21-3128, 21-3405

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ELI LILLY AND COMPANY and LILLY USA, LLC,

Plaintiffs-appellants–cross-appellees,

v.

XAVIER BECERRA, et al.,

Defendants-appellees–cross-appellants.

On Appeal from the United States District Court
for the Southern District of Indiana,
No. 21-81 (Barker, J.).

PRINCIPAL AND RESPONSE BRIEF FOR THE FEDERAL DEFENDANTS

SARAH E. HARRINGTON
Deputy Assistant Attorney General

ZACHARY A. MYERS
United States Attorney

ALISA B. KLEIN
DANIEL AGUILAR
(202) 514-5432
Attorneys, Appellate Staff
Civil Division
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes:

Rules and Regulations:

Other:

INTRODUCTION

Under Section 340B of the Public Health Service Act, as amended by the Patient Protection and Affordable Care Act (ACA or Affordable Care Act), drug manufacturers that choose to be reimbursed under Medicaid or Medicare Part B are subject to an unqualified statutory requirement. They must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). Congress considered but declined to enact a provision that would have confined these price discounts to covered entities that dispense drugs through in-house pharmacies. From the inception of the 340B Program, covered entities have relied on outside pharmacies (known as "contract pharmacies") to dispense the drugs purchased at the 340B price. 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996).

Dissatisfied with the terms of the 340B Program, drug manufacturers recently began adding new conditions of their own. Beginning in 2020, several of the world's largest manufacturers announced that they would no longer offer drugs to covered entities at or below the ceiling price when the covered entity relies on one or more contract pharmacies to dispense the drugs. The stated purpose of the new policies is to prevent duplicative discounts and drug diversion.

The Department of Health and Human Services (HHS) correctly informed Eli Lilly and other manufacturers that their new policies violate the 340B statute and are grounds for civil monetary penalties. Contrary to Eli Lilly's premise, Congress did not allow drug manufacturers to add provisos to their obligations under the 340B statute. That would be akin to letting the fox guard the henhouse. Congress was aware of the use of outside pharmacies, and chose not to restrict covered entities' use of contract pharmacies or allow drug manufacturers to impose such restrictions unilaterally.

The district court correctly recognized that the 340B statute "does not leave room for drug manufacturers to unilaterally condition or control the availability of their 340B pricing * * * such that covered entities are prevented from accessing 340B pricing." SA46-47. The court was mistaken, however, in vacating HHS's enforcement letters and concluding that HHS had made a "change in position regarding its authority to enforce potential violations of the 340B statute." SA52. HHS has consistently explained, from the inception of the statute, that drug manufacturers may not impose unilateral conditions on covered entities that would prevent them from accessing the statutorily discounted price. And HHS has consistently recognized that its interpretive guidance is nonbinding: the

agency's express authority to impose penalties or take other enforcement actions must be grounded in a violation of the statute alone, as it was here.

STATEMENT OF JURISDICTION

Plaintffs-Appellants' jurisdictional statement is correct, but not complete to the extent that further explanation is necessary to explain this Court's jurisdiction over the federal defendants' cross-appeal. The district court entered partial final judgment on October 29, 2021. SA66. Plaintiffs filed a notice of appeal on November 10, 2021 (Dkt. No. 146), and defendants filed a cross-appeal on December 28, 2021 (Dkt. No. 151), which was within the 60 day period allowed under Federal Rule of Appellate Procedure 4(a)(1)(B). As plaintiffs note (Br. 4), this Court issued a limited remand for the district court to issue an amended judgment, which the district court issued on April 14, 2022. SA70-71. This Court explained that no additional notices of appeal were necessary from that amended judgment. Order, *Eli Lilly & Co. v. Becerra*, No. 21-3405 (7th Cir. Apr. 7, 2022).

STATEMENT OF THE ISSUES

Under Section 340B of the Public Health Service Act, as amended by the Affordable Care Act, drug manufacturers that participate in Medicaid and Medicare Part B shall "offer each covered entity covered outpatient

drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). The questions presented are:

1. Whether the district court correctly held that the statute does not allow drug manufacturers to refuse to offer this price discount to a covered entity that uses one or more contract pharmacies to dispense the drugs that the covered entity purchases.

2. Whether the district court erred in vacating and remanding HHS's enforcement letter as arbitrary and capricious.

STATEMENT OF THE CASE

I. Statutory Background And Agency Guidance

A. The 340B Program

This appeal concerns the obligations of drug manufacturers that participate in Medicaid and Medicare Part B, and which accordingly receive reimbursement for their products under those programs. Congress directed that such manufacturers must comply with Section 340B of the Public Health Service Act, which was enacted in 1992 and codified at 42 U.S.C. § 256b. Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992); *see also* 42 U.S.C. § 1396r-8(a)(1), (5) (cross-referencing 42 U.S.C. § 256b).

Under Section 340B, participating manufacturers "must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara County*,

563 U.S. 110, 115 (2011); *see* 42 U.S.C. § 256b(a)(1), (3), (4). Covered entities include, for example, black lung clinics, federally-qualified health centers, certain children's hospitals and free-standing cancer hospitals, critical access hospitals, rural referral centers, and other federally funded health care entities, 42 U.S.C. § 256b(a)(4), which "generally serve low-income or rural communities," *American Hospital Ass'n v. Becerra*, --- S. Ct. ---, 2022 WL 2135490, at *2 (June 15, 2022). The 340B Program enables 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, pt. 2, at 12 (1992). Covered entities can use those cost savings "to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize[,] and expand services and formularies." 61 Fed. Reg. 43549, 43549 (Aug. 23, 1996).

From the outset, Section 340B imposed obligations on both drug manufacturers and covered entities. With respect to manufacturers, the statute specified that the Secretary of Health and Human Services 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" a specified ceiling price. 42 U.S.C. § 256b(a)(1). The statute thus required manufacturers to sell drugs to covered entities at discounted prices.

With respect to covered entities, the statute prohibited requests for duplicate discounts and the diversion of drugs purchased under the 340B Program. To prevent duplicative discounts, the statute specified that a covered entity shall not request a discount for a drug that is already subject to a separate Medicaid rebate requirement. 42 U.S.C. § 256b(a)(5)(A). To prevent diversion, the statute specified that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

To promote transparency, the statute required a covered entity to permit both the Secretary and the manufacturer to audit the covered entity's records. 42 U.S.C. § 256b(a)(5)(C). The statute further provided that, if the Secretary finds that a covered entity is in violation of a requirement, the covered entity shall be liable to the manufacturer for the amount equal to the discount. *Id.* § 256b(a)(5)(D).

B. Covered entities' use of contract pharmacies to dispense drugs purchased under the 340B Program

From the inception of the 340B Program, many covered entities relied on outside pharmacies, which came to be known as "contract pharmacies," to dispense to their patients the drugs purchased at the discounted prices. Indeed, when the program was first implemented, only 5 percent (500 of 11,500) of covered entities had in-house pharmacies. *See* 61 Fed. Reg. at 43550.

When Congress was considering the legislation that established the 340B Program, it considered a bill that would have limited the discounts to drugs "purchased *and dispensed by, or under a contract entered into for on-site pharmacy services with*," a covered entity. S. Rep. No. 102-259, at 2 (1992) (emphasis added) (considering S. 1729, 102d Cong. (1992)). The emphasized language would have prevented covered entities from using outside pharmacies to dispense the drugs purchased at the discounted prices. Congress did not enact that restriction, however. Instead, Congress broadly required manufacturers to provide discounted prices for "drugs * * * purchased by a covered entity," regardless of whether covered entities used in-house or outside pharmacies to dispense the drugs that the covered entities purchased. 42 U.S.C. § 256b(a)(1).

Congress did not authorize HHS to restrict the use of contract pharmacies by covered entities. Congress gave HHS rulemaking authority with respect to only limited aspects of the 340B Program that do not include contract-pharmacy arrangements. *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services*, --- F. Supp. 3d ---, 2021 WL 5150464, at *34 (D.N.J. 2021), *appeals pending*, Nos. 21-3168, 21-3167, 21-3379, 21-3380 (3d Cir.). However, HHS periodically issued nonbinding guidelines on that topic. *See, e.g.*, 61 Fed. Reg. at 43550 (explaining that "these guidelines create no new law and create no new rights or duties").

