilly and Company existing under the laws of the State of Indiana and headquartered in Indianapolis, Indiana.

3. Defendant HHS is an executive branch department in the United States government headquartered in the District of Columbia. HHS oversees the activities of HRSA.

4. Defendant Alex M. Azar II, sued in his official capacity only, is the Secretary of HHS. His official address is in the District of Columbia. Secretary Azar has ultimate responsibility for oversight of the activities of HRSA, including with regard to the administration of the 340B Program and the actions complained of herein.

5. Defendant Robert P. Charrow, sued in his official capacity only, is the General Counsel of HHS. His official address is in the District of Columbia. Mr. Charrow oversees the Office of General Counsel, which publishes final legal decisions on behalf of the agency.

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

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

JURISDICTION AND VENUE

8. Lilly brings this action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

9. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

10. Venue is proper because, among other things, Lilly resides in this judicial district and "no real property is involved in the action." 28 U.S.C. § 1391(e)(1).

11. This Court may grant injunctive and declaratory relief pursuant to 5 U.S.C. §§ 701–706 and 28 U.S.C. §§ 2201–2202.

FACTS

I. Congress Created The 340B Program To Help Vulnerable And Low-Income Patients

12. Congress established the 340B Program, named for the statutory provision authorizing it in the Veterans Health Care Act of 1992, *see* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act), to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 WM. & MARY

L. REV. 637, 638 (2015); *see* H.R. Rep. No. 102-384 (II), at 12 (1992) (The 340B Program "provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans."). The point of the 340B Program, in other words, was to "create[] a low-cost source of pharmaceutical medication for the indigent patients themselves." Baer, *supra*, at 638.

13. Although participation in the 340B Program is formally optional, *see Astra*, 563 U.S. at 117-18, manufacturers have no real choice but to opt in: Manufacturers cannot receive coverage or reimbursement for their products under Medicaid and Medicare Part B unless they participate in the 340B Program. 42 U.S.C. § 1396r-8(a)(1), (5).

14. Manufacturers "opt into" the 340B Program by signing a form contract, known as the Pharmaceutical Pricing Agreement ("PPA"), with HHS. *Astra*, 563 U.S. at 117.

15. A PPA is not an ordinary contract. PPAs are entirely composed by HHS, they "have no negotiable terms," and they "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Id.* at 118. "The statutory and contractual obligations, in short, are one and the same." *Id.*

16. The government may terminate a PPA if it determines that a manufacturer has failed to comply with its obligations. *See* 42 U.S.C. 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412–65,413 (Dec. 12, 1996); PPA §§ IV(c), VI(c).

17. Under the 340B Statute and the terms of the PPA, any manufacturer that participates in the 340B 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." 42 U.S.C. § 256b(a)(1). Only "covered entities"—a class of non-profit

healthcare organizations the 340B Statute defines in painstaking detail—are eligible to participate in the Program and receive these discounts for prescription drugs.

18. The 340B Statute exhaustively defines "covered entities." The statutory definition enumerates 15 categories of "covered entities" (*e.g.*, "A black lung clinic receiving funds under section 937(a) of title 30"), but not the specific eligible entities themselves (*e.g.*, the Philadelphia Black Lung Clinic). *See* 42 U.S.C. § 256b(a)(4).

19. Consistent with the 340B Program's overriding goal of helping vulnerable and low-income patients acquire lower-cost access to life-saving medicines, the statute defines "covered entities" to include only organizations that naturally, and often predominantly, serve low-income individuals. For instance, Federally Qualified Health Centers, children's hospitals, rural hospitals, and other clinics serving vulnerable populations are all specifically defined as "covered entities" eligible to enroll and participate in the 340B Program. *Id.*; *see also Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820 (D.C. Cir. 2020).

20. The statute further makes clear that entities ***not*** on the list—*e.g.*, for-profit hospitals, and commercial businesses such as "contract pharmacies" that profit off manufacturer discounts—are not entitled to receive medications from manufacturers at 340B discounted prices. 42 U.S.C. § 256b(a)(4).

21. Pursuant to the 340B Statute and the terms of the PPA, HRSA publishes on its website a list of specific qualifying "covered entities," which it updates quarterly. *See* 42 U.S.C. § 256b(a)(9); PPA § III.(a). HRSA treats the quarterly list as definitive and binding on manufacturers. *See* 82 Fed. Reg. 1,210, 1,227 (Jan. 5, 2017).

22. Covered entities pay significantly discounted prices for "covered outpatient drugs," a category which includes most drugs used on an outpatient basis, according to a prescribed

statutory formula. *See* 42 U.S.C. § 256b(a)(1), (a)(4), (b)(1). The 340B price is calculated by determining the difference between the manufacturer's Average Manufacturer Price and its Medicaid rebate amount, as determined under the Medicaid Drug Rebate Program statute, codified at Section 1927 of the Social Security Act. *Id.* § 256b(a)(1)-(2) & (b). The resulting prices, known as the 340B "ceiling prices," are significantly lower than what other purchasers would pay for the same product and can even be as low as one penny per pill or per milligram. Covered entities are then able to turn around and bill patients or insurers the drug's full price, pocketing the difference.

23. The 340B Statute delegates oversight and enforcement responsibilities to HHS. In addition to requiring HHS to notify manufacturers of the identity of covered entities, *see id.* § 256b(a)(9), the statute authorizes HHS to monitor unlawful drug diversion by covered entities and to audit covered entities and manufacturers, *see id.* § 256b(d)(1)(B)(vi). HHS has delegated 340B oversight and enforcement to HRSA, one of the defendants in this suit.

24. That authority empowers HRSA to evaluate manufacturer compliance with Program requirements, and it may impose civil monetary penalties ("CMPs") on manufacturers that knowingly and intentionally charge covered entities more than the statutory 340B ceiling price for covered outpatient drugs. In particular, HRSA may impose CMPs of up to $5,883 "for each instance of overcharging" a covered entity. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020); *see* 42 C.F.R. § 10.11(a); 42 U.S.C. § 256b(d)(1)(B)(vi).

25. In addition to limiting the universe of covered entities, Congress also prohibited covered entities from causing "duplicate discounts or rebates," which means they may not request both a 340B discount and a Medicaid rebate for the same drug. 42 U.S.C. § 256b(a)(5)(A).

26. And to help ensure that covered entities and others do not inappropriately benefit from the opportunity of 340B price arbitrage, Congress further forbade any "covered entity" from

engaging in "diversion," *i.e.*, "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). In other words, covered entities may not transfer or sell the discounted drugs to any person or entity except their own patients. The 340B Statute does not extend this diversion prohibition to manufacturers—thereby ensuring that if a covered entity lacks an in-house pharmacy through which it can dispense medicines itself, manufacturers may lawfully opt to deliver discounted product to a dispensing pharmacy of the covered entity's choosing (as Lilly has always done and continues to do still today).

27. There are two potential forms of diversion at play when covered entities use contract pharmacies. First, diversion occurs when the covered entities transfer or sell discounted drugs to any person or entity except their own patients—*i.e.*, to the contract pharmacies. Second, diversion occurs when covered entities (or contract pharmacies) transfer or sell discounted drugs to patients who are not eligible to receive drugs at discounted prices pursuant to 340B. In other words, contract pharmacy arrangements, which instruct wholesalers to honor 340B prices to for-profit commercial pharmacies, may (and frequently do) result in 340B discounted product being diverted—*i.e.*, "otherwise transfer[red]" to another person or entity in violation of the statute.

II. The 340B Statute Neither Requires Manufacturers To Offer Discounts To For-Profit Contract Pharmacies Nor Empowers HHS/HRSA To Impose Such A Requirement

28. The 340B Statute contemplates that manufacturers will provide covered outpatient drugs at 340B discounted prices ***only*** to covered entities.

29. Nothing in the statute allows, let alone mandates, the use of contract pharmacies or that manufacturers respect an unlimited number of covered entity – contract pharmacy relationships. In fact, the opposite is true.

30. Section 340B's plain language limits a manufacturer's obligation to offer 340B prices to "each covered entity." 42 U.S.C. § 256b(a)(1); *see id.* (authorizing the HHS Secretary

(and thus HRSA) to "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price").

31. A contract pharmacy, however, is not a covered entity.

32. The 340B Statute defines the term "covered entity" in exhaustive detail. In 42 U.S.C. § 256b(a)(4)—titled "'Covered entity' defined"—Congress defined the term as "an entity that meets the requirements described in paragraph (5)," which prohibits diversion and duplicate discounts, "and ***is*** one of the following":

> (A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).
>
> (B) An entity receiving a grant under section 256a of this title.
>
> (C) A family planning project receiving a grant or contract under section 300 of this title.
>
> (D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).
>
> (E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.
>
> (F) A black lung clinic receiving funds under section 937(a) of title 30.
>
> (G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.
>
> (H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.
>
> (I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.
>
> (J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).
>
> (K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to

treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

33. The 340B Statute thus lists 15 different types of entities that can qualify as "covered entities" for purposes of the 340B Program. Contract pharmacies do not make the list.

34. Furthermore, neither the 340B Statute nor any other provision of law confers upon Defendants authority to require manufacturers to provide discounts to contract pharmacies through any exception process or carve out through a "safe harbor" for unlisted covered entities, or by claiming that contract pharmacies act as the "agents" of covered entities. That means Defendants have no such authority: As creatures of statute, agencies like HHS and HRSA have no valid power to act "unless and until Congress confers power upon [them]." *Wabash Valley Power Ass'n, Inc. v. Rural Electrification Admin.*, 988 F.2d 1480, 1486 (7th Cir. 1993) (quoting *La. Public Service Comm'n v. FCC*, 476 U.S. 355, 374 (1986)). Congress has not granted any such authority here.

35. Nor does the 340B Statute permit Defendants to obligate manufacturers to offer discounts to contract pharmacies based on the theory that the latter are merely acting as "agents" of covered entities. The 340B Statute contemplates that various entities that themselves are not covered entities may effectively step in the shoes of a covered entity in certain, limited circumstances. *See, e.g.*, 42 U.S.C. § 256b(d)(3)(B)(vi) (referring separately to three types of agents, including "associations or organizations representing the interests of [ ] covered entities," rather than simply calling them "covered entities"); *id.* § 256b(d)(1)(B)(v) (same vis-à-vis "wholesalers"); *id.* § 256b(d)(2)(B)(iv) (same vis-à-vis "distributors"). But Congress did not delegate any discretionary or rulemaking authority to HRSA to add to or subtract from the list of entities that manufacturers are required to treat as "covered entities" under the Program, or to impose a requirement that manufacturers offer 340B discounts to "associations or organizations representing the interests of [ ] covered entities" on pain of penalty.

36. To the contrary, Congress limited HRSA's authority to undertake rulemaking in the 340B Program to three specific areas: (1) the establishment of an administrative dispute resolution process, (2) the issuance of precisely defined standards of methodology for calculation of ceiling

prices, and (3) the imposition of monetary civil sanctions, *see Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014), the latter of which is specifically limited to instances of overcharging ***covered entities themselves***, not any agents thereof, *see* 42 U.S.C. § 256b(d)(1)(B)(vi)(II)-(III).

37. In short, HRSA has no authority to create exceptions to the statutory limitation that only the explicitly enumerated "covered entities" may receive 340B discounts. Only Congress holds that power. Any agency determination to the contrary is in excess of its statutory authority and contrary to law. 5 U.S.C. § 706(2)(A); *see FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000) (An agency "may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted." (internal quotation marks omitted)).

III. Despite These Statutory Limitations, HRSA Issued Guidance Permitting The Use Of Contract Pharmacies In 1996 And Then Expanded That Permission In 2010, But Stopped Short Of Requiring Manufacturers To Offer Contract Pharmacies Discounts

38. Until 1996, covered entities purchased and dispensed 340B drugs exclusively through in-house pharmacies.

39. In 1996, HRSA issued guidance allowing "contract pharmacies"—typically large, commercial, for-profit entities—to sign agreements with covered entities to dispense covered outpatient drugs in connection with the 340B Program. 61 Fed. Reg. 43,549 (Aug. 23, 1996).

40. This initial allowance for contract pharmacies, which are not themselves covered entities, was narrow: Only covered entities without an in-house pharmacy could contract with contract pharmacies to dispense 340B drugs to the covered entity's patients—and even then, each covered entity could contract with just a single contract pharmacy.

41. The 1996 guidance made clear that HRSA itself recognized that it lacks authority to expand or contract the universe of covered entities. *See id.* at 43,550.

42. In issuing the 1996 guidance, moreover, HRSA intentionally chose not to follow the notice-and-comment requirements of the APA. *See* 5 U.S.C. § 553(b), (c). That was because, in HRSA's view, the guidance amounted merely to an interpretive rule that "create[d] no new law and create[d] no new rights or duties." 61 Fed. Reg. at 43,550. *Compare, e.g.*, *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015) ("Interpretive rules do not have the force and effect of law and are not accorded that weight in the adjudicatory process." (internal quotation marks and citation omitted)), *with, e.g.*, *Metro. Sch. Dist. v. Davila*, 969 F.2d 485, 489 (7th Cir. 1992) (legislative rules "create new law, rights, or duties," and must proceed through notice and comment).

43. In short, HRSA's 1996 allowance for contract pharmacies created no new obligations that do not arise from the statute itself, and it did not require (or even purport to require) manufacturers to deliver 340B discounted product to contract pharmacies.

44. The lay of the land from 1996 to 2010 was thus largely consonant with the Program's aims: In the ordinary course, only covered entities—which, again, uniformly are nonprofit healthcare providers that serve large numbers or proportions of vulnerable patients, not shareholders—could receive 340B discounted drugs from manufacturers. But if a covered entity lacked an in-house pharmacy, it could contract with one (but only one) nearby pharmacy to dispense 340B discounted drugs to its patients, near or far.

45. That all changed in 2010, when HRSA issued new guidance significantly expanding covered entities' ability to contract with outside, for-profit pharmacies. *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010).

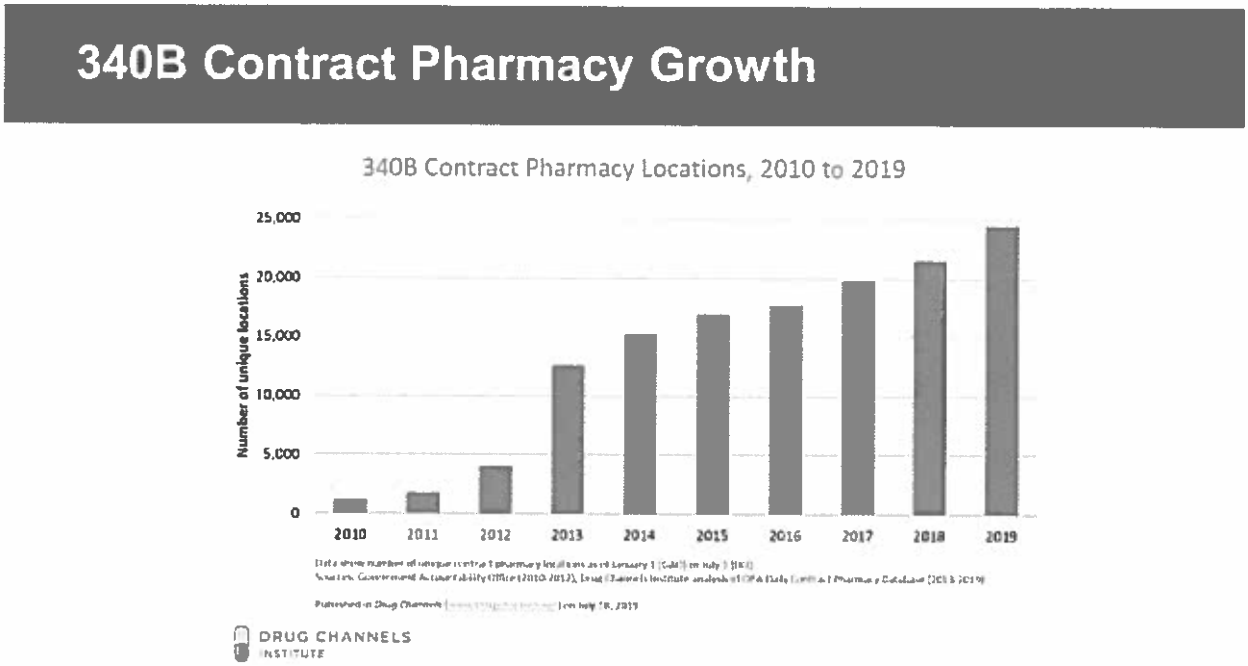
46. This 2010 guidance allows all covered entities, not just those without an in-house pharmacy, to contract with commercial pharmacies to dispense 340B discounted drugs. It further

allows covered entities to enter into an unlimited number of such arrangements with an unlimited number of contract pharmacies—whether the pharmacy is across the street or across the country.

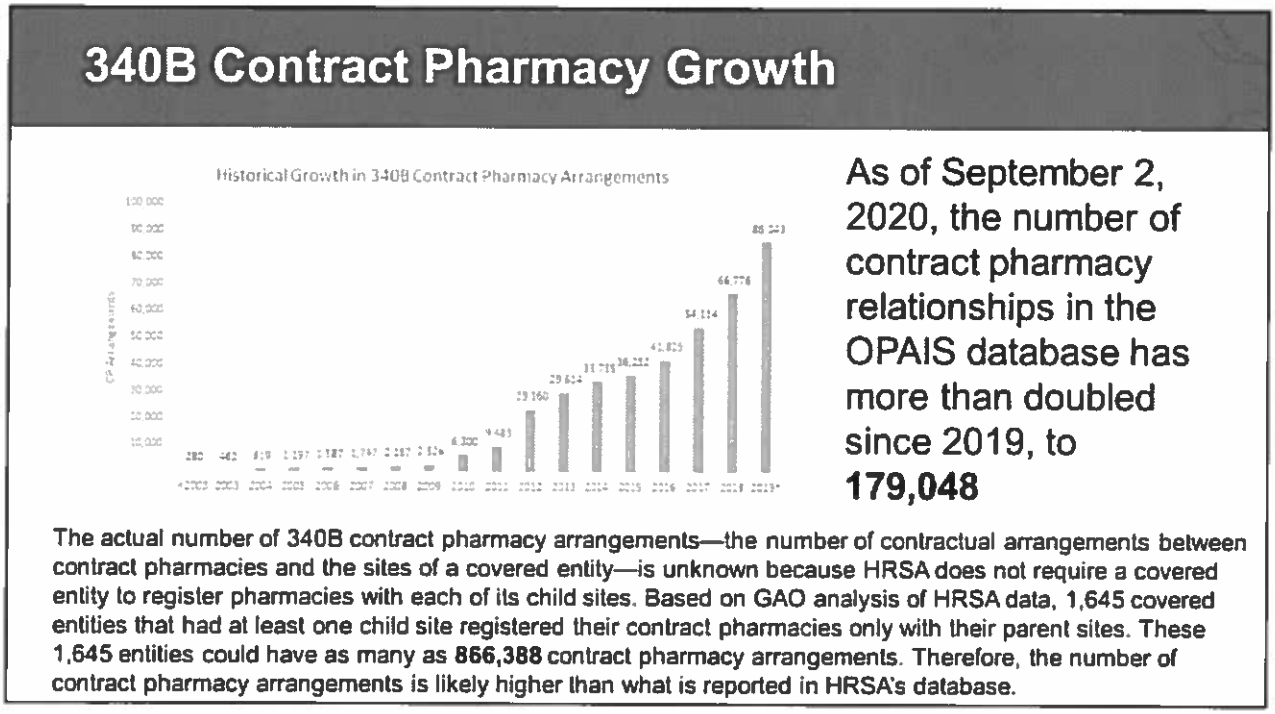
47. As in 1996, HRSA styled the 2010 guidance as an interpretive rule, did not go through the notice-and-comment procedures, and made clear that the guidance imposed no obligations. *Id.* at 10,274; *see also id.* at 10,273 (2010 guidance "neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law").

48. The 2010 guidance has radically altered—and undermined—the 340B Program. No longer is it a program intended to improve access to much-needed drugs among vulnerable patient populations; instead, the Program has become a massive profit-making endeavor for large businesses such as Walgreens, CVS, and other for-profit commercial enterprises.

49. In the first seven years following HRSA's relaxation of the rules, the GAO reported a 1,438% increase in the number of contract pharmacy arrangements, from 1,300 in 2010 to nearly 20,000 in 2017. 2018 GAO Report at 2. A more recent study reported an even greater, ***4,228%*** increase between 2010 and today. Vandervelde et al., *supra*, at 4. And according to HRSA's own figures, there are now tens of thousands of contract pharmacy locations across the country and more than 190,000 arrangements between contract pharmacies and covered entities. *See* HRSA, OPA 340B OPAIS, *340B Contract Pharmacy Database*, https://bit.ly/3nLdX3X (last visited Jan. 12, 2021). That is a remarkable figure, particularly given that HRSA's online 340B Covered Entity Database lists only about 50,000 covered entity locations in the entire Program. *See id.*



Source: https://www.drugchannels.net/2019/07/walgreens-cvs-and-walmart-lead-25000.html.



50. Some covered entities use staggering numbers of contract pharmacies to dispense 340B Program drugs. In 2017, for example, the GAO reported that a single covered entity used as many as 439 distinct contract pharmacies—meaning each of those 439 pharmacies would seek

drugs from manufacturers at the 340B prices. 2018 GAO Report at 18. Covered entities also used contract pharmacies that were ***thousands of miles*** away. *Id.* at 22; *see also id.* at 23 n.38 ("The maximum distance across all covered entities was for a disproportionate share hospital located in Connecticut that contracted with a pharmacy in Hawaii.").

51. This dramatic expansion of the use of contract pharmacies cannot be explained by an increase in the number of covered entities; as of April 2020, the number of arrangements between contract pharmacies and covered entities far exceeds the number of covered entities eligible to receive 340B discounted product.[1] Instead, the "enormous growth in 340B contract pharmacy arrangements seems to boil down to a single factor: outsized profit margins" for pharmacies and covered entities. Vandervelde et al., *supra*, at 4; *see also* 2018 GAO Report at 23 n.38 (noting that the government's "340B database does not provide information on why a covered entity may choose to contract with a pharmacy that is located a long distance away").

IV. Contract Pharmacies Have Repeatedly And Consistently Abused The 340B Program

52. The massive expansion of the 340B Program since 2010 has created a number of program integrity concerns that neither HRSA nor Congress has addressed, despite persistent calls from drug manufacturers and other industry stakeholders.

A. Contract Pharmacies Are Not Required to Pass on 340B Discounted Prices to Patients—And they Rarely Do

53. In addition to transforming the 340B Program from a mechanism for increasing low-income Americans' access to medicines into one enriching for-profit pharmacies, the 2010 guidance has created profound program integrity concerns, enabling (and arguably encouraging) practices the 340B Statute expressly prohibits—namely, drug diversion and duplicate discounts.

[1] Lilly respectfully requests that this Court take notice of the documents cited herein (*i.e.*, the government reports and published news sources), as their contents cannot reasonably be disputed and their accuracy can be readily determined. *See* Fed. R. Evid. 201.

See Vandervelde et al., *supra*, at 4 ("The 2010 guidance created an opportunity for sophisticated, for-profit pharmacy chains to realize larger margins than they otherwise could.").

54. For example, in the Medicare Part B context, government reports have found that covered entities typically paid between 20 and 50 percent below the average sales price for prescription drugs. *See, e.g.*, 85 Fed. Reg. 48,772, 48,886 (Aug. 12, 2020) (the "typical acquisition cost … under the [Medicare Hospital Outpatient Prospective Payment System] is … 34.7 percent" lower than the average sales price). Yet when they dispensed the drugs, they received the full reimbursement from Medicare. GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), https://bit.ly/3q3yG4p. In other words, covered entities with in-house pharmacies have generated considerable revenue via the 340B Program even without contract pharmacies.

55. That transfer of value from manufacturers to covered entities—all non-profit healthcare providers—is one thing. It is quite another for the government to force manufacturers to allow for-profit pharmacy chains like Walgreens and CVS to get in on the action. *See* 2018 GAO Report at 20 (75% of 340B contract pharmacies are commercial chain pharmacies). The five biggest retail chains (including, *e.g.*, CVS and Walgreens) together represent 60% of 340B contract pharmacies, but only 35% of pharmacies nationwide. *Id.* at 21.

56. Yet, under the current model, that is precisely what is happening. Like covered entities, contract pharmacies pay significantly discounted prices, known as ceiling prices, on outpatient drugs when they act on covered entities' behalf. Contract pharmacies are also permitted to—and typically do—bill the patient's third-party insurer or otherwise charge the patient out of pocket, thereby generating profits from the substantial difference between the low acquisition price mandated by the 340B Statute and the higher reimbursement value of the drug. The covered entity

then pockets this "spread" and typically pays the contract pharmacy either a pre-negotiated fee or a share of the spread for each covered outpatient drug dispensed.

57. What that means in practice is simple, but pernicious: Contract pharmacies can use covered entities to secure huge discounts on pharmaceuticals, but then turn around and charge patients full price, and kick back some part of the difference to the covered entity—capturing a nontrivial portion of the discounts intended to benefit vulnerable patient populations in the process.

58. Under the current model, contract pharmacies therefore may purchase prescription drugs at these same steep discounts from the manufacturer list prices (in some cases, as low as one penny), but then turn around and sell them for the full list price. *See* 85 Fed. Reg. at 48,888.

59. Contract pharmacies unsurprisingly have profited greatly from this arrangement. "The average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent, compared with just 22 percent for non-340B medicines dispensed through independent pharmacies." Vandervelde et al., *supra*, at 3; *see also* Raymond James, *340B Pharmacy Follow Up—Less Than $1.4B but Still Yuge*, at 1 (Sept. 9, 2020) (Walgreens generated profits "in the hundreds of millions" through 340B contract pharmacy arrangements).

60. And instead of reinvesting those savings to expand access to affordable prescription drugs, contract pharmacies simply pocket a portion of the savings on each drug dispensed.

61. It gets worse. Despite the 340B Program's objective of providing affordable drugs to underserved patients, contract pharmacies are not even required to "pass along" to patients the spread between the discounted acquisition prices from manufacturers and the reimbursement paid by an insurer (or the price charged to the uninsured patient). Nor are there any restrictions or reporting requirements related to how or even if the contract pharmacy redirects this 340B savings to benefit low-income or underserved patients in other ways. In other words, any entity obtaining

340B discounts—including a contract pharmacy—may decide to keep the full savings without ever passing the discounts along to any patient it serves. Without any reporting requirements to HRSA or otherwise, contract pharmacies can freely direct fungible money generated from the 340B Program savings to any cause without accountability, including their own bottom line.

62. Government reports show that "large numbers of low-income patients" that Congress intended to benefit from the 340B Program do not receive the substantial discounts on drugs dispensed through contract pharmacies. H.R. Rep. No. 102-384, at 10. For example, in response to a 2018 GAO survey, 45 percent of covered entities admitted they do not pass along ***any*** discount to ***any*** patients that use ***any*** of their contract pharmacies. 2018 GAO Report at 30. Nor is there reason to believe the remaining 55 percent does. The GAO specifically noted that the remaining surveyed entities using contract pharmacies may only provide discounts to patients in limited cases. *Id.* By contrast, it noted that 17 of 23 covered entities that used in-house pharmacies—instead of contract pharmacies—reported offering discounts to their patients. *Id.*

63. Likewise, a recent industry analysis found that covered entities and their contract pharmacies generated ***more than $13 billion in estimated profits*** from 340B purchased medicines in 2018 alone. Vandervelde et al., *supra*, at 7. While the 340B Program was "originally intended to provide healthcare services to indigent populations," "more than half of all profits realized by the 27,000 340B contract pharmacies participating in the 340B [P]rogram today are concentrated in just four companies," all of which are for-profit entities that are under no obligation to (and typically do not) pass on any portion of the discounts they receive to the patients the 340B Program is designed to help. *Id.*

64. Add it all up, and a program designed to benefit needy American patients has become a mechanism for multiplying large, for-profit pharmacy chains' profit margins.

65. Many businesses are not even trying to hide what they are doing; some covered entities contract with hundreds of different commercial pharmacies that are located up to 5,000 miles away. Such faraway contract pharmacies rarely, if ever, actually dispense discounted drugs to needy patients; they simply engage in arbitrage, as they are under no obligation to pass on discounts to patients. It is little wonder, then, that a recent *New England Journal of Medicine* study found that covered entities' "[f]inancial gains" under the 340B Program post-2010 "have not been associated with clear evidence of expanded care or lower mortality among low-income patients." Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 N. ENGL. J. MED. 539, 539 (Feb. 8, 2018); *see also* 2018 GAO Report at 10.

66. Even members of Congress have elevated concerns about for-profit, retail pharmacy chains taking advantage of the 340B Program to turn enormous profits. In July 2013, for example, U.S. Senator Chuck Grassley sent a letter to Walgreens CEO Gregory Wasson detailing concerns about Walgreens' 5,400 contract pharmacy locations and demanding information such as a "summary of all profits generated as a result of participating in the 340B [P]rogram as a contract pharmacy." *See* Ltr. from U.S. Sen. C. Grassley to G. Wasson (July 31, 2013), https://bit.ly/3rFSE6N. The letter reported that Walgreens employees projected dispensing 340B discounted drugs through Walgreens contract pharmacies would "add a ***minimum of $250 million***" in revenue over a 5-year period. *Id.* (emphasis added).

67. Those projections were accurate. A September 2020 analysis by an investment bank confirmed that Walgreens generated profits through 340B contract pharmacy arrangements "***in the hundreds of millions***." *See* Raymond James, *supra* (emphasis added). This is why Walgreens' October 15, 2020 10-K regulatory filing reported that any pricing changes "in connection with the federal 340B drug pricing program[] could ***significantly reduce our***

profitability." *See* Walgreens Boots Alliance, Inc., Form 10-K, at 23 (Oct. 15, 2020), https://bit.ly/2MoLX9d (emphasis added).

68. Uninsured patients also suffer from this contract pharmacy abuse. The HHS Office of Inspector General ("OIG") found that many contract pharmacies do not offer 340B discounted prices to uninsured patients. HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 2014), https://bit.ly/2LwZrzl. As a result, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies." *Id.*; *see also* Desai & McWilliams, *supra*, at 539 (340B-related "[f]inancial gains" post-2010 "have not been associated with clear evidence of expanded care or lower mortality among low-income patients.").

B. Contract Pharmacy Arrangements Flout Prohibitions on Diversion and Duplicate Discounts

69. In addition to capturing as profits the price savings intended to benefit patients in need for price assistance on life-saving prescription medicines, contract pharmacy arrangements have also led to diversion and duplicate discounts. As described above, contract pharmacy arrangements increase the incidence of a second form of diversion: contract pharmacies claiming 340B discount prices for drugs provided to patients not eligible under the 340B Program. Contract pharmacies fill prescriptions for both 340B and non-340B patients, and many contract pharmacies do not determine eligibility until weeks after the patient receives her prescription, meaning contract pharmacies can improperly claim discounts for ineligible patients.

70. Since 2010, government agency reports have disclosed shocking numbers of 340B violations by contract pharmacies, including violations of the prohibition on drug diversion to ineligible patients and the prohibition on "duplicate discounts"—*i.e.*, where the entity buying the drug from the manufacturer makes the manufacturer pay both a 340B discount and a Medicaid

rebate on the same utilization, *see* 42 U.S.C. § 256b(a)(5)(A). *See, e.g.*, GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, GAO-11-836 ("2011 GAO Report"), at 28 (Sept. 2011) ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in house pharmacies."), https://bit.ly/2JvWKgJ.

71. In 2018, as the number of contract pharmacies burgeoned without any government oversight, the HHS OIG acknowledged before Congress that it had "identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements." HHS OIG Testimony, *Examining Oversight Reports on the 340B Drug Pricing Program, Testimony of Ann Maxwell, Assistant Inspector Gen. for Evaluation and Inspections, OIG Before the U.S. S. Comm. on Health, Educ., Labor, and Pensions*, at 5 (May 15, 2018), https://bit.ly/3lCv4Uj. That same HHS OIG testimony revealed that certain contract pharmacies unlawfully diverted drugs through their uncontrolled inventory management practices: "many contract pharmacies dispense drugs to all of ***their*** customers—340B-eligible or otherwise—from ***their regular inventory***." *Id.* at 6 (emphases added).

72. Another GAO report found that two-thirds of 340B diversion violations uncovered in HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44.

73. Publicly available HRSA audits underscore pervasive compliance issues involving contract pharmacies. HRSA audits routinely uncover dozens of instances of unlawful 340B drug diversions, despite HRSA auditing fewer than 200 entities per year:

Fiscal Year	Entity Audits	Entities with Contract Pharmacy Adverse Findings (All)	Entities with Contract Pharmacy Adverse Findings (Diversion)
2013	94	32	21
2014	99	51	38
2015	201	92	64
2016	200	81	68
2017	199	83	63
2018	200	63	43
2019	199	30	20

Source: HRSA, *340B Program Integrity, Audits of Covered Entity Results* (Apr. 2020), https://bit.ly/38MxknH.

C. The Government Has Utterly Failed to Rectify These Abuses

74. These marked shifts away from the 340B Program's intended goals come as no surprise to industry players, who vociferously objected to HRSA's 2010 expansion.

75. When HRSA issued the 2010 guidance that allowed covered entities to enter into an unlimited number of contract pharmacy arrangements, industry stakeholders expressed concern that the guidance expanding distribution to an unlimited number of contract pharmacies—entities never mentioned in the 340B Statute—was unlawful and unauthorized under the 340B Statute.

76. Stakeholders also expressed concern that expanding the Program to allow covered entities to enter into an unlimited number of arrangements with commercial contract pharmacies would cause program integrity issues, increasing the risk of the already-widespread noncompliance with the 340B Statute's requirements for covered entities and prohibitions on drug diversion and duplicate discounts, and that the financial incentives related to participating in the 340B Program, coupled with HRSA's proposal to permit unlimited contract pharmacy relationships, would inevitably cause for-profit contract pharmacies to dominate the Program. As

one commenter put it, HRSA's "guidelines do not adequately describe safeguards that will combat drug diversion and duplicate discounts." 75 Fed. Reg. at 10,273.

77. The government was, and remains, well aware of the abuses the contract pharmacy model has precipitated. *See, e.g.*, *id.* (noting but waiving away such concerns); Exhibit ("Exh.") A (Ltr. from Reps. Larry Bucshon, M.D., & Brad Wenstrup, D.P.M., to The Honorable Alex M. Azar, II (Oct. 15, 2020)) ("We have received reports that covered entities and/or their contract pharmacies are able to charge uninsured and potentially under-insured individuals mark-ups on prescriptions [sic] drugs" and "that patients in the 340B program, including the uninsured, can—and often do—bill cash-paying patients the 'usual and customary' pharmacy price plus a dispensing fee."); *see also, e.g.*, 2018 GAO Report at 44 (approximately two-thirds of diversion "involved drugs distributed at contract pharmacies"); HHS OIG Testimony, *supra*, at 5 (OIG "identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements"); H. Energy & Commerce Committee, *Review of the 340B Drug Pricing Program*, at 75 (Jan. 20, 2018) (HRSA's guidance "has led to concerns about whether the money is truly devoted to improving patient care"), https://bit.ly/3pyqNUk; 2011 GAO Report at 28 (contract pharmacy model "creates more opportunities for drug diversion compared to in-house pharmacies").

78. Yet HRSA and HHS have completely ignored these realities—and the text of the 340B Statute—for a decade now, thus allowing for-profit pharmacy chains to come to represent a disproportionate share of this contract pharmacy expansion. *See* 2018 GAO Report at 21; *see also* GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107 ("2020 GAO Report"), at 15-16 (Dec. 2020) (noting that HRSA stopped auditing

contract pharmacies "because the 340B statute does not address contract pharmacy use" and thus provides no standard against which to audit contract pharmacies' abuses), https://bit.ly/3hfFVD8.

V. Lilly Introduced Distribution Plans Designed To Curb Contract Pharmacy Abuses Consistent With The 340B Statute

79. Against this backdrop, Lilly introduced a new distribution program that complies with the 340B Statute's text and purpose and would curb the abuses the 2010 guidance unleashed.

80. Effective July 1, 2020, Lilly instructed its wholesalers to provide 340B discounts exclusively to covered entities and their child sites—and not to contract pharmacies—for certain formulations of Cialis® (tadalafil). Lilly limited its July 2020 plan to those Cialis® products indicated for erectile dysfunction and for which a generic formulation was available. The Cialis® distribution plan included an exception for covered entities that do not have an in-house pharmacy, permitting them to designate one contract pharmacy location as eligible to receive 340B discounts.

81. In August 2020, after rolling out the transition for Cialis® products, Lilly extended its distribution plan to all of Lilly's covered outpatient drugs under the 340B Program.

82. Reflecting Lilly's commitment to the original goal of the Program, however, Lilly is continuing to allow covered entities that lack an in-house pharmacy to designate a single contract pharmacy at which 340B medicines may be dispensed, and Lilly recently began to allow contract pharmacies that are wholly owned by a covered entity to access 340B-priced product. Lilly fully intends to continue to work flexibly with all stakeholders to refine its distribution plan as needed.

83. To be clear: Lilly continues to offer all covered outpatient drugs to all covered entities at (or below) the ceiling price, and even continues to allow contract pharmacies to dispense its 340B product when a covered entity lacks the capacity to dispense prescription medicines itself.

84. Furthermore, reflecting Lilly's commitment to making insulin products affordable, and following on the heels of an Executive Order issued by the President on July 24, 2020, Lilly

made an exception for insulin patients, under which a covered entity may use a contract pharmacy to dispense insulin to 340B patients so long as the contract pharmacy agrees to pass on the entire 340B discount—in this case, one-penny-per-milliliter prices—to the patient.

85. The Executive Order echoes key concerns that many stakeholders, including government entities and officials, have expressed about the 340B Program—namely, that "one penny per unit … steep [340B] discounts … are not always passed through to low-income Americans at the point of sale," and that "[t]hose with low-incomes can be exposed to high insulin and injectable epinephrine prices, as they often do not benefit from discounts negotiated by insurers or the Federal or State governments." Exec. Order No. 13,937, 85 Fed. Reg. 45,755 (July 29, 2020) (ordering HHS to ensure that future grants available to Federally Qualified Health Centers, one type of 340B covered entity, be conditioned on making insulin and injectable epinephrine available to patients at the 340B-discounted price). In other words, contract pharmacies failed to pass along 340B discounts even though they purchased insulin products at ***one penny*** per milliliter.

86. These voluntary measures by Lilly are consistent with other patient-focused programs Lilly has initiated to help patients reduce out-of-pocket expenses, particularly uninsured patients, senior citizens covered by Medicare Part D, and patients with high-deductible plans.

87. For instance, Lilly provides automatic discounts at retail pharmacies to any patient with commercial insurance, capping monthly insulin costs at $95. Lilly also distributes three non-branded insulins with a list price 50 percent lower than brand name alternatives and donates insulin for distribution at free clinics for qualifying patients with demonstrated financial need. In 2019, Lilly's insulin affordability solutions helped up to 20,000 patients per month, decreasing patients' out-of-pocket spending by 65 percent on average. And Lilly expanded its patient affordability

options for insulin last year to respond to the financial consequences of COVID-19, announcing in April 2020 that both uninsured and commercial-insurance patients can purchase a prescription of certain Lilly insulin products for $35 a month through the Lilly Insulin Value Program. Lilly also recently began participating in the CMS Innovation Center's Medicare Part D insulin cost sharing program, making affordable insulin available for patients covered by Medicare Part D.

88. Early in the pandemic, Lilly developed, at its own expense, a highly accurate COVID-19 test that it administered for free to front-line healthcare workers and first responders in Indiana. Lilly has also devised and made available ventilator splitters that allowed ventilators to serve two patients at once. In addition, Lilly has invested hundreds of millions of dollars developing COVID-19 treatments—including two monoclonal antibody treatments already in human trials and two other molecules to treat COVID-19-induced acute respiratory distress syndrome—and recently received emergency use authorization for two COVID-19 treatments.

89. Lilly also donates substantial sums to the Lilly Cares program, an independent 501(c)(3) that provides up to a one-year supply of Lilly medications for free to low-income patients with no insurance, Medicare Part D, and in some instances commercial insurance.

VI. HRSA First Approves Lilly's Distribution Plan, But Then Threatens Sanctions In Response To Lilly's Attempt To Comply With Section 340B And To Halt Contract Pharmacy Diversion.

A. HRSA Repeatedly Confirms that the 1996 and 2010 Contract Pharmacy Guidance Are "Not Legally Enforceable"

90. Lilly was transparent with the government about its distribution plans, informing the government of both the initial Cialis® plan and the later expanded plan.