HHS's 1996 guidelines explained that a covered entity's use of a contract pharmacy was permissible and did not relieve a manufacturer of its obligation to sell the drugs at the discounted price. 61 Fed. Reg. at 43549-50. HHS noted that "[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," because covered entities "would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.*

The 1996 guidelines advised that a covered entity contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. 61 Fed. Reg. at 43555. Starting in 2001, however, HHS began a pilot program under which covered entities used multiple contract pharmacies to increase their patients' access to 340B drugs. 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007). The pilot program's participants were subject to annual, independent audits "for drug diversion and duplicative discounts." *Id.* Based on the results of six years of auditing from the pilot program, HHS proposed new guidelines in 2007 under which covered entities could use multiple contract pharmacies "to provide broader access to 340B discounted drugs to eligible patient[s]." 72 Fed. Reg. at 1540. At the same time, HHS underscored the "particular importance" of the "requirement that appropriate procedures be in place to prevent diversion of 340B drugs or a duplicative 340B drug discount and a Medicaid rebate on the same drug, which are prohibited under the statute." *Id.*

After considering public comments, HHS finalized the proposed guidelines in 2010, shortly before Congress enacted the Affordable Care Act. 75 Fed. Reg. 10272 (Mar. 5, 2010). The 2010 guidelines indicated that covered entities could use multiple contract pharmacies as long as the covered entities complied with guidelines to prevent diversion and

duplicate discounts and adhered to policies regarding the definition of a "patient" of a covered entity. *Id.* at 10273.

C. The Affordable Care Act's amendments to the 340B Program

As part of the Affordable Care Act, Congress amended the 340B statute in a subtitle designed to provide "More Affordable Medicines for Children and Underserved Communities." Pub. L. No. 111-148, Title VII, subtitle B, 124 Stat. 119, 821 (2010).

Section 7101 of the Affordable Care Act, entitled "Expanded Participation In 340B Program," expanded the list of "covered entities" eligible to participate in the 340B Program. 124 Stat. at 821-22 (amending 42 U.S.C. § 256b(a)(4)). It added certain children's hospitals, critical access hospitals, rural referral centers, and sole community hospitals to the list of facilities that may purchase drugs from manufacturers at discounted prices.

Section 7102, entitled "Improvements To 340B Program Integrity," added a series of new provisions designed to improve compliance with 340B Program requirements by both drug manufacturers and covered entities. 124 Stat. at 823-27 (amending 42 U.S.C. § 256b(d)).

First, Congress directed the Secretary to improve oversight of manufacturers in various specified ways and authorized the Secretary to impose sanctions against manufacturers in the form of civil monetary

penalties, not to exceed $5,000 for each instance of overcharging a covered entity. 42 U.S.C. § 256b(d)(1).[1]

Second, Congress directed the Secretary to improve covered entities' compliance with the statute's prohibitions on diversion and duplicate discounts in various specified ways, such as by requiring covered entities to regularly update information on an HHS website. 42 U.S.C. § 256b(d)(2)(b). In addition, Congress significantly increased the penalties if covered entities violate program requirements. Congress authorized the Secretary to impose sanctions against covered entities—including monetary penalties, removal from the 340B Program, and referral to other federal agencies for appropriate action—for diversion, duplicate discounts, or other violations of program requirements. *Id.* § 256b(d)(2)(B)(v).

Third, Congress directed HHS to "promulgate regulations to establish and implement an administrative process for the resolution of" covered entities' claims that they have been overcharged and manufacturers' claims that covered entities violated certain statutory requirements. 124 Stat. at 826-27 (enacting 42 U.S.C. § 256b(d)(3)). Congress specified that the regulations should: (1) designate an HHS official or HHS decision-making

[1] *See also* 87 Fed. Reg. 15100, 15105 (Mar. 17, 2022) (adjusting penalty for inflation to $6,323).

body to be responsible for reviewing such claims; (2) establish deadlines and procedures as necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously; (3) establish procedures for covered entities to obtain relevant information from the manufacturer or third parties; (4) require that a manufacturer conduct an audit of a covered entity pursuant to 42 U.S.C. § 256b(d)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity; and (5) permit the consolidation or joinder of claims by multiple manufacturers against the same covered entity and by multiple covered entities against the same manufacturer. 42 U.S.C. § 256b(d)(3)(B)(i)-(vi). Congress provided that the administrative resolution of a claim or claims under the regulations shall be a final agency decision that is binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction. *Id.* § 256b(d)(3)(C).

The ACA's amendments to Section 340B did not restrict covered entities' longstanding use of contract pharmacies, nor did Congress authorize drug manufacturers or HHS to impose such a restriction. On the contrary, the ACA's amendments specified, without qualification, that the Secretary's agreement with a drug manufacturer "shall require that the manufacturer offer each covered entity covered outpatient drugs for

purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). *Accord* 59 Fed. Reg. 25110, 25111-12 (May 13, 1994) ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.").

Section 7103 directed the Government Accountability Office (GAO) to report to Congress with recommendations for further improvements to the 340B Program. 124 Stat. at 827-28.

II. Factual Background

A. GAO reports on the growth of the 340B Program

In the decade since the Affordable Care Act's amendments, the GAO has submitted a series of reports to Congress on the 340B Program. These reports describe significant growth in the 340B Program and attribute that growth to a combination of factors, including the Affordable Care Act's expansion of the list of covered entities that can participate in the 340B Program, the enrollment of more facilities in the 340B Program, and covered entities' increased use of contract pharmacies to distribute the drugs they purchase.

The GAO reported that participation in the 340B Program grew from nearly 9,700 covered entities in 2010 to 12,700 covered entities in 2020. *See* GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms*

to Help Ensure Compliance with 340B Requirements 2 (2020).[2] The GAO reported that, between 2010 and 2017, the number of contract pharmacies increased from about 1,300 to about 20,000. *See* GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (2018).[3] Elaborating on the use of contract pharmacies, the GAO reported that, as of 2017, about one-third of the covered entities in the 340B Program used contract pharmacies, but the extent varied by type of entity. *See id.* at 16. For example, a higher percentage of hospitals (69.3%) used at least one contract pharmacy compared to federal grantees (22.8%). *See id.* And among the six types of hospitals eligible to participate in the 340B Program, the percentage that used at least one contract pharmacy ranged from 39.2% of children's hospitals to 74.1% of critical access hospitals. *See id.* Among the 10 types of federal grantees, the percentage with at least one contract pharmacy ranged from 3.9% of family planning clinics to 75.2% of federally qualified health centers. *See id.*

The GAO made a number of recommendations to improve HHS's oversight of contract-pharmacy arrangements, while at the same time

[2] https://www.gao.gov/products/gao-21-107
[3] https://www.gao.gov/products/gao-18-480

recognizing that HHS has limited authority to issue regulations governing the 340B Program. *See* GAO-18-480, at 47. For example, the GAO recommended that HHS require covered entities to register contract pharmacies for each site of the entity for which a contract exists. *See id.* at 46. The GAO did not recommend that HHS limit the number of contract pharmacies that a covered entity may use, however, nor did the GAO suggest that drug manufacturers themselves may impose restrictions on covered entities' use of contract pharmacies.

B. Drug manufacturers' new policies restricting covered entities' use of contract pharmacies

Beginning in 2020, a number of the country's largest drug manufacturers announced that they would cease shipping discounted drugs to contract pharmacies used by covered entities, unless various conditions were met. The claimed objective of these new policies is to prevent duplicative discounting and drug diversion.

The details of these policies differ by manufacturer. For example, plaintiffs Eli Lilly and Lilly USA (collectively Eli Lilly), informed HHS that it will "discontinue our practice of voluntarily honoring requests for 340B" prices for covered entities that are purchasing covered drugs to be dispensed by contract pharmacies. Suppl. App'x 129. Eli Lilly stated that the company might "approve[] an exception" to that policy if the covered

entity lacks an in-house pharmacy, *id.*, in which case the covered entity would be required "to submit additional paperwork designating a single contract pharmacy for delivery and [] engage in a process through which Lilly determines the eligibility of that pharmacy," SA12.[4] Eli Lilly stated that it would continue shipping its insulin products to contract pharmacies at the 340B price, but only if (1) the covered entity retains none of the savings and charges no dispensing or administrative fee (2) no insurer or payer is billed, and (3) the covered entity "provides claim-level detail" to Eli Lilly to "validate that the foregoing conditions have been satisfied." Suppl. App'x 130-31.

Drug manufacturer Novo Nordisk will not provide the 340B discounted price unless the covered hospital designates a single contract pharmacy, or if Novo determines "in its discretion" that the contract pharmacy poses a lesser risk of abuse to the 340B Program. *Sanofi-Aventis*, 2021 WL 5150464, at *5. Sanofi-Aventis will not provide discounted prices unless a covered entity uses an in-house pharmacy, has no in-house pharmacy and uses only a single contract pharmacy, or registers with and provides claims-level data to a third-party data-sharing

[4] In its complaint, Eli Lilly states that it will also ship 340B drugs to contract pharmacies wholly owned by covered entities. Dkt. No. 125, ¶ 80.

platform designated by Sanofi. *Id.* Novartis Pharmaceuticals will not provide discounted prices unless the covered entity is a federal grantee (as distinct from a hospital) or if the contract pharmacy is within 40 miles of the covered entity. *Novartis Pharm. Corp. v. Espinosa*, 2021 WL 5161783, at *3 (D.D.C. Nov. 5, 2021), *appeals pending*, Nos. 21-5299, 21-5304 (D.C. Cir.). United Therapeutics, AstraZeneca, and other manufacturers have adopted similar policies. *See id.* at *4; *see also AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587, at *1 (D. Del. Feb. 16, 2022), *appeal pending*, No. 22-1676 (3d Cir.).

As a consequence of these policies, numerous covered entities complained to HHS that they could no longer obtain eligible drugs manufacturered by Eli Lilly at the 340B discounted prices to dispense to their patients through contract pharmacies. For example, the organizations AIDS Response Effort and AIDS Support Group of Cape Cod notified HHS that they could no longer obtain cancer medications manufactured by Eli Lilly at the 340B price. Suppl. App'x 12-17, 21-29. HHS received similar complaints that covered entities could no longer obtain diabetes medications, insulin, and other medications manufactured by Eli Lilly at the 340B price. Suppl. App'x 30-107. When covered entities attempted to purchase Eli Lilly products at the 340B price, they were charged wholesale

prices higher than the statutory discounted price. *See, e.g.*, Suppl. App'x 110 (explaining that the covered entity was "charged [wholesale] price for the purchases" of covered 340B medications after Eli Lilly's new policy took effect).

Covered entities informed HHS that the manufacturers' new policies impair the covered entities' ability to serve their patients. For example, one federally funded health center, Medical Associates Plus, explained that its in-house pharmacies could only serve a minority of its 25,000 patients, who are a "medically underserved population." Suppl. App'x 113-14. It explained that most of its clinical locations do not have an in-house pharmacy, and those that do are only open during work-hours, making it difficult for many patients to access them. *Id.* The center explained that it "depends on its 340B Program savings and revenue to help support approximately 41% of" its expenses not covered by federal grants, and that the new policies will cause a "significant financial loss" that "will also result in reduction in other clinical and/or patient services." Suppl. App'x 116. . *See also* Suppl. App'x 117-21 (covered entity that serves thousands of patients across a 10,000 square mile area, including Michigan's upper peninsula, explains that manufacturers' policies will "significantly and irreparably harm[]" its patients).

Another federally funded health center, North Country HealthCare, informed HHS that it uses dozens of contract pharmacy locations to dispense needed medications to tens of thousands of its patients across northern Arizona. Suppl. App'x 122-24. Without contract pharmacies, many of the center's patients would have to travel over a hundred miles each way to reach one of the center's locations that operates an in-house pharmacy. Suppl. App'x 125. Illustrating its concern, the center noted that this travel was not realistically feasible for one of its uninsured diabetic patients, who was located "approximately 280 miles from our closest in-house pharmacy." Suppl. App'x 127. Starting in October 2020, that patient could no longer access Sanofi's insulin medication at his contract pharmacy. *Id.* Other insulin options, manufactured by Novartis and Eli Lilly—which had adopted similar policies—were "also not available at 340B pricing." *Id.* The center described the consequences in stark terms: "This patient's body is unable to make insulin. Without it he will die." *Id.* The center emphasized that many of its other patients "are being denied access to evidence-based, guideline-driven, best practice quality care because of their inability to access affordable medications." *Id.*

In all, HHS received thousands of pages from covered entities documenting their inability to receive and dispense medications at the

340B price after the various manufacturers implemented their new policies. *See generally* Suppl. App'x 3-6. That included documentation that covered entities could no longer order 340B drugs—including insulin—from Eli Lilly "due to the removal of the 340B pricing by the manufacturer," or that they would be charged above the statutory ceiling price for those drugs. Suppl. App'x 68, 73, 80. The new policies caused a precipitous decline in drug sales at the 340B prices. For example, in the month before announcing its new policy, Eli Lilly had sold 1.55 million units of drugs at the 340B prices—two months later, that number dropped by over 89% to just 170,000 units. Supp. App'x 133. Covered entities lost tens of millions in savings on Eli Lilly products that they had obtained under the 340B Program. In the month before Eli Lilly's new policy took effect, covered entities had saved $67.5 million—two months later, they only saved $3.8 million, losing almost 95% of the previous total savings. Supp. App'x 135. Based on such data, HHS calculated that covered entities had lost hundreds of millions in savings over just the few months after the new policies took effect, and would lose over $3.2 billion over the course of a full year. Supp. App'x 132.

C. HHS's enforcement actions

In December 2020, HHS's general counsel issued an advisory opinion stating that manufacturers are "obligated to deliver [their] covered

outpatient drugs to those contract pharmacies" used by covered entities "and to charge the covered entity no more than the 340B ceiling price for those drugs." App'x 5. However, HHS voluntarily withdrew that advisory opinion "in the interests of avoiding confusion and unnecessary litigation" after a district court declared that it rested on a statutory interpretation that was permissible but not compelled by the statute's text. *See* SA22; *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 61-62 (D. Del. 2021).

In May 2021, HHS took the enforcement action at issue here. HHS sent Eli Lilly and other manufacturers similarly worded letters notifying them that their new policies were in violation of 42 U.S.C. § 256b and resulted in prices above the ceiling price of the 340B Program. HHS's letter to Eli Lilly explained that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." App'x 2. The letter recognized that the manufacturer's claimed rationale for its new restrictions is to prevent diversion and duplicate discounts, and the letter explained that "[t]he 340B statute provides a mechanism by which a manufacturer can address these concerns." App'x 3. "Specifically, the manufacturer must (1) conduct an

audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A)" of the Public Health Service Act. *Id.* The letter directed the manufacturer to immediately resume offering its drugs at discounted prices to covered entities through their contract pharmacy arrangements, and to credit or refund covered entities for all overcharges. *Id.* The letter warned that, if the manufacturer continued its policy, HHS may seek civil monetary penalties of up to $5,000 for each instance of overcharging. *Id.* (citing 42 U.S.C. § 256b(d)(1)(B)(ii)).

III. The District Court's Rulings

In this district court action, Eli Lilly challenged HHS's enforcement letter and advisory opinion. SA2. The district court granted in part and denied in part the parties' cross-motions for summary judgment.

A. The district court's interpretation of the 340B statute

The district court agreed with HHS that "Congress in no way intended to allow regulated entities to unilaterally erect barriers," like Eli Lilly's new policies, which "frustrate the overarching purpose of the [340B] program." SA43. Accordingly, "drug manufacturers may not usurp [Congress's] role through unilateral extra-statutory restrictions." SA49.

The district court rejected Eli Lilly's argument that, because the 340B

statute does not refer explicitly to contract pharmacies, the statute leaves drug manufacturers free to refuse to offer the 340B discount to covered entities that rely on contract pharmacies to dispense the drugs purchased. SA41. The court explained that "Congress clearly utilized broad, generalized language" in establishing the manufacturers' duty to offer the price discount, SA45, and that "there is no such thing as a canon of donut holes, in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception." SA45-46 (quotation marks omitted). The court explained that, "since its enactment, the 340B statute has required drug manufacturers to" honor their obligations "as to the amount covered entities can be required to pay for 340B drugs, which cannot exceed the ceiling prices." SA46. Eli Lilly's policy that denies those prices "based solely on delivery location or dispensing mechanism * * * directly conflicts with the statutory requirement otherwise." *Id.*

The court underscored the practical impediments that Eli Lilly's policy imposes on covered entities. Because many 340B drugs are "controlled substances, they can be shipped only to locations that provide the proper legal infrastructure, including state licensing, DEA registration, staff pharmacists, etc., to accept" and dispense the medications. SA45 n.13.

The court noted that many covered entities lack "the capacity or authority to handle their own dispensing or to take delivery of Lilly's medications." *Id.* And even for those covered entities that may have an in-house pharmacy or a single contract pharmacy, it may be "impossible for all patients to fill their prescriptions each month" at those locations, especially for covered entities that "serve vulnerable populations scattered over large geographic areas." *Id.*

The court accordingly concluded that "Congress's use of broad language in enacting this statute * * * does not leave room for drug manufacturers to unilaterally condition or control the availability of their 340B pricing to a particular delivery location of their choosing." SA46-47. Thus, the "most reasonable interpretation of the 340B statute" does not permit manufacturers to "impose unilateral restrictions" that would "frustrate Congress's manifest purpose in enacting the statute." SA47 (quotation marks omitted).