91. Lilly first notified HRSA in May 2020 that it intended to implement the Cialis® distribution plan effective July 1, 2020. *See* Exh. B. Lilly explained to HRSA that it did "not believe 340B-priced purchases for contract pharmacies are consistent with or required by" the

340B Statute, and it accordingly would "no longer honor contract pharmacy-related requests" for the three Cialis® formulations "[u]nless HRSA objects and states that it believes [Lilly's] proposed discontinuation of voluntary contract pharmacy 340B discounts is unlawful, providing [Lilly] the reasons for its conclusions." *Id.* at 1-2.

92. HRSA responded on June 11, 2020, that "contract pharmacies" "are not independent covered entities" and that its "contract pharmacy advice" was "guidance" and "not binding regulations." Exh. C at 1-2. To be clear: HRSA did not state that Lilly's Cialis® distribution plan was unlawful or identify any statutory provision that it violated.

93. Lilly followed up with HRSA on June 16, 2020, thanking HRSA for "confirming" that the agency's contract pharmacy guidance "does not impose binding obligations on manufacturers" requiring them to offer 340B discounts to contract pharmacies. Exh. D at 2-3. Lilly also pointed out that, in HRSA's June 11 response, the agency "did not say that [Lilly is] prohibited from moving forward" or "that [Lilly's] proposed action would, in fact, violate the statute." Lilly thus asked HRSA to correct any misinterpretation by Lilly on that score. *Id.* at 2.

94. HRSA responded to Lilly on June 18, 2020. Far from stating that Lilly had misunderstood HRSA's position, HRSA confirmed that it "look[ed] forward to receiving" Lilly's manufacturer notice announcing its Cialis® distribution plan for posting on the HRSA website. *Id.* at 1-2. For the second time, HRSA failed to identify any statutory provision that Lilly's distribution plan violated and did not assert that the distribution plan was in any way unlawful.

95. On June 26, 2020, Lilly provided the published notice relating to its Cialis distribution plan, and again invited HRSA to raise any questions or concerns that it might have. *See id.* at 1. HRSA responded on June 29, 2020, stating that it did not have any further questions at this time; HRSA then posted Lilly's notice to covered entities on its 340B Program website on

July 1, 2020, without objection. *See* HRSA, *Manufacturer Notices to Covered Entities* (July 2020) (linking to *Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs*, https://bit.ly/3n3DaWS), https://bit.ly/3hzDOua.

96. Days later, a 340B-focused publication, the *340B Report*, published an article quoting HRSA's reaction to Lilly's Cialis® distribution program and confirming that its 2010 Contract Pharmacy Guidance was non-binding, this time describing it as "not legally enforceable":

> The 2010 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.

Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020), https://bit.ly/2X0I1xe. And far from asserting that Lilly's conduct was unlawful, the article stated that "[i]t appears now that HHS and HRSA have concluded that Lilly cannot be compelled to provide 340B discounts on drugs dispensed by contract pharmacies." *Id.* Lilly came to the same conclusion based on its communications with the agency.

97. Thereafter, on July 16, 2020, 340B Coalition (a trade association for 340B hospitals) and certain other 340B covered entity stakeholders wrote to Defendant Azar, asking him to declare that Lilly's Cialis® distribution program violated the 340B Statute—specifically, that it violated the requirement that manufacturers "offer ***each covered entity***" no more than the ceiling price for all "covered outpatient drugs." *See* 42 U.S.C. § 256b(a)(1) (emphasis added).

98. In response to that intervention, Lilly sent a letter to Defendant HHS the next day, describing its communications with HRSA and explaining why Lilly's distribution plan complies with the 340B Statute. Exh. E. HHS did not respond to Lilly for over two months (as discussed below), and even then, never stated that Lilly's distribution plan would violate the 340B Statute.

B. HRSA and HHS Suddenly Change Course, Threatening Lilly with Sanctions

99. On August 19, 2020, with the transition for the Cialis® products underway, Lilly informed HRSA that it would extend its new distribution plan to include all of Lilly's covered outpatient drugs under the 340B Program (*i.e.*, not just Cialis), by "discontinu[ing] [its] practice of voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products." Lilly explained that HRSA had already confirmed that the 2010 Contract Pharmacy guidance was non-binding when discussing the plan for Cialis® and "the legal analyses performed previously by HRSA and Lilly apply equally here." Exh. F at 1. And as with its Cialis® program, Lilly provided HRSA an opportunity to object to Lilly's plan and, if it did, to explain its reasoning by August 31, 2020. *See id.* Lilly also provided HRSA with an updated Limited Distribution Plan Notice for posting on the agency's manufacturer notices website on September 1, 2020, the effective date of Lilly's new distribution plan. *See* Exh. G.

100. On August 26, 2020, HRSA sent Lilly a letter (Exh. H) purporting to respond not only to Lilly's August 19 expansion letter, but also to the original Cialis® program letter dated May 18, 2020—even though correspondence for that initial program had ended more than a month earlier with HRSA stating that the agency did not have any further questions, *see* Exhs. A, B.

101. Although HRSA and HHS had previously declined to state that Lilly's conduct was unlawful despite at least four opportunities to do so, HRSA threatened that Lilly could be subject to sanctions if it followed through with its expanded distribution plan. Specifically, in its August 26 response to Lilly, HRSA stated that it was "considering whether your new proposed policy constitutes a violation of section 340B and whether sanctions apply," including, but "not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." Exh. H at 1.

102. Given the significance of HRSA's threat, which carried the prospect of subjecting Lilly to CMPs—not to mention the potential revocation of Lilly's PPA and thus ability to

participate in and receive reimbursements pursuant to Medicare Part B and Medicaid—Lilly responded to HRSA the next day (August 27, 2020). *See* Exh. I. In its August 27 letter, Lilly reiterated its position that its distribution program was entirely lawful under the plain text and original understanding of the 340B Statute. *See id.* at 1. Lilly also highlighted the imminent harm resulting from HRSA's "threats of sanctions," which were transparently designed to force Lilly to acquiesce to HRSA's position. *Id.* Lilly accordingly requested that HRSA "confirm by August 31st that nothing in the 340B Statute prohibits the Cialis Limited Distribution Plan or an expansion of that plan," and that if HRSA believed there was a "violation of the statute, [to] please identify with specificity the agency's grounds for that position." *Id.*

103. HRSA neither responded nor posted Lilly's updated notice on its website. Instead, on September 2, 2020, it released a new public statement to the *340B Report* reiterating its threat. HRSA stated to the *340B Report* that it was "considering whether manufacturer policies, ***including Lilly's***, violate the 340B statute and whether sanctions may apply." Bronwyn Mixter, *HRSA is Investigating Whether Manufacturer Policies to Restrict 340B Pricing at Contract Pharmacies Violates Statute*, 340B Report (Sept. 2, 2020) (emphasis added), https://bit.ly/3aWgZPT.

104. In light of these threats, Lilly reached out to HHS on September 8, 2020, seeking "confirmation that HHS is not considering, and will not consider, sanctions against Lilly in response to Lilly's stated plan to discontinue providing 340B discounts to contract pharmacies." Exh. J at 1; *see also id.* at 1-5.

105. HHS responded nearly two weeks later on September 21, 2020. *See* Exh. K. HHS did not state that Lilly's distribution plan was unlawful. *See id.* Nor did it identify a single statutory provision that the plan violates. *See id.* Nevertheless, HHS declined to state that neither HRSA nor HHS was considering sanctions against Lilly. *See id.* And rather than defusing HRSA's

threats of sanctions against Lilly, HHS issued a threat of its own, telling Lilly to "bear in mind" that a private "qui tam False Claims Act" action (which carries the potential of huge damages) is a "potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors." *Id.* at 2.

106. HHS immediately posted this threat on its public website. *See* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf (last visited Jan. 12, 2021). After that public posting, many covered entities reached out to Lilly to demand that Lilly reverse its distribution plan and offer full 340B discounts to all contract pharmacies. HRSA still did not post Lilly's updated manufacturer notice on its 340B website (and has not to this day).

107. On December 9, 2020, HRSA sent a letter to the CEO of 340B Health, a group that represents covered entities, regarding the modified distribution programs of Lilly and other manufacturers, stating that it was "continuing to review the various proposals and whether these actions by manufacturers violate the 340B statute and whether sanctions may apply." Exh. L at 1. HRSA added that it was "working closely with each impacted covered entity," "actively investigating the matter in order to make a final determination as to any potential action." *Id.* at 2. HRSA still did not post Lilly's updated notice on its 340B website (and has not to this day).

108. In early- and mid-December 2020, the GAO reported that HRSA acknowledged that "the 340B statute does not address contract pharmacy use," 2020 GAO Report at 16, and counsel for HHS and HRSA described movements to compel "participation through contract pharmacies" as improper attempts to foist "wholesale changes to an agency program" on the government, *see* Defs.' Mot. to Dismiss for Lack of Jurisdiction 19-20, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Dec. 14, 2020), Dkt. 41.

VII. HRSA Issues A Final Decision Concluding, Contrary To The Text And Purpose Of The Statute, That Manufacturers Must Offer 340B Discounts To An Unlimited Number Of Contract Pharmacies Whenever Covered Entities Ask.

109. On December 30, 2020, Defendants resolved any doubt about their position on the issue. They did so by issuing a decision making clear that they now (incorrectly) "conclude" that "a drug manufacturer in the 340B Program is ***obligated*** to deliver its covered outpatient drugs to those contract pharmacies ***and to charge the covered entity no more than the 340B ceiling price for those drugs***" whenever a contract pharmacy acts as a covered entity's "agent." December 30 Decision at 1 (emphasis added); *see also HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies* (Dec. 30, 2020) (noting that HHS "has clarified that drug manufacturers must provide 340B discounts when a contract pharmacy is acting as an agent of a covered entity, providing services on behalf of the covered entity"), https://bit.ly/38Qh0lB.

110. In issuing that decision, Defendants acknowledged that they are not "authorized to add requirements to the [340B Statute]." December 30 Decision at 2.

111. Defendants further recognized 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***." *Id.* at 2 (emphasis added). (Recall that Lilly in fact is continuing to offer all covered outpatient drugs to covered entities at or below the ceiling price, and has always done so.)

112. Defendants nonetheless "conclude[d]"—for the first time, and in contrast to every other pronouncement HRSA and HHS had previously made on the subject—that "the plain text of the statute" ***requires*** manufacturers participating in the 340B Program to offer discounts to contract pharmacies whenever a covered entity is the one that placed the order for the drugs. *Id.* at 3.

113. Defendants' cursory textual analysis began from the "understand[ing]" that the 340B Program functions as follows in practice: "the medications at issue are sold by the

manufacturer to the covered entity; the covered entity takes title and the covered entity pays the manufacturer either directly or through the manufacturer's distributor." *Id.*

114. Defendants then concluded that, under the 340B Statute, "[t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant" to the statutory obligation to charge no more than the ceiling price. *Id.*

115. That was the sum-total of Defendants' textual analysis. Defendants did not address the fact that Congress exhaustively enumerated 15 types of entities as "covered entities" and specifically limited that class to non-profit healthcare providers, or that the 340B Statute authorizes HHS and HRSA to impose CMPs for "each instance" that a manufacturer "knowingly and intentionally" overcharges "a covered entity," 42 U.S.C. § 256b(d)(1)(B)(vi)(II)-(III), ***not*** "a covered entity or its non-in-house pharmacy" or "a covered entity and its contract pharmacy." And they likewise nowhere reconciled their conclusion with the fact that the 340B Statute unambiguously distinguishes between "covered entities" on the one hand and agents—*i.e.*, "associations or organizations representing the interests of [] covered entities," "wholesalers," and "distributors"—on the other. *See id.* § 256b(d)(1)(B)(v), (2)(B)(iii), (3)(B)(vi). Finally, they did not reconcile how this novel interpretation, which ***requires*** manufacturers to offer 340B discounts to an unlimited number of contract pharmacies, can be squared with the position that Defendants had taken for approximately fifteen years (and that they had reiterated mere months before) that the guidance allegedly creating this "obligation" is "legally unenforceable."

116. Nor did Defendants acknowledge, let alone defend against, the severe constitutional concerns raised by a requirement that one set of private parties (manufacturers) offer another set of for-profit private parties (contract pharmacies) massive discounts on pain of having their ability to participate in and be reimbursed under Medicare Part B and Medicaid. *See Kelo v. City of New*

London, 545 U.S. 469, 477 (2005) ("[I]t has long been accepted that the sovereign may not take the property of A for the sole purpose of transferring it to another private party B.").

117. Instead of tackling any of these arguments head-on, Defendants simply waived them away as bad-faith "attempt[s] to circumvent section 340B's procedures for resolving disputes between manufacturers and covered entities." December 30 Decision at 5.

118. Defendants spent the majority of the Decision rejecting "[t]he argument that [because] the statute also evinces a purpose to prevent drug diversion or duplicate discounting, [it] therefore prohibits contract-pharmacy arrangements." *Id.* at 3 n.2; *see id.* at 4-7. Notably, however, Defendants did not dispute that contract pharmacy arrangements have multiplied the incidence of diversion and duplicate discounting exponentially. Nor could they: Defendants had previously recognized that fact many times. *See, e.g.*, Kenneth Yood, *Maneuvers on the 340B Drug Pricing Program Battlefield: Duplicate Discounts and Contract Pharmacies*, Healthcare Law Blog (Sept. 29, 2020) ("In a 2011 GAO report, … the GAO concluded that the 'increased use of the 340B program by contract pharmacies and hospitals may result in greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants self-policing to oversee the program'"; and "[i]n a 2014 OIG report, … the OIG found that contract pharmacies create 'complications' in preventing diversion and duplicate discounts."), https://bit.ly/3bsQ0fh.

119. Defendants made no mention of the fact that their decision to mandate that manufacturers provide an unlimited number of contract pharmacies with 340B-priced drugs forces manufacturers like Lilly either to transfer their property, in the form of the prescription medicines they manufacture, to for-profit entities at a devastating financial loss, or to choose not to and suffer the economic equivalent of the death penalty by losing their ability to participate in and be reimbursed under critical federal healthcare programs. *See Koontz v. St. Johns River Water Mgmt.*

Dist., 570 U.S. 595, 606 (2013) ("Our precedents … forbid[] the government from engaging in 'out-and-out … extortion' that would thwart the Fifth Amendment" by coercing individuals into relinquishing their property without proper "just compensation." (third alteration in original) (quoting *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987))).

120. Nor did Defendants refute that the two mechanisms contract pharmacies use in capturing 340B discounts intended only for covered entities both necessarily effect a prohibited diversion of 340B-discounted drugs to the contract pharmacy. In fact, the Decision does not mention this at all. But these mechanisms only illustrate how the contract pharmacy system is ripe for abuse. First, under the "retroactive replenishment" model, contract pharmacies do not segregate 340B inventory from non-340B inventory; rather, they have ***their own stock*** of inventory, purport to track dispensed prescriptions to the patients of 340B covered entities with which they have contracts, and then supposedly ***retroactively*** seek to "replenish" product at 340B pricing. For those prescriptions, they secure—through an entirely retrospective process—replacement product at 340B pricing when the covered entity places an order with instructions to ship directly to the contract pharmacy. *See* Alliance for Integrity and Reform of 340B, *The Impact of Growth in 340B Contract Pharmacy Arrangements*, at 1 (July 2014) ("data indicates that neither the pharmacy nor the patient know that the transaction is '340B' at the point of sale"), https://bit.ly/3mRQ4YR; Nat'l Council for Prescription Drug Programs, *340 Information Exchange Reference Guide*, at 8-9 (June 2019), https://bit.ly/2JJVtCY. The 340B product, once transferred to a contract pharmacy, is then sold by the contract pharmacy in its own name to its own patients. Second, under the "physical inventory" system, the product is transferred directly from the wholesaler to the contract pharmacy. The covered entity never takes possession of the product. The contract pharmacy then sells the product to a customer who appears at its counter.

Because both models entail the use of a "ship-to/bill-to" arrangement where covered entities purchase 340B drugs with instructions to ship directly to the contract pharmacy, an action to mandate that manufacturers honor requests for 340B discounts for contract pharmacy transactions would result in statutorily prohibited diversion of 340B-discounted product to independent commercial actors that are not covered entities or patients of covered entities, in violation of the 340B Statute.

VIII. Defendants' Final Agency Action, The Harm To Lilly, And The Need To File Suit

121. Lilly challenges "final agency action" within the meaning of 5 U.S.C. § 704.

122. To constitute final agency action, a decision "must [1] mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature" and "[2] be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *W. Ill. Home Health Care, Inc. v. Herman*, 150 F.3d 659, 662 (7th Cir. 1998) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)); *see also, e.g.*, *Sackett v. EPA*, 566 U.S. 120, 126-27 (2012) (EPA order constituted final agency action, even though it included a proviso inviting regulated parties to "engage in informal discussion of [its] terms and requirements" with the EPA and purported to be non-final, because "'legal consequences'" flowed from the order's "issuance" and the order marked "the 'consummation' of the [agency's] decisionmaking process" (quoting *Bennett*, 520 U.S. at 178)).

123. The December 30 Decision plainly represents the consummation of Defendants' mature decisionmaking process on this issue. This is not an issue Defendants only recently began considering; as the 1996 and 2010 guidance documents as well as the correspondence with Lilly and other manufacturers from last year reflect, Defendants have been evaluating this issue for some time now. Defendants' decision to conclude, once and for all, that manufacturers must offer 340B discounts to contract pharmacies, is the culmination of years' worth of consideration.

124. The December 30 Decision just as plainly determines rights and obligations from which legal consequences will inevitably flow—thereby creating an imminent threat of harm to Lilly. Indeed, Lilly has already begun to receive threats from covered entities in light of the December 30 Decision. *See, e.g.*, Exh. M (Ltr. from Univ. of Wash. Med. Ctr. and Harborview Med. Ctr. to Eli Lilly and Company (Jan. 6, 2021)) ("In light of the [December 30 Decision] your continued denial of 340B pricing [to contract pharmacies] puts Lilly's PPA and reimbursement under the Medicaid and Medicare Part B programs at risk, and subjects Lilly to civil monetary penalties for each overcharge or denied purchase.").

125. Simply put, Defendants' view that manufacturers ***must offer*** 340B discounts to contract pharmacies, on pain of severe penalties and consequences, is now fully operational. *See W. Ill. Home Health*, 150 F.3d at 763 (a letter from the Department of Labor was final agency action because "[l]egal consequences flow from it, both with respect to [plaintiffs'] obligations to their employees and with respect to [their] vulnerability to penalties should they disregard [it]").

126. Furthermore, Defendants have put Lilly to the "painful choice" of either complying with the incorrect "obligation[s]" that result from Defendants' mistaken interpretation of the 340B Statute or "risking the possibility of an enforcement action at an uncertain point in the future." *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 43 (D.D.C. 2015) (quoting *CSI Aviation Servs., Inc. v. U.S. Dep't of Transp.*, 637 F.3d 408, 412 (D.C. Cir. 2011)); *see also Abbott Labs. v. Gardner*, 387 U.S. 136, 153 (1967) (finding agency action fit for judicial review where "continued use of material which [plaintiffs] believe in good faith meets the statutory requirements, but which clearly does not meet the regulation of the Commissioner[,] … would risk serious criminal and civil penalties"), *abrogated on other grounds*, *Califano v. Sanders*, 430 U.S. 99 (1977). Under the December 30 Decision, if Lilly does not comply with the

purported "obligat[ion]" to offer 340B prices to contract pharmacies, it may be subject to allegations of overcharging and even CMPs pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi), which exposes manufacturers to civil penalties of up to $5,000 "***for each instance*** of overcharging a covered entity." (Emphasis added.) That is not a far-off possibility, either: A few months before the December 30 Decision was published, HRSA told Lilly that its distribution plan could subject Lilly to sanctions "includ[ing] civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." Exh. H at 1. Given the 25,000-plus contract pharmacy locations nationwide and the 190,000-plus arrangements between contract pharmacies and covered entities, Lilly's decision to remain faithful to the plain text of the statute could thus have astronomically detrimental financial consequences.

127. And given Defendants' authority to terminate Lilly's PPA if they determine that Lilly has failed to comply with the 340B Statute's obligations, a decision by Lilly not to acquiesce to the new obligations reflected in the December 30 Decision would jeopardize Lilly's participation in the Program altogether—as the Attorney General of Connecticut, who "led a bipartisan coalition of attorneys general urging [HHS] to hold accountable drug manufacturers," has already recognized. *See* Office of the Atty. Gen., *Attorney General Tong Leads Coalition of Attorneys General in Important Win on Prescription Drugs* (Dec. 31, 2020) (recognizing that the December 30 Decision "puts a tremendous amount of pressure on drug companies"), https://bit.ly/356wuB0. That is no small matter. Termination of Lilly's PPA would be devastating to Lilly's business, as it would prohibit Lilly from receiving coverage and reimbursement for pharmaceutical products under Medicaid and Medicare Part B. Given the enormous size and importance of those federal programs, continuing participation in them is functionally necessary for Lilly (or any manufacturer) to be viable. *See, e.g.*, August 2020 Medicaid & CHIP Enrollment Data Highlights, Medicaid.gov (70 million people receive Medicaid), https://bit.ly/3rRO8SX;

Nat'l Comm'n to Preserve Soc. Sec. & Medicare, *Number of People Receiving Medicare (2019)* (56 million people receive Medicare Part B), https://bit.ly/3olIG8D; *see also Allina Health*, 139 S. Ct. at 1808 ("One way or another, Medicare touches the lives of nearly all Americans."). Defendants have thus left Lilly in the untenable position of offering 340B discounts that are not required by the statute or else face crippling financial sanctions simply for asserting its right to comply with the obligations in the statute. *See, e.g., Brown & Williamson Tobacco Corp. v. FTC*, 710 F.2d 1165, 1172 (6th Cir. 1983); *A. O. Smith Corp. v. FTC*, 530 F.2d 515, 524 (3d Cir. 1976).

128. In short, the December 30 Decision—backed by the threat of massive sanctions—imposes "direct and immediate" burdens on Lilly, *Abbott Labs.*, 387 U.S. at 152, and is therefore final agency action subject to immediate review. "To hold otherwise would open a path for the defendants to substitute informal [advisory opinion]-writing for the formal process of notice and comment rulemaking. Perhaps more important, to hold otherwise would insulate the [December 30 Decision] from effective judicial review unless and until an affected party is willing to act contrary to [Defendants] stated position and to risk severe civil … penalties." *Novelty, Inc. v. Tandy*, 2006 WL 2375485, at *1 (S.D. Ind. Aug. 15, 2006); *see id.* (holding that "one of a series of letters" from the Drug Enforcement Agency constituted final agency action even though the agency did not follow "formal procedures" in promulgating it"). It therefore warrants immediate review, and any delay in addressing this dispute would be manifestly inappropriate, as "'[e]ach day [it] wait[s] for the agency to drop the hammer," Lilly risks "accru[ing]" significant penalties ***plus*** losing its eligibility for Medicare and Medicaid programs. *See Sackett*, 566 U.S. at 127.

129. The need for immediate review is all the more acute given that the December 30 Decision does more than put Lilly to the choice between severe penalties and complying with the regulation: It effectuates an unconstitutional taking of property by forcing Lilly to transfer

property in the form of its drugs to private, for-profit entities, not for the benefit of the public, but solely so that those for-profit entities can increase their profit margins. The Fifth Amendment expressly forbids such a regime. *See Kelo*, 545 U.S. at 477; U.S. Const. amend. V.

130. Moreover, the revenues Lilly generates pursuant to the 340B Program constitute personal property that cannot be taken by the government without just compensation. *See Horne v. Dep't of Agriculture*, 576 U.S. 350, 358 (2015).

131. It is also black-letter constitutional law that the government may not condition a benefit, such as participating in Medicare Part B and Medicaid, on the relinquishment of a constitutional right. *Koontz*, 570 U.S. at 604. Yet the December 30 Decision does precisely this: In order to receive reimbursement and coverage from the federal government—the nation's largest insurance provider that provides health insurance to hundreds of millions of individuals—the December 30 Decision forces Lilly to forego billions of dollars in revenue generated by its participation in the 340B Program.

CLAIMS FOR RELIEF

COUNT I

(Violation of the Administrative Procedure Act—Failure to Provide Notice and Comment)

132. Lilly re-alleges and incorporates the allegations in all of the preceding paragraphs of this Complaint.

133. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

134. The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

135. The APA also provides that "final agency action for which there is no other adequate remedy in a court" is "subject to judicial review." *Id.* § 704.

136. The APA further provides that a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be … without observance of procedure required by law." *Id.* § 706(2)(D).

137. The December 30 Decision constitutes "final agency action[s] for which there is no other adequate remedy," *id.* § 704, and Lilly has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile.

138. The APA defines a "rule" to include any "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law." *Id.* § 551(4).

139. To issue a valid rule, an agency "shall [ ] publish[]" "[g]eneral notice of proposed rule making" "in the Federal Register," and shall include in that notice "either the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id.* § 553(b)(3).

140. This notice requirement applies to all rules except "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice," and applies unless the agency "for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." *Id.* § 553(b)(A)-(B).

141. After providing notice of a proposed rule, the agency shall then "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* § 553(c).

142. Because the December 30 Decision definitively "conclude[s]" that manufacturers must provide contract pharmacies with 340B prices, it is plainly an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law." *Id.* § 551(4). It therefore constitutes a "rule" under the APA.

143. The December 30 Decision is not exempt from the APA notice-and-comment requirement under 5 U.S.C. § 553(b)(A), because it is not an "interpretative rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice." It is instead a legislative rule: The December 30 Decision creates rights and obligations on manufacturers with which they must comply, on pain of civil sanction and expulsion from the 340B Program.

144. Indeed, given the existence of the 1996 and 2010 contract pharmacy guidance, as well as HRSA's other repeated insistences that neither of those guidance documents create enforceable obligations, the ***only*** logical explanation for the December 30 Decision is that Defendants wanted to create and did create enforceable obligations under the 340B Statute.

145. Defendants thus needed to comply with the APA's notice-and-comment procedures in order to (attempt to) enshrine these new obligations.

146. Yet Defendants nevertheless failed to provide public notice of their proposed action before issuing the December 30 Decision, and failed to provide the public any opportunity to comment on that proposed action.

147. The December 30 Decision was accordingly issued "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

COUNT II

(Violation of the Administrative Procedure Act—Exceeding Statutory Authority)

148. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

149. Under the APA, a reviewing court shall "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

150. The 340B Statute does not confer on Defendants the authority to require drug manufacturers, on pain of penalty, to provide drugs subject to pricing under the 340B Statute to contract pharmacies, as contract pharmacies are not covered entities as defined by the 340B Statute and the statute does not authorize Defendants to require manufacturers to offer discounts to any other type of entity. *See Pharm. Research & Mfrs. of Am.*, 43 F. Supp. 3d at 31, 39-40.

151. The 340B Statute obligates manufacturers to offer drugs to covered entities—a defined term that does not include contract pharmacies. 42 U.S.C. § 256b(a)(1). And because Congress listed the entities intended to participate in the 340B Program in the definition of covered entity, the addition of contract pharmacies as a new category of recipients of covered outpatient drugs at 340B discount prices is prohibited. *See, e.g., Ethyl Corp. v. EPA*, 51 F.3d 1053, 1061 (D.C. Cir. 1995) ("[M]ention of one thing implies exclusion of another thing.").

152. Similarly, Defendants have no authority to create, through guidance or otherwise, an exception to the prohibition on diversion to any entity that is not a patient of the 340B covered entity under the 340B Statute.

153. Defendants likewise have no authority to broaden the scope of the 340B Statute to effectively expand the statutory term "covered entities" and extend it to contract pharmacies, as they have now purported to do in the December 30 Decision.

154. Rather, HRSA possesses limited, circumscribed authority in only three areas: (1) the establishment of an administrative dispute resolution process; (2) the issuance of precisely defined standards of methodology for calculation of ceiling prices; and (3) the imposition of

monetary civil sanctions. *See Pharm. Research & Mfrs. of Am.*, 43 F. Supp. 3d at 41 (vacating a rule that fell outside HRSA's regulatory authority).

155. Accordingly, the December 30 Decision is "in excess of statutory jurisdiction, authority, or limitations" and must be set aside. 5 U.S.C. § 706(2)(C).

COUNT III

(Violation of the Administrative Procedure Act—Arbitrary and Capricious Agency Action)

156. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

157. Under the APA, a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

158. Agency action is arbitrary and capricious if the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

159. Any change to an agency's policy must also be adequately explained. The agency must "display awareness that it ***is*** changing position," "show that there are good reasons for the new policy," and be aware that longstanding policies may have "engendered serious reliance interests that must be taken into account." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). "[A]n unexplained inconsistency in agency policy is a reason for holding an interpretation

to be an arbitrary and capricious change from agency practice." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (citation and alterations omitted).

160. The December 30 Decision is arbitrary and capricious because Defendants did not consider the relevant factors. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 241 (D.C. Cir. 2008). Indeed, Defendants entirely failed to give adequate consideration to the text of the 340B Statute, which precludes Defendants from imposing an obligation on manufacturers to offer discounts to any entity other than the 15 classes of covered entities Congress specifically enumerated.

161. The December 30 Decision is also arbitrary and capricious because Defendants gave no indication that they gave any, let alone sufficient, consideration to the myriad and far-ranging abuses contract pharmacy arrangements have facilitated.

162. Furthermore, Defendants' application of their misguided view of the statute to mandate that Lilly offer 340B discounts for contract pharmacy transactions enables covered entity diversion that is expressly prohibited by the 340B Statute. *See* 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). Specifically, contract pharmacy transactions result in covered entities selling or otherwise transferring covered outpatient drugs to entities that are not "patients" of the covered entity. Use of contract pharmacies necessarily involves a prohibited "transfer" of 340B discounted product to a non-340B covered entity, the contract pharmacy.

163. Finally, the December 30 Decision is arbitrary and capricious because Defendants did not even attempt to reconcile the "obligation" enshrined in it with their earlier pronouncements

that manufacturers were under no legally enforceable obligation to offer 340B prices to contract pharmacies. The December 30 Decision thus arbitrarily and capriciously fails to explain Defendants' change in policy.

COUNT IV

(Violation of the Administrative Procedure Act—Contrary to the U.S. Constitution)

164. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

165. The APA provides that a reviewing court shall "hold unlawful and set aside agency action, found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

166. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend V.

167. The Takings Clause is not limited to instances where the government physically appropriates property for its own use through eminent domain. Rather, a taking can occur through legislation and regulation that sufficiently deprives a user of his property rights. *Squires-Cannon v. Forest Preserve Dist.*, 897 F.3d 797, 798 (7th Cir. 2018). As the Supreme Court has long recognized, "while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking." *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922); *see also, e.g., Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 537 (2005); *Squires-Cannon*, 897 F.3d at 798.

168. The Takings Clause extends to both real and personal property. "The Government has a categorical duty to pay just compensation when it takes your car, just as when it takes your home." *Horne*, 576 U.S. at 358. Confiscatory regulations that mandate the transfer of personal property from one private party to another private party therefore amount to an unconstitutional taking with or without just compensation. *Id.*; *see E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998).

169. A taking may be found based on "several factors," including "the economic impact of the regulation, its interference with reasonable investment backed expectations, and the character of the governmental action." *Kaiser Aetna v. United States*, 444 U.S. 164, 175 (1979). However, takings claims are inherently fact-intensive, and the ultimate question is whether the government has "forc[ed] some people alone to bear public burdens, which, in all fairness and justice, should be borne by the public as a whole." *Davon, Inc. v. Shalala*, 75 F.3d 1114, 1127 (7th Cir. 1996) (quoting *Armstrong v. United States*, 364 U.S. 40, 49 (1960)).

170. Defendants' decision to mandate that Lilly provide contract pharmacies with 340B-priced drugs is an exceedingly clear example of such a confiscatory regulation. In no uncertain terms, it forces Lilly to transfer its property, in the form of the drugs it manufactures, to contract pharmacies at a devastating financial loss. *See E. Enters.*, 524 U.S. at 529 (plurality opinion) (evaluating economic impact as a prime factor for assessing whether a taking has occurred); *Penn Central Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978) (similar).

171. Under the December 30 Decision, which forces Lilly to offer discounts to an ever-growing number of contract pharmacies, Lilly stands to lose significant sums of money in both the short and long terms. The requirement reflected in December 30 Decision that Lilly offer discounts to contract pharmacies, on pain of severe penalty, is therefore unconstitutional, as "the 'power to regulate is not a power to destroy.'" *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 769 (1968) (quoting *Stone v. Farmers' Loan & Tr. Co.*, 116 U.S. 307, 331 (1886)); *accord, e.g.*, *Ames v. Union Pac. Ry.*, 64 F. 165, 186-89 (C.C.D. Neb. 1894) (Brewer, J.).

172. Defendants' December 30 Decision is especially galling—and constitutionally suspect—because it does not seek to use the confiscated property for a public use, as required by the Fifth Amendment. *See Horne*, 576 U.S. at 371. Rather, it forces Lilly and other manufacturers

to transfer their property ***to other private entities***, many (if not most) of which are large and lucrative corporate pharmacies such as Walgreens and CVS, so that such entities can maximize their profits. The conclusion that manufacturers must offer discounts on all covered outpatient drugs to an unlimited number of contract pharmacies thus amounts to no more than "a naked transfer of property from private party *A* to *B* solely for *B*'s private use and benefit." *Carole Media LLC v. N.J. Transit Corp.*, 550 F.3d 302, 311 (3d Cir. 2008).

173. Such a regulation cannot be reconciled with the Fifth Amendment. "[I]t has long been accepted that the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation." *Kelo*, 545 U.S. at 477; *see also Calder v. Bull*, 3 Dall. 386, 388 (1798) (opinion of Chase, J.) (the legislature has no power to enact "a law that takes property from A. and gives it to B."); *Reagan v. Farmers' Loan & Tr. Co.*, 154 U.S. 362, 399, 410 (1894) (similar). Indeed, such private takings are always unconstitutional, "since [n]o amount of compensation can authorize such action." *Lingle*, 544 U.S. at 543; *see also Coniston Corp. v. Vill. of Hoffman Estates*, 844 F.2d 461, 464 (7th Cir. 1988). As "[a] purely private taking," the December 30 Decision "serve[s] no legitimate purpose of government" and is therefore "void." *Haw. Housing Auth. v. Midkiff*, 467 U.S., 229, 245 (1984). Accordingly, it must be set aside pursuant to the APA as "contrary to constitutional right." 5 U.S.C. § 706(2)(B).

174. Nor can the December 30 Decision be justified if only considered prospectively. Even if the December 30 Decision applies only to sales made in 2021 and afterward, it would still raise serious constitutional concerns given the sheer magnitude of Medicaid and Medicare Part B, participation in which Congress has made contingent on participation in the 340B Program (and thus on offering covered outpatient drugs to all covered entities at no more than the ceiling price established pursuant to the 340B Statute). *See Elrod v. Burns*, 427 U.S. 347, 361 (1976) (plurality

opinion) ("The denial of a public benefit may not be used by the government for the purpose of creating an incentive enabling it to achieve what it may not command directly.").

175. The unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up" to obtain a benefit, such as the ability to participate in a government program. *Koontz*, 570 U.S. at 604; *see also Libertarian Party of Ind. v. Packard*, 741 F.2d 981, 988 (7th Cir. 1984) ("The 'unconstitutional conditions' doctrine is premised on the notion that what a government cannot compel, it should not be able to coerce."). This includes the rights to retain one's own personal (or business) property unless properly taken by the government. *See Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994); *Nollan*, 483 U.S. at 837. The doctrine accordingly "forbid[s] the government from engaging in 'out-and-out … extortion' that would thwart the Fifth Amendment" by coercing private parties, on pain of losing a government benefit, into relinquishing their property without proper compensation. *Koontz*, 570 U.S. at 606 (alteration in original) (quoting *Nollan*, 483 U.S. at 837).

176. The December 30 Decision effectively forces manufacturers to provide steep discounts to an endless number of for-profit contract pharmacies—even though the latter rarely, if ever, pass along the 340B discounts to the patients whom the Program is designed to serve—or else forego billions of dollars in revenues pursuant to Medicaid and Medicare Part B.

177. The December 30 Decision thus imposes a previously nonexistent condition that directly contravenes the unconstitutional conditions doctrine. Indeed, it has all the hallmarks of an "[e]xtortionate demand[]." *Id.* at 605. If Lilly wishes to continue participating in Medicaid, it must forfeit its constitutional "right not to have property taken without just compensation," *id.* at 607, and agree to provide 340B prices to limitless contract pharmacies. If it refuses, Lilly would become unable to contract with one of the largest insurance programs in the country, under which

approximately 70 million Americans receive insurance. *Cf. NFIB v. Sebelius*, 567 U.S. 519, 581 (2012) (striking down use of Spending Power because "the financial 'inducement' Congress [ ] chose[] is much more than 'relatively mild encouragement'—it is a gun to the head").

178. At the very least, the broad reading of the 340B Statute that is required in order for the December 30 Decision to be within Defendants' statutory authority raises serious constitutional concerns. In effect, by eviscerating the "covered entity" requirement, it would give Defendants the ability to confiscate property from private drug manufacturers whenever it sees fit, and to grant rights to that property to whomever it sees fit. The canon of constitutional avoidance weighs heavily against such a reading. *See, e.g.*, *INS v. St. Cyr*, 533 U.S. 289, 299-300 (2001).

PRAYER FOR RELIEF

Lilly respectfully prays that this Court:

a. Issue an order and judgment declaring that Defendants violated the APA in issuing the December 30 Decision because the December 30 Decision was issued without following proper procedure; is in excess of statutory authority; violates the Constitution; and is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law;

b. issue an order and judgment declaring that it would be entirely lawful for Lilly not to offer 340B price discounts to contract pharmacies;

c. preliminarily and permanently enjoin implementation and/or enforcement of the December 30 Decision;

d. award Lilly costs and reasonable attorneys' fees, as appropriate; and

e. grant any other relief the Court deems just and appropriate.

Dated: January 12, 2021

Respectfully submitted,

s/*Andrea Roberts Pierson*

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* Application for *pro hac vice* forthcoming

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CERTIFICATE OF SERVICE

I hereby certify that on **January 12, 2021**, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s/ Andrea Roberts Pierson

Exhibit G

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS
7501 Wisconsin Ave Suite 1100W
Bethesda, MD 20814,

Plaintiff,

v.

ALEX M. AZAR II, Secretary of the United States Department of Health and Human Services, in his official capacity only
200 Independence Avenue, S.W.
Washington, DC 20201,

and

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, DC 20201,

Defendants.

Case No: 20-cv-3032

COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND MANDAMUS RELIEF

Plaintiff, National Association of Community Health Centers ("NACHC"), as an association and authorized representative of its Federally Qualified Health Center ("FQHC") members, brings this action against Defendants Alex M. Azar II and the United States Department of Health and Human Services ("HHS"), and for its Complaint alleges:

NATURE OF ACTION

1. This is a civil action under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(1), to compel the promulgation of administrative dispute resolution ("ADR") regulations—to implement the only process available to Plaintiff and its members to adjudicate and remedy violations of Section 340B of the Public Health Service ("PHS") Act—as required by § 7102 of the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 821-827 (March 23, 2010).

2. Defendants are, and have since September 2010 been, in violation of the clear and nondiscretionary statutory command in PPACA § 7102(a) to promulgate regulations by a date certain. As a direct result, FQHCs across the country that participate in the 340B Drug Pricing Program ("340B Program" or "340B") as "covered entities" are suffering the very harm the statutorily mandated ADR process is designed to remedy—drug manufacturer overcharging.

3. The 340B Program requires drug manufacturers to provide discounts on covered outpatient drugs purchased by covered entities for those manufacturers to have their products covered by Medicare and Medicaid. Since 1996, consistent with HHS guidance, drug manufacturers, either directly or through wholesale distributors, have shipped FQHC-purchased covered outpatient drugs to FQHCs' "contract pharmacies"—pharmacies that dispense drugs to the FQHC's patients under a contractual relationship with the FQHC. These contract pharmacy arrangements are consistent with longstanding HHS guidance, as well as with the authorizing statute for the FQHC program, Section

330 of the PHS Act, *codified at* 42 U.S.C. § 254b *et seq*.

4. A handful of the nation's largest pharmaceutical companies recently announced that, with few exceptions, they would no longer allow covered entities (including FQHCs) to purchase their covered outpatient drugs at 340B Program discount prices when those drugs would be shipped to a covered entity's contract pharmacy.