The court rejected Eli Lilly's other arguments in support of its interpretation. To the extent that Eli Lilly claimed that its policy was motivated by a desire to prevent violations of the 340B Program, the court noted that "Congress explicitly required manufacturers to address diversion and duplicate-discounting concerns" as part of the 340B statute's process

for administrative dispute resolution. SA47 n.14 (citing 42 U.S.C. § 256b(d)(3)(B)(iv)). And while contract pharmacy arrangements had grown in recent years, the court explained that Congress knew that covered entities relied on outside pharmacies "even at the time of the statute's enactment," but still chose to "use broad language to define obligations and entitlements under the statute." SA48. The court recognized that Congress was free to address these and other issues involving contract pharmacies—but emphasized that "drug manufacturers may not usurp" Congress's prerogative "through unilateral extra-statutory restrictions." SA49. Consistent with this analysis, the court held that the enforcement letter was "not only a permissible construction" of the statute, but also "best align[ed] with congressional intent." *Id.*[5]

B. The district court's vacatur of the enforcement letters and remand to HHS

The district court nonetheless vacated HHS's enforcement letter because the court believed that the enforcement action was premised on violations of the agency's interpretive guidance rather than on violations of the statute itself. Based on that assumption, the court declared that HHS

[5] The district court also held that Eli Lilly's challenge to the HHS advisory opinion was not moot, but concluded that remand to the agency was unnecessary since HHS had already withdrawn the advisory opinion. SA29-34.

had insufficiently explained a change of position that the court attributed to HHS, *i.e.*, why HHS now (ostensibly) believed that its guidance was enforceable when HHS had previously described the guidance as "non-binding" and recognized that it did not have authority "to issue enforceable regulations regarding contract pharmacy arrangements." SA53-54. The court vacated and remanded the enforcement letters to HHS for further explanation of the ostensible change in position. SA57-58.

The court rejected Eli Lilly's other claims. The court held that the enforcement letter was not subject to the Administrative Procedure Act's notice-and-comment requirements, SA36-37, and did not constitute a Taking or an unconstitutional condition on the receipt of federal benefits, SA50-52.

SUMMARY OF ARGUMENT

Drug manufacturers that wish to be reimbursed under the federally funded Medicaid and Medicare Part B programs are subject to a separate statutory requirement. Pursuant to Section 340B of the Public Health Service Act, such manufacturers must offer their drugs at discounted prices to specified "covered entities." When Congress enacted the Section 340B Program, it considered a bill that would have confined these price discounts to covered entities that dispense drugs through in-house pharmacies.

Congress declined to enact that bill, however, and covered entities have since the inception of the 340B Program relied on outside pharmacies (known as "contract pharmacies") to dispense the discounted drugs.

In 2020, drug manufacturers including Eli Lilly announced policies that dramatically curtailed the manufacturers' obligations under the 340B Program. Although the details of these policies vary, the manufacturers generally refuse to ship discounted drugs to covered entities' contract pharmacies unless specified conditions are met. For example, Eli Lilly will not provide discounted prices unless the covered entity wholly owns the pharmacy or designates only a single contract pharmacy subject to Eli Lilly's approval. SA12. As a consequence of the manufacturers' new policies, drug sales at the discounted prices plummeted. HHS correctly informed Eli Lilly and other manufacturers that their new policies violate the 340B statute and are grounds for civil monetary penalties.

I. The district court correctly held that drug manufacturers may not "unilaterally impose a wide variety of restrictions" that "control the availability of their 340B pricing to a particular delivery location of their choosing." SA45-47. As the court explained in its comprehensive opinion, that conclusion flows from the text, structure, history, and purpose of the 340B statute. Eli Lilly claims that its new policy is meant only to prevent

drug diversion. But Congress specifically addressed that concern through calibrated program-integrity provisions. Congress did not, however, restrict covered entities' use of contract pharmacies or allow drug manufacturers to impose such restrictions.

II. Although the district court correctly held that drug manufacturers cannot restrict covered entities' use of contract pharmacies, the court erred in vacating HHS's enforcement letter and remanding to HHS for further explanation. The remand and vacatur were based on an incorrect premise: that the enforcement letter was based on violations of HHS's guidance rather than on violations of the statute itself. HHS has consistently recognized that its guidance is non-binding; the enforcement letter at issue here rested on violations of the statute alone.

STANDARD OF REVIEW

The district court's summary judgment ruling is reviewed de novo. *Talignani v. United States*, 26 F.4th 379, 381 (7th Cir. 2022). Agency action is reviewed to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

ARGUMENT

I. The 340B Statute Requires Manufacturers To Sell Drugs To Covered Entities At The Discounted Price, Regardless Of Whether Covered Entities Use Contract Pharmacies To Dispense The Drugs Purchased

A. Drug Manufacturers Cannot Unilaterally Add Provisos To Their Statutory Obligations

Under Section 340B of the Public Health Service Act (42 U.S.C. § 256b), "manufacturers participating in Medicaid must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 115 (2011). Since the inception of the 340B Program, the statute has set forth the manufacturer's obligation in broad terms, requiring the Secretary to enter into an agreement with the manufacturer "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). Likewise, when Congress expanded the 340B Program as part of the Affordable Care Act, it specified—without qualification—that the Secretary's 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.* The bottom line requirement is straightforward: if drug manufacturers want to be

reimbursed for their drugs by the federally funded Medicaid and Medicare Part B programs, they also must sell their drugs to covered entities at a discounted price.

Contrary to Eli Lilly's premise, drug manufacturers cannot add provisos to that straightforward statutory requirement. Congress's choice to use "broad language in enacting this statute and specifically omitting any mention of where 340B drugs are to be delivered does not leave room for drug manufacturers to unilaterally condition or control the availability of their 340B pricing" based on how the drugs are received and dispensed. SA46. There is "no 'such thing as a "canon of donut holes," in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception.'" SA45-46 (quoting *Bostock v. Clayton County*, 140 S. Ct. 1731, 1747 (2020)). Instead, when "Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule." *White v. United Airlines, Inc.*, 987 F.3d 616, 621 (7th Cir. 2021).

Put another way, Congress created the 340B Program to ensure that covered entities could obtain discounted drugs under the conditions that *Congress* established. Accordingly, the statutory scheme must be construed to ensure that "everything necessary to making it effectual, or

requisite to attaining the end, is implied." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 193 (2012) (*Reading Law*). That necessarily precludes manufacturers from imposing their own conditions that would prohibit covered entities from otherwise obtaining drugs at a discounted price. Accordingly, Eli Lilly "may not unilaterally create and establish policies—whatever the underlying rationale"—that "dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs." *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services*, --- F. Supp. 3d ---, 2021 WL 5150464, at *43 (D.N.J. 2021).

"Practical considerations strongly support [this] reading" of the statute, whereas Eli Lilly's interpretation "would frustrate Congress' manifest purpose." *United States v. Hayes*, 555 U.S. 415, 426-27 (2009). Congress established the 340B Program to provide covered entities with drugs at a discounted price, at a time when the vast majority of covered entities dispensed their drugs to patients through outside pharmacies. Yet under Eli Lilly's reading, drug manufacturers could have refused to provide the discounted price to all of the covered entities that relied on those pharmacies to distribute the drugs purchased. Under that interpretation, Section 340B "would have been 'a dead letter' * * * from the very moment

of its enactment," *id.* at 427, because manufacturers could have eliminated their obligation to sell discounted drugs to 95% of covered entities, *see* 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) (explaining that only 500 of 11,500 covered entities had in-house pharmacies when the 340B Program was first implemented).

Such an interpretation is incompatible with basic tenets of statutory construction. The Supreme Court has repeatedly emphasized that it is a court's "job to avoid rendering what Congress has plainly done * * * devoid of reason and effect." *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 217-18 (2002). Accordingly, courts construe statutes to ensure that "a text's manifest purpose is furthered, not hindered." *Reading Law* 63 (collecting cases).

As the district court recognized, these pharmacy arrangements were "known to Congress as a common business practice" when Congress enacted the 340B statute. SA48. Contemporaneously with Congress's original consideration of the statute, Congress considered a bill that would have limited the discounts to drugs "purchased and *dispensed by, or under a contract entered into for on-site pharmacy services with*," a covered entity. S. 1729, at 9, 102d Cong. (Mar. 3, 1992) (emphasis added). But Congress did not enact that limit on the mechanism for dispensing drugs.

Instead, Congress made the discounts available to drugs "purchased by a covered entity," regardless of whether drugs are dispensed by in-house or contract pharmacies. 42 U.S.C. § 256b(a)(1); *accord Sanofi*, 2021 WL 5150464, at *37 (holding that "[b]ecause Congress *eliminated* a clear limitation on contract pharmacy arrangements * * * it likely did not intend *to prohibit* them altogether").

Eli Lilly nonetheless contends that because Section 340B has no *explicit* prohibition on adding conditions to the discounted price, Congress has implicitly permitted it to add on those conditions. But that "inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent." *Burns v. United States*, 501 U.S. 129, 136 (1991) (holding that district court was required by the Federal Rules of Criminal Procedure to provide notice to criminal defendant of an upward departure from the sentence guidelines, even though that requirement was not made explicit in the rules) (abrogated on other grounds). Moreover, "the mere possibility of clearer phrasing cannot defeat the most natural reading of a statute; if it could (with all due respect to Congress), we would interpret a great many statutes differently than we do." *Caraco Pharm. Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012).