5. The manufacturers' abrupt about-face, after decades of shipping FQHCs' purchases of 340B-priced drugs to their contract pharmacies—during a global pandemic and a recession—is not only callous, but also a clear violation of 340B statutory requirements and the binding pharmaceutical pricing agreements ("PPAs") manufacturers have with HHS. Both the 340B statute, codified at 42 U.S.C. § 256b, and the PPAs (which simply incorporate 340B statutory requirements) require that manufacturers "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).

6. Indeed, the documented refusal by these manufacturers to make their covered outpatient drugs available to covered entities at or below 340B ceiling prices when shipped to a contract pharmacy is an emulation of the examples of "knowing and intentional" overcharging given by HHS, by way of illustration, in its civil monetary penalty ("CMP") regulations, 42 CFR § 10.11(b).

7. Although HHS publicly and rightly criticized at least one drug manufacturer's unilateral pricing actions, it has to Plaintiff's knowledge stopped short of

any enforcement or corrective action.

8. HHS's lack of action occurs in a world in which, by failing to promulgate regulations as required by statute, it has tied the covered entities' hands and deprived them of their exclusive means to protect themselves—the mandated ADR process. Per *Astra USA v. Santa Clara County*, 563 U.S. 110, 121–22 (2011), the 340B statute provides an exclusive remedy, and Congress, through the PPACA, opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaints, and to render the agency's resolution of those complaints binding, subject to review under the APA.

9. Outside of 340B's exclusive remedial scheme, covered entities have no other—much less an adequate—remedy available to them to challenge the drug manufacturers' violation of the 340B statute or to remedy the significant harm these violations have caused and will continue to cause.

10. As a direct result of Defendants' unlawful inaction, FQHCs and their patients, who are typically among the most vulnerable and medically underserved, are being irreparably harmed. Those harms, which include threats to FQHCs' patients' health and safety, will continue absent either an immediate enforcement action by HHS, or an injunction compelling the immediate implementation of the FQHCs' remedy for manufacturer overcharging.

PARTIES

11. NACHC is a national, nonprofit corporation whose primary objective is to

further—through extensive education, training, and advocacy—the mission and purpose of FQHCs. FQHCs are community-based, patient-directed nonprofit organizations that play a vital role in our nation's health care safety net by providing primary and other health care and related services—including pharmaceutical services—to medically underserved populations throughout the nation and its territories, regardless of any individual patient's insurance status or ability to pay for such services.

12. To facilitate that role, FQHCs are afforded special status, reimbursement rights, and other privileges in various federal health care programs, including a recognition as 340B Program covered entities since the program's 1992 inception. Each FQHC is obligated by the PHS Act and its implementing regulations to reinvest any program income—*e.g.* revenue generated through 340B, Medicare, Medicaid, or private insurance reimbursement for services—in furtherance of its health care safety net mission.

13. The 340B Program is designed to reduce drug costs for certain classes of safety net providers enumerated in the 340B statute, including FQHCs, that care for medically underserved and vulnerable populations. Any savings, or "nongrant income," the 340B Program generates for FQHCs is derived directly from the statutorily-mandated and defined discount pricing scheme that, by placing a non-discretionary duty on manufacturers to offer discount drugs to covered entities, costs taxpayers nothing.

14. The failure or refusal of HHS to implement the ADR process, despite a statutory mandate to do so, is an issue of substantial significance and considerable

importance to FQHCs across the nation and its territories and to their over 30 million patients. The ADR process provides an exclusive remedy for covered entities overcharged by drug manufacturers for covered outpatient drugs in violation of the 340B statute. *Astra USA*, 563 U.S. at 121–22. Until that process is implemented, FQHCs are left with no remedy, and are entirely dependent on HHS's unilateral enforcement authority.

15. As an association, NACHC has standing to bring this action on behalf of its FQHC members because: they would otherwise have standing to sue in their own right; the ability of FQHCs to effectively participate in the 340B Program and to remedy instances of manufacturer overcharging is directly linked to NACHC's own existence, as a trade association of and for FQHCs; and, the individual participation of FQHCs as parties is unnecessary, as the relief sought—namely, declaratory and injunctive relief (not damages)—applies equally to all covered entity FQHCs.

16. NACHC's board of directors voted unanimously to authorize this action.

17. Defendant Alex M. Azar II is Secretary of HHS and is sued in his official capacity.

18. Defendant HHS, a federal agency within the meaning of the APA, is responsible for administering a variety of federal health care programs, including the 340B Program, 42 U.S.C. § 256b, and the Section 330 Health Center Program, 42 U.S.C. § 254b. The Secretary of HHS has delegated responsibility for the 340B Program to HHS's Health Resources and Services Administration ("HRSA") division, which

oversees both the 340B Program and the Section 330 Health Center Program.

JURISDICTION AND VENUE

19. This Court has jurisdiction over this matter under 28 U.S.C. §§ 1331 and 1361. Venue is proper in this district under 28 U.S.C. § 1391(e) because Defendants are agencies, officers, or employees of the United States and a substantial part of the events or omissions giving rise to the claim occurred in this District.

ALLEGATIONS

Federally Qualified Health Centers

20. "FQHCs occupy a unique place in the health services ecology," *Community Health Care Association of New York v. Shah et al.*, 770 F.3d 129, 157 (2d Cir. 2014). Indeed, the FQHC designation reflects and is a product of a carefully reticulated legislative scheme, as between the PHS, Medicaid, Medicare, and 340B statutes.

21. By and large, and for purposes of this action, an FQHC is a community-based non-profit "health center" that receives (or is eligible to receive) federal grant funds under Section 330 of the PHS Act to provide care to medically underserved populations in communities that otherwise would not have those services available. 42 U.S.C. § 254b(a), (e), (k).

22. A health center is required by Section 330 to, among other things: (1) serve an area or population designated by the Secretary to be medically underserved; (2) have a community-based board of directors (*i.e.* a majority of its directors must be patients of the center "who, as a group, represent the individuals being served by the center . . ."); (3)

provide primary health care services, including "pharmaceutical services as may be appropriate for particular centers," and related services; (4) provide enabling services such as outreach and transportation, education, and patient case management; (5) participate in Medicaid; and (6) serve all residents of its community and make all of its "required" and "additional" services equally available to all of its patients, regardless of any individual's ability to pay for them. *See* 42 U.S.C. § 254b(a), (b), (j), (k).

23. Section 330 expressly authorizes each health center to provide its services, including pharmaceutical services, through its own staff or through "contracts or cooperative arrangements" with other entities, or a combination thereof. 42 U.S.C. § 254b(a)(1).

24. As HHS has long recognized, that statutory authority affords FQHCs the flexibility to provide pharmacy services to their patients through contractual arrangements with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy (one owned, controlled, and operated by the health center). *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01 (Aug. 23, 1996); Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010).

25. Section 330 grant funds are appropriated to cover or subsidize the cost of services to *un*insured or *under*insured individuals who are unable to pay for them. 42 U.S.C. § 254b(e)(5)(A). Section 330 grant funds are not to be used as a subsidy for

private or public health insurance programs, such as Medicaid. To prevent such a subsidy, health centers are statutorily (a) required to "make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits," including Medicaid. *id.* at § 254b(k)(3)(F). For the same reason, FQHCs are prohibited from giving discounts on their services absent a patient's inability to pay. *Id.* at § 254b(k)(3)(F), (G).

26. The purpose of the FQHC designation (first established in 1989) and the associated payment right in Medicaid—is to "ensure that health centers receiving funds under [Section 330] would not have to divert Public Health Services Act funds to cover the cost of serving Medicaid patients." *Three Lower Counties Community Health Services v. Maryland*, 498 F.3d 294, 297–98 (4th Cir. 2007) (citing H.R. Rep. No. 101-247, at 392–93, *reprinted in* 1989 U.S.C.C.A.N. 2118–19). This is accomplished through a requirement that states reimburse 100 percent of each FQHC's reasonable costs in furnishing covered ambulatory services to Medicaid beneficiaries. Consolidated Appropriations Act, 2001, Pub. L. 106-554, (Dec. 21, 2000), *codified at* 42 U.S.C. § 1396a(bb) (requiring states to pay each FQHC a prospective per-visit payment rate based on its historical costs in base years and with annual adjustments for inflation and changes in scope of services).

27. Given the purpose and history of the FQHC designation in Medicaid and Medicare, it should come as no surprise that FQHCs appear first on the statutory list of provider types that qualify as "covered entities" eligible to purchase discounted drugs

under the 340B Program. 42 U.S.C. § 256b(a)(4)(A). Those discounts complement and reinforce each FQHC's statutory duty to make all its services equally available to all its patients, regardless of any individual patient's ability to pay for them.

The 340B Program

28. The 340B Program, 42 U.S.C. § 256b, requires drug manufacturers (as a condition of having their drugs covered by Medicare and Medicaid) to enter into an agreement with HHS (known as a pharmaceutical pricing agreement, or PPA) to make "covered outpatient drugs" available to "covered entities" at prices that do not exceed a "ceiling price," as determined by a statutory formula. 42 U.S.C. § 256b(a)(1).

29. By reducing drug costs to FQHCs and other 340B covered entities—which are predominantly providers of safety net services to poor, underserved, and either *un*insured or *under*insured populations—the 340B Program furthers its legislative objective to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), 12 (1992).

30. Plaintiff's FQHC members use the savings they generated through the 340B Program to provide additional services in their federally designated service (or "catchment") area. For example, FQHCs use their 340B savings to cover the cost of medication for *un*insured or *under*insured patients who could not otherwise afford it. FQHCs also use the savings to expand access to necessary medical and crucial enabling services, including but not limited to medication therapy management, behavioral health

care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

31. FQHCs have some flexibility in determining how best to meet the needs of their patient population and community, but their use of any 340B savings must further their health center project. 42 U.S.C. § 254b(e)(5)(D).

32. Each 340B covered entity is statutorily prohibited from: (a) reselling or transferring a drug purchased at a 340B discount to a person who is *not* a patient of the covered entity ("diversion"), and (b) causing a manufacturer to provide a 340B discount and a fee-for-service Medicaid rebate for the same drug ("duplicate discount"). 42 U.S.C. § 256b(5)(A), (B).

33. Each covered entity is subject to audits by both HHS and manufacturers to ensure compliance with the diversion and duplicate discount prohibitions. 42 U.S.C. § 256b(a)(5)(C). Many, if not most, FQHC covered entities also perform their own internal auditing functions to ensure compliance. Each covered entity is ultimately solely responsible for its own compliance with 340B Program requirements.

34. Prior to 2010, HHS had implemented an informal dispute resolution process, akin to nonbinding mediation, to provide for adjudication and resolution of (a) claims by covered entities that drug manufacturers were charging above the ceiling price for their drugs ("overcharging"); and (b) claims by manufacturers that covered entities were causing or failing to adequately prevent diversion or duplicate discounts.

35. That process, however, was "underutilized (because it was a voluntary process)." 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57233-01 (Sept. 20, 2010). It was underutilized by covered entities, in particular, because the entities could not independently verify the 340B ceiling prices they were being charged and thus could not identify or quantify any overcharge (as noted *infra*, such access was not provided until 2019).

36. In its 1996 informal dispute resolution guidance, 61 Fed. Reg. 65406-01, HHS stated that a manufacturer must extend the ceiling price to covered entities even if it believes it has ample evidence to indicate prohibited entity activity (diversion or duplicate discounts). In that case, the guidance states that "the manufacturer may bring the claim to the Department through the informal dispute process." Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65406-01 (Dec. 12, 1996). But HHS stresses that only if "the entity is found *guilty* [by HHS] of prohibited activity and a decision is made to *remove the entity from the covered entity list*, will the manufacturers no longer be required to extend the discount." *Id.* (emphasis added).

37. Over the years, the HHS Office of Inspector General ("OIG") has concluded that a lack of drug price transparency and statutory "oversight mechanisms" hampered HHS's ability to administer the 340B Program. *See, e.g.*, HHS OIG, D. Levinson, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, p. ii (OEI-05-02-00072, Oct. 2005) ("HRSA lacks the oversight mechanisms and authority to

ensure that [covered] entities pay at or below the 340B ceiling price."); HHS OIG, D. Levinson, *Review of 340B Prices*, p. 11 (OEI–05–02–00073, July 2006) (estimating that covered entities overpaid $3.9 million in June 2005 alone); *accord Astra USA*, 563 U.S. at 121 (recognizing and citing same).

The PPACA's 2010 Improvements to 340B Program Integrity

38. In 2010, the PPACA made significant changes and improvements to the 340B Program. First, it expanded the program by adding new categories of covered entities. Second, and especially important here, it directed the HHS Secretary to promulgate regulations to implement an ADR process to adjudicate and remedy disputes between the program's participants. PPACA, §§ 7101, 7102; *see also Astra USA*, 563 U.S. at 121–22.

39. In particular, § 7102(a)(3), under the title "Improvements to 340B Program Integrity," provides in pertinent part:

> *Not later than* 180 days after the date of enactment of the [PPACA], the Secretary *shall promulgate regulations* to establish and implement an administrative process *for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section*, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B),[1] including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

42 U.S.C. § 256b(d)(3) (emphasis added).

40. The clear purpose and plain meaning of § 256b(d)(3) is to impose a

[1] Subsections (a)(5)(A) and (B) of § 256b prohibit duplicate discounts and diversion, respectively.

nondiscretionary duty on the HHS Secretary to implement, within 180 days of PPACA's enactment, a dispute resolution process capable of fairly and expeditiously resolving program participant claims of noncompliance—such as those at issue here—through binding and enforceable decisions of a designated HHS official or body (the "HHS adjudicator").

41. The Secretary's statutory deadline to implement the ADR process expired on September 19, 2010, 180 days after the PPACA became law on March 23, 2010. *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 46 (D.D.C. October 14, 2015) (noting, in 2015, that HHS was "five years overdue in complying with Congress's mandate that it set up an administrative dispute resolution process within 180 days of the ACA's passage").

42. Instead of promulgating the mandated regulations by the statutory deadline, HHS waited until the eve of its expiration to issue two *advance* notices of proposed rulemaking: one for the ADR process, and one covering both CMPs to be levied against manufacturers that knowingly and intentionally overcharge a covered entity and ceiling price calculation requirements. It is unclear why HHS split the rulemaking in this manner, but § 256b(d)(3) explicitly commands the implementation of the entire set of program integrity rules within the same 180-day deadline.

43. In the advance notice of proposed rulemaking ("ANPRM") for the ADR process, HHS solicited information and public comments "to help" develop and draft a proposed rule, even though HHS had fourteen years of experience under its informal

dispute resolution process by then. *See* 75 Fed. Reg. 57233 (publishing informal dispute resolution guidance four years after the program's enactment). The ANPRM specifically sought comments on the following issues: "(1) Administrative procedures, (2) existing models, (3) threshold requirements, (4) hearings, (5) decision-making officials or bodies, (6) appropriate appeals procedures, (7) deadlines, (8) discovery procedures, (9) manufacturer audits, (10) consolidation of manufacturer claims, (11) covered entity consolidation of claims; (12) claims by organizations representing covered entities, and (13) integration of dispute resolution with other 340B requirements added by the Affordable Care Act." *Id.* at 57234.

44. Both ANPRMs afforded a 30-day comment period (until November 19, 2010) for interested parties, but otherwise said nothing about a timeline for either anticipated rulemaking. And thereafter HHS proceeded with no hint of urgency, despite the statutory deadline and the rules' important purpose.

45. To the contrary, it was not until five years later that HHS issued its first notice of proposed rulemaking ("NPRM") for its Ceiling Price and CMP rules. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34583-01 (June 17, 2015). The NPRM indicated that "[t]he administrative dispute resolution process remains under development" and "HHS intends to address dispute resolution in future rulemaking." *Id.* at 34584.

46. More than a year later—and nearly six years beyond the statutory deadline—HHS issued a NPRM for the ADR rules, indicating that, in developing the

proposal, it had considered the comments it received in response to the 2010 ANPRM. *See* 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53381-01 (Aug. 12, 2016). The 2016 NPRM afforded a two-month comment period (until October 11, 2016) and indicated that the ADR rules, when finalized, would "replace" the informal, nonbinding dispute resolution process HRSA had published twenty years earlier in December 1996. *Id.* at 53382.

47. On January 5, 2017, after an earlier reopening of the applicable comment period, HHS issued its final Ceiling Price and CMP rules, with a delayed effective date of March 6, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210-01 (Jan. 5, 2017). In the preamble, HHS noted that "CMPs provide a critical enforcement mechanism for HHS *if manufacturers do not comply with statutory pricing obligations under the 340B Program*." *Id.* (emphasis added). At the same time, HHS noted that "issues related to overcharges," since the program's inception, "have been resolved between a manufacturer and a covered entity and any issues have generally been due to technical errors in the calculation." *Id.* at 1227. HHS anticipated that the imposition of a CMP "would occur very rarely if at all" because such penalties are reserved for manufacturer overcharging that is "knowing and intentional." *Id.* at 1227–28.

48. Even though HHS, in publishing its January 5, 2017 rules, "envision[ed] using these penalties in rare situations," it did provide illustrations of the sort of "rare" situation it would consider as "knowing and intentional" overcharging by a manufacturer.

Id. at 1221–27.

49. HHS's examples of knowing and intentional manufacturer overcharges included situations in which a covered entity places an order for non-340B priced drugs where the covered entity was doing so *because the manufacturer had refused to sell or make the drug available at the 340B ceiling price. Id.* at 1224–26. HHS explained, in other words:

> Covered entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer's documented refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price. When a manufacturer's documented refusal to sell or make drugs available at the 340B ceiling price results in the covered entity purchasing at the non-340B price, a manufacturer's sale at the non-340B price could be considered an instance of overcharging. An example of 'documented refusal' would include *any type of manufacturers' written communication related to reasons a manufacturer is not providing 340B ceiling prices* to either a single covered entity or group of covered entities. *HHS does not agree that a manufacturer could consider not selling a 340B drug at the 340B ceiling price to a covered entity based on possible non-compliance with program requirements*.

Id. at 1226 (emphasis added).

50. Per the Federal Register notice, multiple commenters suggested that a manufacturer should be able, as an exception to an otherwise knowing and intentional overcharge, to deny a covered entity a 340B price (and charge retail prices) if, in doing so, the manufacturer is acting on "credible evidence that a covered entity is engaged in diversion of 340B drugs." *Id.* at 1223. The commenters asserted that "if a manufacturer has evidence a covered entity is improperly diverting a drug, it should be able to charge the covered entity a price above the 340B ceiling price." *Id.* The commenters suggested

that manufacturers would be in a better position than HHS to provide this "check on 340B drug diversion, since manufacturers have better and timelier access to sales data than does HHS." *Id.*

51. HHS squarely rejected the notion that a manufacturer can exercise such self-help or act as judge and jury of disputes between covered entities and manufacturers. In particular, HHS stated:

> HHS does not believe that unilaterally overcharging a covered entity based upon suspicion of diversion is warranted under the statutory language. Manufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity. Manufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly.

Id.

52. On the issue of knowledge and intent, HHS also explained that the manufacturer need not have acted knowingly or intentionally at the time of the covered entity's drug purchase. That is, the requisite knowledge and intent for a civil monetary penalty could arise thereafter, if the manufacturer subsequently learned of the overcharge and refused to refund or issue a credit to the covered entity. *Id.* at 1225–26. Such a willful disregard for the fact that a covered entity had been overcharged would constitute a reverse liability, so to speak.

53. Finally, in the January 5, 2017 Ceiling and CMP final rule notice, HHS indicated that it "anticipates finalizing the administrative dispute resolution regulation after the comments [to its 2016 NPRM, 81 Fed. Reg. 53381-01] have been reviewed and

considered." 82 Fed. Reg. at 1212.

54. But no ADR regulation was ever made final. Instead, HHS withdrew its proposed ADR rules on August 1, 2017, with no indication as to when future action on those already long-overdue rules would be forthcoming.

55. HHS also delayed the effective date of its Ceiling Price and CMP rules several times, until it was sued, on September 11, 2018, for arbitrarily and unlawfully withholding or delaying a mandatory agency action, in violation of the APA. *See, American Hosp. Ass'n v. U.S. Dept. of Health and Human Serv.*, No. 18-cv-02112 (D.D.C. voluntarily dismissed Apr. 25, 2019).

56. While the lawsuit remained pending, Defendants, for the first time, provided two things: a final effective date of January 1, 2019 for its Ceiling Price and CMP regulation, and covered entity access—as of April 1, 2019 and through an HHS website—to "the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary," as required by 42 U.S.C. § 256b(d)(B)(iii). 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 61,563-01 (Nov. 30, 2018). Within the first 24 hours the pricing system was accessible to covered entities, it was accessed by over 275 authorized users. Decl. of Krista Pedley, ECF No. 35-1, *The American Hosp. Ass'n*, 18-cv-02112.

57. Thereafter, on April 25, 2019, the parties stipulated to the dismissal of the lawsuit as moot, under Federal Rule of Civil Procedure 41(a)(1)(A)(ii). Joint Status Report and Stipulation of Dismissal, ECF No. 36, *American Hosp. Ass'n*, 18-cv-02112.

Recent Drug Manufacturer Actions Contrary to 340B Program Requirements

58. On or about July 1, 2020, pharmaceutical company Eli Lilly and Company ("Eli Lilly") posted a notice on HHS's designated 340B Program webpage informing 340B covered entities that, effective immediately, it would no longer distribute multiple formulations of the drug Cialis purchased at 340B pricing to the covered entities' contract pharmacies.

59. On or about September 2, 2020, Eli Lilly disseminated another notice (which HHS declined to post on its webpage) informing 340B covered entities that, effective the day prior, it would no longer distribute *any* of its 340B-priced products to any contract pharmacies of a covered entity, providing an infeasible exception for certain insulin products and allowing for possible mercy for covered entities that had no other pharmacy outlet.

60. The Cialis notice in early July preceded (or triggered) a series of other actions. Merck Sharpe & Dohme Corp., Sanofi, and Novartis, through a vendor called Second Sight Solutions, threatened "less collaborative" and "substantially more burdensome" steps (Merck) or to withhold shipping 340B drugs to contract pharmacies altogether beginning October 1 (Sanofi and Novartis) unless covered entities handed their patient contract pharmacy claims data over to the vendor for the vendor's perpetual use. Neither the manufacturers nor Second Sight Solutions had any right to access or exploit the valuable data, so they threatened to hold 340B drugs hostage instead. Novartis and Merck have not yet followed through with their threats (though they have not withdrawn

them), but Sanofi did on October 1, 2020.

61. In August 2020, drug manufacturer AstraZeneca informed covered entities that it would no longer ship 340B drugs purchased by covered entities to their contract pharmacies effective October 1, 2020. AstraZeneca followed through on its threat, with limited exceptions for covered entities that lack any other pharmacy outlet.

62. By imposing such conditions, these other drug manufacturers are (like Eli Lilly) effectively refusing to make their covered outpatient drugs available to covered entities at 340B pricing, as required by the 340B statute and their respective PPAs. The result is that FQHCs and other covered entities must purchase the manufacturers' drugs at retail prices to make those drugs available to their patients through a contract pharmacy.

Defendants' Preliminary Response to Eli Lilly's Unilateral Pricing Action

63. In a September 21, 2020 letter, HHS General Counsel Robert P. Charrow responded to a September 8, 2020 request from Eli Lilly for an advisory opinion as to whether Eli Lilly's "new unilateral policy" on 340B contract pharmacies "would subject Lilly to sanctions." HHS posted a copy of General Counsel Charrow's letter on HHS's 340B webpage. *See* Charrow Letter, attached hereto as Exhibit A, at 1.

64. Although General Counsel Charrow indicated that HHS "has significant initial concerns" with Eli Lilly's new policy, it "has yet to make a final determination as to any potential action." Exh. A at 1.

65. In any event, HHS has not taken any action to ensure that Eli Lilly, and the other drugs manufacturers described *supra*, are making their covered outpatient drugs

available at 340B discount prices to covered entities for dispensing at their contract pharmacies.

Mandated ADR Process and Remedies

66. The mandated ADR regulations are the only recourse available to covered entities—those whom the 340B program is designed to benefit—when drug manufacturers overcharge them for 340B drugs. *Astra USA*, 563 U.S. at 121–22.

67. Once implemented, the mandated ADR regulations would afford FQHC covered entities a substantial remedy against the manufacturer's unilateral pricing and overcharging actions.

68. In particular, the ADR regulations will implement a process and procedures by which the HHS adjudicator reviews and resolves covered entity claims of manufacturer overcharging, such as those at issue here, "fairly, efficiently, and expeditiously," through a final and binding decision, subject only to APA review. 42 U.S.C. § 256b(d).

69. The procedures will permit covered entities to "discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price," and present such "documents and information" for the designated official's or body's consideration in adjudicating the claim. 42 U.S.C. § 256b(d)(3)(B)(iii).

70. The ADR procedures will also "permit multiple covered entities to jointly

assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members." 42 U.S.C. § 256b(d)(3)(B)(vi).

71. The HHS adjudicator's resolution of a claim or claims under the ADR process "shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C).

72. For example, if the HHS adjudicator were to substantiate an overcharge claim, the adjudicator would require the manufacturer to "issue refunds . . . with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued." 42 U.S.C. § 256b(d)(1)(B)(ii). Thereafter, the HHS adjudicator would exercise continuing "[o]versight" authority "to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs." *Id.*

73. Moreover, if a manufacturer's overcharging is alleged or found to be knowing and intentional, the matter would be referred to the Office of Inspector General for the potential imposition of "sanctions in the form of civil monetary penalties," up to "$5,000 for each instance of overcharging." 42 U.S.C. § 256b(d)(1)(B)(vi). Such penalties will be assessed "according to standards established in regulations to be

promulgated by the Secretary not later than 180 days after March 23, 2010." *Id.*

74. As explained above, the CMP regulations were not timely promulgated, but they are now final, with an effective date of January 1, 2019.

Irreparable Harms

75. Had the Secretary implemented the mandatory ADR process, as and when required, Plaintiff would have been able to submit a claim—as an association on behalf of FQHCs—as to each manufacturer listed above, and had those claims adjudicated and resolved expeditiously.

76. Indeed, had there been a final, binding ADR regulation providing covered entities a way to challenge prohibited overcharges, drug manufacturers may well have been reticent to take the unauthorized, unilateral actions at the heart of this suit.

77. There are no disputed facts. The manufacturers unilaterally stopped making their covered drugs available at or below ceiling prices to FQHC covered entities when those drugs are being shipped to contract pharmacies.

78. Moreover, it is highly likely that Plaintiff's claims, presented in such a process, would be successful, as HHS, in the preamble to its CMP rules (three years ago), described similar refusals to allow covered entities to purchase drugs at 340B discount pricing as examples of "knowing and intentional" overcharging.

79. By not implementing the mandatory ADR process, and by not exercising their enforcement authority independent of the ADR process, Defendants are depriving FQHCs of the only remedy they have to protect against manufacturer overcharging, and

Defendants are abdicating their statutory enforcement duties.

80. Plaintiff, as an association of and for FQHCs, is also aware of irreparable harm to FQHC patients that has occurred, is occurring, and will occur due to the drug manufacturers' overcharging activity and the lack of an administrative remedy to expeditiously hold them to account.

81. FQHC covered entities serve a patient population that is largely low-income and/or poor, and many FQHC patients are *under*insured (with, for example, high-deductible plans) or entirely uninsured, making them especially vulnerable to shifts in pharmaceutical pricing.

82. Many covered entity patients experience significant barriers to accessing healthcare—some caused by geography and infrastructure, some by the quotidian realities of life for low-income, working poor, migrant farmworker, or homeless individuals—and others caused by health or disability status, including comorbid chronic conditions such as diabetes and heart disease, mental and behavioral health diagnoses, and substance use disorder. For example, many of these patients have little to no disposable income to allocate to healthcare expenses, lack access to reliable transportation, live far from service providers in areas with extreme weather and/or poor infrastructure, communicate in a language other than English, or are mobility impaired.

83. The significant, irreparable harm these patients have suffered and will suffer is both direct and indirect.

84. Direct harm to covered entity patients has included, and will include,

drastic increases in the price of life-sustaining medications for chronic conditions like diabetes, respiratory diseases, cardiovascular disease, HIV/AIDS, and substance use disorder (*e.g.* opioid addiction). For example, uninsured health center patients accustomed to paying less than $16 for Eli Lilly insulin—purchased at 340B pricing and dispensed through their health center's contract pharmacy—now have to shoulder a cost of nearly $550 in some areas (and upwards of $700 in others) for the same amount of medication, or coordinate with and wait for their providers to approve the substitution of a more affordable alternative medication, if such substitution is possible.

85. Patients' geographic, transportation, and time-availability barriers also hinder access to discount medications, even where a health center's existing in-house pharmacy or pharmacies could theoretically make such medications available. For example, without contract pharmacy access or services, certain FQHCs serve patients would have to travel several hours to reach an in-house pharmacy at which they could fill a prescription purchased at 340B pricing.

86. A delay in obtaining certain health maintenance and life-sustaining medications can cause significant adverse health effects. In some cases, such a delay can be fatal. Likewise, a shift to a similar, but not identical, clinical alternative medication—assuming one exists—may not be well-tolerated or of the same efficacy, may result in serious side effects, or may cause medication compliance issues due to patient confusion or difficulty in adapting to a new regimen.

87. Covered entity patients also stand to be indirectly harmed by cuts to non-

reimbursable services that FQHCs currently support with 340B savings. These services—which may be drastically reduced or eliminated entirely due to significant decreases in 340B savings—include, for example, medication therapy management, behavioral health care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

COUNT ONE

87. The allegations contained in paragraphs 1–86 above are re-alleged and incorporated by reference.

88. The APA provides a remedy to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

89. Defendants have failed to comply with 42 U.S.C. § 256b(d)(3)'s clear and unequivocal mandate to establish and implement by regulation an ADR process to fairly, efficiently, and expeditiously adjudicate and remedy claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers participating in the 340B Program.

90. The PPACA became law on March 23, 2010. The statutory deadline for the mandated regulations expired on September 19, 2010. They are now more than ten years overdue.

91. Thus, Defendants have unlawfully withheld and unreasonably delayed the promulgation of final rules within the meaning of 5 U.S.C. § 706(1).

92. In the absence of the required rules and process, FQHCs are being deprived of an exclusive statutory remedy for manufacturer overcharging.

93. Neither Plaintiff nor FQHCs have any other adequate remedy to pursue or exhaust under the 340B Program or otherwise. An action under 5 U.S.C. § 706(1) is the only available means for Plaintiff or FQHCs to compel Defendants' compliance with 42 U.S.C. § 256b(d)(3).

94. Defendants' failure to fulfill 42 U.S.C. § 256b(d)(3)'s clear mandate, within the specified period, and despite the significant interests it seeks to protect, warrants declaratory and injunctive relief under 5 U.S.C. § 706(1).

COUNT TWO

95. The allegations contained in paragraphs 1–94 above are re-alleged and incorporated by reference.

96. A federal court may issue a writ in the nature of mandamus under 28 U.S.C. § 1361 to compel a federal official or agency to perform a mandatory duty.

97. Defendants have failed to perform a clear, nondiscretionary duty required by 42 U.S.C. § 256b(d)(3)—and owed to FQHC and other covered entities—to promulgate regulations by a certain (long past) deadline to implement an administrative process for the resolution of claims by covered entities that participating manufacturers have overcharged them for drugs purchased under the 340B Program.

98. Defendants' statutory deadline to do so expired more than ten years ago.

99. By failing to promulgate the mandated ADR regulations, Defendants are

depriving FQHCs and other covered entities of their exclusive statutory remedy for drug manufacturer overcharging.

100. FQHCs and other covered entities are currently experiencing that very harm—manufacturer overcharging—without a remedy.

101. Defendants' failure to fulfill 42 U.S.C. § 256b(d)(3)'s mandate, within the specified period, warrants a writ of mandamus under 28 U.S.C. § 1361.

PRAYER FOR RELIEF

WHEREFORE Plaintiff respectfully requests the Court:

A. Declare that Defendants violated 42 U.S.C. § 256b(d)(3) by failing to promulgate ADR regulations to implement a process to adjudicate and remedy 340B Program violations;

B. Declare that Defendants violated 5 U.S.C. § 706(1) by unlawfully withholding or unreasonably delaying ADR regulations mandated by 42 U.S.C. § 256b(d)(3);

C. Order Defendants to promulgate final ADR regulations, as required by 42 U.S.C. § 256b(d)(3), no later than 60 days from the Court's order;

D. Retain jurisdiction over this matter pending Defendants' promulgation of the final ADR regulations;

E. Award Plaintiff's reasonable litigation expenses, including attorneys' fees; and

F. Order such other relief as this Court deems just and proper.

Dated October 21, 2020

Respectfully submitted,

/s/ *Matthew S. Freedus*
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Counsel for Plaintiff

Exhibit H

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, Plaintiff, v. ALEX M. AZAR II, *et al.*, Defendants.	No. 20-cv-3032 (KBJ)

JOINT MOTION FOR STAY OF PROCEEDINGS

Plaintiff National Association of Community Health Centers brought this "action under the Administrative Procedure Act … to compel the promulgation of administrative dispute resolution ("ADR") regulations" mandated by the 2010 Patient Protection and Affordable Care Act. *See* ECF No. 1, Complaint, ¶ 1. Plaintiff's members wish to rely on that dispute-resolution mechanism—the only process available to them to remedy violations of Section 340B of the Public Health Service Act—to resolve a dispute with drug manufacturers regarding statutory requirements to provide access to discounted drugs. *Id.* ¶¶ 1, 2-6.

The final rule Plaintiff sought to compel was published in the Federal Register on December 14, 2020. *See* 85 Fed. Reg. 80,632. Once the rule takes effect on January 13, 2021, Plaintiff will be able to bring a claim before the Secretary to resolve its members' dispute with drug manufacturers that precipitated this action against the Secretary.

The parties have met and conferred in advance of Defendants' upcoming December 22, 2020 deadline to respond to Plaintiff's complaint, specifically in order to comply with this Court's General Order and Guidelines Applicable to APA Cases Assigned to Judge Ketanji Brown

Jackson, entered in this action at ECF No. 5, November 9, 2020. During their discussions the parties agreed jointly to seek a stay of this action for 60 days, through February 15, 2021, to allow the rule Plaintiff sought to compel to take effect and Plaintiff or its members to avail themselves of that process.

The parties respectfully suggest that the proposed stay will best serve judicial economy while also preserving the resources of the parties by avoiding briefing a matter that ultimately may not be necessary for the Court to address. Plaintiff promptly intends to bring a claim or claims for relief before the agency when the ADR rule takes effect on January 13, 2021, and the proposed stay would permit the parties to file no later than February 15, 2021, a status report indicating whether (1) the parties believe this action should remain stayed pending further developments before the agency, (2) whether the action should be dismissed by stipulation of the parties, or (3) whether briefing should resume. "District courts have broad discretion to stay all proceedings in an action pending the resolution of independent legal proceedings." *Nat'l Industries for the Blind v. Dep. of Veterans Affairs*, 296 F. Supp. 3d 131, 137 (D.D.C. 2017) (Jackson, J.) (citing *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)). That is no less true when the independent proceedings will take place before a federal agency to which Congress has granted authority to resolve a dispute in the first instance. And the power to grant such a stay stems from a court's ability to manage its docket "with economy of time and effort for itself, for counsel, and for litigants." *Id.* (citation omitted). Here, the parties agree that the proposed stay will best serve their interests and the interests of judicial economy.

Absent a stay, Defendants intend to move to dismiss this action as moot on the ground that the rule sought in Plaintiff's complaint now has been issued. Defendants further respectfully request that, should the proposed stay be denied, the Court consider this motion to serve as the

notice required in conformance with General Order 3(b), to indicate their intent to file a motion to dismiss this action as moot in lieu of filing an answer, and to further permit Defendants a period no later than ten days to discuss with Plaintiff a briefing schedule for that motion and to serve that motion on Plaintiff, as required by this Court's General Order.

The parties hereby jointly request that the Court stay this action through February 15, 2021, with the parties to file a further joint status report no later than that date indicating proposed next steps for this matter.

Dated: December 17, 2020

Respectfully submitted,

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Acting Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Kate Talmor
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Exhibit I

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

August 26, 2020

Mr. Derek L. Asay
Senior Director, Government Strategy
Lilly USA, LLC
Lilly Corporate Center
893 Delaware St
Indianapolis, Indiana 46285

Dear Mr. Asay:

This is in response to your letters of May 18, 2020, and August 19, 2020. In your May 18 letter, you indicated the Lilly USA ("Lilly") would cease selling the drug Cialis at the section 340B ceiling price to pharmacies operating under contract with a covered entity unless the covered entity lacked an in-house pharmacy, in which case Lilly would offer the ceiling price to one contract pharmacy. In your August 19 letter, you indicated that Lilly was planning to extend this policy to all of its drugs.

HRSA is considering whether your new proposed policy constitutes a violation of section 340B and whether sanctions apply. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi).

Lilly claims that HRSA concluded that Lilly's plan "did not give rise to any enforceable violation of the 340B statute." That is not correct. In fact, in HRSA's response letter dated June 11, 2020, HRSA expressed its concern that the plan would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute. HRSA encouraged Lilly to reconsider its decision to restrict access to 340B drugs and HRSA warned Lilly of the plan's impact on underserved and vulnerable populations.

Under 42 U.S.C. § 256b(a)(1), manufacturers must offer covered entities outpatient drugs at specified prices. HRSA continues to examine whether Lilly's actions amount to attempts to circumvent that statutory requirement by inappropriately restricting access to 340B drugs for at least some covered entities.

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

HRSA will respond to your other requests as quickly as possible. However, given the urgent demands of the COVID-19 pandemic and other demands, HRSA may not be in a position to respond by your requested date.

Sincerely,

Krista M. Pedley

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration

Exhibit J

AstraZeneca

July 24, 2020

BY FEDERAL EXPRESS & EMAIL

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

Re: AstraZeneca: 340B Contract Pharmacies

Dear Rear Admiral Pedley:

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

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

Contract Pharmacy Background and HRSA Guidance

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

AstraZeneca

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

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

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

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

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

AstraZeneca

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

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

AstraZeneca's Contract Pharmacy Approach Beginning October 1, 2020

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

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

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

AstraZeneca

* * *

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

Sincerely,

C Bloomquist

Christie Bloomquist

Vice President Corporate Affairs, North America

Exhibit K

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
V.	)	Civil Action No. 1:20-cv-03032
ALEX M. AZAR II, ET. AL	)	

Declaration of J.R. Richards

I, J.R. Richards, declare as follows:

1. I am the CEO at Neighborhood Improvement Project. Inc., d/b/a Medical Associates Plus ("MAP") and have held this role since in or around January 2015. As CEO, I am responsible for overall operations and implementation of the policies of the Board of Directors. I supervise a senior leadership team consisting of the Chief Operations Officer, the Chief Financial and Business Development Officer, the Chief Medical Officer, the Chief Information Officer, the Chief Compliance Officer, and the Satellite Operations Administrator. I am also responsible for oversight of all departments within the organization, including the Pharmacy Department, whose members have regular access as part of their job duties to all information related to pharmacy operations. To prepare this declaration, I consulted with all members of the senior management team, as well as our Director of Pharmacy Operations, and reviewed relevant data and information.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. MAP is a Federally Qualified Health Center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved population in Augusta, Georgia and surrounding areas, including in Richmond, Burke, and Jefferson counties. MAP has served this patient population regardless of patient insurance status or ability to pay since in or around 1997.

4. MAP estimates it will serve over 25,000 patients in 2020, over 5,000 of whom are uninsured and below 200% of the federal poverty level. MAP currently provides primary care, woman's health, dental, pediatrics, behavioral health, diabetes management, pharmacy, endocrinology, pulmonary, dermatology, infusion therapy, and infectious disease services for our patients and community.

5. In 2019 alone, MAP provided over $8,000,000 in uncompensated care to patients who could not, either through insurance or independently, cover some or all the costs for their care.

6. MAP is a "covered entity" for purposes of the 340B Drug Pricing Program ("340B Program") and first received Health Resources and Services Administration (HRSA) approval to participate in the 340B Program in or around 2008. MAP recertifies its status annually with HRSA to maintain that approval.

7. The 340B Program allows MAP to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. MAP purchases these discounted medications for dispensing at its in-house pharmacies, clinics, and contract pharmacies from several wholesalers, including Cardinal, McKesson, Henry Schein, and other independent companies. MAP currently spends an estimated $410,000 per month—close to $5 million per year—in 340B drugs for its patients.

8. MAP uses a combination of in-house pharmacy and contract pharmacy arrangements to provide all-inclusive access to its patients for their prescription needs. Due to several patient-related factors, MAP is only able to serve about 40% of its patients through in-house pharmacies. Most of MAP's patients thus rely on our contract pharmacy network to fulfill their prescription needs. All contract pharmacy arrangements are memorialized in written agreements between MAP and the pharmacy. Dispensing is available through contract pharmacies only after an agreement is finalized and approved by HRSA's Office of Pharmacy Affairs (OPA).