On Eli Lilly's logic, a drug manufacturer could offer their drugs to covered entities at the discounted price—but only if the covered entity agreed to purchase the manufacturer's drugs whenever possible, and never a competitor's. There is nothing in the 340B statute that explicitly prohibits such a unilateral condition. But the fact that Congress did not directly bar such a self-serving business practice does not mean that Congress *permitted* it. A contrary conclusion "not only would defy common sense, but also would defeat Congress' stated objective" of ensuring that covered entities could consistently—and without hindrance—obtain drugs at a discounted price. *See Quarles v. United States*, 139 S. Ct. 1872, 1879 (2019) ("We should not lightly conclude that Congress enacted a self-defeating statute."). As Eli Lilly acknowledges (at 31-32), its logic likewise would allow it to unilaterally force every covered entity in the country to pick up all their 340B drugs from Eli Lilly's headquarters in Indianapolis. Congress plainly did not allow drug manufacturers to undermine the 340B Program by erecting such barriers.

The district court thus correctly held that the "fairest and most reasonable interpretation of the 340B statute" prohibits Eli Lilly and other manufacturers from "impos[ing] unilateral restrictions on the distribution of the drugs that would frustrate Congress' manifest purpose." SA47

(quotation marks omitted); *accord Sanofi*, 2021 WL 5150464, at *43 ("Congress' use of general language * * * does not permit Plaintiffs to take specific actions, like their policies, just because those actions are not expressly prohibited by the broad text.").

B. Drug Manufacturers Cannot Supplement The Statute's Mechanisms For Preventing Diversion And Duplicative Discounts

Eli Lilly claims that its new policy is intended only to prevent the diversion of drugs that the 340B statute itself prohibits. Br. 34-35. But Congress specified in the statute the means to be used to prevent diversion and duplicative discounts.

From the inception of the 340B Program, Congress provided that covered entities "shall not resell or otherwise transfer" the discounted drug to non-patients, and provided that covered entities "shall not request payment" that would result in a duplicate discount in the form of a Medicaid rebate. 42 U.S.C. § 256b(a)(5)(A)-(B). Congress also mandated that covered entities must permit both HHS and drug manufacturers to conduct audits of the entity's records "that directly pertain to" these requirements. *Id.* § 256b(a)(5)(C). And Congress provided that a covered entity "shall be liable to the manufacturer" for the discount if HHS

determined, after notice and a hearing, that a covered entity had committed a statutory violation. *Id.* § 256b(a)(5)(D).

Congress expanded these measures when it amended the statute as part of the Affordable Care Act. Congress enacted a series of provisions explicitly designed to enhance program integrity, including provisions that guard against diversion and duplicative discounts and authorize substantial penalties for noncompliance by covered entities.

For example, Congress directed HHS to develop procedures by which the agency would obtain and verify information from covered entities on a regular basis to ensure their compliance with the 340B Program. 42 U.S.C. § 256b(d)(2)(B)(i)-(ii). Congress also required HHS to develop "more detailed guidance describing methodologies and options" to avoid duplicate Medicaid discounts, and to establish a "single, universal, and standardized" system for identifying covered entities so that HHS, manufacturers, and others could confirm it and "facilitate the ordering, purchasing, and delivery of covered outpatient drugs * * * including the processing of chargebacks for such drugs." *Id.* § 256b(d)(2)(B)(iii)-(iv). And Congress further provided that covered entities would face significant sanctions for intentional violations of the 340B Program, including monetary payments to affected manufacturers, disqualification from the 340B Program for

"systematic and egregious" violations, and potential referral to various federal agencies for additional measures. *Id.* § 256b(d)(2)(B)(v).

Congress thus addressed the risks of diversion and duplicative discounts through a calibrated statutory scheme. Congress did not, as Eli Lilly contends, implicitly authorize manufacturers to augment these carefully crafted provisions with policies that undermine the ability of covered entities to provide patients with 340B drugs through their contract pharmacies. *See supra* pp.19-20 (describing the precipitous drop in discounted sales that the manufacturers' new policies caused). To the contrary, Congress enacted numerous measures to ensure that manufacturers sold their drugs to covered entities at the ceiling price, that manufacturers would provide refunds when they overcharged, that HHS would audit manufacturers "to ensure the integrity of the drug discount program," and that HHS would impose money penalties of up to $5,000 "for each instance of overcharging a covered entity." 42 U.S.C. § 256b(d)(1)(B). Congress thus recognized that *both* manufacturers and covered entities must be well regulated in order to ensure compliance with the 340B Program. And if there is a dispute about compliance, Congress provided for an administrative dispute resolution process to address those concerns, *see id.* § 256b(d)(3), but did not permit manufacturers to make

such determinations on their own and impose whatever consequences they saw fit.

Nothing in this statutory scheme allows manufacturers to engage in self-help, impose the cost of proving compliance on the covered entities, or otherwise deny them the statutory discount. *Cf.* 42 U.S.C. § 256b(a)(5)(D) (penalty for a covered entity's noncompliance is an after-the-fact refund of the discounted amount to the manufacturer). Thus, even if Eli Lilly's policy "share[s] the same goals" as the statute, "[t]he fact of a common end hardly neutralizes conflicting means." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 379 (2000).

Instead of permitting manufacturer-imposed restrictions on access to the 340B price, the statute authorizes manufacturers to audit covered entities as the means to uncover diversion or duplicative discounts. 42 U.S.C. § 256b(a)(5)(C). Notably, Congress required manufacturers to bear the expense of such audits, rather than impose those costs on the covered entities. *Id.* Moreover, Congress has made an audit conducted pursuant to that statutory provision a prerequisite for a manufacturer's administrative claim against a covered entity. *Id.* § 256b(d)(3)(B)(iv).

Contrary to Eli Lilly's assertion, it cannot ignore this reticulated scheme for auditing and adjudicating potential violations by demanding

that covered entities instead designate a single contract pharmacy that Eli Lilly alone determines is "eligib[le]" to receive 340B drugs. SA12. As HHS explained at the inception of the 340B Program, a "manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions" because the program's enforcement "is a Federal responsibility." 58 Fed. Reg. 68922, 68925 (Dec. 29, 1993). Accordingly, manufacturers may not require covered entities to "submit[] information related to drug acquisition, purchase, and inventory systems" as a condition of obtaining discounted drugs. *Id.* at 68925. So while a manufacturer can appropriately ask a covered entity for "routine information necessary to set up and maintain an account" as part of its "normal business policies," the manufacturer "may not enforce" its own *sui generis* requirements that a covered entity prove its "compliance with section 340B." 59 Fed. Reg. 25110, 25112 (May 13, 1994).

Moreover, it is not just Eli Lilly's policy that is at issue here. Many drug manufacturers have recently imposed their own new policies and restrictions on covered entities' ability to access drugs under the 340B Program. *See Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services*, --- F. Supp. 3d ---, 2021 WL 5150464 (D.N.J. 2021); *Novartis Pharm. Corp. v. Espinosa*, 2021 WL 5161783 (D.D.C. Nov. 5,

2021); *AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587 (D. Del. Feb. 16, 2022). Under plaintiff's logic, there is no reason for these manufacturer policies to follow the same criteria—and indeed these policies impose different substantive limitations and requirements on covered entities simply to obtain the same 340B price that was previously available. For example, Eli Lilly requires covered entities to have no in-house pharmacy and to designate a single contract pharmacy that Eli Lilly alone determines is "eligib[le]," SA12, while Novartis requires contract pharmacies to be within a 40-mile radius of the covered entity, *Novartis*, 2021 WL 5161783, at *3, while Novo Nordisk requires that covered entities designate a single contract pharmacy location, *Sanofi*, 2021 WL 5150464, at *5, while Sanofi requires the regular submission of claims data, *id.* Covered entities thus must seek to accommodate a web of restrictive manufacturer conditions simply to obtain the discounted drug price that Congress enacted the 340B Program to provide them.

That manufacturer-imposed burden increases costs for covered entities, diverts their time away from medical care, and seriously harms their patients. As the administrative record demonstrates, even in the limited time these new policies have been in place, covered entities have been unable to purchase drugs at the discounted price and patients have

struggled to obtain their needed medications from their pharmacies. *Supra* pp.17-20. The result is billions' worth of savings lost, and people's health put in jeopardy. Accordingly, HHS properly informed the manufacturers that their new policies violate the statutory scheme and must end.