9. Our contract pharmacy network expands our ability to offer 340B savings and reach more of our vulnerable patients to fulfill their pharmacy needs. Because of 340B, MAP is able to provide its qualified patients medications such as insulin and epinephrine for as little as $4 to $7 a dose, or even at no cost at all.

10. Six of our eleven sites do not have an in-house pharmacy and MAP's patients who rely on these sites for care strictly rely on contract pharmacies to meet their prescription needs at affordable prices. Additionally, because our in-house pharmacies are only open during clinic hours—weekdays from 8AM to 5PM—our contract pharmacy network allows our patients to access 340B discounted drugs outside of these hours. A lack of available time during the traditional workday is a significant barrier for our patient population.

11. An optimized network of contract pharmacies also allows MAP to generate additional revenue by increasing its "capture rate," which in turn enables MAP to retain more 340B savings and therefore support more services for its patients. As required, we reinvest all 340B savings and revenue in services that expand access for its medically underserved patient population.

12. Our participation in the 340B Program further allows us to provide services to vulnerable populations such as the homeless, migrant workers, people living in public housing, and low-income individuals and families.

13. MAP does not—and legally cannot—refuse to see an individual based on his or her inability to pay for services. We offer all our services on a sliding fee scale for those that are 200% below the poverty level, and many patients receive services for free. This means that a patient can see a provider for a primary care medical visit valued at $175 including lab work, for as little as $25, or for free depending on their family's income and size.

14. MAP also uses 340B Program savings and revenue to provide patient services that could not be offered without these funds. These services include behavioral health, dental, mobile van services, a patient assistance program, and free prescription delivery services, which annually entail an estimated 6,000 free prescription deliveries to our underserved community to overcome major transportation barriers to care.

15. Across all pharmacies, MAP currently fills an average of approximately 7,500 prescriptions per month, and approximately 90,000 prescriptions per year.

16. All our contract pharmacies operate on a virtual inventory model, which means pharmacies dispense medications from their retail stock, identify qualified 340B claims, and replenish their stock with 340B medications. The claim matching process is handled by Third-party Administrators (TPAs) and goes through several filters before a claim is deemed eligible for 340B pricing. MAP pays a fee to the contract pharmacies (for providing dispensing services) and TPAs (for qualifying claims and ordering medications).

17. As required by HRSA, MAP does not and will never enter into an agreement with contract pharmacies where it does not retain the majority of the savings from the 340B discount. MAP views compliance of contract pharmacies very seriously and has hired a pharmacist who is a 340B Apexus Certified Expert (340BACE) to audit and reconcile inventories on all contract pharmacy claims. In or around July 2020, MAP underwent a 340B HRSA Audit where there were no findings.

18. Beginning on or about July 22, 2020, I became aware that certain drug manufacturers including Eli Lilly, Sanofi, and AstraZeneca had unilaterally decided to cease providing outpatient prescription drugs at 340B prices to MAP's contract pharmacies.

19. Because of this action, many of MAP's patients can no longer fill their prescriptions for life-saving and life-sustaining medications through MAP's contract pharmacy network.

20. MAP currently has no access to Eli Lilly or Sanofi medications at 340B pricing to be dispensed through its contract pharmacies.

21. MAP likewise has no access to AstraZeneca drugs at 340B pricing at most of its contract pharmacies. After its initial announcement, AstraZeneca indicated it would ship drugs purchased at 340B prices to certain contract pharmacies. On or about October 14, 2020, MAP requested that AstraZeneca approve six of its contract pharmacies for this exception. MAP received notice on or about November 30, 2020, that AstraZeneca would continue to ship drugs at 340B pricing to three of the six requested pharmacies. MAP is currently working with its TPA to implement 340B purchases and dispensing for these pharmacies.

22. We have been working to switch patients to alternate medications and to convince our patients, where possible, to fill their prescriptions at our own, in-house pharmacies where they will still have access to discount pricing.

23. Both efforts have challenges. Even for patients who don't face significant barriers to filling their prescriptions at one of MAP's in-house pharmacies, many are reticent to switch because of familiarity and comfort. Switching patients to alternate formulations to avoid paying full price for these medications may cause patients to become unstable and potentially cause adverse health consequences. For example, a patient whose diabetes was fully controlled by Humalog (an Eli Lilly insulin) may be forced to switch to Novolog (a Novo Nordisk insulin) since Eli Lilly has banned or restricted shipments of its products at 340B pricing to our contract pharmacies. This patient's diabetes may become uncontrolled or the patient may experience adverse effects from switching. In 2019, approximately 19% of MAP's patients were diabetics compared to the State and National averages of 12% and 9%, respectively.

24. Additionally, MAP estimates we will lose up to approximately $350,000 in annual net revenue as a result of these manufacturer's actions. MAP receives grant dollars to help serve its patients, but these grants only cover about 28% of MAPs total expenses, and MAP depends on its 340B Program savings and revenue to help support approximately 41% of the remaining expenses, which include underfunded and unfunded programs and services such as behavioral health and dental services.

25. This significant financial loss, if not prevented or recovered, will also result in reduction in other clinical and/or patient services, increased work for clinicians, and increases in costs where MAP is covering costs for its uninsured patients and/or patients who are unable to pay.

26. MAP has actively tried to find ways to mitigate the negative financial consequences of the manufacturers' actions. We have considered eliminating or charging a fee for our current free prescription delivery program, increasing per-provider patient volume, and making reductions in some clinical services. Each of these options, however, ultimately negatively impacts patient care and still falls short of an adequate remedy.

27. These restrictions from manufacturers, and MAP's inability to access an administrative remedy through HRSA, will drastically impact our health center's operations and could severely alter our ability to provide access to low-cost services to our underserved community, which is the premise of the FQHC program.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: DECEMBER 9, 2020

By: _____
J.R. Richards, MPA
Chief Executive Officer

Exhibit L

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS PLAINTIFF, V. ALEX M. AZAR II, ET. AL	)	Civil Action No. 1:20-cv-03032

Declaration of Donald A. Simila

I, Donald A. Simila, declare as follows:

1. I am Chief Executive Officer at Upper Great Lakes Family Health Center, Inc. ("Upper Great Lakes"), and I have held this role since on or about October 1, 2009. As Chief Executive Officer, I am responsible for oversight of all services, including pharmacy services. To fulfill my job duties, I have access to all pharmacy-related transactions generated by prescriptions written by our physicians. Additionally, Upper Great Lakes has a dedicated analyst and 340B/pharmacy committee that reviews program activity, and educates me, as well as the board, staff, and patients, on the program. To prepare this declaration, I reviewed wholesaler invoices, pharmacy contracts, and pharmacy invoices.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Upper Great Lakes is a Federally-Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide primary health care and related services across a 10,000 square mile service area at 11 distinct and dispersed clinic sites, 20 congregate care facilities, and various school-based clinics.

4. Upper Great Lakes has been in business as an FQHC since approximately May 2010, and is a member of the National Association of Community Health Centers.

5. On an annual basis, Upper Great Lakes provides approximately 25,000 unique patients with 80,000 clinical visits for comprehensive primary care, OB/GYN, Behavioral Health including Medication Assisted Treatment for Opioid Use Disorder, and preventative and restorative dental services. As a rural community, Upper Great Lakes' target population is significantly underserved, aging, and impoverished. Sixty percent of Upper Great Lakes patients are either on Michigan Medicaid or on Medicare. Seventy percent of our patients

are at or below 200% of the federal poverty level ("FPL"), and 25% are at or below 100% of the FPL.

6. Upper Great Lakes is a "covered entity" for purposes of the 340B Drug Program ("340B Program). As a covered entity, Upper Great Lakes can purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

7. Upper Great Lakes has been a covered entity since in or around 2010 and, as required, annually recertifies its locations as 340B eligible sites with the Health Resources and Services Administration ("HRSA").

8. As a covered entity, Upper Great Lakes is permitted to choose how it will deliver pharmacy services to its patients. Upper Great Lakes—across its 10,000-mile service area—maintains contractual arrangements with local retail pharmacies to support its patients by ensuring local access to reduced price medications for those who meet federal poverty guidelines.

9. Upper Great Lakes requests HRSA approval for each of its contracted pharmacy partners. Once approved, Upper Great Lakes enters into a contractual relationship with the individual pharmacy's wholesaler under which Upper Great Lakes purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped to the contract pharmacy. The health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services to eligible Upper Great Lakes patients.

10. When an Upper Great Lakes provider writes a prescription, it is electronically transmitted to a local pharmacy where the prescription is filled by the retail pharmacist; a third-party application identifies patients who qualify to purchase medications at 340B pricing, as well as claims that are submitted to insurance plans.

11. The "virtual inventory" owned by Upper Great Lakes is tracked by an Upper Great Lakes 340B analyst through real-time data reporting from third-party administrator software. Reconciliations occur each month.

12. Upper Great Lakes carves in a select few pharmacies that bill a single managed Medicaid plan for most claims; as required, Medicaid is not billed for outpatient medications. The retail pharmacy directly submits claims to Medicaid for medications purchased at retail pricing from non-340B inventory.

13. Upper Great Lakes passes its 340B savings directly to eligible patients who meet federal poverty guidelines.

14. Savings generated through claims made to commercial insurance and other third-party payers ensure that Upper Great Lakes can continue to provide essential health care services to its underserved rural community.

15. With its 340B savings, Upper Great Lakes is able to provide its vulnerable patient population access to a board-certified addiction medicine physician for treatment of Opioid

Use Disorder—the only Addiction Medicine Specialist in the entire Upper Peninsula of Michigan, which encompasses 15 counties and approximately 17,000 square miles—and is able to support the training of an additional 4 physicians to meet DEA licensing requirements for Medication Assisted Treatment. The approximate annual cost to support the addiction services above and beyond reimbursement is $200,000.

16. Additionally, as the only dental provider that accepts Medicaid in large volumes in the service area, Upper Great Lakes is able, due in part to 340B savings, to maintain a dental service at two locations with combined annual operating losses of approximately $450,000.

17. 340B savings also support OB/GYN services in a 4-county area with a population of approximately 45,000. The approximate annual operating loss of this service for the community exceeds $225,000 annually. Without this service, women in our service area and target population would be required to travel more than 100 miles one-way for access to OB/GYN care.

18. Clinic locations in rural counties such as Ontonagon, Iron, and Menominee all carry annual operating losses as the cost of employing physicians and operating a clinic exceed reimbursement from Medicaid, Medicare, and private insurance. In total, clinic services for these counties add up to an annual operating loss of more than $600,000.

19. Federal grant money falls far short of covering the operating losses outlined in the preceding paragraphs. 340B savings help to fill these gaps.

20. Finally, as an organization, Upper Great Lakes has completed over 10,000 COVID-19 tests in local communities through mobile services and walk-up or drive-up testing. Funds from 340B savings have supported the costs associated with standing up testing teams, purchasing test kits, and underwriting coordination of this service. Our health center has been the only source of community testing in most communities we serve. In addition, Upper Great Lakes has been instrumental at two local Universities commencing face-to-face instruction; at those institutions, we conduct random COVID-19 surveillance testing for students and employees daily, providing approximately 600 tests per week. This service enabled the Universities to bring 6,700 students back to campus. Without the safe integration of students into these communities, the economic impact to the greater community would be dire.

21. Upper Great Lakes follows HRSA requirements and the 340B statute to ensure all contract pharmacies are engaged in a binding contractual agreement with the Health Center. Each pharmacy has executed a contract with Upper Great Lakes prior to registering and obtaining approval for including the pharmacy in Upper Great Lakes' approved network.

22. Upper Great Lakes designed its contract pharmacy network to ensure that all patients across the 10,000-mile, 11-county rural service area have access to discount medications. In addition to being located in the communities we serve, most contract pharmacies have expansive hours of operation that many of our patients need.

23. Our annual operating margin is approximately 1-2% on a budget of $22 million. The average salary for a primary care physician in this region is approximately $240,000 plus benefits of about $50,000. Without 340B savings, all our primary care practices lose money. On an annual basis, across all 11 locations, Upper Great Lakes' drug sales through the 340B Program at all contract pharmacies amounts to approximately $6 million dollars. After administrative fees, ingredients costs, and dispensing fees, the health center nets approximately $250,000 to $300,000 per month (or approximately $3 million to $3.6 million annually).

24. Beginning on or about September 1, 2020, I became aware that certain drug manufacturers, including Eli Lilly, Sanofi, and AstraZeneca would cease providing outpatient prescription drugs at 340B prices to Upper Great Lakes' contract pharmacies.

25. Because of these actions by the drug manufacturers, health center patients, staff, and the community Upper Great Lakes serves will be significantly and irreparably harmed both clinically and economically.

26. Although Eli Lilly at least appeared to offer us the option of selecting one single contract pharmacy through which 340B-priced medications could be dispensed to eligible patients, a single pharmacy for all our patients would severely limit our patients' access to life saving medications.

27. The travel distance between our northern most and southern most clinical delivery sites is 200 miles. The Upper Peninsula of Michigan is a roughly 17,000 square mile region that is sparsely populated with approximately 300,000 individuals. Only one 90-mile stretch of interstate highway exists in the region, running north and south on the Peninsula's extreme eastern edge. Most of the population is served by two-lane state and county highways. As a region, the Peninsula will receive annual snowfalls in excess of 200 inches. Some areas receive more than 300 inches annually. Given the geographic and weather realities here, travel is hampered nine months of any given year.

28. The drug manufacturers' decisions were seemingly made without regard for the narrow margins on which safety net providers like Upper Great Lakes operate, or for the immediate and unplanned-for financial losses that result from these actions. Since September 1, 2020, and on a monthly basis, Upper Great Lakes has lost and will lose anticipated revenues in excess of approximately $50,000 from Eli Lilly's actions alone. Annualized, this amounts to approximately $600,000 from Eli Lilly alone.

29. As a result of this loss, we are currently planning major reductions in services, which will include closure of access points/service delivery sites, termination of employees, reductions in health center providers, and likely closure of OB/GYN (for which we have already reduced staffing), dental, and mental health services.

30. The ultimate result of the manufacturers' actions will be a significant reduction in access to comprehensive care for an elderly, impoverished, and underserved rural community with chronic health conditions that require ongoing care.

31. Additionally, as a major employer in the region with a monthly payroll in excess of approximately $1.2 million, a likely necessary staff reduction of about 50% will have a direct economic impact on our communities of approximately $7.2 million annually.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 12/03/2020

By _____
Donald A. Simila
Chief Executive Officer, Upper Great Lakes Health Center, Inc.

Exhibit M

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
V.	)	Civil Action No. 1:20-cv-03032
ALEX M. AZAR II, ET. AL	)	

Declaration of Patricia DeShields

I, Patricia DeShields, declare as follows:

1. I am the CEO at Project H.O.P.E., Inc. in Camden, New Jersey, and have held this role since on or about March 10, 2003. As CEO, I am responsible for providing leadership and direction to the organization to ensure that Project H.O.P.E. improves our patients' health outcomes and addresses health disparities.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Project H.O.P.E. is a Federally Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide culturally sensitive primary care, behavioral health care, and substance abuse treatment services to the medically underserved homeless population in Camden County and the City of Camden, New Jersey.

4. The City of Camden is the largest urban center in southern New Jersey, with a population of approximately 78,675 residents, and is ranked as the most economically depressed city in New Jersey and one of the most economically depressed cities in the United States.

5. Project H.O.P.E. is unique in that it is the only provider of integrated primary care and behavioral health services specifically for the homeless population in Camden County.

6. Project H.O.P.E. provided approximately 25,105 medical and behavioral health visits for about 5,679 unique homeless patients in 2019 alone. That year approximately: 78% of our patients identified as being homeless, 79% were at or below the poverty level, and 17% were without any form of health insurance.

7. Our patient population experiences significant barriers to care, due to, among other factors, homelessness, lack of stable housing, socioeconomic status, race, and lack of insurance or income. We provide our services regardless of patient insurance status or ability to pay.

8. Project H.O.P.E. is a "covered entity" for purposes of the 340B Drug Pricing Program (the "340B Program")—which affords access to discounted outpatient prescription drugs—and has held this status since in or around 2006. We complete the required Health Resources and Services Administration (HRSA) annual recertification every year to maintain our status.

9. Project H.O.P.E. meets our patients' outpatient pharmaceutical needs through a contract pharmacy arrangement with local pharmacy Farmacia Sunray. The relationship has been approved by HRSA's Office of Pharmacy Affairs and serves our patients well. Our patients, who have significant barriers to obtaining their medications, are provided with patient-centered services within their community. The accommodations and convenience offered by our contract pharmacy locations are crucial to ensuring continuity of care and patient control of chronic illnesses such as diabetes, hypertension, and depression (our patients' three most common disease states).

10. Project H.O.P.E. primarily purchases drugs at 340B pricing through wholesaler Cardinal Health, which invoices Project H.O.P.E. for all 340B-eligible prescriptions filled for Project H.O.P.E. patients at Farmacia Sunray. The relationship operates on a replenishment model. Project H.O.P.E. pays Farmacia Sunray a 12.5% dispensing fee for its services, and works with an administrator to ensure that the partnership between Farmacia Sunray and Project H.O.P.E. is compliant and all claims are processed appropriately.

11. In or around early September 2020, Project H.O.P.E. received notice from Farmacia Sunray that drug manufacturers including Eli Lily and AstraZeneca would no longer ship outpatient prescription drugs at 340B prices to be dispensed by contract pharmacies.

12. Our participation in the 340B Program—and the savings and revenue our participation generates—allows us to absorb medication-related costs and provide increased access to prescriptions for very vulnerable patients who would otherwise be unable to obtain prescriptions due to cost.

13. The sudden unavailability of discount medications for our patients is extremely harmful and will inevitably reduce our patients' access to life-saving and life-sustaining medications. As detailed above, many of our patients are well below the Federal Poverty line. Our most vulnerable patients simply cannot afford increased medication costs, and there is a limit to the costs Project H.O.P.E. can absorb, especially with a loss of access to 340B pricing.

14. Pricing changes for various insulin formulations in particular greatly impact our underserved patient population, which suffers high rates of diabetes. Increased costs may cause diabetic patients to stop taking their insulin, which can lead to increased

complications, hospitalizations, and other associated diabetic acuities such as loss of vision, kidney damage, neuropathy, and amputation.

15. Price changes to Suboxone pricing threaten our patients with substance abuse disorder, who may not be able to afford to continue in their Medicated Assisted Treatment (MAT), and thus may suffer relapses and possible fatal overdoses. Suboxone is a medication approved by the FDA for the treatment of opiate dependence such as heroin addiction. Experts say it works well because it's a very "sticky" drug, meaning it binds well with the same receptors as opiates. This binding of Suboxone essentially inhibits the ability of opiates to bind. Project H.O.P.E. currently has 478 active Suboxone patients and dosage amounts vary among patients. The changes in costs by dosage is as follows:

Dosage	Current Cost	Previous Cost	Net Cost Increase
90 films (dose 3 films daily)	$286.59	$15.81	$270.78
84 films (dose 2.5 films daily)	$241.33	$15.76	$225.57
28 films (dose 2 films daily)	$99.49	$15.25	$84.24

16. In 2019, 340B savings and revenue not only enabled Project H.O.P.E. to cover the cost of medications provided to uninsured patients, but also to provide bus tickets to those who otherwise could not afford to travel to the health center or to see specialists. Additionally, Project H.O.P.E. used 340B savings to purchase medical supplies, pay patients' labs fees, and cover the cost of vaccinations that are not covered by grants. Without 340B revenue, we will have a significantly reduced ability to fund these and other services that do not generate revenue, such as outreach to encourage preventive treatment and screenings.

17. Moreover, this comes at a time when health centers are serving as the front line in the fight against the COVID-19 pandemic. According to the New Jersey Department of Health, by the beginning of December 2020 New Jersey reported more than 387,000 cases and more than 15,700 deaths, with Southwest New Jersey designated as has having a high COVID-19 Activity Level.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: 12/11/2020

By: Patricia DeShields

Patricia DeShields
CEO at Project H.O.P.E., Inc.

Exhibit N

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS PLAINTIFF, V. ALEX M. AZAR II, ET. AL	)	Civil Action No. 1:20-cv-03032

Declaration of Heather Rickertsen

I, Heather Rickertsen, PharmD, declare as follows:

1. I am Director of Clinical Pharmacy Services at Crescent Community Health Center (Crescent) in Dubuque, Iowa. I began working with Crescent in or around the spring of 2006, just prior to the clinic's official opening. I have served as Crescent's Director of Clinical Pharmacy Services since in or around August 2016. As director I have developed our pharmacy services to better serve our patients' health through improved medication access and compliance.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Crescent is a Federally-qualified health center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act. Crescent opened in or around the fall of 2006. Our health center serves approximately 6,500 patients annually; a third of the patients identify as racial or ethnic minority, 92% are 200% below poverty level, and 50% are uninsured. Compared to other health centers, we have slightly higher rate of hypertension at 29% of patients and diabetes at 17%, whereas within Iowa the average rates for hypertension is 26% and diabetes is 15%.

4. The cornerstone of Crescent's pharmacy services is patient access to necessary medications. In addition to providing our patients discounted medications, we cover the entire cost of medications for patients who cannot afford even discounted drugs. We also cover the cost of medication compliance packaging to assist those individuals with complex medication regimens.

5. Further refining pharmacy services, we provide pharmacists embedded within Crescent's medical and behavioral health clinic. These pharmacists provide a variety of services from medication reviews, anticoagulation, diabetes, and hypertension management, as well as support to providers for prior authorizations and pharmaceutical education.

6. Crescent is a "covered entity" for purposes of the 340B Drug Pricing Program (the "340B Program"). We have been eligible for 340B since in or around January 2008 and added a second contract pharmacy in or around January 2020. We maintain a physical inventory at each pharmacy and review reports, inventory, and eligibility on a monthly basis.

7. The 340B Program allows Crescent to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

8. As a covered entity, Crescent is permitted to choose how it will deliver pharmacy services to its patients. We use Cardinal Health as our wholesaler. Reorder points are set at the pharmacy, once prescriptions are dispensed and the inventory falls below order point, the pharmacy will generate replenishment to maintain physical inventory to allow a three-month supply of medication to be dispensed.

9. We contract with two pharmacies, both within walking distance of Crescent. The first contract is with Mercy Family Pharmacy (Mercy One Elm) at 1920 Elm Street. This was approved by the Office of Pharmacy Affairs (OPA) on January 1, 2008. The second contract pharmacy is Infocus Pharmacy Services, at 1690 Elm Street Suite 200. This was approved by the OPA on January 1, 2020. Our pharmacy model is 'physical on hand inventory' where prescriptions are dispensed to the patient at 340B acquisition cost of the drug plus a $9.50 dispensing fee. When patients are unable to afford the cost of drugs, Crescent covers the total cost for them.

10. Crescent retains all savings from each contract pharmacy model and does not utilize a third-party administrator ("TPA"). Crescent reimburses each pharmacy approximately $20 per prescription for dispensing fee, which we believe is in alignment with national and regional averages.

11. Both contract pharmacies offer a variety of services for patients including same day or next day delivery services within the city and free mail out services for our rural patients. Both pharmacies provide medication compliance packaging. Mercy One Elm offers additional transitions of care services for patients being discharged from their health systems and Infocus provides transitions of care services through their connection with Midwest Medical Center in Galena, Illinois. Both pharmacies offer flexibility to meet patients' needs, providing additional care coordination and leveraging referral-based prescriptions; the leveraging of additional funds allows medications to be affordable and guidance on regimens to meet patients' needs.

12. Both of our pharmacies maintain a physical inventory, reorder points are routinely set to allow for a three-month supply of a prescription to be dispensed, however as a result of the COVID-19 pandemic, and ongoing threats to the 340B Program, we have increased inventory to a 6 to 12 month supply. The pharmacies report when inventory falls below that threshold, and orders are directly uploaded to inventory. Additionally, for those items that are above acquisition cost of $100, the pharmacy has an inventory on demand and can order the medication for next day, rather than having physical inventory. Each contract pharmacy then provides a monthly report to the health center on prescription medications dispensed,

and a variety of detail on transaction and community benefit services offered, as well as specific therapeutic class and demographic information. These reports are reviewed and collated monthly for compliance to 340B policy, patient eligibility, and referral data. Additionally, report out on financial and volume data is reviewed and compiled for monthly reports to quality improvement, financial and board.

13. Annual prescription purchases in the 2020 fiscal year include over 2,300 unique National Drug Codes (NDCs) and current 340B purchase prices of approximately $350,000, 50% of which is directly tied to treatment of diabetes, hypertension, and mental health.

14. In the past 5 years, we have seen our annual prescription volume grow from about 10,000 to about 20,000, with approximately half of prescriptions for uninsured patients. Of the medications dispensed, the largest percentage of therapeutic classes include 17% to treat diabetes, 15% for hypertension, and 14% for mental health, these three categories represent nearly 50% of overall prescriptions dispensed.

15. Approximately 20% of our patients access prescriptions through the community health center. If out-of-pocket expense becomes a barrier for a patient, Crescent pays for the entire cost of the medication.

16. Our 340B Program participation also helps us to provide pharmacy services at no cost to patients, including medication management, anticoagulation management, diabetes education and management, and hypertension management.

17. Crescent's participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Federal law and regulations, as well as Crescent's mission, require that every penny of 340B savings be invested in services that expand access for its medically underserved patient population.

18. In addition to various prescription medications—including insulin—Crescent also currently provides the following at no cost to any patient who is unable to afford a copay: blood pressure cuffs, diabetic testing supplies, and wound care supplies. This service is available to all patients who report being unable to afford medication, all patients on medication compliance services, and all Pacific Islander patients. We are able to do this for our most vulnerable patients because of the savings and revenue we generate through the 340B Program.

19. Furthermore, with 340B savings, we cover the cost of medication compliance packaging for patients with complex medication regimens that can make compliance a challenge.

20. 340B savings and revenue support our non-revenue generating Pacific Islander programs, which serve the unique needs of pocket populations of individuals from Marshall Islands and Federated State of Micronesia located in Dubuque and surrounding counties. These individual's may legally live and work in the area but may not rely on Medicaid or Medicare. Many of these patients are uninsured, food insecure, and in poor health.

Additionally, many were exposed to radiation during routine nuclear testing on these islands and suffer direct and ancillary health consequences. These unique patients are frequently found to have poorly controlled diabetes, higher rates of cancer, and heart disease.

21. The COVID-19 pandemic has exacerbated the situation for these patients, many of whom work in meat packing plants and reside in overcrowded living arrangements, both of which are ideal environments for rapid virus spread. To help meet the needs of this population, Crescent has implemented our Pacific Islander Health Project, which provides dedicated community health workers, as well as language interpreters and translators, social workers, and nursing staff. Participation in this program provides monthly group classes, free access to all medication, and frequent outreach.

22. Crescent's other non-revenue generating activities aimed at its general population include social services, community health workers, offsets to wellness center costs, and care coordination.

23. In early April 2020, we became aware of Bausch Health reducing distribution to one limited wholesaler in "direct distribution model" for 340B medication via a phone call by the new wholesaler appointed by Bausch Health. We did not receive direct notice of this change. This contact came on the heels of the COVID-19 outbreak, particularly devastating to a subset of Pacific Islander population, as well as having little prescription volume for our program. As seen as a limited threat, I choose not to register with a new wholesaler due to timing, limited use, and uncertainty surrounding COVID-19.

24. Additionally, on June 29, 2020, Merck notified us that it would only continue shipment of drugs we purchase to contract pharmacies, if we registered with 340B ESP to report data on prescriptions. We did initially register and attempted to submit data for July, but we were hampered by technical issues; we were able to upload and report data for August and September, but changes in terms and conditions on part of 340B ESP effective October 1, 2020 have made it impossible for us to upload data.

25. On or about August 17, 2020, we received notices from drug manufacturers Sanofi and Novartis, also requiring us to report data via 340B ESP.

26. Additionally, Astra Zeneca has informed health centers that they will only ship drugs to in-house pharmacies or, if a health center lacks that capacity, to a single contract pharmacy. Limiting shipment to a single contract pharmacy choice would severely limit patients' access as well as create inconsistent pharmacy services for patients.

27. Finally, on or about September 2, Eli Lilly indicated to the media that while it had ceased shipping covered entity-purchased drugs to contract pharmacies, it might be willing to ship insulin products to a single contract pharmacy per health center if the health center and pharmacy agreed to (1) dispense insulin at 340B purchase price and (2) to not leverage reimbursement from patients' private insurers.

28. Because of the actions by Bausch Health, Merck, Eli Lilly, AstraZeneca and Novartis, we face the possibility of losing 340B savings and revenue. Without these funds, we would no longer be able to cover patient copays, Pacific Islander programing, or our wellness center. We will also need to consider limiting patient access to dentures due to our loss of savings and the increasing cost of goods sold.

29. Beginning in or around July 2020, as changes began to develop with the 340B Program, we not only looked closely at revenue and expense specifically supporting the 340B Program, but also prepared a drug utilization review of distribution of medications based on manufactures and therapeutic classes.

30. We have determined that based on the manufacturers' actions, many patients will lose access to medications to treat diabetes, hypertension, asthma/COPD, and heart disease. Approximately thirty-two uninsured patients will no longer be able to afford their Asthma/COPD medications including rescue inhaler albuterol, 76 diabetic patients will lose access to critical oral medications to treat diabetes, an additional 51 patients will lose access to their insulin, an additional 40 patients will no longer have access to the medication to treat both acute and chronic health conditions. We would anticipate in response that patients will start to ration medications, and we will see an accompanying chronic decline in diabetes control over a period of 3 to 6 months; specifically for diabetic patients this will cause an uninsured hospital expense due to untreated diabetes including diabetic ketoacidosis, infections, heart disease, and renal disease.

31. For many patients on maintenance medication regimens, there are alternative drugs on the market; however, the appropriateness of a medication change is complicated by differing medication potencies, renal dosing, insurance formularies, and challenges in medication adherence posed by a new routine.

32. I have approximately nine patients who currently take Humulin U-500 from Eli Lilly, this medication has no alternative and patients who require this medication take insulin dosing well outside of dosing ranges in typical insulin products on market. Due to these patients' high insulin dosing requirements, we would expect a more rapid decline in diabetes control and rapid increase in negative patient outcomes.

33. The cost of medication for our patients is expected to rise from an average of approximately $180 annually, to approximately $5,000 for patients with large chronic disease burden.

34. Starting our new budget year in November 2020, our health center anticipates an annual reduction of $1,000,000 in lost revenue, and $500,000 in increased costs of goods sold. However, some cost projections are upwards of $2,000,000 cost increase of goods sold just in the top 100 drugs dispensed.

35. We are also now having to consider costs associated with opening an in-house pharmacy, which are estimated to be an additional $250,000 annually.

36. As we shift expenses, we would no longer be able to cover patient copays. We will also need to decrease our clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health project.

37. We have increased inventory levels to attempt to weather the storm, increasing monthly cost of goods sold from $30,000 to approximately $50,000. Unfortunately, our inventory will only last 3 to 6 months, and if this destruction of 340B structure continues, in a year we would no longer be able to provide access to medications or clinical pharmacy services.

38. Our number one goal in navigating these unfortunate circumstances will be to continue to provide our patients access to life-saving and life-sustaining medications. If needed will move to patient assistance programs and samples; however, this is known to increase patient burden and decrease patient compliance and is not a sustainable long-term solution.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 12/9/2020 (Date) Signature Marcelle Reed

Exhibit O

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
V.	)	Civil Action No. 1:20-cv-03032
ALEX M. AZAR II, ET. AL	)	

Declaration of Lee Francis, MD, MPH

I, Lee Francis, MD, MPH, declare as follows:

1. I am the President and CEO of Erie Family Health Center, Inc. ("Erie"), located in and around Chicago, Illinois. I joined Erie in 1991 and have held the role of President and CEO since 2007. As President and CEO, I am charged with enacting Erie's strategic vision of serving as a national leader in the provision of community-based health care. I am responsible for the overall health of the organization, including financial stability, operational success, and clinical quality.

2. Regarding the 340B Drug Pricing Program ("340B Program"), as President and CEO, I have regular access to 340B financial and operational updates. I also receive regular updates on the 340B Program from Erie's Chief Financial Officer, who serves as the federal OPAIS Authorizing Official. As part of my regular duties, I am also made aware of provider and staff feedback related to 340B successes and barriers. Additionally, in my role as an Internal Medicine physician at Erie, I am keenly aware of the benefit the 340B Program offers for my own patients. To prepare this declaration, I have reviewed 340B Program metrics and feedback from providers and staff.

3. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

4. Erie is a Federally-qualified health center, and a member of the National Association of Community Health Centers. The health center receives federal funding under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population residing across over 185 zip codes in the Chicagoland region.

5. Erie is an approximately 63-year-old primary healthcare provider that delivers integrated and affordable medical, dental, and behavioral health care for patients of all ages. We also encourage good health in our underserved patient population through ongoing health education, case/care management, strong hospital partnerships, and community outreach.

6. Motivated by our belief that high-quality health care is a human right, Erie serves more than 80,000 patients per year at 12 locations throughout Chicago and the surrounding suburbs, regardless of patient insurance status, immigration status, or ability to pay for Erie's services. Almost all of Erie's patients are low income, and approximately 27% of Erie's patients are uninsured. Approximately 71% of patients are Hispanic and about 44% are best served in a language other than English.

7. Erie is a "covered entity" for purposes of the 340B Program. Erie has been registered with the Health Resources and Services Administration ("HRSA") as a 340B covered entity since on or about January 1, 1997. As required, we maintain accurate management of our clinic registrations within HRSA's OPAIS database. We recertify our 340B covered entity status annually, and most recently recertified for all twelve of our participating 340B locations on or about February 18, 2020. A list of our covered entity locations, downloaded from HRSA's 340B OPAIS database on October 7, 2020, is attached as Exhibit A.

8. The 340B Program allows Erie to purchase significantly discounted outpatient prescription drugs for pharmacy dispensing and as clinic-administered drugs. We acquire 340B discounted drugs for pharmacy dispensing through wholesaler AmerisourceBergen; we are also in the process of adding Cardinal Health as another 340B wholesaler account. For clinic-administered medications, we have 340B drug purchasing accounts with Allergan, Henry Schein, Paragard Direct, Theracom, and R&S Northeast, LLC.

9. Erie's participation in the 340B Program allows us to help our low-income uninsured and underinsured patients afford their medications. Without 340B discounts, critical medications—including, among many others, insulin, asthma inhalers, blood pressure medications, Pre-Exposure Prophylaxis (PrEP) for HIV, Suboxone and Narcan to treat opioid use disorder—would be unaffordable and inaccessible for these patients. 340B contract pharmacies enable our patients to access, and many other medications.

10. As required by federal law and regulations, and in keeping with our mission, we reinvest 100% of 340B savings and revenue from third-party reimbursement into expanding access for our underserved patients. For example, this money is used to cover costs associated with comprehensive care, a Medication-Assisted Treatment Program for opioid use disorder, and telemedicine and electronic population health tools, which enable Erie to serve patients at greatest risk for missing health screenings or services.

11. Many Erie patients have chronic conditions exacerbated by social challenges. Improving health outcomes depends on Erie providing: 1:1 Care Management, Maternal and Child Case Management, HIV/AIDS Case Management, Health Coaching, Referrals support,

Care Coordination and Outreach, Public Benefits navigation, Resource navigation, and PrEP navigation services. Because robust comprehensive care and case management are not usually reimbursed by third-party payers, Erie would not be able to offer these services without 340B savings.

12. As a covered entity, Erie is permitted to choose how it will deliver pharmacy services to its patients. While we use drugs purchased at 340B pricing for a select portion of our in-clinic medication supply, Erie contracts with local pharmacies to dispense all other 340B medications to its patients. We do not own or operate our own pharmacies. We currently contract with many local Walgreens pharmacy stores and one independent community pharmacy, Allcare Discount Pharmacy, which is co-located within one of our clinic sites.

13. Erie has a written agreement with Walgreens to dispense the 340B drugs we purchase to eligible Erie patients. We first contracted with Walgreens in or around 2011 and received HRSA approval for our first Walgreens contract pharmacy location on or about August 22, 2011. In the intervening years—following guidance from HRSA and Apexus—we have registered additional Walgreens locations. Our current Pharmacy Services Agreement with Walgreens—which applies to of all our active Walgreens pharmacy locations and all of our active covered entity locations, as registered in HRSA's 340B OPAIS database—was executed on or about April 4, 2017.

14. Erie likewise has a written agreement with Allcare Discount Pharmacy to dispense 340B drugs to eligible patients. We first contracted with Allcare Discount Pharmacy in or around September 2010; HRSA approved the pharmacy arrangement on or about May 23, 2011. Our current Pharmacy Services Agreement with Allcare Discount Pharmacy was executed on or about August 7, 2019.

15. As described in our Pharmacy Services Agreements, Erie purchases 340B drugs from wholesalers and directs those drugs to be shipped to the contract pharmacy as part of a "bill-to, ship-to" arrangement. Under this arrangement, Erie maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the drugs and provide dispensing services to our eligible patients. Some of our contract pharmacies use a precise accumulation software to dispense a retail pharmacy product to patients and perform a careful 340B eligibility assessment; if the dispense meets all eligibility criteria, the accumulator will be replenished with an Erie-purchased 340B drug for that dispense.

16. Understanding that 340B compliance falls squarely on Erie, we have multiple compliance safeguards in place and perform extensive auditing, including an audit of all contract pharmacy 340B dispenses for patient and provider eligibility and audits to verify that Medicaid Fee-For-Service was not billed for any contract pharmacy 340B claim (to avoid prohibited duplicate discounts). All audits are completed on a monthly basis and reported out quarterly to our 340B Compliance Committee. We also commission an annual external 340B audit. Our most recent external audit, in January 2020, yielded positive feedback on Erie meeting HRSA 340B compliance standards.

17. Our contract pharmacies dispense over 115,000 340B discounted prescriptions annually to our eligible patients. On average, Erie spends approximately $470,000 on 340B drug products monthly for dispensing through our contract pharmacies.

18. The critical benefit the 340B drug discount to patient outcomes is illustrated in an email from an Erie pediatrician attached as Exhibit B. In the email, the pediatrician explains how one of her patients benefited from access to affordable insulin through the 340B Program. The patient turned 18 this year, moved out to live independently, started working, and lost his Medicaid coverage. Previously, the patient's Type 1 diabetes had been managed by providers at the local children's hospital. During this transition to adulthood, he was unable to stay with his care team and could no longer afford the insulin he was prescribed. The Erie pediatrician was able to work collaboratively with the patient's previous provider to assume care for his diabetic condition and prescribed an affordable Lantus pen (a Sanofi product) through the 340B Program. Aligning the patient with access to the affordable 340B drug helped to keep his sugars under control, keep him out of diabetic ketoacidosis, and keep him out of the hospital until he was able to get his insurance reinstated. The 340B Program helped this young adult access life-saving medicine and avoid hospitalization.

19. Erie's ability to offer our patients—who are dispersed across more than 185 zip codes—access to affordable life-saving and life-sustaining medications is entirely dependent on our contract pharmacy partnerships.

20. Our contracts with local pharmacies to dispense 340B medications allow our patients to receive their critical 340B medication at a pharmacy close to their home. Erie patients generally experience multiple barriers to accessing care, including significant transportation barriers. Even though Erie has twelve clinic locations, some Erie patients still have significant travel times to attend their visit at the health center. The trip for some patients requires multiple segments on public transportation, as well as walking. Providing medication access near a patient's home supports that patient's ability to take their medication regularly, without potentially dangerous gaps around refills.

21. Many of our patients are hourly wage-earners, essential workers, work long hours, hold multiple jobs, or have care-giving responsibilities during the business day, and most will not get paid to take time away from work to obtain medications. Our contract pharmacy partners include 24-hour pharmacies and those with home delivery capabilities, providing crucial access to our patients, both day-to-day and in times of crisis.

22. Beginning on or about July 7, 2020, I became aware that certain drug manufacturers—starting first with Eli Lilly and its Cialis products and now including Eli Lilly, Sanofi, and AstraZeneca, Merck, and Novartis—had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of Erie's contract pharmacies.

23. Eli Lilly's notification affecting all products made or distributed by the company was implemented without advance notice on September 1, 2020, which did not allow Erie adequate time to respond to protect our patients' access to Lilly medication. Sanofi, Merck, and Novartis, for their parts, have requested that covered entities enroll in an unsanctioned and burdensome data collection platform called 340B ESP. Erie will not be participating in this data collection; our patients have thus lost access to Sanofi products. To date, Novartis has not yet followed through on threats to block 340B price access at contract pharmacies.

24. Because of these actions, our ability to provide patients with affordable medications has been dramatically reduced—Erie patients who were regularly receiving a 340B drug made by Eli Lilly, Sanofi, or AstraZeneca no longer have access to that medication at the discounted 340B price. Without the 340B discount, these medications are inaccessible for an Erie patient paying out-of-pocket. The following table provides Erie's average annual 340B prescription volumes prior to the manufacturers' actions:

Medication Impacted	**Medication Type**	**Average number of Erie 340B prescription fills annually at contract pharmacies, prior to recent manufacturer limitations**
Eli Lilly		
Basaglar	Insulin (diabetes)	840
Humalog	Insulin (diabetes)	1080
Humulin	Insulin (diabetes)	240
Trulicity	GLP-1 Agonist (diabetes)	120
Sanofi		
Admelog	Insulin (diabetes)	300
Lantus	Insulin (diabetes)	2400
AstraZeneca		
Brilinta	Antiplatelet (heart, circulation)	120
Bydureon	GLP-1 Agonist (diabetes)	240
Byetta	GLP-1 Agonist (diabetes)	480
Farxiga	SGLT2 Inhibitor (diabetes)	180
Symbicort	Inhaler (LABA+ICS) (asthma)	840

25. Erie is in communication with AstraZeneca regarding designating one exception contract pharmacy. This process is not finalized, and at present, our contract pharmacies are unable to purchase 340B priced AstraZeneca drugs. Even if the AstraZeneca exception process comes to fruition, it would only allow 340B access at one of our contract

pharmacies. To provide just one example of how unworkable this will be for our patients, patients of our Erie HealthReach Waukegan clinic would need to travel nearly three hours one-way on public transportation to arrive at our one remaining contract pharmacy in the Humboldt Park neighborhood of Chicago.

26. Erie is actively assessing opportunities to switch patients to affordable alternative medications. But I know as a medical provider that it is neither easy nor seamless to switch patients from one product to another. Many medication alternatives require a medical provider to review the patient chart, consider comorbidities, and assess appropriate dosing for the substitute medication. Several of the impacted diabetic treatments have very different dosing—for example daily versus weekly dosing—which requires extensive patient education and provider troubleshooting.

27. Language barriers add another layer of difficulty for patients who proceed to the pharmacy to pick-up their 340B refill and are told the price will potentially be hundreds of dollars more than it was last month. Forty-four percent of Erie patients are best served in a language other than English, and in 2019 Erie, through our interpretation service, provided care in 77 unique languages.

28. Erie has teams of Diabetes Educators who help teach patients how to use their insulin, diabetes medications, and glucose monitoring systems. As an Erie clinician, I directly see how important it is for my patients to thoroughly understand how to use their medication as directed. Frequent and/or rushed switching between medication formulations increases the opportunity for medication errors.

29. The loss of 340B savings and revenue—100% of which is reinvested into expanding access for our underserved patients—threatens Erie's ability to (1) provide comprehensive care to existing patients and (2) expand services to reach more individuals in its underserved target population. During the COVID-19 pandemic especially, 340B savings have been critical to our ability to continue serving patients and to maintain capacity to provide future services.

30. We already know that critical patient programs will need to be reduced or eliminated because of the decline in 340B savings and revenue. Erie is proud of the work of our care managers, case managers, health educators, and patient navigators, who provide personalized services that address social determinants of health and help Erie patients navigate their chronic health conditions. Without 340B savings, we would not have the capacity to fund these unreimbursed comprehensive care programs.

31. Erie is exploring all available options, but there is no action we can take to promptly remedy the drug manufacturers' refusal to provide 340B discount pricing. Erie has always used contract pharmacy partnerships to provide 340B medication access to patients. We do not have the pharmacy infrastructure to participate in the 340B program as an in-house pharmacy, and creating that infrastructure would involve a lengthy and expensive endeavor. Our patients cannot wait, they need access to affordable medications now.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: _____

By: _____ December 2, 2020
Lee Francis, MD, MPH, President and CEO
Erie Family Health Center, Inc.

EXHIBIT

A

Exported On:	10/7/2020 15:14
Exported By:	Guest

Covered Entity Details

Grant Number	Site ID	340B ID	Organization Status	Entity Type	Registration Date
H80CS00115	BPS-H80-005187	CH053210	Active	CH	1/1/1997
H80CS00115	BPS-H80-001454	CH05321C	Active	CH	1/1/1997
H80CS00115	BPS-H80-009298	CH05321CG	Active	CH	8/10/2007
H80CS00115	BPS-H80-011953	CH05321CH	Active	CH	8/16/2012
H80CS00115	BPS-H80-010610	CH05321CJ	Active	CH	8/16/2012
H80CS00115	BPS-H80-010649	CH05321CK	Active	CH	8/16/2012
H80CS00115	BPS-H80-013007	CH05321CL	Active	CH	9/28/2012
H80CS00115	BPS-H80-012779	CH05321CN	Active	CH	4/7/2014
H80CS00115	BPS-H80-012805	CH05321CP	Active	CH	8/6/2014
H80CS00115	BPS-H80-005301	CH05321D	Active	CH	1/1/1997
H80CS00115	BPS-H80-008136	CH05321H	Active	CH	3/17/2010
H80CS00115	BPS-H80-012615	CH05321J	Active	CH	10/14/2013

Participating	Participating Start Date	Participating Approval Date	Termination Code	Termination Date	Last Recertification Date
True	1/1/1997	1/1/1997			2/18/2020
True	1/1/1997	1/21/2010			2/18/2020
True	10/1/2007	8/14/2007			2/18/2020
True	10/1/2012	8/30/2012			2/18/2020
True	10/1/2012	8/29/2012			2/18/2020
True	10/1/2012	8/30/2012			2/18/2020
True	1/1/2013	11/16/2012			2/18/2020
True	7/1/2014	5/2/2014			2/18/2020
True	10/1/2014	8/14/2014			2/18/2020
True	1/1/1997	1/21/2010			2/18/2020
True	4/1/2010	3/17/2010			2/18/2020
True	1/1/2014	11/6/2013			2/18/2020

Entity Name	Entity Sub-Division Name
ERIE FAMILY HEALTH CENTER, INC.	ERIE WEST TOWN HEALTH CENTER
ERIE FAMILY HEALTH CENTER, INC.	Erie Humboldt Park Health Center
ERIE FAMILY HEALTH CENTER, INC.	ERIE HELPING HANDS HEALTH CENTER
ERIE FAMILY HEALTH CENTER, INC.	Erie Division Street Health Center
ERIE FAMILY HEALTH CENTER, INC.	Erie Amundsen School Based Health Center
ERIE FAMILY HEALTH CENTER, INC.	Erie Lake View School Based Health Center
ERIE FAMILY HEALTH CENTER, INC.	Erie Evanston/Skokie Health Center
ERIE FAMILY HEALTH CENTER, INC.	Erie Johnson School-Based Health Center
ERIE FAMILY HEALTH CENTER, INC.	Erie Waukegan Health Center
ERIE FAMILY HEALTH CENTER, INC.	Erie Westside Health Center at Laura S. Ward Elementary
ERIE FAMILY HEALTH CENTER, INC.	Erie Clemente Wildcats Student Health Center
ERIE FAMILY HEALTH CENTER, INC.	Erie Foster Avenue Health Center

Covered Entity Address						
Address 1	Address 2	Address 3	City	State	Zip	Second Zip
1701 W Superior St			Chicago	IL	60622	5646
2750 W North Ave			Chicago	IL	60647	5247
4747 N Kedzie Ave			Chicago	IL	60625	4420
2418 W Division St			Chicago	IL	60622	2940
5110 N Damen Ave			Chicago	IL	60625	1317
4015 N Ashland Ave			Chicago	IL	60613	2593
1285 Hartrey			Evanston	IL	60202	1056
1504 S. Albany Ave.			Chicago	IL	60623	2209
2323 Grand Ave			Waukegan	IL	60085	3312
646 N Lawndale Ave			Chicago	IL	60624	1254
1147 N Western Ave			Chicago	IL	60622	2931
5215 N. California Avenue		F700	Chicago	IL	60625	

Medicaid Billing		Contact Informatic
Medicaid Numbers	Npi Numbers	Contact Name
363088628002 (IL)	1760499545 ( )	Hannah Rowell
363088628005 (IL)	1407043912 ( )	Hannah Rowell
363088628017 (IL)	1952598468 ( )	Hannah Rowell
363088628004 (IL) , 363088628024 (IL)	1700144243 ( ) , 1134316631 ( )	Hannah Rowell
363088628022 (IL)	1164713129 ( )	Hannah Rowell
363088628023 (IL)	1215228192 ( )	Hannah Rowell
363088628025 (IL)	1629328836 ( )	Hannah Rowell
363088628027 (IL)	1043407547 ( )	Hannah Rowell
363088628028 (IL)	1851712053 ( )	Hannah Rowell
363088628008 (IL)	1770770273 ( )	Hannah Rowell
363088628021 (IL)	1144461385 ( )	Hannah Rowell
363088628026 (IL)	1396181590 ( )	Hannah Rowell

ɔn			Authorizing Official Information	
Contact Title	Contact Telephone	Contact Extension	Authorizing Official Name	Authorizing Official Title
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO
340B Program Manager	3124327467		David Bruce	CFO

Authorizing Official Telephone	Authorizing Official Extension
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EXHIBIT

B

From: [redacted]
To: [redacted]
Subject: 340B benefit story
Date: Wednesday, September 23, 2020 1:07:02 PM
Attachments: image821606.png
image728513.png
image878271.png
image451767.png
image507007.png

Hi [redacted]

I am a pediatrician, so don't use 340B very often, as most of my patients have insurance. However, I have a patient who turned 18 earlier this year, and moved out to live independently. He started working, and lost his Medicaid coverage. He has Type1 diabetes, among other chronic conditions. I have never managed his insulin, but when he lost insurance in August, I could not get an appointment for him at [redacted], and he could not afford the insulin they were prescribing. I was able to prescribe a Lantus pen through the 340B program, and the team at [redacted] provided phone advice to him/me to keep his sugars under control/keep him out of diabetic ketoacidosis/out of the hospital until he could get his insurance reinstated.

The 340B program helped him access life-saving medicine. Without it, he would have required hospital admission and incurred must greater costs to himself or more likely the health care system.

Let me know if you need any other details.

[redacted]
Pediatrician
Erie Family Health Centers
4747 N. Kedzie Avenue
Chicago, IL 60625
[redacted]

Exhibit P

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. _____
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of Kiame Jackson Mahaniah

I, Kiame Jackson Mahaniah, declare as follows:

1. I am CEO at Lynn Community Health Center ("LCHC") in Lynn, Massachusetts and have held this role since October 2017. As CEO, I am responsible for overall compliance and adherence to all HRSA requirements, including requirements related to our participation in the 340B Program. To prepare this declaration, I reviewed relevant internal patient and prescribing data with Kim Macleod, our CFO, and discussed the current situation and its challenges in depth with my executive team, the Board of Directors, and most of our external stakeholders.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. LCHC is a nonprofit community health center that receives federal grant funds under Section 330 of the Public Health Service Act to provide healthcare and related services to a medically underserved population in the city of Lynn, Massachusetts regardless of patient insurance status or ability pay. We have been designated as a federally qualified health center (FQHC) since 1993.

4. Since 1971, LCHC that has served as the primary source of healthcare services in Lynn, Massachusetts, a dense, urban community with high rates of poverty. In 2019, LCHC provided approximately 286,980 medical, behavioral health, vision, and dental visits to approximately 41,115 patients.

5. Over 94% of our patients live at or below 200% of the federal poverty level, over 83% are racial/ethnic minorities, and about 59% are best served in a language other than English. Close to 60% of LCHC patients are on Medicaid, 9% are on Medicare, and 12% are uninsured.

6. The COVID-19 emergency is having a severe impact on Lynn and our patients. As of November 30, 2020, Lynn had 7,537 cases and 134 deaths in a city with 94,655 residents.

7. Lynn Community Health Center is a "covered entity" for purposes of the 340B Program. Our participation in the 340B Program, which provides us discount pricing on outpatient prescription drugs, began in or around 1999. We certify our covered entity status annually with the Health Resources and Services Administration (HRSA).

8. LCHC has contracted with pharmacies—principally Walgreens and CVS—to provide dispensing services to our eligible patients. We purchase drugs at 340B pricing from wholesalers McKesson, Cardinal, and AmeriSource Bergen and direct those drugs to be shipped to our contract pharmacies on a replenishment basis. LCHC maintains title to the drugs, but storage, distribution, and patient-related information is done by the contract pharmacies. LCHC's contract pharmacies undergo an annual certification process with HRSA's Office of Pharmacy Affairs.

9. One of the consistent barriers our patients face to accessing healthcare, including filling prescriptions, is transportation. In addition, we have a growing number of elderly patients for whom ambulation is also difficult. Contracting with pharmacies close to where our patients resides ensures convenient access, increases medication adherence, and provides opportunities for education within established patient-pharmacist relationships. Although always difficult to measure, this type of preventative and community-oriented care ultimately benefits total cost of care.

10. LCHC's average number of monthly 340B prescriptions is 14,000. Although that number is astounding, LCHC has one of the lowest ER use rates of any outpatient institution in Massachusetts.

11. Our annual purchases of pharmaceuticals at 340B pricing is approximately $4 million.

12. We ensure 340B Program compliance—including compliance with prohibitions on diversion and duplicate discounts—through a monthly reviews and independent third-party compliance testing.

13. LCHC's participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients.

14. We are a national leader in integration of behavioral health (BH), Substance Use Disorder (SUD) treatment, and primary care. BH in particular does not have payment parity: providing psychopharmacologic services for children would simply be impossible without the margin provided by 340B discount pricing.

15. Support services, though vital to our patients, are generally not reimbursed. We use 340B savings and revenue to fund:
    - foreign language interpretation/translation services, which are currently provided in 30+ languages, with the top five languages accounting for 85% of our patients;

- social services, including assiduous screening for social determinants of health and a referral system through which we coordinate access to various services in the area (such as housing services coordinated through our relationship with the Massachusetts Coalition for the Homeless);
- recovery coaches and case management for our highest risk tier of patients, which includes patients suffering from homelessness, serious mental illness, and social isolation.

16. We respond to the needs of our most vulnerable constituents. Although we maximize our efficiency through lean management practices, we have limited flexibility given that we cannot choose our market, but instead simply answer identified community needs.

17. Without 340B discount pricing, we could not cover the cost of the programming listed above. With our care and services, there is a way forward for the most vulnerable in our underserved patient population. Our patients' needs will not disappear in the absence of such services, they will instead be pushed onto law enforcement, the schools, and/or the courts.

18. In September 2020, I became aware that certain drug manufacturers, including Eli Lilly and Sanofi, had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of LCHC's contract pharmacies.

19. Because of this action, we estimate an approximate loss of $6 million from our roughly $8 million budget.

20. As a result of this loss, we are preparing for the permanent layoff of about 5% of our employees, or about 35 people. This includes all data management capabilities (3 FTE) that allow us to use our funding in the most efficient way possible; a dramatic scaling back of our mental health team, particularly in the psychopharmacology realm, to include our recovery coaches and most of our case managers.

21. We will also have to cut services, most of which are exactly those that heighten our efficiency and our ability to deliver targeted services: case management for vulnerable patients, programs targeting mentally ill folks suffering from homelessness, and therapy provided in our patients' native languages.

22. As a health center, we are used to operating very close to bare bone. Two years ago, for the first time in decades, we were ecstatic to realize a margin above 2%. A good month is one in which we clear $200,000. We normally have 4 good months a year.

23. LCHC would simply cease to exist as we now know it without our ability to purchase prescription drugs for our patients at 340B discount pricing. We would retrench to very basic care.

24. Crucially, our most vulnerable and marginalized patients would suffer the most. These patients will suffer untreated mental illness, lack of access to substance use disorder/addiction treatment, and lack of support services. I fear that the gains we have made in tackling some of the most profound problems in our community will be lost.

25. There are no good strategies we could employ to mitigate the drug manufacturers' actions. We could certainly develop a mail-in pharmacy program, yet we already have a 20% mail rejection rate. Trusting life-sustaining medication to this process seems unwise. Could we act as a wholesaler? Perhaps, but we currently don't have our own pharmacy and to expand in that way would require the development of a complex process that clearly lies outside our current services. It would take precious funds and bandwidth away from areas that cannot afford to spare either money, time, or expertise. There is no reasonable alternative to the 340B Program in its current iteration.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 12/3/2020

By: _____
Dr. Kiame Jackson Mahaniah
CEO
Lynn Community Health Center

Exhibit Q

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS Plaintiff, v. ALEX M. AZAR II, et. al	)	Civil Action No. 1:20-cv-03032

Declaration of Kimberly Christine Chen

I, Kimberly Christine Chen, declare as follows:

1. I am the Director of Pharmacy at North Country HealthCare, Inc. ("NCHC") in Flagstaff, Arizona and have held this role since July 2012. As the Director of Pharmacy, I am responsible for oversight of our 340B compliance program, our in-house pharmacy programs, our contract pharmacy partnerships, and our clinical pharmacy services. I am also part of our management team, and to fulfill my job duties have access to financial and strategic planning information, including information related to the application of pharmacy revenue to other areas of the organization. My role reports directly to the Chief Financial Officer (CFO), who in turn reports to the Chief Executive Officer (CEO).

2. To prepare this declaration, I met with my pharmacy management team—which includes the pharmacy manager, pharmacy business manager, and clinical pharmacist representative—met with our CEO and CFO, and reviewed relevant internal data and reporting. I also met with my clinical pharmacists to discuss general patient impact and specific patient cases in which recent changes to our access to 340B discount pricing have impacted patient care.

3. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

4. NCHC, a member of the National Association of Community Health Centers, is a Federally-Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population regardless of patient insurance status or ability to pay. NCHC has its historical roots in a free health clinic model that transitioned to FQHC status upon community health center funding in 1996. The center has approximately 500 employees, approximately 85 of whom are medical providers.

5. Our primary clinic site and administrative hub is located in Flagstaff, Arizona, a population center with Medically Underserved Population (MUP) designation.

6. We also provide primary care services at behavioral health centers and homeless shelters, and operate satellite clinics targeting uninsured patients in Seligman, Winslow, Holbrook, Round Valley, Show Low, Williams, Grand Canyon, Dolan Springs/Kingman, Bullhead City, Lake Havasu City, and Payson communities. All, excluding Lake Havasu City, are designated Medically Underserved Areas (MUA's) and Health Professional Shortage Areas (HPSA's). These communities vary in distance from Flagstaff, primarily across the Interstate 40 corridor of Northern Arizona. The table below indicates the approximate distance and direction of these communities from our Flagstaff location.

Site (PCA)	Distance from Flagstaff (miles)	Direction from Flagstaff
Seligman	70	W
Winslow	60	E
Holbrook	90	E
Round Valley	180	SE
Show Low	140	E
Williams-Grand Canyon	35	NE
Dolan Springs/Kingman	143	W
Bullhead City	184	W
Lake Havasu City	208	W
Payson	115	SE

7. NCHC's services include diagnosis, treatment and referral for all illnesses, chronic disease management, prenatal/perinatal and delivery care, well woman checks, well child services/immunizations, pharmacy, laboratory and radiology services, preventive care/health education, oral health services, and integrated behavioral health. We also provide significant health promotion/disease prevention and enabling programs.

8. The Center has grown rapidly over the past twenty-five years, providing approximately 164,000 patient visits in calendar year ending December 31, 2019 to approximately 52,000 unduplicated users who call NCHC their "medical home."

9. The current payer mix from our most recent financials show that approximately: 7.2% of our patients are uninsured; 38% are Medicaid; 19.1% are Medicare; and 32.8% are commercially insured. The Medicare user population is expected to continue growing as few local providers accept new Medicare assignment.

10. According to the three Medicaid Managed Care plans in our service areas, diabetes, hypertension, and cardiovascular issues are the top three medical issues among that population. NCHC sees these issues similarly reflected in their patient population regardless of payer type.

11. NCHC has three in-house pharmacies situated within our Flagstaff, Grand Canyon, and Kingman locations. Our Grand Canyon and Kingman pharmacies are tele-pharmacies, staffed by pharmacy technicians (with Flagstaff-based pharmacists performing all

pharmacist's duties, oversight, and counseling). These tele-pharmacies were the first in Arizona—approved by special waiver from the Arizona Board of Pharmacy in 2010—and represent two of only a handful across the state. Tele-pharmacies help address the critical and unique needs in rural health care.

12. NCHC is a "covered entity" for purposes of the 340B Drug Program ("340B Program") and has been registered as such with the Health Resources and Services Administration (HRSA) since July 1, 1998. As required, NCHC recertifies all its eligible locations annually with HRSA. A current covered entity listing pulled from HRSA's Office of Pharmacy Affairs Information System (OPAIS) 340B database is attached as Exhibit A.

13. The 340B Program allows NCHC to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

14. NCHC uses a combination of both in-house and contract pharmacies to meet our patients' pharmaceutical needs. In addition to NCHC's three in-house pharmacies, NCHC utilizes 52 contract pharmacies in 12 different communities. Specific contract pharmacies, contract dates, HRSA OPA registration dates, and active dates are included as Exhibit B.

15. NCHC works with both McKesson and Cardinal distributors in a "bill-to/ship-to" replenishment model for providing 340B medications to eligible patients. The 340B medications are purchased after the prescription has been filled at a contract pharmacy and it has been confirmed that the prescription is (1) eligible for the 340B Program and (2) is not a Medicaid claim.

16. Our claims are managed by a third-party administrator (TPA) and audited by NCHC compliance staff. The TPA matches the prescriptions to patient, provider and encounter files to "carve in" those claims as 340B eligible. Depending on the TPA, there are also additional mechanisms to ensure accuracy, such as embedded coding in electronic prescriptions from our electronic medical record and bar coding on printed prescriptions. Once the TPA has "carved in" a prescription, a record of that eleven-digit national drug code (NDC) is recorded. When the TPA identifies that a full package of a medication (11-digit NDC match required) has been dispensed to eligible patients, an order is generated for that medication. The drug is purchased by NCHC (aka "bill-to") and provided to the contract pharmacy where the medication was originally filled (aka "ship-to"). At no point in this process can the contract pharmacy order 340B medications directly or see the 340B drug pricing.

17. All claims the TPA "carves in" are communicated to NCHC and audited to ensure compliance. No such claims are billed to Medicaid—the TPA is provided with all Bank Identification Numbers (BIN) and Processor Controller Number (PCN) listed on Arizona's Medicaid Exclusion File and NCHC audits all carved in claims to additionally ensure that all prescriptions were eligible and that none were billed to Medicaid.

18. NCHC also achieves compliance through (1) ongoing internal and external audits of both in-house pharmacy and contract pharmacy claims; and (2) extensive staff training.

19. NCHC providers prescribe roughly 280,000 prescriptions annually. Of those prescriptions, only about 13.97% were filled by NCHC's in-house pharmacy; approximately 65.33% were filled by NCHC contract pharmacies. However, of the prescriptions sent to the contract pharmacies, only about 26% were ultimately applied to the 340B Program. The other 74% were either Medicaid or otherwise not eligible for the 340B Program.

20. Contract pharmacy agreements are critical to provide our most vulnerable patients access to affordable medications for several reasons.

21. First, NCHC's service area spans approximately 576 miles across all of Northern Arizona. Without contract pharmacies, patients would have to travel (one-way trip), to reach the closest of NCHC's in-house pharmacies:

Service Areas	Pharmacy Locations		
	Flagstaff Pharmacy	Kingman Pharmacy	Grand Canyon Pharmacy
Seligman	70	74	
Lake Havasu		60	
Bullhead City		37	
Williams	35		59
Winslow	50		
Payson	115		
Holbrook	90		
Show Low	140		
Round Valley	180		

22. Traveling such tremendous distances to access affordable medications is not feasible for our patients, especially in northern Arizona where inclement weather is a significant factor during the winter months.

23. Our contract pharmacy agreements provide our patients access to affordable medications within their communities.

24. Second, our contract pharmacies, unlike our in-house pharmacies, are open on nights, weekends, and holidays. Even in the communities where we have an in-house pharmacy, contract pharmacies are critical to provide medication access outside regular business hours.

25. Finally, our homeless populations are best served by community pharmacies near where they are located to increase their adherence and reduce their significant barriers to care.

26. NCHC's participation in the 340B Program allows us to provide our uninsured and underinsured patients—including low-income workers and homeless individuals—access to affordable or no-cost medications. All our contract pharmacies provide a modified sliding fee scale pricing to our patients who are 200% or more below the federal poverty level.

27. Additionally, revenue from prescriptions filled for our insured patients is used in furtherance of our mission and federal grant project.

28. For example, 340B Program proceeds support our clinical pharmacy program, in which pharmacists work in the clinics as members of interdisciplinary care teams to optimize medication regimens, promote adherence, generate medication alternatives and provide both group and individual patient education. Clinical pharmacists are critical on teams that provide chronic disease management, anticoagulation services, and pain management. Clinical pharmacy services expand patient access to care, improve patient outcomes, decrease medical providers' workloads, and improve provider satisfaction. This service is not reimbursable by CMS or commercial insurance, and would not be possible without the 340B Program.

29. Revenue generated from the 340B contract pharmacy environment is also used to support our most rural clinics. Without this subsidy, these clinics, which have lower patient volumes, would not be sustainable. Without this funding source, NCHC may be forced to close as many as six of our locations and lay off approximately 100 staff and providers.

30. Beginning in or around June 2020, I became aware that certain drug manufacturers, including Merck (notified June 29, 2020), Sanofi (notified July 31, 2020), AstraZeneca (notified August 20, 2020; position since modified to permit limited use of contract pharmacies) and Eli Lilly (notified September 1, 2020) had unilaterally decided, without government approval, to cease providing most or all outpatient prescription drugs at 340B prices to most or all of NCHC's contract pharmacies.

31. These actions significantly and negatively impact our patients.

32. Without contract pharmacies, only three of the twelve communities NCHC serves would have access to pharmacy.

33. Without contract pharmacies, patients will not be able to afford their medications at commercial pricing and most will not be able to travel the great distances required to procure their medication from our in-house pharmacies.

34. For example, Symbicort, made by AstraZeneca, is the only approved first line medication in the treatment of asthma according to the 2020 guidelines by Global Initiative for Asthma (GINA). NCHC has multiple patients who are homeless who were tried and failed on other alternative treatments. The clinical pharmacist was able to switch them to Symbicort and the patients experienced marked improvement in their asthma, decrease in their exacerbations, and quality of life due the medication change. Many of these patients can no longer use a contract pharmacy for Symbicort and instead must find a way to access the medication through an NCHC in-house pharmacy. Although NCHC identified and implemented workarounds for these patients, there is a limit to what we can do, and inevitably patients' health outcomes will be negatively impacted by limits on medication access.

35. An uninsured, Type 1 diabetic patient of our Show Low clinic, which is located approximately 280 miles from our closest in-house pharmacy, was taking Novartis-produced Novolin N, an insulin medication, but was experiencing frequent hypoglycemia (low blood sugar). Our clinical pharmacy staff worked with this patient to switch him to Sanofi-produced Lantus, on which he was able to keep his blood sugars stable. On or about October 1, his Lantus was no longer available through the contract pharmacy. Additionally, even if he could tolerate being switched back to Novolin N, the product and its comparable product made by Eli Lilly (Humulin N) are also not available at 340B pricing.

36. This patient's body is unable to make insulin. Without it he will die. Insulin is not a choice. Type 1 diabetes is not a choice.

37. I would also add that with the loss of contract pharmacy revenue, the clinical pharmacist who was able to get this patient on a stable, healthy insulin regimen targeted to his particular needs is potentially in jeopardy of losing their job, leaving this patient and all the others like him struggling to manage chronic diseases and navigate access to affordable mediations.

38. While this is just one patient story, all our diabetic patients face similar terrible outcomes. In the short term, switching insulins on stable patients can increase weight gain, reduce adherence due to formulations that require more frequent dosing throughout the day, and increase the risk of hypoglycemia, which can lead to seizures, coma, and even death. Insulin changes are difficult to titrate and require frequent contact with a clinical pharmacist, whose jobs are hanging in the balance. In the long term, these patients face higher risk for renal damage, retinopathy and blindness, and cardiovascular events.

39. Our patients are being denied access to evidence-based, guideline-driven, best practice quality care because of their inability to access affordable medications. Our providers are being forced to deviate from the standards of care based on a patient's payer type.

40. These changes have caused immediate harm and will cause additional harm the longer this is allowed to continue. Due to our geographical barriers, NCHC has had to scramble to get couriers in place at our various clinics and establish other workarounds for access to affordable care. We have also placed additional staffing burdens on our pharmacy team to identify those patients most impacted by these manufacturer's actions and to determine what treatment options may be available that the patient can both afford and access. Our pharmacy team has also had to create and support new processes for these deliveries and solutions for managing the influx of changed prescriptions. Our clinic staff has scrambled to navigate processes to allow patients to pick up medications in our clinics, a process that many front office clinic staff have never had to do before.

41. These additional burdens come at a time when health care across the nation is trying to adapt to the global pandemic.

42. If these actions continue, NCHC will have to make crucial decisions on what will need to be cut to compensate for the reduction in program income derived from our participation in the

340B Program. We will likely have eliminate our clinical pharmacists and determine which rural clinic location would need to be the first of possibly multiple clinic closures.

43. Last fiscal year, NCHC's in-house pharmacy wrote off more than $3.2 million in direct patient medication costs. As an FQHC, NCHC does not have the capacity to continue to provide the scope and depth of our services to patients if these attacks on the 340B Program continue.

44. NCHC has done its best to protect our patients during this crisis, but our solutions fall short.

45. For example, the courier deliveries we have established occur weekly and cannot address acute patient needs. If a patient realizes that they will run out of their insulin after the courier has left the clinic, they will not be able to access their medications for another week, putting the patient in danger of significant medical emergency that may require hospitalization or even result in death. Additionally, in northern Arizona, where severe snowstorms can occur on short notice during the winter months, it is common for couriers to have to cancel deliveries. The resulting delays in therapy are detrimental for patients and pose significant costs and burdens to the healthcare system.

46. Mailing prescriptions to patients poses challenges as well. Many of our patients do not have consistent addresses, our homeless patients have no addresses at which they can receive mail, our insurance contracts prohibit mailing beyond individual patient exceptions, and even if we were to secure mail-order status, all mail in our region is routed through Phoenix, where summer heat exceeds manufacturer recommendations for safe medication storage. Safely and legally mailing medications would involve significant expense and would still fail to help many of our most vulnerable patients.

47. A longer-term solution to consider is expanding our tele-pharmacy program. These pharmacies are very expensive to maintain, and the Arizona Board of Pharmacy requirements state that the pharmacy technician that staffs these locations must have a minimum of 1,000 hours of technician experience prior to working in tele-pharmacy. This is a huge barrier due to the rural nature of these locations. Staffing in these locations by skilled, credentialed team members is an ongoing issue and this would also be the problem for tele-pharmacy. Additionally, due to the parameters of operation, these pharmacies do not demonstrate a high capture rate of prescriptions for those patients who have insurance, making the model not financially sustainable without outside funding.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: December 3, 2020

By: Kimberly Chen

Kimberly Christine Chen
Director of Pharmacy
North Country HealthCare, Inc.

Additional Details

Current Prog

Regist

Participatin

Participating Ap

Last Recertifi

Addresses

Street Address

2920 N 4th St
Flagstaff, AZ 86004-1816

Billing Address

NORTH COUNTRY HEALTHCARE
PO BOX 3630
FLAGSTAFF, AZ 86003

C.

NIC

act

HealthCare

IEN, DIRECTOR OF PHARMACY

2

Exhibit R

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
V.	)	Civil Action No. 1:20-cv-03032
ALEX M. AZAR II, ET. AL	)	

Declaration of Ludwig M. Spinelli

I, Ludwig M. Spinelli declare as follows:

1. I am the Chief Executive Officer at Optimus Health Care Inc ("Optimus"), which serves approximately 50,000 patients in the Bridgeport and Stamford regions of Connecticut. In this position, which I have held since in or around September 1983, I am ultimately responsible to the Board of Directors for health center performance and patient care.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Optimus is a Federally-qualified health center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population regardless of patient insurance status or ability to pay. Optimus is a member of the National Association of Community Health Centers.

4. Optimus has been in operation since approximately December 1976, and presently offers some 210,000 annual visits to approximately 50,000 unduplicated patients at our 35 service locations. Our target population is low-income residents in our southwestern Connecticut service area that ranges from western New Haven county to the New York border.

5. Approximately 22% of our patients have no insurance and are thus placed on a sliding fee scale based on their income. Some 60% of our patients qualify for Medicaid and approximately 8% for Medicare.

6. We have around 7,000 patients with diabetes, hypertension, and asthma, and we provide comprehensive support to approximately 500 HIV positive patients.

7. Optimus is a covered entity for purposes of the 340B Drug Pricing Program ("340 Program") and has been for some 10 years. Optimus recertifies its covered entity status

annually with the Health Resources and Services Administration (HRSA) in keeping with HRSA's Office of Pharmacy Affairs guidelines and directives.

8. The 340B Program allows Optimus to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. Optimus purchases drugs at 340B pricing from two main wholesalers: Cardinal Health and McKesson. We purchase approximately $1.4 million in prescription medications from our 340B wholesalers every year.

9. Optimus dispenses the drugs it purchases at 340B pricing to eligible patients via contracted pharmacy partners. These contracted pharmacies include Walgreens, CVS, Walmart, Rite Aid, and three local pharmacies in our service area: Slavins, Cornerstone, and Bridgeport Pharmacy.

10. From a patient perspective, these pharmacies are accessible and conveniently located. Many also have home delivery options, which help out patients to obtain their medications and remain compliant with medication regimens.

11. Optimus has written agreements with each contract pharmacy that detail how the program works. In compliance with 340B rules, each of these pharmacies was registered with and approved by HRSA, before any 340B medications were dispensed to any of our patients. The approximate date of approval for each pharmacy is as follows:

    - Walgreens Pharmacies executed on 8/24/2011
    - Rite Aid Pharmacies executed on 7/1/2014
    - Slavins-Hancock Pharmacy executed on 1/1/2013
    - Cornerstone Pharmacy executed on 9/18/2013
    - Bridgeport Pharmacy executed on 4/4/2019
    - Wal-Mart Pharmacy (Stratford CT) executed on 4/1/2019
    - CVS Pharmacies executed on 7/22/2019

12. With the exception of Walgreens, our 340B operations are managed by our Third-Party Administrators ("TPAs") CaptureRx and Wellpartner. Through the services provided by the TPAs, we ensure 340B Program compliance including:

    - Patient, prescriber and covered entity eligibility
    - Exclusion of Medicaid prescriptions to prevent duplicate discounts
    - Purchasing and tracking inventory
    - Reports for auditing

13. Although the TPAs assist us in fulfilling these responsibilities, we know that Optimus is ultimately accountable for adherence with 340B Program requirements. Our Finance Department tracks the activity overseen by our in-house pharmacist, who helps to manage the program and is a resource to the contract pharmacies and the patients. Our 340B Committee and our Compliance Department are actively involved in ensuring that we meet all relevant HRSA and program requirements.

14. At the pharmacy level, each prescription is verified for eligibility in accordance with 340B rules. Patient eligibility, covered entity and prescriber eligibility, and all other 340B criteria must be met. We achieve this through our TPA's, CaptureRx, WellPartner, and Walgreens. If a prescription does not meet any of the qualifying criteria, it is excluded from our 340B Program. This applies to both insured and uninsured patients.

15. Optimus' participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Uninsured patients get 100% of the savings at our partner (contract) pharmacies, as explicitly spelled out in our agreements with these pharmacies, and pharmacists do not mark-up our 340B medications. In addition to the 340B cost of the medication, a reasonable, pre-negotiated dispensing fee is charged to patients who can afford it. For our patients who cannot afford the dispensing fee, we cover the entire cost of their prescription.

16. Any net revenue we derive from the 340B Program also goes directly to our patients. Our Dental, Podiatry, and Clinical Nutrition departments are excellent examples of how we provide enhanced patient care with 340B dollars. In our geographical area, we are one of the only sites to offer dentures and other procedures at deep discounts.

17. Similar to dentistry, our Podiatry and Clinical Nutrition Departments are supported by 340B dollars. These departments reach some of our most needy patients, including those with diabetes, for whom podiatry and clinical nutrition services can be crucial to overall wellbeing.

18. Optimus has a robust 340B Program with approximately 3,200 unique patients participating. Of these, about 1,500 patients have no prescription insurance. The remaining 1,700 some odd patients have prescription insurance; however, they may still need additional assistance affording their medications. Through our partnerships with contract pharmacies, our patients receive approximately 17,000 prescriptions every year.

19. At Optimus, pharmacy services are an integral part of comprehensive health care. In addition to 340B dispensing services, our community pharmacy partners provide pharmacy-based health care to our patients and support to our clinical staff. Some of these services include chronic disease state monitoring, medication adherence programs, medication therapy management services, and timely feedback to our clinicians. The strong communication link between our providers and pharmacists allows for easy communication and delivery of patient care.

20. Convenient locations and service hours, coupled with culturally competent staff, make our 340B partner pharmacies the best choice for our patients. To accommodate patient care priorities, we do not require patients to change pharmacies for 340B pricing. Instead, we expand 340B access to the patients' pharmacies of choice.

21. Beginning on or about July 23, I became aware that certain drug manufacturers, including Eli Lilly, AstraZeneca, and Sanofi had unilaterally decided, without government approval,

to cease providing outpatient prescription drugs at 340B prices to most or all of Optimus' contract pharmacies. These restrictions have impacted our uninsured patients' ability to acquire life-saving and life-improving medications. We have determined the impact from these three manufacturers alone to be as follows:

- Uninsured patients will lose access to approximately 773 affordable prescription medications for their chronic health conditions. Our records show that before COVID-19, annually 1,610 unique (unduplicated) patients received one or more medications made by one of these three manufacturers. The need for affordable medications in underserved communities has been amplified by the pandemic and the economic fall-out that resulted. Access to insulin, asthma controllers, and other essential medications are cut off when people need them the most. Patients that were paying about $12 to $15 for three months' supply of these medications will now have to pay about $300 to $600 per month to continue their treatment.

- Our health center will lose over $560,000 a year in 340B revenue, this does not include the impact from Merck and other manufacturers who have also announced plans to restrict access to 340B pricing but have not implemented their plans to date. If the current trend is allowed to continue, we believe this figure will be much higher. 340B is a vital revenue stream that allows us to expand primary care to patients who need it the most. As a result, vital programs like Dental, Podiatry, Clinical Nutrition, and others will be at risk of losing their funding. Without 340B revenue, our expanded dental services would become an expense we could not afford to cover.

- To limit the loss to our patients, we are actively searching for suitable alternatives for medications made by Eli Lilly, AstraZeneca, and Sanofi. Please see the attached list of recommendations developed by our Clinical Pharmacist to help support our providers and patients.

22. There is significant harm done to our patients due to the sudden discontinuation of 340B pricing of maintenance medications. As pharmaceutical companies continue to exclude more medications from the 340B Program, we are quickly running out of options for our patients.

    - The sudden discontinuation of 340B pricing did not allow time to notify patients and work out an effective strategy.

    - Providers are forced to change medication therapies without adequate time to evaluate the health outcome of new therapies to their patients.

    - In the case of the "one contract pharmacy only" requirement imposed by certain manufacturers, providers are put in the uncomfortable (and sometimes inappropriate) position of telling patients which pharmacy they can go to for their medications.

23. Patients who rely on our 340B Program for their medications have been harmed directly. Mrs. P. is an uninsured patient. Since 2017 her diabetes has been controlled on insulin

made by Eli Lilly, for which she paid $15 a month. On September 4, 2020, she went to the pharmacy and she was asked to pay $270. Without any prior notice or a reasonable alternative, she was left without her medication. To complicate matters more, Mrs. P. is a visually impaired patient who does not speak English. She depended on the 340B Program to access her medication at a local pharmacy that accommodates her needs. She has been let down.

24. Mrs. A. has a similar story. She is followed in our ob-gyn practice in Stamford for gestational diabetes. While her pregnancy is high risk, she has been managed well on an insulin product made by Eli Lilly. However, 27 weeks into her pregnancy, she was asked to pay full price for her insulin, $320 which she could not afford. Like many of our patients, Mrs. A. is not eligible for discount programs sponsored by pharmaceutical companies due to her undocumented immigrant status.