C. Eli Lilly's Other Arguments Lack Merit

Eli Lilly suggests that if it is not allowed to place conditions on its sale of drugs in the 340B Program, then its sale of drugs at the discounted price through the program might constitute a Fifth Amendment Taking. *See* Br. 47-53. The district court rightly rejected this assertion. SA50-52. The 340B Program does not qualify as a physical taking because HHS does not acquire title to Eli Lilly's drugs, *United States v. Pewee Coal Co.*, 341 U.S. 114, 115-17 (1951) (plurality op.), obtain them for a third party, *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021), or compel Eli Lilly to surrender them, *Horne v. Department of Agriculture*, 576 U.S. 350, 364 (2015). Nor does it qualify as a regulatory taking. The only reason that Eli Lilly is subject to the 340B Program is because the company has willingly chosen to participate in (and profit from) the federally funded Medicaid and Medicare Part B programs. 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1), (5). Thus, although the statute requires Eli Lilly to sell some of its drugs at a discounted price, that is a voluntary choice it has made in order to

"receive[] a 'valuable Government benefit' in exchange," and does "not subject[] [Eli Lilly] to a taking." *Horne*, 576 U.S. at 366; *accord Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984) (the "voluntary" relinquishment of property "in exchange for the economic advantages * * * can hardly be called a taking").

Eli Lilly's reliance on *Horne* (at 49) is thus misplaced. *Horne* explained that a farmer's ability to sell "produce in interstate commerce" was not a government benefit for purposes of this takings analysis. 576 U.S. at 366. Eli Lilly is of course free to sell its drugs in interstate commerce without participating in the 340B Program—the company does not do so, however, because it prefers to receive money from federal healthcare programs. As this Court has explained in rejecting a similar takings challenge in the Medicare context, "provider participation [in Medicare] is voluntary," and those who participate "made a voluntary choice to accept both the obligations and the benefits" of the program. *St. Francis Hospital Center v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (per curiam). And that "voluntariness forecloses the possibility that the statute could result in an imposed taking of private property." *Southeast Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (collecting cases

and holding that conditions on receiving Medicare reimbursement are not takings).

Eli Lilly's reliance on *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) is similarly off the mark, as that case concerned the alleged violation of federalism principles through a statutory scheme that impermissibly coerced sovereign States to implement a federal program. *Id.* at 575. None of that is at issue here. Even if it were, the Supreme Court explained that "[n]othing in our opinion precludes Congress from offering funds" to expand Medicaid "and requiring that States accepting such funds comply with the conditions on their use." *Id.* at 585. And in all events, it is reasonable and appropriate for the 340B statute to prohibit manufacturer-created restrictions that "would assuredly render 340B drugs inaccessible to many covered entities." SA45 & n.13.

Eli Lilly reliance (at 35) on the so-called "major-questions doctrine" is wholly misplaced.[6] This is not a case where "an agency claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy.'" *Utility Air Regulatory Group v. EPA*,

[6] Eli Lilly raises this argument for the first time on appeal, as it did not appear in its district court briefing. *See* Dkt. Nos. 89, 129. *See Mahran v. Advocate Christ Medical Center*, 12 F.4th 708, 713 (7th Cir. 2021) ("Arguments raised for the first time on appeal are deemed waived.").

573 U.S. 302, 324 (2014). Indeed, this case does not involve an agency's regulatory authority at all. As discussed below, the enforcement letter rests on violations of the 340B statute itself.

II. The District Court Erred In Partially Vacating The Enforcement Letters And Remanding To HHS

Having correctly held that the statute "does not permit drug manufacturers, such as Plaintiffs, to impose unilateral extra-statutory restrictions on their offer to sell 340B drugs to covered entities," the district court should have entered judgment in HHS's favor. SA71. Instead, the court vacated the enforcement letters and remanded to HHS to address what the court perceived as a "change in position regarding [HHS's] authority to enforce potential violations of the 340B statute." SA52.

That was error. HHS has consistently recognized that its guidance is unenforceable and that any enforcement action must be grounded in violations of the statute itself. There is no doubt that HHS has statutory authority to enforce the requirements of the 340B statute. *See* 42 U.S.C. § 256b(a)(5)(D), (d)(1)(B), (d)(2)(B), (d)(3) (statutory enforcement provisions). And that is precisely what the enforcement letter at issue here did.

Thus, there was no change in the agency's position to be explained. As the district court correctly noted, HHS has consistently described its

guidance as unenforceable. SA52-55. Indeed, HHS emphasized at the outset of the 340B Program that its guidelines regarding contract-pharmacy arrangements are nonbinding. *See, e.g.*, 61 Fed. Reg. at 43550 (explaining that "these guidelines create no new law and create no new rights or duties"). HHS reiterated that nonbinding nature of its guidance when it advised covered entities to use a single contract pharmacy to dispense medications, *id.* at 43550, 43555, and when HHS later advised that covered entities could use multiple contract pharmacies to do so, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010) (explaining that "[t]his guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities").

At the same time, HHS has consistently interpreted *the statute* as prohibiting drug manufacturers from creating extra-textual barriers to a covered entity's ability to obtain drugs at the 340B price. For example, as early as 1993, shortly after Congress enacted Section 340B, HHS explained that "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." 58 Fed. Reg. at 68925. HHS thus explained that manufacturers "may not" require covered entities to demonstrate program eligibility, use drugs only for authorized services, keep drug pricing confidential, or "submit[]

information related to drug acquisition, purchase, and inventory systems." *Id.* at 68925; *see also, e.g.*, 59 Fed. Reg. at 25111-12 ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.").[7] The enforcement letter at issue here applied the agency's longstanding view that manufacturers may not erect barriers that undermine covered entities' access to the 340B price.

[7] The GAO report discussed by the district court (SA55) was not an HHS document and concerned covered entity's oversight responsibilities, not whether drug manufacturers may impose unilateral restrictions on covered entities' access to the statutory discount.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed insofar as it vacated the enforcement letters and remanded to HHS. The judgment should otherwise be affirmed.

Respectfully submitted,

SARAH E. HARRINGTON
Deputy Assistant Attorney General

ZACHARY A. MYERS
United States Attorney

ALISA B. KLEIN
/s/ Daniel Aguilar
DANIEL AGUILAR
(202) 514-5432
Attorneys, Appellate Staff
Civil Division
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

June 2022

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a) (5) and (6) because it has been prepared in 14-point Georgia, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 9,435 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word 2016.

/s/ Daniel Aguilar
Daniel Aguilar

CERTIFICATE OF SERVICE

I certify that on June 24, 2022, I filed a copy of this brief with the Clerk of Court for the Seventh Circuit Court of Appeals through the Court's CM/ECF system, which will serve counsel for all parties.

/s/ Daniel Aguilar
Daniel Aguilar

CIRCUIT RULE 30(d) STATEMENT

I certify that all the materials required by Circuit Rules 30(a) and (b) are included in the appendix of appellants Eli Lilly & Co. and Lilly USA, LLC and need not be included in the brief of the federal defendants as cross-appellants under Circuit Rule 30(c).

/s/ Daniel Aguilar
Daniel Aguilar

STATUTORY ADDENDUM

TABLE OF CONTENTS

42 U.S.C. § 256b. Limitation on prices of drugs purchased by covered entities.

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to--

(i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State Medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

(4) "Covered entity" defined

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) 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.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) Prohibiting resale of drugs

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.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs[1] (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs[1] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions--

(1) In general

In this section, the terms “average manufacturer price”, “covered outpatient drug”, and “manufacturer” have the meaning given such terms in section 1927(k) of the Social Security Act.

(2) Covered drug

In this section, the term “covered drug”--

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub.L. 111-152, Title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary 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.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which--

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which--

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered

entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, 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)(C), of violations of subsections[2] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall--

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may 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 under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require 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;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to 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

Nos. 21-3128, 21-3405

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ELI LILLY AND COMPANY and LILLY USA, LLC,

Plaintiffs-appellants–cross-appellees,

v.

XAVIER BECERRA, et al.,

Defendants-appellees–cross-appellants.

On Appeal from the United States District Court
for the Southern District of Indiana,
No. 21-81 (Barker, J.).

SUPPLEMENTAL APPENDIX

SARAH E. HARRINGTON
Deputy Assistant Attorney General

ZACHARY A. MYERS
United States Attorney

ALISA B. KLEIN
DANIEL AGUILAR
(202) 514-5432
Attorneys, Appellate Staff
Civil Division
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

TABLE OF CONTENTS

Page

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

ELI LILLY AND COMPANY *et al.* *Plaintiffs*, v. XAVIER BECERRA, in his official capacity as Secretary of Health & Human Services, *et al.* *Defendants.*	Case No. 1:21-cv-81-SEB-MJD

CERTIFICATION OF ADMINISTRATIVE RECORD

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

Executed this 11th day of June 2021, in Frederick, MD.