25. Many of our asthmatic patients are also affected by Astrazeneca's restriction on 340B priced medications. Mr. O. can be cited as an example. He suffers from severe asthma. While his illness has been difficult to control, he and his doctor have worked closely together to manage his condition and stabilize him on the right medication. Mr. O. paid $15 a month and visited the local pharmacy frequently since 2014. In October 2020, his medication therapy was interrupted due to Astrazeneca's policy change. Mr. O. could not afford to pay $315 a month for his inhaler. He is now starting treatment on a new medication, uncertain how well it will control his asthma. Even more uncertain of what might happen to him if more pharmaceutical companies block access to the 340B Program.

26. These patient experiences demonstrate the challenges uninsured individuals face to pay for their medications. The pandemic has worsened the problem with additional health problems and a lack of jobs to pay for these medications. At a time of dire need, access to 340B priced medications is being restricted by some pharmaceutical companies.

27. The harms listed above are in addition to the financial burden levied on Optimus to continue to provide comprehensive health services, without the vital dollars to reach more patients. To fill the gap created by the 340B loss, Optimus anticipates a $1.5 million budget reduction. At risk are our patients who receive free and reduced-cost care, many of the same patients who lost their 340B savings at the pharmacy.

28. Optimus is coming out of the last fiscal year with an overall loss caused by COVID-19. We did participate in the Payroll Protection Program, but our revenue remains below that of the pre-COVID period. Our visits are down approximately 20%, and many patients are reluctant to visit Optimus for routine care due to recent COVID-19 positive spikes in the population.

29. We are working with some drug manufacturers that will ship our drug purchases to one contract pharmacy, but our service area is approximately 25 miles wide. It is impossible to expect all of our patients to travel to one single pharmacy given the significant practical barriers that stand in the way such as time and transportation availability.

30. Additionally, many patients are hesitant to use mail order pharmacies, and those pharmacies are not part of our 340B Program. Thus, this option does not improve access to needed medications.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 12/8/20

By: Ludwig M Spinelli

Ludwig M. Spinelli
Chief Executive Officer
Optimus Health Care Inc

Exhibit S

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS PLAINTIFF, V. ALEX M. AZAR II, ET. AL	)	Civil Action No. _____

Declaration of Daniel Fulwiler, President and CEO of Esperanza Health Centers

I, Daniel Fulwiler, declare as follows:

1. I am the President and CEO at Esperanza Health Centers (Esperanza) and have held this role since April 2008. As President and CEO, I am responsible for the overall leadership and management of Esperanza programs and services. To prepare this declaration, I reviewed Esperanza's 340B Program and financial data including, but not limited to, financial statements, contracts, and government filings. I have access to this information to perform my job duties.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Esperanza is a Federally Qualified Health Center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act to serve a medically underserved population within our designated service area regardless of patient ability to pay. Founded in 2004, we serve over 30,000 patients annually in Chicago, Illinois. Over 90% of our patients identify as Hispanic/Latino, and over 95% live near or below the federal poverty level. Roughly, 50% of our adult patients is uninsured.

4. Esperanza is a "covered entity" for purposes of the 340B Drug Program, and has been for approximately seven years, since in or around April 2013. As required, we recertify this status annually with the Health Resources and Services Administration's Office of Pharmacy Affairs (HRSA OPA) OPAIS system.

5. The 340B Drug Program allows Esperanza to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. We pass this discount on to our uninsured patients, who can purchase life-saving medications at 340B cost, plus minor administrative and dispensing fees.

6. Esperanza's participation in the 340B Drug Program helps it to stretch scarce resources and meet the needs of its medically underserved patients in other ways as well. As an FQHC, we must serve any patient who comes in with a medical need, regardless of that individual's ability to pay or insurance status. Because a large portion of our adult medicine patients are uninsured, on average we lose money on each patient visit. The 340B program is critical in keeping our adult medicine program financially sustainable.

7. Esperanza's participation in the 340B Drug Program allows us to serve approximately 30,000 patients a year who fill, on average, approximately 59,000 prescriptions a year.

8. As a covered entity, Esperanza is permitted to choose how it will deliver pharmacy services to its patients. We utilize contract pharmacies to provide 340B benefits to our patients. For all our contract pharmacies, there are written agreements between Esperanza and the contract pharmacy:

    a. We have a Pharmacy Service Agreement with Surecare Pharmacy Inc. (Surecare) dated July 29, 2011. This Contract Pharmacy Agreement was approved by HRSA in OPAIS on August 9, 2011.

    b. We have a Pharmacy Service Agreement with Walgreen Co. (Walgreens) dated October 11, 2011. This Contract Pharmacy Agreement was approved by HRSA in OPAIS on October 11, 2011.

9. Esperanza's contract pharmacies operate on a "virtual inventory" system. Each contract pharmacy dispenses covered prescriptions to our patients, and when enough medication is dispensed to our eligible patients, Esperanza places an order via our 340B wholesaler to replenish the contract pharmacies' stock.

10. Contract pharmacies have expanded our patients' ability to access affordable drugs by offering both (1) more convenient geographic locations for drug refills and (2) service on evenings and weekends. Contract pharmacies also allow us to focus on providing excellent care to our patients without having to bear administrative work that comes with operating an onsite pharmacy. The communities in which we operate have always been underserved by pharmacies, and this has been exacerbated by current events including the COVID-19 pandemic and civil unrest.

11. Esperanza maintains responsibility for compliance with all 340B rules for drugs dispensed at contract pharmacies and undertakes the following efforts:

    a. For Surecare, we utilize a live information feed from our Electronic Medical Records (EMR) system that allows us to verify that only eligible Esperanza patients are included in our 340B Program.

    b. For Walgreens, we include a barcode in our electronic prescriptions that allows Walgreens to verify that the prescriptions came from Esperanza and should, where applicable, be processed under our program.

c. We annually engage an outside entity to complete an audit of our 340B program, to ensure its integrity and compliance with all regulations.

12. In the 12 months ended September 30, 2020, Esperanza purchased approximately $910,000 of drugs at 340B pricing. These include medications to treat and prevent diabetes, HIV, and Hepatitis C.

13. During the period from July to September 2020, I became aware that certain drug manufacturers, including Eli Lilly, Merck Sharpe & Dohme Corp., Sanofi, Astra-Zeneca and Novartis Pharmaceuticals (Manufacturers) had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of Esperanza's contract pharmacies.

14. These actions will likely cause irreparable harm to our patients and affect clinical outcomes:

a. Limiting our contract pharmacy network will cause uninsured patients to lose access to certain drugs because they would be too expensive without the discount 340B pricing we pass on to these patients. For example, the average 340B price for a 30-day supply Humalog, a fast-acting insulin made by Eli Lilly, including dispensing fee, is less than $17.00. Without 340B discount pricing, the price for a 30-day supply of Humalog is around $700. The difference in price can result in up to $8,200 of extra costs every year for each of our uninsured patients taking this life saving drug. These drugs would be unaffordable to our uninsured patients at these prices.

b. Certain Manufacturers, such as Eli Lilly, now allow only one contract pharmacy for all our patients. This change means that around 12,000 of our patients will have to travel 4 miles or more in an urban area just to get access to Eli Lilly drugs. Several of our patients depend on public transportation, which puts an added burden on them in accessing drugs, and, during the ongoing pandemic, increases the likelihood that they may contract COVID-19.

c. The 340B Program allows providers to prescribe drugs that are in our patients' clinical best interests. Changing medications for financial—rather than clinical efficacy— reasons creates the potential for harmful and/or unpleasant side effects and contraindications with these new medications.

d. Switching patients' medications also inevitably creates the potential for confusion and medication errors. Many of our patients primarily speak Spanish, rather than English, and some have low literacy levels even in their primary language. It can take months or years for our patients to get used to a particular medication regimen. Rapid, forced changes can cause significant patient harm.

e. Our patients, who are historically and systematically disenfranchised, have not always brought medication cost concerns to our attention. There have been instances in which patients who could not afford their medication simply stopped refilling their

prescriptions. This has happened with diabetic patients, who did not voice cost concerns initially and only came to our attention months later when their blood sugar levels were uncontrolled.

15. The Manufacturers' actions have caused and will cause irreparable harm to Esperanza:

    a. Undercutting the 340B program will severely impact our ability to provide healthcare to our patients without regard to their ability to pay. Of the approximately $2,900,000 in net 340B Program revenue generated in fiscal year ended June 30, 2020, every penny, as required by law, has been invested in medical care and services that expand access for our medically underserved patient population. During the same period, we provided approximately 34,555 uninsured visits at a total cost to Esperanza of around $6,700,000. Our net surplus for the year—which we are also required to use in furtherance of our mission—is only around $550,000, a small amount considering our $25,000,000 budget. Taking away or limiting our ability to participate meaningfully in the 340B program would put us in a deficit of roughly $2,400,000. Such a deficit would be catastrophic to Esperanza and our patients.

    b. The changes have also increased work for our care teams, which have had to scramble to switch patients from one prescription drug to another, and to monitor these patients for potential adverse reactions and medication compliance. If the changes continue we will have to consider adding clinical staff such as nurses merely to deal with an administrative burden unfairly placed upon us by the manufacturers. This will divert critical resources from devoting meaningful clinical care to our underserved patients.

    c. In the case of Eli Lilly, we were notified of the change 3 days after it took effect, which left Esperanza no time to prepare either our care teams or our patients for significant shifts in both prescribed medications and cost.

16. Esperanza has explored alternatives to mitigate the harms described here, but all either fall short of an adequate remedy or are administratively unfeasible:

    d. We could theoretically mail drugs to our patients, but there is no way with current staff and resources for Esperanza to process and mail out approximately 59,000 prescriptions a year.

    e. It would take years and significant capital investment to build out our own onsite pharmacies. Our patients cannot wait months, let alone years, to get access to life-saving and life-sustaining medications.

    f. Esperanza could purchase and accept all drugs for our patients and, acting as a wholesaler, distribute the drugs to our contract pharmacies. But such a massive, costly, and logistically complex effort would create no real value for Esperanza, the manufacturers, or our patients.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: November 30, 2020

By: _____

Dan Fulwiler
President and CEO, Esperanza Health Centers

Exhibit T

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS PLAINTIFF, V. ALEX M. AZAR II, ET. AL	)	Civil Action No. _____

Declaration of Ronald E. Castle

I, Ronald E. Castle, declare as follows:

1. I am the Chief Executive Officer (CEO) at Community Health Centers of the Central Coast, Inc. (CHCCC) and have held this role since in or around September 1978. As CEO, I am responsible for overseeing 30 health centers and seven mobile dental and medical units. I also oversee our participation in the 340B Drug Pricing Program and, to prepare this declaration, I reviewed CHCCC data relevant to that program and consulted with knowledgeable staff.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. CHCCC is a Federally-qualified health center ("FQHC") operating in California's San Luis Obispo and Northern Santa Barbara counties and funded in part through federal grants made under Section 330 of the Public Health Service Act. CHCCC has been in business since 1978 and is a member of the National Association of Community Health Centers.

4. In 2019, according to our Uniform Data System (UDS) reporting, CHCCC provided primary care services to approximately 111,735 unduplicated patients in approximately 549,173 patient encounters.

5. Also, according to that report, approximately:
   - 52,952 CHCCC patients were at or below 100% of the Federal Poverty Level (FPL)
   - 19,031 were 101–150% below FPL
   - 7,375 were 151–200% below FPL
   - 9,516 were more than 200% below FPL

6. CHCCC special populations include approximately:
   - 32,245 migrant/seasonal patients

- 31,272 patients living in public housing
- 8,877 homeless patients
- 6,797 school-based health center patients
- 2,157 veterans

7. Per that same data, our patients suffer high rates of diabetes mellitus, obesity, hypertension, heart disease, and mental health conditions including anxiety disorders, PTSD, depression and mood disorders, and substance use disorders.

8. CHCCC is a "covered entity" for purposes of the 340B Program and has held that status since on or about April 1, 1996. As required, CHCCC recertifies its covered entity status annually with the Health Resources and Services Administration (HRSA). CHCCC's HRSA Office of Pharmacy Affairs has the following information related to CHCCC's covered entity status:

   Grant Number: H80CS00621
   Site ID Number: BPS-H80-002350
   Employer ID Number: 953253302 340BID: CH090710
   Participating: True
   Date: 4/1/1996
   Last Recertification Date: 1/27/2020
   Entity Name: Community Health Centers of the Central Coast, Inc. Entity Sub-Division Name: Nipomo Community Medical Center

9. CHCCC passes on its 340B savings to its patients. Uninsured CHCCC patients making less than 200% of the FPL qualify for a sliding scale discount on all our services, including significant discounts for medications.

10. CHCCC makes drugs purchased at 340B discount pricing available to its patients in three ways: through clinic administered drugs, in-house pharmacy dispensed prescriptions (including by mail and courier delivery), and via seventy-five contracted pharmacies that dispense drugs to eligible CHCCC patients on CHCCC's behalf. A list of pharmacies with which CHCCC has contractual relationships for the dispensing of 340B drugs to eligible CHCCC patients is attached as Exhibit A.

11. Third-party administrators (TPAs) largely manage the logistics of our day-to-day participation in the 340B Program. Our contract pharmacy partners use their own inventory for 340B eligible fills, and third-party administrators tally 340B accumulations and automatically trigger drug orders from the appropriate wholesaler to replenish their inventory whenever a full package size of a particular drug has been used. The cost of the 340B purchases are billed to CHCCC and the drugs are shipped to the contract pharmacies.

12. CHCCC is responsible for and ensures program compliance in part through daily self-audits of prescription claims and drug purchasing records.

13. From in or about January 1, 2020 to in or about September 30, 2020, CHCCC's in-house Pharmacy filled approximately 53,834 prescriptions; of that number, about 28,657

prescriptions were for filled for uninsured patients. CHCCC's contract pharmacies filled over 500,000 prescriptions during that period.

14. CHCCC's relationships with its contract pharmacies significantly expand our patients' access to the medications they need.

15. CHCCC's 30 clinics and 7 mobile units span a service area of nearly 110 miles across California's Central Coast. Our in-house pharmacy is located at roughly the midway point between all clinics and mobile units, which makes it difficult for patients at each extreme of our service area to reach.

16. A large population of our patients are working, low-income individuals. Many work late and are only able to pick up their medications either after hours or on weekends. Many do not have transportation and can only fill their prescriptions at a pharmacy within walking distance. Our contract pharmacies meet these patients' needs.

17. Our contract pharmacy relationships also allow CHCCC to retain more savings and generate revenue on eligible claims billed to appropriate third-party payers.

18. CHCCC estimates 340B savings generated from contract pharmacies account for about 20% of our direct patient care staffing expenses.

19. 340B-generated savings and revenue also fund expanded patient services—including, but not limited to, patient transportation to appointments, a Navigation Center to assist with patient calls, centralized referral capabilities, and health educations programs—as well as in-house outreach staff, case managers, care coordinators, referral staff, call center staff, and pharmacy technicians. These types of services are crucial to patient health but generally non-billable/non-reimbursable.

20. Beginning in or around August 17, 2020, I became aware that certain drug manufacturers, including Eli Lilly, Sanofi, Novartis, and AstraZeneca, had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to all of CHCCC's contract pharmacies. Sanofi conditioned continued shipment of 340B priced drugs to our contract pharmacies on our participation in burdensome reporting via a platform called 340B ESP. CHCCC decided not to enroll in 340B ESP.

21. As of this writing, CHCCC has been blocked from purchasing Eli Lilly, Sanofi, and AstraZeneca drugs at 340B pricing where those drugs would be dispensed via contract pharmacies. Novartis has not yet followed through on blocking 340B prices at contract pharmacies.

22. Although we are doing our very best, despite these changes, to meet our most vulnerable patients' pharmaceutical needs—including by mailing prescriptions and using a courier service to deliver prescriptions to our clinic sites and even to patients' homes—we cannot absorb the cost of these changes indefinitely while losing 340B-related program income.

23. Because of the drug manufacturers' actions, CHCCC patient services and programs such as our call center, referral center, case management services, pharmacy technicians, care

coordinators, in-house behavioral services, and dental services are at risk of being significantly reduced or eliminated.

24. Such reductions put our patients' access to care at risk, which can threaten patient health and potentially increase health care costs to the entire primary care medical home health care system.

25. In addition to loss of services, higher costs, poorer patient outcomes, and loss of employee positions, losing contract pharmacy 340B savings would negatively impact our strategic plans for a much needed facility expansion within the next five years aimed at increasing our ability to serve more of the uninsured and underinsured population in our service area.

26. The result of the drug manufacturers' refusal to supply drugs at required 340B pricing is a dismantling of the safety net that is so needed and which we worked so hard to build.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed On December 2, 2020

By: _____
Ronald E. Castle
Chief Executive Officer, Community Health Centers of the Central Coast, Inc.

CHCCC CONTRACT PHARMACY

Contract Pharmacy Name	Address	Address Cont.	City	State	Zip Code	Office of Pharmacy Affairs (OPA) Begin Date	Wholesaler
ACCREDO HEALTH GROUP INC	2040 W RIO SALADO PKWY STE 101B		TEMPE	AZ	85281-2010	1/1/2021	CURASCRIPT SPECIALTY DISTRIBUTION/ AMERISOURCE BERGEN
ACCREDO HEALTH GROUP INC	3000 ERICSSON DRIVE, SUITE 100		WARRENDALE	PA	15086-7502	1/1/2021	CURASCRIPT SPECIALTY DISTRIBUTION/ AMERISOURCE BERGEN
ACCREDO HEALTH GROUP INC	1620 CENTURY CENTER PKWY	# 109	MEMPHIS	TN	38134-8849	1/1/2021	CURASCRIPT SPECIALTY DISTRIBUTION/ AMERISOURCE BERGEN
ACCREDO HEALTH GROUP, INC.	2 BOULDEN CIR STE 1		NEW CASTLE	DE	19720-3492	1/1/2021	CURASCRIPT SPECIALTY DISTRIBUTION/ AMERISOURCE BERGEN

ACCREDO HEALTH GROUP, INC.	6272 LEE VISTA BLVD SUITE 100		ORLANDO	FL	32822-5148	1/1/2021	CURASCRIPT SPECIALTY DISTRIBUTION/ AMERISOURCE BERGEN
ACCREDO HEALTH GROUP, INC.	2825 W PERIMETER RD SUITE 112		INDIANAPOLIS	IN	46241-3614	1/1/2021	CURASCRIPT SPECIALTY DISTRIBUTION/ AMERISOURCE BERGEN
ALBERTSONS LLC	SAV-ON PHARMACY #1348	2320 S BROADWAY	SANTA MARIA	CA	93454	7/1/2017	MCKESSON
ALBERTSONS LLC	SAV-ON PHARMACY #1394	1120 E CLARK AVE	ORCUTT	CA	93455	7/1/2017	MCKESSON
ALBERTSONS LLC	SAV-ON PHARMACY #0314	189 NIBLICK ROAD	PASO ROBLES	CA	93446	7/1/2017	MCKESSON
BESTCARE PHARMACY	1051 E GRAND AVE		ARROYO GRANDE	CA	93420-2504	7/1/2013	MCKESSON
CHC TEMPLETON PHARMACY	1330 LAS TABLAS ROAD	SUITE 140	TEMPLETON	CA	93465	9/29/2020	CARDINAL HEALTH
DIPLOMAT SPECIALTY PHARMACY	15211 VANOWEN ST	STE 301	VAN NUYS	CA	91405	10/1/2019	CARDINAL HEALTH
DIPLOMAT SPECIALTY PHARMACY	4100 S SAGINAW ST	STE D	FLINT	MI	48507-2683	8/17/2012	CARDINAL HEALTH

DIPLOMAT SPECIALTY PHARMACY OF PHOENIX,	DIPLOMAT SPECIALTY PHARMACY	485 N. JUNIPER DR	CHANDLER	AZ	85226	10/1/2019	CARDINAL HEALTH
GARFIELD BEACH CVS, L.L.C.	DBA: CVS/PHARMACY # 09750	1830 NORTH BROADWAY	SANTA MARIA	CA	93454	7/1/2013	MCKESSON
GARFIELD BEACH CVS, L.L.C.	DBA: CVS/PHARMACY # 09782	610 WEST TEFFT STREET	NIPOMO	CA	93444	7/1/2013	MCKESSON
GARFIELD BEACH CVS, L.L.C.	DBA: CVS/PHARMACY # 09662	3960 BROAD STREET	SAN LUIS OBISPO	CA	93401	7/1/2013	MCKESSON
GARFIELD BEACH CVS, L.L.C.	CVS PHARMACY # 16105	223 E BETTERAVIA RD	SANTA MARIA	CA	93454	1/1/2018	MCKESSON
GARFIELD BEACH CVS, L.L.C.	CVS PHARMACY # 16488	2305 THEATRE DR	PASO ROBLES	CA	93446	1/1/2018	MCKESSON
GARFIELD BEACH CVS, L.L.C.	CVS PHARMACY # 17619	11990 LOS OSOS VALLEY RD	SAN LUIS OBISPO	CA	93405	1/1/2018	MCKESSON
IMGRX SLO, INC. DBA	CHC PHARMACY SLO	77 CASA STREET, SUITE 205	SAN LUIS OBISPO	CA	93405	1/10/2019	CARDINAL HEALTH

IMGRX SLO, INC. DBA	CHC PHARMACY PASO ROBLES	416 SPRING STREET	PASO ROBLES	CA	93446	1/10/2019	CARDINAL HEALTH
LONGS DRUG STORES CALIFORNIA, L.L.C.	DBA: CVS/PHARMACY # 09592	1435 E GRAND AVE	ARROYO GRANDE	CA	93420	7/1/2013	CARDINAL HEALTH

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Exhibit U

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS PLAINTIFF, V. ALEX M. AZAR II, ET. AL	)	Civil Action No. 1:20-cv-03032

Declaration of Timothy E. Starkey

I, Timothy E. Starkey, declare as follows:

1. I am Chief Executive Officer (CEO) at Great Salt Plains Health Center, Inc. (GSP Health) and have held this role since April 2008. As CEO, I oversee all patient care. In the normal course of my job I have access to financial and clinical records for our 340B Drug Pricing Program (340B Program) as well as agreements with our contract pharmacies. To prepare this declaration, I reviewed internal patient and prescribing data including information related to prescribing and billing for patients receiving 340B drugs from our contract pharmacies.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. GSP Health is a Federally-qualified health center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services in Northwestern Oklahoma regardless of patient insurance status or ability to pay. Our records indicate that in 2019 we served 10,690 patients through 37,018 encounters.

4. GSP Health has been in operation since 2008, serves most of northwestern Oklahoma with four rural FQHC sites, and is the only FQHC in all of Northwestern Oklahoma.

5. Approximately 61% of our patients are below 200% of Federal Poverty Level and receive discounted services. About 25% of our patients are uninsured and have absolutely no way to pay for services or prescription medications.

6. GSP Health is a "covered entity" for purposes of the 340B Program. GSP Health received its "covered entity" status after registration with and approval by the Health Resources and Services Administration's Office of Pharmacy Affairs (HRSA OPA) in 2008. GSP Health is required to recertify annually with OPA and has done so every year since 2008. Attached as Exhibit A is a copy of our OPA registration records for 2020.

7. The 340B Program allows GSP Health to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. We use both McKesson and Amerisource Bergen for wholesalers.

8. As a covered entity, GSP Health is permitted to choose how it will deliver pharmacy services to its patients. We deliver pharmacy services to our patients through contracts with seven local retail pharmacies located throughout our service area. In every case, we have a written agreement with the local pharmacy outlining the relationship. Some of these agreements date back to 2008 when GSP Health began seeing patients. HRSA OPA approved each of these arrangements before services commenced.

9. GSP Health opted to contract with local pharmacies rather than to establish an internal pharmacy for several reasons. GSP Health clinics are located in mostly rural communities with limited infrastructure and public services. The local pharmacies with which we contract provide the best possible services to our patients in return for a minimal fee for processing our prescriptions. Additionally, GSP Health does not have to cover overhead costs associated with establishing and maintaining a pharmacy, including labor costs for highly compensated pharmacist employees. This leaves more dollars within the health center budget to provide more services to our patients.

10. GSP Health works with a third-party administrator (TPA) who carefully monitors all 340B prescription transactions utilizing data from (1) the pharmacy and (2) GSP Health's Electronic Medical Records system. The TPA identifies GSP Health patients, determines patient and prescription eligibility for 340B pricing, and informs the pharmacy how much to collect from self-pay patients based on GSP Health's sliding fee scale. The pharmacy collects a small fee per prescription dispensed and remits any remaining prescription fees to GSP Health on a regular basis. The TPA also determines when inventory needs to be replenished and places corresponding drug orders with our wholesalers, who bill associated costs to GSP Health.

11. Our TPA is responsible, in exchange for a monthly fee, for ensuring compliance with all 340B rules. Additionally, GSP Health regularly audits claims to ensure compliance.

12. With our 340B savings, we are able to provide affordable medications to all of our patients regardless of their ability to pay or insurance status. We put revenue received from insurance companies for prescriptions we purchase at 340B discount pricing toward hiring more medical providers and behavioral health providers to treat more low-income patients.

13. GSP Health providers annually write more than 42,000 prescriptions for our patients. The estimated savings and revenue generated through 340B discounts is more than $1 million annually, all of which is used in furtherance of GSP Health's mission and for the benefit of GSP Health patients.

14. During 2019, GSP Health purchased approximately 42,756 drug doses through the 340B Program for a total expenditure of approximately $293,315. In particular, we provide large

quantities of inhalers for our respiratory patients through the program. For most of these patients, inhalers keep them alive and functioning and would otherwise be very expensive, and thus unaffordable, to many of our patients.

15. I recently became aware that certain drug manufacturers, including Eli Lilly, Sanofi, and others, had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of our contract pharmacies.

16. Because of these actions, GSP Health patients will be denied access to medications that are critical to their survival, such as rescue inhalers, blood pressure medications, and insulin. Still other patients will decide not to purchase their medications due to increased costs at a time when there are intense economic pressures on the community we serve and some patients are forced to choose between food and medications.

17. Because of this action, GSP Health will likely lose nearly $1 million annually, which will necessarily result in cuts to services for all our patients. The amount we project we will lose is roughly 10% of our total annual budget.

18. To absorb this loss, we anticipate having to make drastic cuts to dental and mental health and reductions of medical providers and their staffs. At this time it appears we will have to eliminate at least two provider positions. These providers, like all our providers, are currently treating low-income, uninsured patients who are in need of care and have no other options.

19. We have no realistic alternative to meeting our patients' prescription needs outside of our contract pharmacy network.

20. GSP Health is not currently licensed to provide in-house pharmacy services and does not employ pharmacists. Our facilities are not built to provide a secure location for storing and distributing drugs. Our budget cannot accommodate a pharmacist at each of our sites during all of the hours we are serving patients.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 12/3/20

By _____
Timothy E. Starkey
Chief Executive Officer, Great Salt Plains Health Center, Inc.

CH0627800 GREAT SALT PLAINS HEALTH CENTER, INC. (Active) - information as of 11/16/2020 5:29:49 PM

Main Details

Name

GREAT SALT PLAINS HEALTH CENTER, INC.

Subdivision Name

Great Salt Plains Health Center

Type

Consolidated Health Center Program

Site ID

BPS-H80-010483

340B ID

CH0627800

Grant Number

H80CS08744

Employer Identification Number (EIN)

20-8787477

Contacts

Authorizing Official

Great Salt Plains Health Center
TIM STARKEY, CEO/EXECUTIVE DIRECTOR
(580) 596-2800
tstarkey@gsphealth.org

Primary Contact

Great Salt Plains Health Center, Inc.
Marcus Stephens, CFO
(580) 596-2800
mstephens1@gsphealth.org

Additional Details

Current Program Status

Active

Registration Date

2/7/2008

Participating Start Date

4/1/2008

Participating Approval Date

3/3/2008

Last Recertification Date

1/29/2020

Addresses

Street Address

405 S. Oklahoma Ave
Cherokee, OK 73728-2545

Billing Address

Great Salt Plains Health Center
205 W. Maple
Suite 800
Enid, OK 73701

Comments

Comment	Comment Type	Last Updated By	Last Updated On
7/08/11 - CHANGED PHYSICAL ADDRESS FROM 400 S OHIO AVE AND AO FROM ASA WILSON AND CHANGED CONTACT.	Public	OPA Reviewer	07/08/2011

Medicaid Billing

At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices? No

Attachment

ID	FileName	Document Name	Attachment Type	Process	Uploaded By CE Name	Uploaded On	Uploaded By	Comment	Quarter/Year

No attachments to display.

ID	FileName	Document Name	Attachment Type	Process	Associated By CE Name	Uploaded By CE Name	Uploaded On	Uploaded By	Comment	Year/Quarter

No attachments to display.

Shipping Addresses

Same as Street Address

Contract Pharmacies

Contract Detail	Pharmacy Name	Address	Address Cont.	City	State	Zip Code	Approval Date	Begin Date	Carve-In Effective Date	Termination Date	340B Status	Last Updated On
Contract Detail	FAIRVIEW RX, INC.	210 E STATE RD		FAIRVIEW	OK	73737	07/14/2017	10/01/2017			Active	10/01/2017
Contract Detail	FAMILY PHARMACY #3	DIELRX, LLC	221 S 30TH ST	ENID	OK	73701-6455	04/13/2016	07/01/2016			Active	04/13/2016
Contract Detail	HAWKINS PHARMACY	DBA SMITH DRUG	121 SOUTH GRAND	CHEROKEE	OK	73728	04/22/2008	04/22/2008			Active	03/28/2013

Contract Detail	Pharmacy Name	Address	Address Cont.	City	State	Zip Code	Approval Date	Begin Date	Carve-In Effective Date	Termination Date	340B Status	Last Updated On
Contract Detail	HEROD DISCOUNT DRUG STORE	THOMAS DRUG, INC	212 W MAIN P O BOX 419	CANTON	OK	73724-0419	04/17/2017	07/01/2017			Active	04/17/2017
Contract Detail	WAL-MART CENTRAL FILL 10-2670	608 SPRING HILL DR # 3 SUITE 300		SPRING	TX	77386	07/07/2017	10/01/2017			Active	10/01/2017
Contract Detail	WAL-MART PHARMACY 10-0178	914 EAST OKLAHOMA BLVD.		ALVA	OK	73717	04/10/2017	07/01/2017			Active	04/10/2017
Contract Detail	WAL-MART PHARMACY 10-0499	5505 W. OWEN K GARRIOTT RD		ENID	OK	73703	04/10/2017	07/01/2017			Active	04/10/2017
Contract Detail	WAL-MART PHARMACY 10-5997	9600 PARKSOUTH CT. SUITE 100		ORLANDO	FL	32837	07/07/2017	10/01/2017			Active	10/01/2017
Contract Detail	WALMART PHARMACY 10-4390	1018 N CLEVELAND STREET		ENID	OK	73703	04/10/2017	07/01/2017			Active	04/10/2017

Grantee Sites

340B ID	340B Status	SiteId	Name	Sub Name	Address	Address Cont.	City	State

340B ID	340B Status	SiteId	Name	Sub Name	Address	Address Cont.	City	State
CH0627800	Active	BPS-H80-010483	GREAT SALT PLAINS HEALTH CENTER, INC.	Great Salt Plains Health Center	405 S. Oklahoma Ave		Cherokee	OK
CH062780A	Active	BPS-H80-012019	GREAT SALT PLAINS HEALTH CENTER, INC.	GSPHC - Medford Satellite Location	619 N Front St		Medford	OK
CH062780B	Active	BPS-H80-018320	GREAT SALT PLAINS HEALTH CENTER, INC.	GSPHC - Enid Satellite Location	231 S. 30th		Enid	OK
CH062780C	Active	BPS-H80-019218	GREAT SALT PLAINS HEALTH CENTER, INC.	GSP Health Canton	310 E. Walnut		Canton	OK

Grantee Sites Contract Pharmacies

340B ID	Pharmacy Name	Address	Address Cont.	City	State	Zip Code	Begin Date	Carve-In Effective Date	Termination Date
CH0627800	FAIRVIEW RX, INC.	210 E STATE RD		FAIRVIEW	OK	73737	10/01/2017		
CH0627800	FAMILY PHARMACY #3	DIELRX, LLC	221 S 30TH ST	ENID	OK	73701-6455	07/01/2016		
CH0627800	HAWKINS PHARMACY	DBA SMITH DRUG	121 SOUTH GRAND	CHEROKEE	OK	73728	04/22/2008		

340B ID	Pharmacy Name	Address	Address Cont.	City	State	Zip Code	Begin Date	Carve-In Effective Date	Termination Date
CH0627800	HEROD DISCOUNT DRUG STORE	THOMAS DRUG, INC	212 W MAIN P O BOX 419	CANTON	OK	73724-0419	07/01/2017		
CH062780C	HEROD DISCOUNT DRUG STORE	THOMAS DRUG, INC	212 W MAIN P O BOX 419	CANTON	OK	73724-0419	07/01/2017		
CH062780B	HUGHES PHARMACY	107 EAST CHEROKEE		MEDFORD	OK	73759	01/01/2015		
CH062780A	HUGHES PHARMACY	107 EAST CHEROKEE		MEDFORD	OK	73759	01/01/2014		
CH0627800	WAL-MART CENTRAL FILL 10-2670	608 SPRING HILL DR # 3 SUITE 300		SPRING	TX	77386	10/01/2017		
CH0627800	WAL-MART PHARMACY 10-0178	914 EAST OKLAHOMA BLVD.		ALVA	OK	73717	07/01/2017		
CH0627800	WAL-MART PHARMACY 10-0499	5505 W. OWEN K GARRIOTT RD		ENID	OK	73703	07/01/2017		
CH0627800	WAL-MART PHARMACY 10-5997	9600 PARKSOUTH CT. SUITE 100		ORLANDO	FL	32837	10/01/2017		
CH0627800	WALMART PHARMACY 10-4390	1018 N CLEVELAND STREET		ENID	OK	73703	07/01/2017		

History

Section	Field	Action	Activity	Value Before	Value After	Timestamp	Username

Section	Field	Action	Activity	Value Before	Value After	Timestamp	Username
Addresses	Billing Address	Insert	Recertificatio		Great Salt Plains Health Center 205 W. Maple Suite 800 Enid, OK 73701	1/29/2020 1:44 PM	tstarkey@gsphe
Details	Last Recertificatio Date	Update	Recertificatio	1/31/2019 12:52:26 PM	1/29/2020 1:44:42 PM	1/29/2020 1:44 PM	tstarkey@gsphe
Details	Last Recertificatio Date	Update	Recertificatio	2/8/2018 5:03:39 PM	1/31/2019 12:52:26 PM	1/31/2019 12:52 PM	tstarkey@gsphe
Contacts	Primary Contact	Update	Recertificatio	STARKEY, TIM CEO/EXECUTIVE DIRECTOR Great Salt Plains Health Center 5805962800	Stephens, Marcus CFO Great Salt Plains Health Center, Inc. 5805962800	2/8/2018 5:03 PM	tstarkey@gsphe
Contacts	Primary Contact Email Address	Update	Recertificatio	tstarkey@gsphe	mstephens1@gsp	2/8/2018 5:03 PM	tstarkey@gsphe
Details	Last Recertificatio Date	Update	Recertificatio	1/25/2017 12:00:00 AM	2/8/2018 5:03:39 PM	2/8/2018 5:03 PM	tstarkey@gsphe

Section	Field	Action	Activity	Value Before	Value After	Timestamp	Username
Contacts	Authorizing Official	Update		STARKEY, TIM CEO/EXECUTIVE DIRECTOR 5805962800	STARKEY, TIM CEO/EXECUTIVE DIRECTOR Great Salt Plains Health Center 5805962800	9/29/2017 10:21 AM	OPA
Contacts	Primary Contact	Update		STARKEY, TIM CEO/EXECUTIVE DIRECTOR 5805962800	STARKEY, TIM CEO/EXECUTIVE DIRECTOR Great Salt Plains Health Center 5805962800	9/29/2017 10:21 AM	OPA
Contacts	Authorizing Official	Insert			STARKEY, TIM CEO/EXECUTIVE DIRECTOR 5805962800	7/14/2017 4:02 PM	OPA
Contacts	Authorizing Official Email Address	Insert			tstarkey@gsphe	7/14/2017 4:02 PM	OPA
Contacts	Primary Contact	Update		FERGUSON, KEENAN MEDICAL DIRECTOR 5805962800	STARKEY, TIM CEO/EXECUTIVE DIRECTOR 5805962800	7/14/2017 4:02 PM	OPA
Contacts	Primary Contact Email Address	Update		kferguson@gsph	tstarkey@gsphe	7/14/2017 4:02 PM	OPA

Section	Field	Action	Activity	Value Before	Value After	Timestamp	Username
Addresses	Main Address	Insert			405 S. Oklahoma Ave Cherokee, OK 73728-2545	1/25/2017 5:28 PM	OPA
Details	Last Recertificatio Date	Update		2/12/2016 12:00:00 AM	1/25/2017 12:00:00 AM	1/25/2017 5:28 PM	OPA
Details	Last Recertificatio Date	Update		2/3/2015 12:00:00 AM	2/12/2016 12:00:00 AM	2/12/2016 8:22 AM	OPA
Details	Last Recertificatio Date	Update		3/17/2014 12:00:00 AM	2/3/2015 12:00:00 AM	2/3/2015 1:38 PM	OPA
Details	EIN	Update			208787477	4/30/2014 10:39 AM	OPA
Details	Last Recertificatio Date	Update		4/1/2013 12:00:00 AM	3/17/2014 12:00:00 AM	3/17/2014 11:25 AM	OPA
Details	Entity Subname	Update			Great Salt Plains Health Center	3/17/2014 11:25 AM	OPA
Contacts	Primary Contact	Insert			FERGUSON, KEENAN MEDICAL DIRECTOR 5805962800	2/20/2013 8:46 AM	OPA

Section	Field	Action	Activity	Value Before	Value After	Timestamp	Username
Contacts	Primary Contact Email Address	Insert			kferguson@gsph	2/20/2013 8:46 AM	OPA
Details	Last Recertificatio Date	Update			4/1/2013 12:00:00 AM	2/20/2013 8:46 AM	OPA
Details	Site ID	Update			BPS-H80-010483	2/20/2013 8:46 AM	OPA
Details	Last Recertificatio Date	Insert				7/8/2011 11:16 PM	OPA
Details	EIN	Insert				7/8/2011 11:16 PM	OPA
Details	Grant Number	Insert			H80CS08744	7/8/2011 11:16 PM	OPA
Details	340B ID	Insert			CH0627800	7/8/2011 11:16 PM	OPA
Details	Is Authorizing Official EHB Data	Insert				7/8/2011 11:16 PM	OPA
Details	Is Medicare Cost Report	Insert				7/8/2011 11:16 PM	OPA
Details	Is Provider Based Hospital	Insert				7/8/2011 11:16 PM	OPA

Section	Field	Action	Activity	Value Before	Value After	Timestamp	Username
Dates	Last Date That 340B Drugs Purchased	Insert				7/8/2011 11:16 PM	OPA
Details	Local State Contract	Insert				7/8/2011 11:16 PM	OPA
Details	Medicare Provider Number	Insert				7/8/2011 11:16 PM	OPA
Details	Entity Name	Insert			GREAT SALT PLAINS HEALTH CENTER, INC.	7/8/2011 11:16 PM	OPA
Details	Outpatient Facility Grant Number	Insert				7/8/2011 11:16 PM	OPA
Details	Outpatient Facility Medicare Provider Number	Insert				7/8/2011 11:16 PM	OPA
Details	Outpatient Service Clinic Name	Insert				7/8/2011 11:16 PM	OPA
Details	Program Code	Insert			CH	7/8/2011 11:16 PM	OPA
Details	Shipping Justification	Insert				7/8/2011 11:16 PM	OPA

Covered Entity Details

Section	Field	Action	Activity	Value Before	Value After	Timestamp	Username
Details	Site ID	Insert				7/8/2011 11:16 PM	OPA
Details	Entity Subname	Insert				7/8/2011 11:16 PM	OPA
Dates	Participating Approval Date	Insert			3/3/2008 12:00:00 AM	7/8/2011 11:16 PM	OPA
Details	State	Insert			Active	7/8/2011 11:16 PM	OPA
Dates	Registration Date	Insert			2/7/2008 12:00:00 AM	7/8/2011 11:16 PM	OPA
Dates	Signed By Date	Insert			12/28/2007 12:00:00 AM	7/8/2011 11:16 PM	OPA
Dates	Start Date	Insert			4/1/2008 12:00:00 AM	7/8/2011 11:16 PM	OPA
Terminations	Termination Comments	Insert				7/8/2011 11:16 PM	OPA
Terminations	Termination Date	Insert				7/8/2011 11:16 PM	OPA
Terminations	Termination Effective Date	Insert				7/8/2011 11:16 PM	OPA
Terminations	Termination Reason	Insert				7/8/2011 11:16 PM	OPA

Section	Field	Action	Activity	Value Before	Value After	Timestamp	Username
Details	Comments	Insert			7/08/11 - CHANGED PHYSICAL ADDRESS FROM 400 S OHIO AVE AND AO FROM ASA WILSON AND CHANGED CONTACT.	7/8/2011 11:16 PM	OPA

Exhibit V

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS PLAINTIFF, V. ALEX M. AZAR II, ET. AL	)	Civil Action No. 1:20-cv-03032

Declaration of David Steven Taylor

I, David Steven Taylor, declare as follows:

1. I am the Director of Pharmacy Operations for Appalachian Mountain Community Health Centers (Appalachian Mountain) in western North Carolina, and have held this position since September 2018. As Director of Pharmacy Operations, I am responsible, among other duties, for overseeing Appalachian Mountain's 340B program participation, our Hepatitis Treatment program, and many aspects of our Outpatient Based Opioid Therapy.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Appalachian Mountain, a member of the National Association of Community Health Centers, is a Federally-qualified health center that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved population in a mixed urban and rural six-county area of roughly 2,916 square miles, much of which is deep in the Appalachian Mountains. As required, we provide our care and services regardless of patient insurance status or ability to pay.