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

I. 340B Violation Letters

II. Statutes, Regulations, and Related Content

III. Notices, Guidance, and Proposed Guidance

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

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

V. Administrative Dispute Resolution Petitions and Supporting Documentation

VI. Correspondence

VII. Meeting Notes and Materials

VIII. Reports and Miscellaneous Content

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

Apexus 340B Prime Vendor PROGRAM

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

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

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

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

Background Information

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

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

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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

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

Table 1: Unavailable at 340B Price

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

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

Apexus 340B Prime Vendor PROGRAM

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

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

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

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

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

  _____

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

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

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

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

Apexus 340B Prime Vendor PROGRAM

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

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

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

_____
_____
_____
_____
_____
_____

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

Date issue first observed: _____

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

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

Apexus 340B Prime Vendor PROGRAM

Signature

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

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

Email Address: kvance3@valleyhealthlink.com

Contact Role/Organization: Executive Director, AIDS Response Effort

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

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

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

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

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

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

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

Background Information

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

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

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

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

00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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

00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

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

00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

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

00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

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

00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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

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

Table 1: Unavailable at 340B Price

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

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

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

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

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

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

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

  _____

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

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

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

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

Table 2: Incorrect 340B Price

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

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

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

_____
_____
_____
_____
_____
_____

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

Date issue first observed: _____

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

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

Signature

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

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

Email Address: pgoddu@asgcc.org

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

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

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

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

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

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

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

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

Background Information

Entity Name: Alice Hyde Medical Center **340B ID:** DSH330084

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

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00002-1433-80	Trulicity .75 mg/0.5ml	Eli Lilly	0.5	4	mg/ml	Cardinal Health, McKesson
00002-1434-80	Trulicity 1.5 mg/0.5ml	Eli Lilly	0.5	4	mg/ml	Cardinal Health, McKesson
00002-1436-11	Emgality 120 mg/ml	Eli Lilly	1	1	mg/ml	Cardinal Health, McKesson
00002-1445-11	Taltz 80 mg/ml	Eli Lilly	1	1	mg/ml	Cardinal Health, McKesson
00002-6145-11	Baqsimi one pack 3mg/dose	Eli Lilly	1	1	mg	Cardinal Health, McKesson
00002-6145-27	Baqsimi two pack 3mg/dose	Eli Lilly	1	2	mg	Cardinal Health, McKesson
00002-7510-01	Humalog 100 unit/ml	Eli Lilly	10	1	ml	Cardinal Health, McKesson
00002-7712-27	Humalog Kwikpen 200 unit/ml	Eli Lilly	3	2	ml	Cardinal Health, McKesson

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

00002-7714-59	Humalog Junior Kwikpen 100 unit/ml	Eli Lilly	3	5	ml	Cardinal Health, McKesson
00002-7715-59	Basaglar Kwikpen 100 unit/ml	Eli Lilly	3	5	ml	Cardinal Health, McKesson
00002-7724-11	Taltz 80 mg/ml	Eli Lilly	1	1	mg/ml	Cardinal Health, McKesson
00002-8031-01	Glucagon Emergency Kit 1 mg	Eli Lilly	1	1	mg	Cardinal Health, McKesson
00002-8315-01	Humulin N 100 unit/ml	Eli Lilly	10	1	ml	Cardinal Health, McKesson
00002-8799-59	Humalog Kwikpen 100 unit/ml	Eli Lilly	3	5	ml	Cardinal Health, McKesson
00002-8824-27	Humulin R U-500 Kwikpen 500 unit/ml	Eli Lilly	3	2	ml	Cardinal Health, McKesson

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

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

Table 1: Unavailable at 340B Price

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

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

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- X Other (*please describe*): Manufacturer has blocked 340B pricing at contract pharmacies
- ☐ Unknown

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

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

For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer

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

hospitals, the term "covered outpatient drug" does not include orphan drugs.

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

  _____

  _____

- ☐ Other (*please describe*): _____

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

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

Table 2: Incorrect 340B Price

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

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

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

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

- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____

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

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

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

☐ Other (*please describe*):

_____

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

Date issue first observed: _____

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

Signature

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

Contact Name (printed): Michael Dufort **Phone**: (518) 481-2404

Email Address: mdufort@alicehyde.com

Contact Role/Organization: Director of Pharmacy, Alice Hyde Medical Center

Contact Signature: _____ **Date**: 10/14/2020

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

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

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

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

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

Background Information

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

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

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

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

00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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

00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

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

00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

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

00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

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

00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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

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

Table 1: Unavailable at 340B Price

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

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

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

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

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

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

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

  _____

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

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

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

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

Table 2: Incorrect 340B Price

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

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

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

_____
_____
_____
_____
_____
_____

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

Date issue first observed: _____

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

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

Signature

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

Contact Name (printed): Kelly Thompson **Phone**: 860-447-0884

Email Address: kthompson@allianceforliving.org

Contact Role/Organization: CEO

Contact Signature: Kelly Thompson **Date**: 2/11/21

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

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

Apexus 340B

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

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

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

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

Background Information

Entity Name: The Alliance of AIDS Services-Carolina **340B ID:** STD27604

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

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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

00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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

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

Table 1: Unavailable at 340B Price

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

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

Apexus 340B

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

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

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

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

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

  _____

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

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

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

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

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

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

_____
_____
_____
_____
_____
_____

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

Date issue first observed: _____

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

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

Signature

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

Contact Name (printed): Melissa Haithcox-Dennis **Phone**: 9199342437

Email Address: M.haithcoxdennis@aas-c.org

Contact Role/Organization: Executive Director, Alliance of AIDS services-Carolina

Contact Signature: Melissa Haith-De **Date**: 11/10/2020

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

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

Background Information

Entity Name: Presence St. Francis Hospital **340B ID:** DSH140080

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

NDC	Drug Name	Manufacturer	Package Size	Case Package Size	Unit of Measure	CE Wholesaler
	List Attached	Eli Lilly & Co				McKesson

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

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

Table 1: Unavailable at 340B Price

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

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

- ☐ Drug Shortage
- ☐ Drug Subject to limited distribution or specialty pharmacy plan
- ☐ Other (please describe):
- ☐ Unknown

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

- ☐ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)
  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)
- ☐ Other (please describe):

Date issue first observed:

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

Table 2: Incorrect 340B Price

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

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

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

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

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

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

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

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

Date issue first observed: 10/1/2020

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

Signature

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

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

Email Address: Rick.Fischer@amitahealth.org

Contact Role/Organization: 340B Program Director

Contact Signature: Rick Fischer **Date:** 2/1/2021

Supplier	NDC	Product Number	Label Name	Generic Name	Brand Description
Eli Lilly & Co	00002764001	00002764001	ALIMTA 100 MG VIAL	pemetrexed disodium	ALIMTA
Eli Lilly & Co	00002762301	0002-7623-01	ALIMTA 500 MG VIAL	pemetrexed disodium	ALIMTA
Eli Lilly & Co	00002120001	00002120001	AMYVID VIAL	florbetapir F-18	AMYVID
Eli Lilly & Co	00002197590	00002197590	AXIRON 30 MG/ACTUATION SOLN	testosterone	AXIRON
Eli Lilly & Co	00002614511	00002614511	BAQSIMI 3 MG SPRAY ONE PACK	glucagon	BAQSIMI
Eli Lilly & Co	00002614527	00002614527	BAQSIMI 3 MG SPRAY TWO PACK	glucagon	BAQSIMI
Eli Lilly & Co	00002771559	00002771559	BASAGLAR 100 UNIT/ML KWIKPEN	insulin glargine,hum.rec.anlog	BASAGLAR KWIKPEN U-100
Eli Lilly & Co	00002446330	00002446330	CIALIS 10 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446534	00002446534	CIALIS 2.5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446430	00002446430	CIALIS 20 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446234	00002446234	CIALIS 5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446230	00002446230	CIALIS 5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002323560	00002323560	CYMBALTA 20 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002324090	00002324090	CYMBALTA 30 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002324030	00002324030	CYMBALTA 30 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002327030	00002327030	CYMBALTA 60 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002327004	00002327004	CYMBALTA 60 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002766901	00002-7669-01	CYRAMZA 100 MG/10 ML VIAL	ramucirumab	CYRAMZA
Eli Lilly & Co	00002767801	00002-7678-01	CYRAMZA 500 MG/50 ML VIAL	ramucirumab	CYRAMZA
Eli Lilly & Co	00002512377	00002512377	EFFIENT 10 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512330	00002512330	EFFIENT 10 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512130	00002512130	EFFIENT 5 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512152	00002512152	EFFIENT 5 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002143611	00002143611	EMGALITY 120 MG/ML PEN	galcanezumab-gnlm	EMGALITY PEN
Eli Lilly & Co	00002237711	00002237711	EMGALITY 120 MG/ML SYRINGE	galcanezumab-gnlm	EMGALITY SYRINGE
Eli Lilly & Co	00002311509	00002311509	EMGALITY 300 MG (100 MG X3SYR)	galcanezumab-gnlm	EMGALITY SYRINGE
Eli Lilly & Co	66733094823	66733094823	ERBITUX 100 MG/50 ML VIAL	cetuximab	ERBITUX
Eli Lilly & Co	66733095823	66733095823	ERBITUX 200 MG/100 ML VIAL	cetuximab	ERBITUX
Eli Lilly & Co	00002418407	00002418407	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002418430	00002418430	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002418402	00002418402	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002840001	00002840001	FORTEO 600 MCG/2.4 ML PEN INJ	teriparatide	FORTEO
Eli Lilly & Co	00002750201	00002750201	GEMZAR 1 GRAM VIAL	gemcitabine HCl	GEMZAR
Eli Lilly & Co	00002750101	00002750101	GEMZAR 200 MG VIAL	gemcitabine HCl	GEMZAR
Eli Lilly & Co	00002803101	0002-8031-01	GLUCAGON 1 MG EMERGENCY KIT	glucagon,human recombinant	GLUCAGON EMERGENCY KIT