4. In 2019, we served over 12,000 unduplicated patients at our six clinic locations.

5. Our overall uninsured patient count tops 2,000, or about 20% of our patient population, depending on the month. We treat over 1,000 patients with some form of substance use disorder, and this patient population is growing rapidly. Our more urban clinics currently serve just under 1,000 homeless and completely indigent patients.

6. Appalachian Mountain is a "covered entity" for purposes of the 340B Program.

7. The 340B Program allows Appalachian Mountain to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

8. As a covered entity, Appalachian Mountain is permitted to choose how it will deliver pharmacy services to its patients. We have a single in-house pharmacy located in Robbinsville, North Carolina, which, due to its size, is only able to service the patients of that particular clinic.

9. Additionally, we use a network of over 20 community partner pharmacies to provide care for Appalachian Mountain patients seen at our other five clinics. Each one of these partnerships was created with the execution of a unique contract that lays out the terms agreed upon by both parties, including the manner in which the avoidance of duplicate discounts and diversion will be accomplished (as required by statute). Each contract is also certified and enrolled via the Health Resources and Services Administration (HRSA) OPAIS web portal.

10. Our contract pharmacy relationships are absolutely necessary to our patients. It would be highly unreasonable to ask our patients in Asheville or those who are homeless to drive to our in-house pharmacy roughly two hours away to retrieve their medications. It would be equally unreasonable to force single parents working two jobs to find the time to come to a 9-to-5 pharmacy when they could use a Walgreens that is open 24 hours.

11. We currently purchase drugs to be dispensed by our contract pharmacies from three wholesalers: Amerisource Bergen, McKesson, and Smith Drug. The primary drive for determining which wholesaler to use is the established relationship of the contract pharmacy in question. By using the pharmacy's primary wholesaler, we ensure cohesiveness between all parties.

12. These relationships are managed with the utmost attention to detail and always keeping in mind the intended goal of expanding care. Our wholesalers create separate 340B accounts for each pharmacy and establish individual "ship-to, bill-to" arrangements under which medications sent to each pharmacy are owned by Appalachian Mountain and are audited every two weeks to ensure that 340B medications have only been used for eligible patients and prescriptions, and that the medications have been dispensed in a way that avoids duplicate Medicaid discounts. The contracted pharmacy provides these medications to our patients often at a highly discounted rate—sometimes at only 1–2% of the medication's wholesale value—while only charging a nominal dispensing fee.

13. Appalachian Mountain's participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Through participation in the 340B program, we have established avenues through which our patients can get ultra-low cost and even free medications.

14. We have also used our 340B savings to expand numerous services within our community: we have hired staff for community outreach who build bridges to access for care; provided a fleet to take homeless patients to and from appointments and to pick up their medications; hired behavioral health staff and embedded them in each of our clinics; expanded access to Outpatient Based Opioid Treatment to each of our clinics; and overall created a place where those less fortunate in our community can come to get care that is equal to or better than the care provided by anyone else.

15. Appalachian Mountain processes over 38,000 out-patient medications a year under the 340B Program, many of which would not be affordable to our patients were it not for the discount pricing that is extended to us under the statute. These include, but are not limited to, medications necessary to treat hepatitis, diabetes, behavioral health diagnoses, and cardiac conditions, as well as addiction treatment medicines.

16. Appalachian Mountain currently purchases over $100,000 a month in 340B medications, which results in over $250,000 in net 340B savings at a margin of between 64% and 70%. Just under half of these purchases are dispensed to patients through our contract pharmacy relationships. We do our best to utilize our in-house services when possible, but we should not be required to do so at the expense of our patient's care.

17. Beginning on or about August 15, 2020, I became aware that certain drug manufacturers, including AstraZeneca, Eli Lilly, and Sanofi, would no longer provide outpatient prescription drugs at 340B prices to most or all of Appalachian Mountain's contract pharmacies.

18. After only a few short weeks, I saw first-hand the extent to which the actions taken by these drug manufacturers caused irreparable harm to our patient population. For example:

    - Numerous patients who live miles away from our offices have already gone without insulin because when they arrived at the pharmacy, instead of a $20 out of pocket cost they were met with a $285 cost.
    - Individuals who were on Farxiga, an AstraZeneca drug used in the treatment of diabetes, cannot always be switched to Invokana (a similar medication produced by Janssen Pharmaceuticals, Inc.) due to certain comorbidities, so they are forced to take an inferior class of medication altogether.
    - Patients who were taking Lantus, a Sanofi insulin medication used in the treatment of diabetes, are having to be switched to the only remaining affordable, long-acting insulin, Levemir, which is an inferior molecule and requires 2 shots a day versus just one with Lantus. With such a switch, not only is the patient inconvenienced with twice as many shots per day, he or she now also must purchase twice as many lancets for use.
    - Having to travel long distances for medications that are needed acutely puts an unneeded strain on a population that already struggles to simply afford medication, let alone transportation costs.

19. Our attempts to switch patients to alternate medications create an ethical (as well as practical/logistical) dilemma. Our providers want our patients to be on the drug that is best-suited to treat their current disease state, not on whatever medication is left over after multibillion-dollar companies disassemble the 340B statute.

20. Since its initial announcement, AstraZeneca has walked back its position, allowing some health centers to designate one contract pharmacy location for each health center site that does not already have an in-house pharmacy. Appalachian Mountain applied for this exception on or about November 11, 2020, using an AstraZeneca form. This process was not straightforward—AstraZeneca was not clear about which covered entities or sites would qualify—but Appalachian Mountain received notice on or about November 17, 2020 that AstraZeneca had approved its application retroactive to October 1, 2020. On or about

November 24, 2020 pricing for the contract pharmacies selected was updated within our wholesaler ordering platform. Although this is an improvement, it does not restore access to all of our contract pharmacies.

21. The actions taken by these drug manufacturers have caused and will continue to cause irreparable harm to our health center, which in turn harms our patients. Between September 1, 2020 and October 1, 2020, we lost just under 4% of our 340B savings due to Eli Lilly's actions alone. After reviewing September and October data, we project that because of the drug manufacturers' actions, we will lose approximately 7–8% of 340B revenue, or approximately $250,000 over the next year. That figure assumes that no additional manufacturers limit our access to 340B pricing.

22. The money we have lost and will lose has been used to fill gaps in programs for our most vulnerable patients. As described above, among other patient-focused uses, this money is used to provide transportation to individuals without vehicles and to pay for medications for those without sufficient income.

23. Additionally, finding a way to fit scores of patients into a full schedule for additional visits to consult on medication alterations without being able to bill for those visits is a near impossibility.

24. If the actions taken by drug manufacturers are not reversed, our ability to be the safety net provider in our community—our very mission and the reason we receive federal grant funds—will be diminished. I am concerned we will be reduced to nothing more than an Urgent Care facility, and that we will lose our ability to provide affordable medications to patient who need them.

25. Our efforts to mitigate the harm done by these manufacturers unfortunately have fallen, and will continue to fall, short of the mark. We could establish a mail order pharmacy, but this would take almost a year to set up and we would still be left with no solution for highly indigent Appalachian Mountain patients and those experiencing homelessness.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 12 - 3 - 2020

By: _____
David Steven Taylor
Director of Pharmacy Operations,
Appalachian Mountain Community Health Centers

1. DATE ISSUED: 07/13/2017	**2. PROGRAM CFDA:** 93.224	
3. SUPERSEDES AWARD NOTICE dated: 05/16/2017 except that any additions or restrictions previously imposed remain in effect unless specifically rescinded		
4a. AWARD NO.: 6 H80CS28348-03-01	**4b. GRANT NO.:** H80CS28348	**5. FORMER GRANT NO.:**
6. PROJECT PERIOD: FROM: 05/01/2015 THROUGH: 05/31/2018		
7. BUDGET PERIOD: FROM: 06/01/2017 THROUGH: 05/31/2018		

U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration

NOTICE OF AWARD
AUTHORIZATION (Legislation/Regulation)
Public Health Service Act, Title III, Section 330
Public Health Service Act, Section 330, 42 U.S.C. 254b
Affordable Care Act, Section 10503
Public Health Service Act, Section 330, 42 U.S.C. 254, as amended.
Authority: Public Health Service Act, Section 330, 42 U.S.C. 254b, as amended
Public Health Service Act, Section 330, 42 U.S.C. 254b, as amended
Public Health Service Act, Section 330(e), 42 U.S.C. 254b
Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b, as amended) and Section 10503 of The Patient Protection and Affordable Care Act (P.L. 111-148)
Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b)
Public Health Service Act, Section 330, as amended (42 U.S.C. 254b)
Section 330 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 254b, as amended)
Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b, as amended)

8. TITLE OF PROJECT (OR PROGRAM): Health Center Program

9. GRANTEE NAME AND ADDRESS:
APPALACHIAN MOUNTAIN COMMUNITY HEALTH CENTERS.
123 Hendersonville Rd
Asheville, NC 28803-2868
DUNS NUMBER:
079416500
BHCMIS # 04E01135

10. DIRECTOR: (PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR)
Nicholas H Apostoleris
APPALACHIAN MOUNTAIN COMMUNITY HEALTH CENTERS.
PO BOX 2597
Asheville, NC 28802-2597

11.APPROVED BUDGET:(Excludes Direct Assistance)
[ ] Grant Funds Only
[X] Total project costs including grant funds and all other financial participation

a . Salaries and Wages :	$1,475,682.00
b . Fringe Benefits :	$351,898.00
c . Total Personnel Costs :	$1,827,580.00
d . Consultant Costs :	$0.00
e . Equipment :	$41,891.00
f . Supplies :	$3,180,604.00
g . Travel :	$40,563.00
h . Construction/Alteration and Renovation :	$0.00
i . Other :	$667,908.00
j . Consortium/Contractual Costs :	$3,593,324.00
k . Trainee Related Expenses :	$0.00
l . Trainee Stipends :	$0.00
m . Trainee Tuition and Fees :	$0.00
n . Trainee Travel :	$0.00
o . TOTAL DIRECT COSTS :	$9,351,870.00
p . INDIRECT COSTS (Rate: % of S&W/TADC) :	$0.00
q . TOTAL APPROVED BUDGET :	$9,351,870.00
i. Less Non-Federal Share:	$8,647,870.00
ii. Federal Share:	$704,000.00

12. AWARD COMPUTATION FOR FINANCIAL ASSISTANCE:

a. Authorized Financial Assistance This Period	**$704,000.00**
b. Less Unobligated Balance from Prior Budget Periods	
i. Additional Authority	$0.00
ii. Offset	$0.00
c. Unawarded Balance of Current Year's Funds	$0.00
d. Less Cumulative Prior Awards(s) This Budget Period	$704,000.00
e. AMOUNT OF FINANCIAL ASSISTANCE THIS ACTION	**$0.00**

13. RECOMMENDED FUTURE SUPPORT: (Subject to the availability of funds and satisfactory progress of project)

YEAR	TOTAL COSTS
Not applicable	

14. APPROVED DIRECT ASSISTANCE BUDGET:(In lieu of cash)

a. Amount of Direct Assistance	$0.00
b. Less Unawarded Balance of Current Year's Funds	$0.00
c. Less Cumulative Prior Awards(s) This Budget Period	$0.00
d. AMOUNT OF DIRECT ASSISTANCE THIS ACTION	**$0.00**

15. PROGRAM INCOME SUBJECT TO 45 CFR 75.307 SHALL BE USED IN ACCORD WITH ONE OF THE FOLLOWING ALTERNATIVES:
A=Addition B=Deduction C=Cost Sharing or Matching D=Other **[D]**

Estimated Program Income: $5,851,901.00

16. THIS AWARD IS BASED ON AN APPLICATION SUBMITTED TO, AND AS APPROVED BY HRSA, IS ON THE ABOVE TITLED PROJECT AND IS SUBJECT TO THE TERMS AND CONDITIONS INCORPORATED EITHER DIRECTLY OR BY REFERENCE IN THE FOLLOWING:

NOTICE OF AWARD (Continuation Sheet)

Date Issued: 7/13/2017 10:51:19 AM

Award Number: 6 H80CS28348-03-01

a. The grant program legislation cited above. b. The grant program regulation cited above. c. This award notice including terms and conditions, if any, noted below under REMARKS. d. 45 CFR Part 75 as applicable. In the event there are conflicting or otherwise inconsistent policies applicable to the grant, the above order of precedence shall prevail. Acceptance of the grant terms and conditions is acknowledged by the grantee when funds are drawn or otherwise obtained from the grant payment system.

REMARKS: (Other Terms and Conditions Attached [X]Yes [ ]No)
This NoA is issued to remove one or more Grant Conditions imposed on projects.

Electronically signed by Sarah Hammond , Grants Management Officer on : 07/13/2017

17. OBJ. CLASS: 41.51 | **18. CRS-EIN:** 1463984362A1 | **19. FUTURE RECOMMENDED FUNDING:** $704,000.00

FY-CAN	CFDA	DOCUMENT NO.	AMT. FIN. ASST.	AMT. DIR. ASST.	SUB PROGRAM CODE	SUB ACCOUNT CODE
17 - 398160G	93.527	17H80CS28348	$0.00	$0.00	CH	HealthCareCenters_17
17 - 398879G	93.527	17H80CS28348	$0.00	$0.00	HCH	HealthCareCenters_17

HRSA Electronic Handbooks (EHBs) Registration Requirements

The Project Director of the grant (listed on this NoA) and the Authorizing Official of the grantee organization are required to register (if not already registered) within HRSA's Electronic Handbooks (EHBs). Registration within HRSA EHBs is required only once for each user for each organization they represent. To complete the registration quickly and efficiently we recommend that you note the 10-digit grant number from box 4b of this NoA. After you have completed the initial registration steps (i.e.,created an individual account and associated it with the correct grantee organization record), be sure to add this grant to your portfolio. This registration in HRSA EHBs is required for submission of noncompeting continuation applications. In addition, you can also use HRSA EHBs to perform other activities such as updating addresses, updating email addresses and submitting certain deliverables electronically. Visit https://grants3.hrsa.gov/2010/WebEPSExternal/Interface/common/accesscontrol/login.aspx to use the system. Additional help is available online and/or from the HRSA Call Center at 877-Go4-HRSA/877-464-4772.

Terms and Conditions

Failure to comply with the remarks, terms, conditions, or reporting requirements may result in a draw down restriction being placed on your Payment Management System account or denial of future funding.

Grant Specific Term(s)

1. The grant condition stated below on NoA 2 H80CS28348-03-00 is hereby lifted. As of 05/10/2017, HRSA has not received the submission for the condition stated below which was originally issued in Notice of Award# 6 H80CS28348-02-14 . This condition is being transferred from the previous budget period (06/01/2016 - 05/31/2017) to the new budget period (06/01/2017 - 05/31/2018). **The due date for the related submission is 06/13/2017.**

   "**R.2.3.120 Required or Additional Services:** Health centers are expected to comply with all applicable statutory and regulatory requirements. In your most recent Notice of Award (NoA), your organization was required to provide an action plan detailing the steps the health center will implement in order to comply with providing required and additional services OR provide board approved documentation that action(s) have been implemented resulting in compliance with this requirement. (Section 330(a) of the PHS Act). Based upon a review of the required response, HRSA has approved your action plan. Within 120 days, provide board approved documentation that action(s) have been implemented resulting in compliance with this requirement in accordance with the HRSA approved action plan. Please contact your project officer for additional assistance and/or information on the required elements of your response. (45 CFR 75.207(a) and 45 CFR 75.371)"

2. The grant condition stated below on NoA 2 H80CS28348-03-00 is hereby lifted. As of 05/10/2017, HRSA has not received the submission for the condition stated below which was originally issued in Notice of Award# 6 H80CS28348-02-19 . This condition is being transferred from the previous budget period (06/01/2016 - 05/31/2017) to the new budget period (06/01/2017 - 05/31/2018). **The due date for the related submission is 09/07/2017.**

   "**R.7.1.120 Board Authority:** Health centers are expected to comply with all applicable statutory and regulatory requirements. In your most recent Notice of Award (NoA), your organization was required to provide an action plan detailing the steps the health center will implement in order to comply with all applicable board authority requirements OR provide board approved documentation that action(s) have been implemented resulting in compliance with this requirement. (Section 330(k)(3)(H) of the PHS Act and 42 CFR 51c.304). Based upon a review of the required response, HRSA has approved your action plan. Within 120 days, provide board approved documentation that action(s) have been implemented resulting in compliance with this requirement in accordance with the HRSA approved action plan. Please contact your project officer for additional assistance and/or information on the required elements of your response. (45 CFR 75.207(a) and 45 CFR 75.371)"

3. The grant condition stated below on NoA 2 H80CS28348-03-00 is hereby lifted. As of 05/10/2017, HRSA has not received the submission for the condition stated below which was originally issued in Notice of Award# 6 H80CS28348-02-14 . This condition is being transferred from the previous budget period (06/01/2016 - 05/31/2017) to the new budget period (06/01/2017 - 05/31/2018). **The due date for the related submission is 06/13/2017.**

   "**R.2.5.120 Quality Improvement/Quality Assurance Program:** Health centers are expected to comply with all applicable statutory and regulatory requirements. In your most recent Notice of Award (NoA), your organization was required to provide an action plan detailing the steps the health center will implement in order to comply with the requirement for having a QI/QA program OR provide board approved documentation that action(s) have been implemented resulting in compliance with this requirement. (Section 330(k)(3)(C) of the PHS Act and 42 CFR 51c.303(c)(1-2)) Based upon a review of the required response, HRSA has approved your action plan. Within 120 days, provide board approved documentation that action(s) have been implemented resulting in compliance with this requirement in accordance with the HRSA approved action plan. Please contact your project officer for additional assistance and/or information on the required elements of your response. (45 CFR 75.207(a) and 45 CFR 75.371)"

All prior terms and conditions remain in effect unless specifically removed.

Contacts

NoA Email Address(es):

Name	Role	Email
Nicholas H Apostoleris	Point of Contact, Program Director, Authorizing Official	nha@appalachianmountain.org
Paul C Tax	Business Official	pct@appalachianmountain.org

Note: NoA emailed to these address(es)

Program Contact:

For assistance on programmatic issues, please contact Darryl Burnett at:
HHS/BPHC/DHCM
5600 Fishers Ln
Rockville, MD, 20852-1750
Email: DBurnett@hrsa.gov
Phone: (301) 594-4449
Fax: (301) 594-2470

Division of Grants Management Operations:

For assistance on grant administration issues, please contact Vincent Mani at:
MailStop Code: 10SWH03
HRSA/OFAM/DGMO/HCB
5600 Fishers Lane
Rockville, MD, 20857-
Email: vmani@hrsa.gov
Phone: (301) 945-0900

Exhibit E

340B Administrative Dispute Resolution (ADR)

What is the 340B ADR Process?

In accordance with section 340B(d)(3) of the Public Health Service Act (PHSA), HHS is required to establish and implement a binding ADR process for certain disputes arising under the 340B Program. The ADR final rule (PDF - 309 KB) sets forth the requirements and procedures for the 340B Program's ADR process.

The purpose of the ADR process is to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts.

The ADR final rule establishes an ADR Board consisting of members with complex litigation, drug distribution, drug pricing, or 340B Program expertise and who are appointed by the HHS Secretary. From the ADR Board, three members are selected to form an ADR Panel. Each Panel is selected and convened by the HRSA Administrator and will be assisted by one, ex-officio, non-voting HRSA, Office of Pharmacy Affairs (OPA) staff member. The ADR Panel reviews petitions on a case-by-case basis and has the authority to make final agency decisions.

How can Stakeholders Submit a Petition?

HRSA continues to encourage covered entities and manufacturers to attempt to resolve issues in good faith prior to initiating a formal ADR process, which should be used as a method of last resort. Covered entities and manufacturers should carefully evaluate whether the ADR process is appropriate given the investment of the time and resources required of the parties involved.

Specific steps about the ADR process are outlined in detail below. HRSA also encourages stakeholders to review the ADR final rule for additional information regarding the submission process and timelines.

What are the steps in the ADR Process?

In general, the ADR process will involve the following steps:

1. A petitioner emails HRSA at 340BADR@hrsa.gov with a request to file a petition through the ADR process.
2. HRSA responds with specific instructions on accessing a secure email and file transfer system in order to file the petition.
3. Once the petition, including any supporting documentation, is received, HRSA reviews the petition for completeness and will notify the petitioner of whether the petition will move forward to the ADR Panel for review.
4. If HRSA deems the petition complete, ADR Panel members are selected from the 340B ADR Board and are convened to begin their review of the petition.
5. The petitioner (or initiating party) must provide a copy of their petition with any attachments to the General Counsel or other senior official of the opposing party at its principal place of business by certified mail, return receipt requested, within three days of filing the claim.
6. The opposing party (or respondent) will have an opportunity to respond to the petition.
7. HRSA will provide both the petitioner and the opposing party access to a secure email and file transfer system upload any relevant documents related to the petition.
8. The ADR Panel will review the petition, the opposing party's response, and all supporting documentation or other information from the parties.
9. Following its review of all of the evidence, the ADR Panel will make a final agency decision that will be sent to the parties and HRSA.
10. HRSA then will take enforcement actions or apply sanctions as appropriate, including referral to the HHS Office of Inspector General for its consideration of civil monetary penalties, as appropriate.

FAQs

Below are some frequently asked questions (FAQs) related to 340B ADR process. If you have a question related to the 340B ADR process that is not covered by the information on this page or in the FAQs listed below, please submit your question to 340BADR@hrsa.gov.

When can parties begin submitting petitions?

Stakeholders can begin submitting petitions once the 340B Administrative Dispute Resolution (ADR) final (85 FR 80632, December 14, 2020) rule becomes effective on January 13, 2021. The information on this webpage provides detailed information on the petition submission process.

Who is involved in the ADR process?

The ADR Board consists of at least six voting members with equal representation from the Centers for Medicare & Medicaid Services, the Health Resources and Services Administration (HRSA) and the HHS Office of General Counsel. The ADR Board members are appointed by the HHS Secretary and will be HHS employees with complex litigation, drug pricing, drug distribution, and other relevant 340B expertise.

The HRSA Administrator will select and convene 3-member ADR Panels from the ADR Board to review claims and make final agency decisions. Each ADR Panel will be assisted by one, ex-officio, non-voting HRSA Office of Pharmacy Affairs (OPA) staff member, who will also be selected by the HRSA Administrator. All panelists (voting and non-voting) will be screened for conflicts of interest prior to reviewing a claim.

What kinds of petitions are to be submitted for review by the ADR Panel?

In accordance with the 340B ADR final rule (85 FR 80632, December 14, 2020), petitions may be submitted by 1) covered entities that may have been overcharged for covered outpatient drugs purchased from manufacturers and 2) manufacturers of 340B drugs, after the manufacturer has conducted an audit of the covered entity, that the covered entity may have violated the prohibitions against duplicate discounts or diversion. In addition, the petition must be within three years of the date of the alleged violation. Stakeholders should also submit documentation of any prior good faith efforts to resolve the dispute at issue.

In addition, the final rule established a monetary threshold that must be satisfied in order for a claim to move forward for review to the ADR Panel.

What is the monetary threshold for filing an ADR claim?

The petition must seek monetary damages in excess of $25,000 or equitable relief with a likely value in excess of $25,000 during the twelve-month period after the 340B ADR Panel's final agency decision (see 42 C.F.R. §10.21(b) of the ADR final rule (85 FR 80632, December 14, 2020).

What type of information is needed from stakeholders prior to submitting a petition through the ADR process?

HRSA continues to encourage covered entities and manufacturers to attempt to resolve issues in good faith prior to initiating a formal ADR process, which should be used as a last resort. Covered entities and manufacturers should carefully evaluate whether the ADR process is appropriate given the investment of the time and resources required of the parties involved.

When submitting a petition, stakeholders should include any documentation of prior good faith efforts. This webpage provides detailed information on the petition submission process. Stakeholders can submit petitions to 340BADR@hrsa.gov to begin the 340B ADR process.

Consistent with the 340B statute, manufacturers must have completed an audit of a covered entity prior to initiating the ADR process and submit the final audit report with their petition, along with the covered entities written response to the audit findings.

How long is the ADR process expected to take?

The timeframe for each case will vary based on the information submitted and the complexity of the matter.

How does an ADR Panel formulate the final agency decision?

The ADR Panel will review the petition, the opposing party's response, and supporting documentation or other information from the parties. Following its review of all of the evidence, the ADR Panel will make a final agency decision that will be sent to the parties and HRSA.

After the final decision, HRSA will take enforcement actions or apply sanctions as appropriate, including referral to the HHS Office of Inspector General for its consideration of civil monetary penalties, as appropriate.

Can organizations or associations representing covered entities file an ADR action?

Yes. Covered entities must be members of the organization or association filing a petition on their behalf. All petitions must allege violations by the same manufacturer and for the same drug(s). Petitions must also include a letter requesting consolidation that is signed by a representative of each covered entity that has agreed to representation by the association or organization on its behalf.

What rules govern the ADR process?

The ADR process will be governed, to the extent applicable, by the Federal Rules of Civil Procedure (PDF - 431 KB) and Federal Rules of Evidence (PDF - 188 KB), unless the parties agree otherwise and the 340B ADR Panel concurs. In addition, the ADR Panel may entertain motions to dismiss pursuant to Rule 12 of the Federal Rules of Civil Procedure, may permit limited discovery by covered entities, as necessary, may entertain motions for summary judgment (see Fed. R. Civ.P. 56), and may hold evidentiary hearings as necessary.

Can claims be combined for covered entities?

Joint claims are permitted for covered entities if certain criteria are met. Multiple covered entities, or their membership organizations or associations, can file together against one manufacturer for the same drug(s) (a joint claim), but each must submit all documentation required to file a claim (e.g., invoice, 340B ceiling price, attempts to purchase at 340B). A letter requesting combination must also be submitted that is signed by a representative of each covered entity that is included in the joint claim.

Can claims be combined for manufacturers?

Multiple manufacturers can file together against a single covered entity (a consolidated claim), but each must submit all documentation required to file a claim. A letter requesting consolidation must also be submitted that is signed by a representative of each manufacturer that is included in the consolidated claim.

Claims by associations or organization representing manufacturers are not permitted.

Date Last Reviewed: January 2021

Exhibit F

340BHEALTH

STATEMENT ON ELI LILLY CUTTING OFF ALL ACCESS TO 340B PRICING THROUGH COMMUNITY-BASED PHARMACIES

September 01, 2020 in 340B Health News Releases

WASHINGTON, D.C., SEPT. 1, 2020— The following statement on Eli Lilly's decision to refuse 340B pricing for any of its drugs that are dispensed through community-based pharmacies is attributed to 340B Health President and CEO Maureen Testoni:

"Eli Lilly's refusal to offer 340B drug discounts through community pharmacies will hurt hospitals, health centers, and clinics as well as the patients they serve who are living with low incomes and in rural areas. Lilly's action violates federal law. Lilly and other manufacturers must not be permitted to make an end run around the 340B statute in a brazen attempt to avoid their responsibilities under the program. We call on Health and Human Services Secretary Azar to enforce the statute and prevent these actions."

"Lilly is the manufacturer of some of the costliest and top-selling drugs used by patients with diabetes. By blocking access to 340B ceiling prices on drugs that covered entities dispense through pharmacies in their communities, the company is preventing those savings from going toward expanded care for those patients, including direct assistance with patient care costs. Lilly's stated 'exception' to this new policy for insulin is no real exception at all, as it prevents covered entities from realizing any 340B savings by barring pharmacies from filing insurance claims on insulin or even charging a fee for the cost of administering the drugs."

"As we said after Lilly first announced its refusal to offer 340B discounts for one of its drugs (an action that several other manufacturers closely followed), if the administration will not use its authority to enforce the law, we will pursue all legislative and legal avenues available to us to defend the safety net."

Contact: Richard Sorian at richard.sorian@340bhealth.org or 202-536-2285.

340B Health is a nonprofit membership organization of more than 1,400 public and private non-profit hospitals and health systems throughout the U.S. that participate in the 340B drug pricing program. We are the leading advocate and resource for those hospitals who serve their communities through participation in 340B.

CONNECT WITH 340B HEALTH

https://www.linkedin.com/company/340b-health?trk=company_logo

https://www.facebook.com/340BHealth

http://twitter.com/340BHealth

http://www.youtube.com/snhpa

info@340bhealth.org

202-552-5850

Exhibit G

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware St
Indianapolis, IN 46225,

and

LILLY USA, LLC,
1500 South Harding St
Indianapolis, IN 46221,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services
Office of the Secretary
200 Independence Avenue, SW
Washington, DC 20201,

ROBERT P. CHARROW, in his official capacity as General Counsel of Health & Human Services
Office of the General Counsel
200 Independence Avenue, S.W.
Washington, D.C. 20201,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington D.C. 20201,

THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20852,

and

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20852,

No. 1:21-cv-81-SEB-MJD

Defendants.

DECLARATION OF DEREK L. ASAY

I, Derek L. Asay, declare and state as follows:

1. I am Senior Director, Government Strategy, Federal Accounts and Quality at Eli Lilly and Company ("Lilly").

2. Since Lilly announced its 340B distribution plan in July 2020, hundreds of covered entities have threatened legal action against Lilly.

3. Many of those threats have come in the form of letters emailed to an inbox Lilly set up for questions or concerns about Lilly's 340B distribution program, 340B@lilly.com, to which I have access.

4. Those threats include the following examples, among many others.

5. On September 28, 2020, law firm Hall, Render, Killian, Heath & Lyman, P.C. sent a letter to the 340B@lilly.com address, stating that "this dispute may also implicate administrative and private rights of action, and our Clients reserve all rights to pursue such actions," threatening to ask HRSA to "impose the maximum civil penalty," and "reserv[ing] the right to purse all other remedies available to our Clients." *See* Ex. 1. The letter purported to be on behalf of a list of 168 covered entities. *Id.*

6. On October 23, 2020, law firm Reed, Claymon, Meeker & Hargett, PLLC wrote on behalf of Comanche County Medical Center, "reserv[ing] all legal rights and remedies available to it." *See* Ex. 2.

7. On October 30, 2020, law firm Polsinelli sent a letter on behalf of covered entities University of Washington Medical Center and Harborview Medical Center, stating that "[i]f Lilly does not respond to our good faith efforts to resolve these disputes in a timely manner, and in any

event does not rescind its unlawful policy by November 30, 2020, we will consider our obligations to attempt resolution to be satisfied and proceed to filing a complaint with HRSA." *See* Ex. 3.

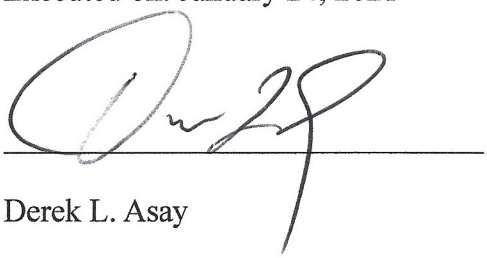
8. On December 18, 2020, the law firm Hall, Render, Killian, Heath & Lyman, P.C. sent another letter to the 340B@lilly.com address, stating that it "now represent[ed] additional Covered entities." *See* Ex. 4. The law firm now purported to act on behalf of 226 covered entities. *Id.*

9. On January 6, 2021, Polsinelli wrote again on behalf of those same entities, referring to the December 30, 2020 "Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program" and stating that "[i]t is UW Medicine Hospitals' intent to seek reimbursement of these losses through administrative action, including applicable fees and costs, should you not reverse your policy." *See* Ex. 5.

10. On January 19, 2021, the Jamestown S'Klallam Tribe sent a "Demand Letter" that invokes the December 30, 2020 Advisory Opinion in support of its claim that "[m]anufacturers are required to provide 340B pricing at all contract pharmacies, and failure to do so could subject them to civil and monetary penalties and other legal action." *See* Ex. 6.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: January 24, 2021



Derek L. Asay

Exhibit 1

HALL RENDER
KILLIAN HEATH & LYMAN

Hall, Render, Killian, Heath & Lyman, P.C.
330 East Kilbourn Avenue, Suite 1250
Milwaukee, WI 53202
https://www.hallrender.com

Todd A. Nova
(414) 721-0464
tnova@hallrender.com

September 28, 2020

Via Certified Mail and E-Mail

Rachel Cramer
Government Pricing Analyst
Eli Lilly and Company
Corporate Center
Indianapolis, IN 46285
340B@LILLY.com

RE: Illegal and Discriminatory 340B Limited Distribution Model

Dear Ms. Cramer:

We represent the 340B drug discount program ("340B Program") participating covered entities listed in the attached Exhibit A ("Clients" or "Covered Entities"). Together, these organizations utilize 340B Program savings to make available vital safety-net care directly affecting the lives of millions of our country's most vulnerable patients. As you are aware, the United States Health Resources and Services Administration ("HRSA") Office of Pharmacy Affairs ("OPA") has a longstanding process for resolving disputes between 340B Program covered entities and manufacturers.[1] This letter represents our Clients' good-faith effort to engage in dialogue to reach a mutually acceptable resolution pursuant to that process. We note that this dispute may also implicate administrative and private rights of action, and our Clients reserve all rights to pursue such actions.

Since at least September 1, 2020 Eli Lilly and Company ("Lilly") has refused to make required 340B pricing available to our Clients for prescriptions dispensed to their eligible patients at contracted pharmacy locations.[2] Lilly has stated publicly to HRSA OPA that it will only ship 340B drugs to a Covered Entity's contracted pharmacy if the Covered Entity "do[es] not have an in-house pharmacy." In communications with our Clients, however, Lilly has disconcertingly conditioned eligibility for this limited distribution plan on Covered Entity acceptance of objectionable contractual terms that: i) require Covered Entities to affirmatively forego rights afforded to them under applicable laws governing the 340B Program; and ii) grant additional rights to Lilly not available to it under applicable law. Some of our Clients have attempted in good faith to designate contract pharmacies without agreeing to Lilly's demands to waive their rights, and

[1] *See* 61 Fed. Reg. 65,406, 65,412 (Dec. 12, 1996).

[2] Lilly took similar actions with respect to its drug Cialis beginning on July 1, 2020. The demands in this letter also apply to any amounts owed to our Clients for purchases of Cialis for which Lilly denied 340B pricing.

Lilly has plainly denied their designations on that basis without any offer to discuss these concerns in good faith.

As a bipartisan majority of the U.S. House of Representatives communicated to HHS Secretary Azar, "[t]hese actions are in violation of the statutory requirement that drug companies charge no more than the 340B ceiling price when selling their products to 340B providers."[3] As such, on behalf of each Client, we are writing to demand that Lilly make available 340B pricing for all Lilly NDCs dispensed to Covered Entity 340B eligible patients through their contracted pharmacies, beginning from the date that Lilly unilaterally refused to offer such required pricing, which we believe to be September 1, 2020, and, in the case of Cialis, July 1, 2020.

Lilly has taken this action unilaterally, without explanation, and without identifying any suspected violation on the part of any Client. Lilly caused direct and immediate harm to our Clients and their patients when it refused to ship 340B-eligible drugs to properly enrolled contract pharmacies providing services to Covered Entity patients. Of course, if and to the extent Lilly has any reasonable allegations of noncompliance associated with a Covered Entity's contract pharmacy patients, we would welcome the opportunity to engage in a dialogue to reach a mutually acceptable resolution. Absent any such allegation, we note that we agree with the statement from HHS that False Claims Act liability is "a potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges[.]"[4] As noted above, we reserve the right to take any additional actions available to our Clients in order to enable them to access the 340B Program pricing to which they are entitled and which Lilly has unilaterally, and unreasonably, refused to make available.

More generally, we note that the 340B Program is available only to safety-net providers who, by definition, care for the most medically vulnerable patients and are either non-profit or government-operated providers. Our Clients use the savings from 340B drug sales to expand access to health care in underserved communities, consistent with Congress's intent in establishing the 340B Program. Congress's explicit goal in creating the 340B Program was to protect covered entities against manufacturer price increases, "enabl[ing] these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[5] The 340B Program establishes, as a matter of law, a privileged place for safety-net providers where they are protected from unreasonable manufacturer price hikes.

In the wake of Lilly's refusal to provide 340B pricing to Covered Entities, our Clients have been forced to reassess the viability of crucial safety-net programs. This is especially concerning in light of the financial success Lilly has enjoyed in recent months as noted in the HHS General Counsel Letter. As a direct result of Lilly's unilateral and unlawful action, our Clients may be

[3] Letter from Rep. David B. McKinley et al. to Sec. Azar, Sept. 14, 2020 (hereinafter "Letter from 243 Members of Congress").

[4] Letter to Eli Lilly and Company (Ms. Anat Hakim) from HHS General Counsel Mr. Robert P. Charrow (September 21, 2020) (hereinafter "HHS General Counsel Letter.").

[5] H.R. Rep. No. 102-384, *12.

required to limit hours, close service lines, and otherwise limit the availability of health care services during a pandemic that has wrought havoc on underserved communities. This immediate impact shows just how crucial the 340B Program is to ensuring that our nation's most vulnerable patients receive adequate medical care.

Under its Pharmaceutical Pricing Agreement ("PPA"), Lilly is prohibited from charging Covered Entities a price that exceeds the 340B ceiling prices. Lilly's discriminatory distribution model violates this requirement. To be clear, Lilly was not obligated to execute the PPA. It did so voluntarily in order to make available Medicaid and Medicare Part B reimbursement for its drugs.[6]

Lilly is reported to have deployed the limited distribution model "as a precaution to avoid duplicate discounts that could be offered at [contract] pharmacies."[7] Contract pharmacy arrangements are a legitimate mechanism used by Covered Entities to treat their patients, and their use is founded on soundly reasoned, longstanding agency guidance. As HRSA OPA noted in 1996, "[i]t would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program."[8] Lilly executed its initial PPA in 1998,[9] three years after HRSA proposed,[10] and two years after it finalized,[11] its initial contract pharmacy guidance. Lilly executed its current PPA in 2014,[12] seven years after HRSA proposed,[13] and four years after it finalized,[14] its revised contract pharmacy guidance. Lilly executed the addendum to its PPA in 2018.[15] At each of these junctures, Lilly was aware of HRSA's position with respect to

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[6] 42 U.S.C. § 1396r-8(a)(1).

[7] Maia Anderson, Eli Lilly Stops Giving 340B Discounts to Contract Pharmacies, Becker's Hospital Review (Sept. 3, 2020) (https://www.beckershospitalreview.com/pharmacy/eli-lilly-stops-giving-340b-discounts-to-contract-pharmacies.html) (last accessed Sept. 17, 2020).

[8] 61 Fed. Reg. 43,550 (Aug. 23, 1996).

[9] HRSA OPA, 340B OPAIS Entry for Eli Lilly (Sept. 24, 2020) (available at https://340bopais.hrsa.gov/manufacturerdetails/56774) (last accessed Sept. 24, 2020).

[10] 60 Fed. Reg. 55,586 (Nov. 1, 1995).

[11] 61 Fed. Reg. 43,549 (Aug. 23, 1996).

[12] HRSA OPA, 340B OPAIS Entry for Eli Lilly (Sept. 24, 2020) (available at https://340bopais.hrsa.gov/manufacturerdetails/56774) (last accessed Sept. 24, 2020).

[13] 72 Fed. Reg. 1540 (Jan. 12, 2007).

[14] 75 Fed. Reg. 10,272 (Mar. 5, 2010)

[15] HRSA OPA, 340B OPAIS Entry for Eli Lilly (Sept. 24, 2020) (available at https://340bopais.hrsa.gov/manufacturerdetails/56774) (last accessed Sept. 24, 2020).

contract pharmacy arrangements. If Lilly determines that the costs of participating in the 340B Program outweigh the benefits, it may terminate its PPA at any time upon 60 days' notice.[16]

Neither the 340B Statute nor the PPA permit Lilly to take "precautionary" measures against speculative harms. If Lilly believes that a covered entity has engaged in wrongful conduct, its recourse is through HRSA's audit and dispute resolution process. This audit process, like the 340B Program generally, is designed to protect both covered entities and manufacturers. Manufacturers are not allowed to engage in the kind of self-help that Lilly has implemented. Even where the manufacturer has evidence showing that an identified covered entity has violated the statute, it must continue to sell the entity drugs at 340B prices. "Not until the entity is found guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, will the manufacturers no longer be required to extend the discount."[17] At that time, HRSA can require the covered entity to repay the manufacturer for noncompliant discounts, and may impose civil monetary penalties for egregious conduct.

The power and responsibility to enforce the 340B Statute rest with HRSA, by delegation of the Secretary. As recognized by a bipartisan majority of the U.S. House of Representatives, "[t]here are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts."[18] As such, we believe Lilly's unilateral limitation on 340B Covered Entity contracted pharmacy patient dispensing to be discriminatory and in violation of Lilly's legal obligations.

As a next step, we again request that Lilly reverse its position relative to our Clients and make them whole for any 340B discounts due for prescriptions dispensed to eligible patients beginning as of the date that 340B pricing was terminated, which we believe to be September 1, 2020.[19] If Lilly is unwilling to engage in good-faith efforts with us to resolve these issues, we intend to request that HRSA OPA impose the maximum civil monetary penalty, $5,883, for each instance of overcharging a Covered Entity for 340B drugs.[20] We also reserve the right to pursue all other remedies available to our Clients.

---

[16] HRSA Pharmaceutical Pricing Agreement, § VI(b) (2019).

[17] HRSA Manufacturer Audit Guidelines, 61 Fed. Reg. at 65,408 (Dec. 12, 1996).

[18] Letter from 243 Members of Congress.

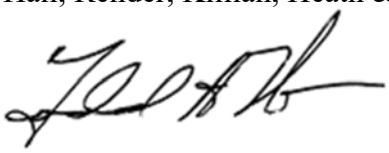
[19] July 1, 2020 for Cialis.

[20] 45 C.F.R. § 102.3; 42 U.S.C. § 256b(d)(1)(B)(vi).

Please reach out to me at tnova@hallrender.com or (414) 721-0464 to respond to our good-faith request to discuss and resolve this issue or with any questions.

Very truly yours,

Hall, Render, Killian, Heath & Lyman, P.C.



Todd A. Nova

cc: RADM Krista Pedley
Elizabeth Elias, Esq.
Daniel Miller, Esq.

Rachel Cramer
September 28, 2020
Exhibit A

EXHIBIT A

Covered Entities

Advocate Christ Medical Center
DSH140208

Advocate Lutheran General Hospital
RRC140223-00

Advocate North Side Health Network
DSH140182

Advocate Trinity Hospital
DSH140048

Alamance Regional Medical Center
DSH340070

Aria Health Jefferson Northeast
DSH390115

Aurora Health Care Central Inc. d/b/a Aurora Sheboygan Memorial Medical Center
DSH520035

Aurora Health Care Metro, Inc.
DSH520138

Baraga County Memorial Hospital
CAH231307

Bixby Medical Center n/k/a Charles and Virginia Hickman Hospital
DSH230005

Bon Secours Maryview Medical Center
DSH490017

Bon Secours Richmond Community Hospital
DSH490094

Centura Health - Avista Adventist Hospital
DSH060103

Children's Hospital of San Antonio
PED453315

Children's Hospital of Wisconsin
PED523300

CHRISTUS Health Central Louisiana d/b/a CHRISTUS Coushatta Health Center
CAH191312

CHRISTUS Hospital
RRC450034

CHRISTUS Jasper Memorial Hospital
DSH450573

CHRISTUS Lake Area Hospital
DSH190201

CHRISTUS Mother Frances Hospital – Tyler
RRC450102

CHRISTUS Santa Rosa Hospital - San Marcos
DSH450272

CHRISTUS Santa Rosa Health System – Santa Rosa Hospital Medical Center
RRC450237

CHRISTUS Spohn Hospital Alice
DSH450828

CHRISTUS Spohn Hospital Beeville
DSH450082

Rachel Cramer
September 28, 2020
Exhibit A

CHRISTUS Spohn Hospital Corpus Christi Memorial
DSH450046

CHRISTUS Spohn Hospital Kleberg
DSH450163

CHRISTUS St. Frances Cabrini Hospital
DSH190019

CHRISTUS St. Michael
DSH450801

CHRISTUS Health Shreveport - Bossier
DSH190041

Clermont Mercy Hospital
DSH360236

Community Health Center of Branch County n/k/a Coldwater Regional Hospital
DSH230022

Cookeville Regional Medical Center
RRC440059-00

Cottage Grove Community Hospital
CAH381301-00

D.W. McMillan Memorial Hospital
DSH010099

Defiance Regional Hospital
CAH361328-00

Dickinson County Healthcare System
SCH230055-00

Ephraim McDowell Regional Medical Center, Inc.
DSH180048

Fisher-Titus Medical Center
RRC360065

Fort Logan Hospital
CAH181315-00

Fostoria Community Hospital
CAH361318-00

Good Samaritan Hospital Corvallis
RRC380014-00

Good Samaritan Regional Health Center
RRC140046-00

Good Shepherd Medical Center - Marshall
DSH450032

Gundersen Lutheran Medical Center, Inc.
DSH520087

Helen Newberry Joy Hospital
CAH231304-00

Herrick Memorial Hospital
CAH231334-00

Holy Rosary Healthcare
CAH271347

HSHS Holy Family Hospital, Inc.
DSH140137

James B. Haggin Memorial Hospital
CAH181302-00

Kennedy University Hospital - New Jersey
DSH310086

Lake View Memorial Hospital Inc.
CAH241308-00

Lee Memorial Health System d/b/a Lee Memorial Hospital
DSH100012

Lutheran Medical Center
DSH060009

Rachel Cramer
September 28, 2020
Exhibit A

Longmont United Hospital
DSH060003

McKenzie Memorial Hospital
CAH231314-00

Memorial Hospital of Boscobel
CAH521344-00

Mercy Allen Hospital
CAH361306-00

Mercy Health - St. Charles Hospital
DSH360081

Mercy Health - St. Vincent Medical Center
DSH360112

Mercy Health Lourdes Hospital LLC
RRC180102-00

Mercy Health-Love County
CAH371306-00

Mercy Health-Marcum & Wallace Hospital, LLC
CAH181301-00

Mercy Hospital - St. Louis
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Mercy Hospital ADA Inc.
DSH370020

Mercy Hospital Ardmore Inc.
SCH370047-00

Mercy Hospital Aurora
CAH261316-00

Mercy Hospital Berryville
CAH041329-00

Mercy Hospital Booneville
CAH041318-00

Mercy Hospital Carthage
CAH261338-00

Mercy Hospital Cassville
CAH261317-00

Mercy Hospital Columbus
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Mercy Hospital Fort Smith
DSH040062

Mercy Hospital Healdton Inc.
CAH371310-00

Mercy Hospital Joplin
DSH260001

Mercy Hospital Kingfisher Inc.
CAH371313-00

Mercy Hospital Lebanon
DSH260059

Mercy Hospital Lincoln
CAH261319-00

Mercy Hospital Logan County
CAH371317-00

Mercy Hospital OKC
RRC370013-00

Mercy Hospital Springfield
DSH260065

Mercy Hospital Tishomingo Inc.
CAH371304-00

Mercy Hospital Watonga Inc.
CAH371302-00

Mercy Memorial Hospital
CAH361312-00

Rachel Cramer
September 28, 2020
Exhibit A

Mercy Regional Medical Center
DSH060013

Mercy St. Francis Hospital
CAH261335-00

Mercy Willard Hospital
CAH361310-00

MidMichigan Medical Center
SCH230222-00

MidMichigan Medical Center - Alpena
DSH230036

MidMichigan Medical Center - Gladwin
CAH231325-00

MidMichigan Medical Center - Gratiot
DSH230030

Molokai General Hospital
CAH121303-00

Monument Health Custer Hospital
CAH431323-00

Monument Health Lead - Deadwood Hospital
CAH431320-00

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Monument Health Spearfish Hospital
SCH430048

Monument Health Sturgis Hospital
CAH431321-00

Mother Frances Hospital – Jacksonville
CAH451319

Mother Frances Hospital – Sulphur Springs – CHRISTUS Hopkins Health Alliance
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Mother Frances Hospital – Winnsboro
CAH451381

Moundview Memorial Hospital and Clinics, Inc.
CAH521309-00

New Hanover Regional Medical Center
DSH340141

Niagara Falls Memorial Medical Center
DSH330065

North Hawaii Community Hospital
DSH120028

Northeast Alabama Regional Medical Center
DSH010078

Northwest Ohio Hemophilia Treatment Center
HM11574

Palmer Lutheran Health Center
CAH161316-00

PeaceHealth d/b/a Ketchikan Medical Center
CAH021311-00

PeaceHealth d/b/a Peace Harbor Medical Center
CAH381316-00

PeaceHealth d/b/a Peace Island Medical Center
CAH501340-00

PeaceHealth Southwest Medical Center
DSH500050

Rachel Cramer
September 28, 2020
Exhibit A

PeaceHealth St. John Medical Center
DSH500041

Penn State –Milton S. Hershey Medical Center
DSH390256

Penrose/St. Francis Healthcare
DSH060031

ProMedica Memorial Hospital
DSH360156

Platte Valley Medical Center
DSH060004

Raphael Health Center, Inc.
CH0514720

Rappahannock General Hospital
CAH491308-00

Regional One Health
DSH440152

Ripon Medical Center, Inc.
CAH521321-00

St. Mary's Hospital and Medical Center
HV00593

Sanford Bagley Medical Center
CAH241328-00

Sanford Bemidji Medical Center
DSH240100

Sanford Bismarck
DSH350015

Sanford Canton - Inwood Medical Center
CAH431333-00

Sanford Clinic Brookings
FP572012

Sanford Clinic Watertown
FP572011

Sanford Health Network d/b/a Sanford Canby Medical Center
CAH241347-00

Sanford Health Network d/b/a Sanford Chamberlain Medical Center
CAH431329-00

Sanford Health Network d/b/a Sanford Medical Center Clear Lake
CAH431307-00

Sanford Health Physicians Partners
FP571057

Sanford Health Westbrook Medical Center
CAH241302-00

Sanford Hillsboro
CAH351329-00

Sanford Hospital Webster
CAH431311-00

Sanford Jackson Medical Center
CAH241315-00

Sanford Medical Center Fargo
DSH350011 + HM10193

Sanford Medical Center Luverne
CAH241371-00

Sanford Medical Center Mayville
CAH351309-00

Sanford Medical Center Wheaton
CAH241304-00

Sanford Sheldon Medical Center
CAH161381-00

Rachel Cramer
September 28, 2020
Exhibit A

Sanford Thief River Falls
CAH241381-00

Sanford Tracy Medical Center
CAH241303-00

Sanford USB Medical Center Sioux Falls
HM57117

Sanford USD Medical Center
DSH430027

Sanford Vermillion Medical Center
CAH431336-00

Sanford Worthington Medical Center
DSH240022

Schneck Medical Center
DSH150065

Sedgwick County Hospital & Nursing Home
CAH061310-00

Shawnee Health Service and Development Corporation
CH050040

St. James Healthcare
SCH270017

Saint Joseph Hospital
DSH060028

St. Mary's Hospital and Medical Center Inc.
DSH060023

South Suburban Hospital
RRC140250-00

Spectrum Health Big Rapids Hospital
SCH230093-00

Spectrum Health Gerber
CAH231338-00

Spectrum Health Hospitals
HM935

Spectrum Health Hospitals
DSH230038

Spectrum Health Ludington
SCH230110-00

Spectrum Health Pennock Hospital
CAH231339-00

Spectrum Health Reed City Hospital
CAH231323-00

Spectrum Health United Hospital
DSH230035

Springfield Regional Medical Center
DSH360086

SSM Cardinal Glennon Children's Medical Center
HM13100

SSM DePaul Health Center
DSH260104

SSM Health Saint Louis University Hospital
DSH260105

SSM St. Anthony Hospital
DSH370037

SSM St. Joseph Health Center
DSH260005

SSM St. Mary's Health Center
DSH260091

St. Anthony North Health Campus
DSH060104

Exhibit 2

Reed + Clayman

Robert L. Spurck
Member
Board Certified, Health Law
Texas Board of Legal Specialization

512 660 5964 direct
rspurck@rcmhlaw.com

October 23, 2020

VIA EMAIL
Eli Lilly
340B@lilly.com

Re: 340B Drug Discount Program ("340B Program")

To Whom it May Concern:

Comanche County Medical Center ("CCMC"), a critical access hospital located in Comanche, Texas, is in receipt of your correspondence regarding your decision to no longer provide some 340B pricing to covered entity contract pharmacies.

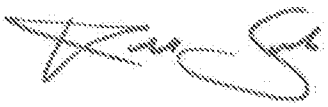
We respectfully ask that you reconsider this decision. As you know, the 340B statute requires manufacturers that participate in the Medicaid program to enter into agreements with the Department of Health and Human Services (HHS) that "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." Further, there is no statutory provision allowing manufacturers to deny 340B pricing to eligible hospitals for any drug. In addition, 340B Program guidance states that, "[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price."

Like many other rural hospitals, CCMC uses contract pharmacies to improve access to 340B drugs for vulnerable communities served by CCMC and the 340B program. Contract pharmacies expand access to affordable health care services for everyone in these vulnerable communities and the financial relief provided to CCMC from the exorbitant drug prices it would otherwise have to pay help keep CCMC operating and to stretch its resources to serve more patients and offer more comprehensive services.

To the extent that you cut off or limit 340B pricing for drugs dispensed through contract pharmacies you are denying access to affordable health care in these vulnerable communities and jeopardizing operations of rural hospitals.

Accordingly, CCMC respectfully requests that you reconsider your decision to no longer provide some 340B pricing to covered entity contract pharmacies. CCMC reserves all legal rights and remedies available to it as a result of this unilateral conduct.

Sincerely,



Robert L. Spurck

Exhibit 3

POLSINELLI

1000 Second Avenue, Suite 3500, Seattle, WA 98104 · (206) 393-5400

November 19, 2020

Jessica M. Andrade
Shareholder
206.393.5422
206.299.9423 Fax
jessica.andrade@polsinelli.com

Via Email

Derek Asay
Senior Director, Government Strategy, Federal Accounts & Quality
asay_derek_l@lilly.com
Heather Dixson
Director, Government Price Reporting
dixson_heather_a@lilly.com
Eli Lilly & Company

Re: Eli Lilly Proposed Form Demanding Waiver of Statutory Claims in Exchange for 340B Pricing

Dear Mr. Asay and Ms. Dixson:

On behalf of University of Washington Medical Center ("UWMC") and Harborview Medical Center ("HMC") (collectively, "UW Medicine Hospitals"), we write to discuss the "Eli Lilly and Company 340B Limited Distribution Exception for Wholly Owned Contract Pharmacies" form provided on October 9, 2020, and the revised version of the same form provided on November 12, 2020.

We appreciate that the revised form you sent does away with the previous version's requirements that: (1) UW Medicine Hospitals make a statement that Lilly (or other manufacturers) are not obligated to provide 340B prices to community contract pharmacies, regardless of ownership, and that Lilly's provision of such prices to UW Medicine Hospitals' wholly-owned pharmacies is "discretionary;" and (2) that UW Medicine Hospitals affirm that its wholly-owned pharmacies are owned by the same exact entity registered as a covered entity.

These changes do not, however, make the form lawful under the 340B statute. The form still includes multiple inappropriate requirements, including that UW Medicine Hospitals:

- Agree to the inappropriate characterization of application of 340B pricing to wholly-owned contract pharmacies as an "exception";
- Notify Lilly within one business day of any change in ownership of any UW Medicine Hospitals pharmacy;

POLSINELLI

- Acknowledge that Lilly's application of 340B pricing to wholly-owned pharmacies would only occur after signing, and would not be retroactive;
- Acknowledge and agree that it must comply with all requirements of the form;
- Make unnecessary written acknowledgement of 340B program laws and regulations regarding reporting of discounts and audits;
- Agree that Lilly may invoice, and hospitals must pay within 30 days, for any discounts that Lilly, in its discretion, determines to be in "error"; and
- Make unnecessary written acknowledgement of Lilly's legal position.

As articulated in our September 15, 2020 letter to Lilly CEO David A. Ricks,[1] Lilly has no legal authority to limit 340B discounts to drugs dispensed through different UW Medicine Hospitals' pharmacies. This includes in-house pharmacies, wholly-owned pharmacies, and community pharmacies—regardless of any designation as "contract" in the OPAIS database. Lilly's demand that UW Medicine Hospitals sign its proposed form expands the impact of its previously-stated policy beyond just community contract pharmacies, and exposes Lilly to further penalties under the 340B statute. Indeed, guidance issued by HHS specifically contemplates that a manufacturers' conditioning of the sale of covered outpatient drugs to a covered entity "on the entity's provision of assurances or other compliance with the manufacturers' requirements that are based upon section 340B provisions," is improper.[2]

Furthermore, the form's requirement that UW Medicine Hospitals certify that the covered entity and pharmacy are "wholly-owned by the same common parent entity" ignores the complexity that often exists in health care systems. Covered entity HMC, a county-owned hospital that is operated by UW Medicine through legislative authorization, obviously would not have the same parent entity as UW Medicine Hospitals-owned pharmacies. This is just another example of how Lilly's unlawful form puts inappropriate requirements on participation in the 340B program, which have no basis in statute or regulations.

UW Medicine Hospitals cannot and will not participate in such unlawful circumvention of the purposes of the 340B program and expansion of risk that does not rightfully belong with UW Medicine Hospitals. We urge Lilly to retract its unlawful form. Further, we urge Lilly to honor

[1] We enclose this prior letter for reference.
[2] Health Resources and Services Administration Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406, 65412 (Dec. 12, 1996).

POLSINELLI

340B discounts on drugs dispensed through all UW Medicine Hospitals' pharmacies, including wholly-owned, and community pharmacies, regardless of designation. It bears repeating that Lilly's implementation of this unlawful policy while UW Medicine Hospitals and other covered entities struggle to marshal resources to fight COVID-19 is unconscionable. *See also* September 21, 2020 Letter of Robert Charrow, General Counsel to HHS (noting Lilly's dramatic profits compared to the sharp impacts its policy has on covered entities fighting the global pandemic).

As with our previous correspondence of September 15, 2020, this letter constitutes UW Medicine Hospitals' good faith effort to resolve the dispute created by Lilly's multiple unlawful actions. Lilly has thus far failed to respond to our September 15th letter, and engaged in an over month-long delay in revising the unnecessary form it is setting as an unlawful precondition to 340B program benefits. If Lilly does not respond to our good faith efforts to resolve these disputes in a timely manner, and in any event does not rescind its unlawful policy by November 30, 2020, we will consider our obligations to attempt resolution to be satisfied and proceed to filing a complaint with HRSA.[3]

Sincerely,

Jessica Andrade

Jessica M. Andrade

JMA:jlb

Enclosure

cc: Jill Simatic
Market Manager, Integrated Health-PNW
Managed Healthcare Services
Lilly USA, LLC
Email: Simatic_Jill@lilly.com

[3] *Id.*

Exhibit 4

HALL RENDER
KILLIAN HEATH & LYMAN

Hall, Render, Killian, Heath & Lyman, P.C.
330 East Kilbourn Avenue, Suite 1250
Milwaukee, WI 53202
https://www.hallrender.com

Todd A. Nova
(414) 721-0464
tnova@hallrender.com

December 18, 2020

Via Certified Mail and E-Mail

Rachel Cramer
Government Pricing Analyst
Eli Lilly and Company
Corporate Center
Indianapolis, IN 46285
340B@LILLY.com

RE: Illegal and Discriminatory 340B Limited Distribution Model: Additional Covered Entities

Dear Ms. Cramer:

We sent your company letters on September 28, 2020, September 30, 2020, October 2, 2020 and October 16, 2020 advising you of our representation of certain Covered Entities. The purpose of this letter is to inform you that we now represent additional Covered Entities. Exhibit A to those letters has been revised to reflect those additional entities as of today's date and is attached hereto.

Please reach out to me at tnova@hallrender.com or (414) 721-0464 to respond to our good-faith request to discuss and resolve this issue or with any questions.

Very truly yours,

Hall, Render, Killian, Heath & Lyman, P.C.

Todd A. Nova

cc: RADM Krista Pedley
Derek L. Asay
Elizabeth Elias, Esq.
Daniel Miller, Esq.

EXHIBIT A

Covered Entities

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DSH140208

Advocate Lutheran General Hospital
RRC140223-00

Advocate North Side Health Network
DSH140182

Advocate Trinity Hospital
DSH140048

Alamance Regional Medical Center
DSH340070

Aria Health Jefferson Northeast
DSH390115

Aurora Health Care Central Inc. d/b/a Aurora Sheboygan Memorial Medical Center
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Aurora Health Care Metro, Inc.
DSH520138

Baraga County Memorial Hospital
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Bixby Medical Center n/k/a Charles and Virginia Hickman Hospital
DSH230005

Bon Secours Maryview Medical Center
DSH490017

Bon Secours Richmond Community Hospital
DSH490094

Cardeza Hemophilia Treatment Center
HM1270

Centura Health - Avista Adventist Hospital
DSH060103

Children's Hospital of San Antonio
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Children's Hospital of Wisconsin
PED523300

Children's National Hemophilia Care
HM20010

Children's National Medical Center
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CHRISTUS Health Central Louisiana d/b/a CHRISTUS Coushatta Health Center
CAH191312

CHRISTUS Hospital
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CHRISTUS Jasper Memorial Hospital
DSH450573

CHRISTUS Lake Area Hospital
DSH190201

CHRISTUS Mother Frances Hospital – Tyler
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CHRISTUS Santa Rosa Hospital - San Marcos
DSH450272

CHRISTUS Santa Rosa Health System – Santa Rosa Hospital Medical Center
RRC450237

CHRISTUS Spohn Hospital Alice
DSH450828

CHRISTUS Spohn Hospital Beeville
DSH450082

CHRISTUS Spohn Hospital Corpus Christi Memorial
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CHRISTUS Spohn Hospital Kleberg
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CHRISTUS St. Frances Cabrini Hospital
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CHRISTUS St. Michael
DSH450801

CHRISTUS Health Shreveport - Bossier
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Clara Maass Medical Center
DSH310009

Clermont Mercy Hospital
DSH360236

Community Health Center of Branch County n/k/a Coldwater Regional Hospital
DSH230022

Cookeville Regional Medical Center
RRC440059-00

Cottage Grove Community Hospital
CAH381301-00

Defiance Regional Hospital
CAH361328-00

Dickenson Community Hospital
CAH491303-00

Dickinson County Healthcare System
SCH230055-00

Door County Memorial Hospital
CAH521358-00

Eaton Rapids Medical Center
CAH231324-00

Ephraim McDowell Regional Medical Center, Inc.
DSH180048

Fisher-Titus Medical Center
RRC360065

Fort Logan Hospital
CAH181315-00

Fostoria Community Hospital
CAH361318-00

Franklin Woods Community Hospital
DSH440184

Good Samaritan Hospital Corvallis
RRC380014-00

Good Samaritan Regional Health Center
RRC140046-00

Good Shepherd Medical Center - Marshall
DSH450032

Greeneville Community Hospital
DSH440050

Gundersen Lutheran Medical Center, Inc.
DSH520087

Hancock County Hospital
CAH441313

Harbor Beach Community Hospital, Inc.
CAH231313-00

Helen Newberry Joy Hospital
CAH231304-00

Herrick Memorial Hospital
CAH231334-00

Holston Valley Medical Center
RRC440017

Holy Rosary Healthcare
CAH271347

HSHS Holy Family Hospital, Inc.
DSH140137

Indian Path Community Hospital
DSH440176

James B. Haggin Memorial Hospital
CAH181302-00

Jersey City Medical Center, Inc.
DSH310074

Johnson City Medical Center
DSH440063

Johnson County Community Hospital
CAH441304-00

Kennedy University Hospital - New Jersey
DSH310086

Lake View Memorial Hospital Inc.
CAH241308-00

Lee Memorial Health System d/b/a Lee Memorial Hospital
DSH100012

Lonesome Pine Hospital
DSH490114

Lutheran Medical Center
DSH060009

Longmont United Hospital
DSH060003

McKenzie Memorial Hospital
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Memorial Hospital of Boscobel
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DSH360081

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DSH360112

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DSH180102

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DSH040062

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Mercy Hospital Joplin
DSH260001

Mercy Hospital Kingfisher Inc.
CAH371313-00

Mercy Hospital Lebanon
DSH260059

Mercy Hospital Lincoln
CAH261319-00

Mercy Hospital Logan County
CAH371317-00

Mercy Hospital OKC
RRC370013-00

Mercy Hospital Springfield
DSH260065

Mercy Hospital Tishomingo Inc.
CAH371304-00

Mercy Hospital Watonga Inc.
CAH371302-00

Mercy Memorial Hospital
CAH361312-00

Mercy Regional Medical Center
DSH060013

Mercy St. Francis Hospital
CAH261335-00

Mercy Willard Hospital
CAH361310-00

MidMichigan Medical Center
SCH230222-00

MidMichigan Medical Center - Alpena
DSH230036

MidMichigan Medical Center - Gladwin
CAH231325-00

MidMichigan Medical Center - Gratiot
DSH230030

Molokai General Hospital
CAH121303-00

Monmouth Medical Center, Inc.
DSH310075

Monmouth Medical Center, Inc. d/b/a Monmouth Medical Center Southern Campus
DSH310084

Monument Health Custer Hospital
CAH431323-00

Monument Health Lead - Deadwood Hospital
CAH431320-00

Monument Health Rapid City Hospital
DSH430077

Monument Health Spearfish Hospital
SCH430048

Monument Health Sturgis Hospital
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Mother Frances Hospital – Jacksonville
CAH451319

Mother Frances Hospital – Sulphur Springs – CHRISTUS Hopkins Health Alliance
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Mother Frances Hospital – Winnsboro
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DSH340141

Newark Beth Israel Medical Center, Inc.
DSH310002

Niagara Falls Memorial Medical Center
DSH330065

North Hawaii Community Hospital
DSH120028

Northeast Alabama Regional Medical Center
DSH010078

Northwest Ohio Hemophilia Treatment Center
HM11574

Norton Community Hospital
DSH490001

Palmer Lutheran Health Center
CAH161316-00

PeaceHealth d/b/a Ketchikan Medical Center
CAH021311-00

PeaceHealth d/b/a Peace Harbor Medical Center
CAH381316-00

PeaceHealth d/b/a Peace Island Medical Center
CAH501340-00

PeaceHealth Southwest Medical Center
DSH500050

PeaceHealth St. John Medical Center
DSH500041

Penn State –Milton S. Hershey Medical Center
DSH390256

Penrose/St. Francis Healthcare
DSH060031

ProMedica Memorial Hospital
DSH360156

Platte Valley Medical Center
DSH060004

Raphael Health Center, Inc.
CH0514720

Rappahannock General Hospital
CAH491308-00

Regional One Health
DSH440152

Ripon Medical Center, Inc.
CAH521321-00

Robert Wood Johnson University Hospital, Inc.
DSH310038

Russell County Hospital
DSH490002

St. Mary's Hospital and Medical Center
HV00593

Sanford Bagley Medical Center
CAH241328-00

Sanford Bemidji Medical Center
DSH240100

Sanford Bismarck
DSH350015

Sanford Canton - Inwood Medical Center
CAH431333-00

Sanford Clinic Brookings
FP572012

Sanford Clinic Watertown
FP572011

Sanford Health Network d/b/a Sanford Canby Medical Center
CAH241347-00

Sanford Health Network d/b/a Sanford Chamberlain Medical Center
CAH431329-00

Sanford Health Network d/b/a Sanford Medical Center Clear Lake
CAH431307-00

Sanford Health Physicians Partners
FP571057

Sanford Health Westbrook Medical Center
CAH241302-00

Sanford Hillsboro
CAH351329-00

Sanford Hospital Webster
CAH431311-00

Sanford Jackson Medical Center
CAH241315-00

Sanford Medical Center Fargo
DSH350011 + HM10193

Sanford Medical Center Luverne
CAH241371-00

Sanford Medical Center Mayville
CAH351309-00

Sanford Medical Center Wheaton
CAH241304-00

Sanford Sheldon Medical Center
CAH161381-00

Sanford Thief River Falls
CAH241381-00

Sanford Tracy Medical Center
CAH241303-00

Sanford USB Medical Center Sioux Falls
HM57117

Sanford USD Medical Center
DSH430027

Sanford Vermillion Medical Center
CAH431336-00

Sanford Worthington Medical Center
DSH240022

Schneck Medical Center
DSH150065

Sedgwick County Hospital & Nursing Home
CAH061310-00

Shawnee Health Service and Development Corporation
CH050040

St. James Healthcare
SCH270017

Saint Joseph Hospital
DSH060028

St. Mary's Hospital and Medical Center Inc.
DSH060023

South Suburban Hospital
RRC140250-00

Spectrum Health Big Rapids Hospital
SCH230093-00

Spectrum Health Gerber
CAH231338-00

Spectrum Health Hospitals
HM935

Spectrum Health Hospitals
DSH230038

Spectrum Health Ludington
SCH230110-00

Spectrum Health Pennock Hospital
CAH231339-00

Spectrum Health Reed City Hospital
CAH231323-00

Spectrum Health United Hospital
DSH230035

Springfield Regional Medical Center
DSH360086

SSM Cardinal Glennon Children's Medical Center
HM13100

SSM DePaul Health Center
DSH260104

SSM Health Saint Louis University Hospital
DSH260105

SSM St. Anthony Hospital
DSH370037

SSM St. Joseph Health Center
DSH260005

SSM St. Mary's Health Center
DSH260091

St. Anthony North Health Campus
DSH060104

St. Anthony Shawnee Hospital
DSH370149

St. Anthony Summit Medical Center
DSH060118

St. Catherine Hospital
SCH170023-00

St. Elizabeth Boardman Health Center
DSH360276

St. Elizabeth Health Center
RRC360064-00

St. Elizabeth's Hospital of Wabasha, Inc.
CAH241335-00

St. Joseph Health Center
DSH360161

St. Joseph Medical Center
RRC390096

St. Joseph's Health Services, Inc. dba St. Joseph's Health Services-Gundersen
CAH521304-00

St. Luke's Hospital of Duluth
DSH240047

St. Mary-Corwin Medical Center
DSH060012

St. Mary's Hospital, Centralia, Illinois
RRC140034-00

St. Ritas Medical Center LLC
DSH360066

St. Thomas More Hospital
CAH061344-00

St. Vincent Hospital of the Hospital Sisters of the Third Order of St. Francis
DSH520075

St. Vincent Hospital
DSH320002

St. Vincent Healthcare
DSH270049

Sullivan County Community Hospital
CAH151327-00

The Moses H. Cone Memorial Hospital Operating Corporation
DSH340091

The Queen's Medical Center
DSH120001

The Toledo Hospital
DSH360068

ThedaCare Medical Center Berlin, Inc.
CAH521355-00

ThedaCare Medical Center - New London, Inc.
CAH521326-00

ThedaCare Medical Center Shawano, Inc.
CAH521346-00

ThedaCare Medical Center – Waupaca
CAH521334-00

ThedaCare Medical Center Wild Rose, Inc.
CAH521303-00

Thomas Jefferson University Hospitals
DSH390174

Tri-County Memorial Hospital, Inc.
CAH521316-00

Twin Lakes Regional Medical Center
DSH180070

United General Medical Center
CAH501329-00

University of Connecticut Health Center
RWI06030

University of Connecticut Hemophilia Treatment Center
HM06030

University of Toledo Medical Center
DSH360048

Waupun Memorial Hospital
CAH521327-00

Wayne County Hospital, Inc.
CAH181321-00

West Allis Memorial Hospital Inc. d/b/a Aurora West Allis Medical Center
DSH520139

Exhibit 5

POLSINELLI

1000 Second Avenue, Suite 3500, Seattle, WA 98104 • (206) 393-5400

January 6, 2021

Jessica M. Andrade
206.393.5422
206.299.9423 Fax
jessica.andrade@polsinelli.com

Via Email

Eli Lilly & Company
340B@lilly.com

Derek Asay
Senior Director, Government Strategy, Federal Accounts & Quality
asay_derek_l@lilly.com

Heather Dixson
Director, Government Price Reporting
dixson_heather_a@lilly.com

Re: **HHS Advisory Opinion 20-06**

Dear Mr. Asay and Ms. Dixson:

On behalf of University of Washington Medical Center ("UWMC") and Harborview Medical Center ("HMC") (collectively, "UW Medicine Hospitals"), we write with regard to your continued policies unlawfully restricting covered entities' ability to purchase covered outpatient drugs at 340B prices through contract pharmacies. UW Medicine Hospitals have previously reached out with regard to the unlawfulness of your policy, under both statutory and regulatory provisions, and the negative impact your policy is having on UW Medicine Hospitals and their patients, especially during the fight against COVID-19.

Since the time of our original correspondence, the Department of Health and Human Services ("HHS") has issued Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program.[1] This Advisory Opinion makes clear, as UW Medicine Hospitals' previous correspondence has explained, 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." Further, the Advisory Opinion outlines that the statutory language, the Pharmaceutical Pricing Agreement ("PPA"), and the purpose and the history of the 340B Program all support this conclusion. In light of the Advisory Opinion your continued denial

[1] *Available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

POLSINELLI

of 340B pricing puts Lilly's PPA and reimbursement under the Medicaid and Medicare Part B programs at risk, and subjects Lilly to civil monetary penalties for each overcharge or denied purchase.

Given the Advisory Opinion and the numerous other indications from both government and industry authorities that your policy with regard to contract pharmacies is unlawful and harmful to covered entities, we ask that you revoke your policy effective immediately. We also ask that you reverse any transactions where you have charged UW Medicine Hospitals above the applicable ceiling price for 340B covered outpatient drugs, and compensate UW Medicine Hospitals for its losses otherwise incurred in being blocked from purchasing covered outpatient drugs at 340B pricing through its contract pharmacies.

It is UW Medicine Hospitals' intent to seek reimbursement of these losses through administrative action, including applicable fees and costs, should you not reverse your policy. Given the negative impacts of your policy and the need to seek administrative relief, we would appreciate your swift response by January 14, 2021.

Sincerely,

Jessica Andrade

Jessica M. Andrade

JMA:jma

Exhibit 6

JAMESTOWN S'KLALLAM TRIBE
1033 Old Blyn Highway, Sequim, WA 98382 360/683-1109 FAX 360/681-4643

January 19, 2021

Eli Lilly and Company
893 Delaware Street
Indianapolis, IN 46225 340B@Lilly.com

Re: Jamestown S'Klallam Tribe Demand Letter Regarding 340B Access and Repayment

To Whom It May Concern:

On behalf of the Jamestown S'Klallam Tribe (Tribe), I write to request that Eli Lilly immediately resume providing 340B Program pricing at the Tribe's contract pharmacies and repay amounts that Eli Lilly has overcharged the Tribe. Since September 1, 2020, Eli Lilly has restricted access to the 340B Program by charging higher than the ceiling price at the Tribe's contract pharmacies. This restriction of 340B access is illegal, as recognized by the Department of Health and Human Services (HHS) Office of General Counsel (OGC) Advisory Opinion 20-06.[1] Additionally, Eli Lilly has an obligation to repay all amounts it has overcharged the Tribe as a result of this illegal restriction.

Importance of 340B Access and Contract Pharmacies to the Tribe

The Tribe and the patients it serves depend on the 340B Program for access to important medications. As you may be aware, despite treaty and trust obligations to provide for Indian health care, the federal government only funds the Indian health system at approximately 60 percent of need, making it the most underfunded federal health care program. Because of this reality, we depend on various protections in law that assist us in maximizing limited resources in order to serve our patients. One such important protection is access to the 340B Program, which Congress created with the intent "to stretch scarce Federal resources as far as possible."[2] Every dollar we save due to 340B discount pricing is put toward meeting the Tribe's patient care needs.

The Tribe relies on contract pharmacies to deliver 340B drugs to its patients. Each pharmacy that the Tribe contracts with is an agent of the Tribe for the purposes of the 340B Program,[3] and these contract pharmacies are essential to getting much-needed medications into the hands of the Tribe's patients.

Illegal Restriction of 340B Access

Eli Lilly's restriction of 340B access violates the company's statutory obligations and leaves it vulnerable to civil and monetary penalties as well as other legal action.

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[1] HHS OGC, Advisory Op. 20-06, *On Contract Pharmacies Under the 340B Program* (Dec. 30, 2020) [hereinafter "Advisory Op. 20-06"], https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

[2] H.R. Rep. No. 102-384, Pt. 2 at 12 (1992).

[3] See Advisory Op. 20-06 at 6.

The 340B program is governed by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, and it requires drug manufacturers to participate in the 340B drug discount program for the manufacturers to receive payment for their outpatient drugs from Medicaid or Part B of Medicare. The statute requires the Secretary of Health and Human Services (HHS) to enter into a rebate agreement with each manufacturer of covered outpatient drugs. The rebate agreement must require the manufacturer to offer each covered entity covered outpatient drugs for purchase at or below the applicable discount ceiling price.

Since its inception, the 340B Program has relied on the existence of contract pharmacy arrangements to achieve its objectives,[4] and the Health Resources and Services Administration (HRSA) long ago published guidelines in the Federal Register approving the purchase of drugs by covered entities for shipment to a contract pharmacy. See, 61 Fed. Reg. 43549 (Aug. 23, 1996). HRSA issued final guidance in 2010 allowing covered entities to use multiple contract pharmacies. 75 Fed. Reg. 10272, 10274–10278 (Mar. 5, 2010).

HHS OGC concluded in Advisory Opinion 20-06, "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients."[5] HHS OGC based this conclusion on the plain language of Section 340B, which requires 340B pricing to be provided for covered drugs "purchased by a covered entity" and places no restriction on where such drugs may be delivered.[6] HHS OGC specifically found that "the situs of delivery … is irrelevant."[7]

Eli Lilly's Single Contract Pharmacy Exception is Insufficient

Even after HHS OGC's Advisory Opinion made it clear that Eli Lilly's restriction of 340B access is illegal, Eli Lilly sent the Tribe a request to select a single contract pharmacy. Eli Lilly is obligated under law to immediately resume shipment of 340B drugs to all of the Tribe's contract pharmacies. It is not permitted to insist that the Tribe choose only one pharmacy.

HHS OGC stated in Advisory Opinion 20-06 that "neither the agency nor a private actor is authorized by section 340B to add requirements to the statute."[8] Thus, manufacturers may not add to the statute a requirement that only a single contract pharmacy arrangement will be honored under the 340B Program. Manufacturers are required to provide 340B pricing at all contract pharmacies, and failure to do so could subject them to civil and monetary penalties and other legal action.

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[4] Advisory Op. 20-06 at 3–4.

[5] *Id.* at 8.

[6] *Id.* at 2 ("This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs.").

[7] *Id.* at 3.

[8] *Id.* at 2.

Repayment of Overcharges

Eli Lilly is additionally required to repay the Tribe for the amounts it has overcharged the Tribe by refusing to provide 340B pricing to the Tribe's contract pharmacies since September 1, 2020. The Tribe requests that Eli Lilly immediately remit the amount of these illegal overcharges to the Tribe.

HRSA has previously stated that "manufacturers are required to issue refunds if it is determined that a covered entity paid a price higher than the 340B ceiling price."[9] Further, "[i]f a manufacturer refuses to refund covered entities after it has been determined covered entities were overcharged … that could meet the knowingly and intentionally standard to apply a civil monetary penalty."[10]

Conclusion

The Tribe requests that Eli Lilly immediately resume providing 340B access to all of the Tribe's contract pharmacies and repay the Tribe the amounts the company has overcharged the Tribe for 340B covered drugs since September 1, 2020.

Sincerely,

W. Ron Allen, Chairman/CEO

Cc: National Congress of American Indians (NCAI)
National Indian Health Board (NIHB)
Portland Area Indian Health Board (PAIHB)
American Indian Health Commission (AIHC)

[9] 83 Fed. Reg. 1210, 1219 (Jan. 5, 2017).
[10] *Id.* at 1218.