VLTR_000393

Eli Lilly & Co	00002751001	00002751001	HUMALOG 100 UNIT/ML VIAL	insulin lispro	HUMALOG
Eli Lilly & Co	00002751017	00002751017	HUMALOG 100 UNIT/ML VIAL	insulin lispro	HUMALOG
Eli Lilly & Co	00002751659	00002751659	HUMALOG 100 UNITS/ML CARTRIDGE	insulin lispro	HUMALOG
Eli Lilly & Co	00002879959	00002879959	HUMALOG 100 UNITS/ML KWIKPEN	insulin lispro	HUMALOG KWIKPEN U-100
Eli Lilly & Co	00002771227	00002771227	HUMALOG 200 UNITS/ML KWIKPEN	insulin lispro	HUMALOG KWIKPEN U-200
Eli Lilly & Co	00002771459	00002771459	HUMALOG JR 100 UNIT/ML KWIKPEN	insulin lispro	HUMALOG JUNIOR KWIKPEN
Eli Lilly & Co	00002879859	00002879859	HUMALOG MIX 50-50 KWIKPEN	insulin lispro protamin/lispro	HUMALOG MIX 50-50 KWIKPEN
Eli Lilly & Co	00002751201	00002751201	HUMALOG MIX 50-50 VIAL	insulin lispro protamin/lispro	HUMALOG MIX 50-50
Eli Lilly & Co	00002879759	00002879759	HUMALOG MIX 75-25 KWIKPEN	insulin lispro protamin/lispro	HUMALOG MIX 75-25 KWIKPEN
Eli Lilly & Co	00002751101	00002751101	HUMALOG MIX 75-25 VIAL	insulin lispro protamin/lispro	HUMALOG MIX 75-25
Eli Lilly & Co	00002814801	00002814801	HUMATROPE 12 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002814901	00002814901	HUMATROPE 24 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002733511	00002733511	HUMATROPE 5 MG VIAL	somatropin	HUMATROPE
Eli Lilly & Co	00002814701	00002814701	HUMATROPE 6 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002871501	00002871501	HUMULIN 70-30 VIAL	insulin NPH hum/reg insulin hm	HUMULIN 70-30
Eli Lilly & Co	00002871517	00002871517	HUMULIN 70-30 VIAL	insulin NPH hum/reg insulin hm	HUMULIN 70-30
Eli Lilly & Co	00002880359	00002880359	HUMULIN 70/30 KWIKPEN	insulin NPH hum/reg insulin hm	HUMULIN 70/30 KWIKPEN
Eli Lilly & Co	00002831501	00002831501	HUMULIN N 100 UNIT/ML VIAL	insulin NPH human isophane	HUMULIN N
Eli Lilly & Co	00002831517	00002831517	HUMULIN N 100 UNIT/ML VIAL	insulin NPH human isophane	HUMULIN N
Eli Lilly & Co	00002880559	00002880559	HUMULIN N 100 UNITS/ML KWIKPEN	insulin NPH human isophane	HUMULIN N KWIKPEN
Eli Lilly & Co	00002821501	00002821501	HUMULIN R 100 UNIT/ML VIAL	insulin regular, human	HUMULIN R
Eli Lilly & Co	00002821517	00002821517	HUMULIN R 100 UNIT/ML VIAL	insulin regular, human	HUMULIN R
Eli Lilly & Co	00002882427	00002882427	HUMULIN R 500 UNITS/ML KWIKPEN	insulin regular, human	HUMULIN R U-500 KWIKPEN
Eli Lilly & Co	00002850101	00002850101	HUMULIN R 500 UNITS/ML VIAL	insulin regular, human	HUMULIN R U-500
Eli Lilly & Co	66733082259	66733082259	INSULIN LISPRO 100 UNIT/ML PEN	insulin lispro	INSULIN LISPRO KWIKPEN U-100
Eli Lilly & Co	00002822259	00002822259	INSULIN LISPRO 100 UNIT/ML PEN	insulin lispro	INSULIN LISPRO KWIKPEN U-100
Eli Lilly & Co	00002773701	00002773701	INSULIN LISPRO 100 UNIT/ML VL	insulin lispro	INSULIN LISPRO
Eli Lilly & Co	66733077301	66733077301	INSULIN LISPRO 100 UNIT/ML VL	insulin lispro	INSULIN LISPRO
Eli Lilly & Co	00002775205	00002775205	INSULIN LISPRO JR 100 UNIT/ML	insulin lispro	INSULIN LISPRO JUNIOR KWIKPEN
Eli Lilly & Co	00002823305	00002823305	INSULIN LISPRO MIX 75-25 KWKPN	insulin lispro protamin/lispro	INSULIN LISPRO PROTAMINE MIX
Eli Lilly & Co	00002719001	0002-7190-01	LARTRUVO 190 MG/19 ML VIAL	olaratumab	LARTRUVO
Eli Lilly & Co	00002892601	00002892601	LARTRUVO 500 MG/50 ML VIAL	olaratumab	LARTRUVO
Eli Lilly & Co	00002473230	00002473230	OLUMIANT 1 MG TABLET	baricitinib	OLUMIANT
Eli Lilly & Co	00002418230	00002418230	OLUMIANT 2 MG TABLET	baricitinib	OLUMIANT
Eli Lilly & Co	00002771601	0002-7716-01	PORTRAZZA 800 MG/50 ML VIAL	necitumumab	PORTRAZZA
Eli Lilly & Co	00777310402	00777310402	PROZAC 10 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310530	00777310530	PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310507	00777310507	PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC

VLTR_000394

Eli Lilly & Co	00777310502	00777310502	PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310730	00777310730	PROZAC 40 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00002140701	0002-1407-01	QUINIDINE GLUC 80 MG/ML VIAL	quinidine gluconate	QUINIDINE GLUCONATE
Eli Lilly & Co	00002714001	00002714001	REOPRO 10 MG/5 ML VIAL	abciximab	REOPRO
Eli Lilly & Co	00002397760	00002397760	RETEVMO 40 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002298026	00002298026	RETEVMO 80 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002298060	00002298060	RETEVMO 80 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002449108	00002449108	REYVOW 100 MG TABLET	lasmiditan succinate	REYVOW
Eli Lilly & Co	00002431208	00002431208	REYVOW 50 MG TABLET	lasmiditan succinate	REYVOW
Eli Lilly & Co	00002322730	00002322730	STRATTERA 10 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002325130	00002325130	STRATTERA 100 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323830	00002323830	STRATTERA 18 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002322830	00002322830	STRATTERA 25 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002322930	00002322930	STRATTERA 40 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323930	00002323930	STRATTERA 60 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002325030	00002325030	STRATTERA 80 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323230	00002323230	SYMBYAX 12-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323430	00002323430	SYMBYAX 12-50 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323030	00002323030	SYMBYAX 3-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323130	00002323130	SYMBYAX 6-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323330	00002323330	SYMBYAX 6-50 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002144527	00002144527	TALTZ 80 MG/ML AUTOINJ (2-PK)	ixekizumab	TALTZ AUTOINJECTOR (2 PACK)
Eli Lilly & Co	00002144509	00002144509	TALTZ 80 MG/ML AUTOINJ (3-PK)	ixekizumab	TALTZ AUTOINJECTOR (3 PACK)
Eli Lilly & Co	00002144511	00002144511	TALTZ 80 MG/ML AUTOINJECTOR	ixekizumab	TALTZ AUTOINJECTOR
Eli Lilly & Co	00002772411	00002772411	TALTZ 80 MG/ML SYRINGE	ixekizumab	TALTZ SYRINGE
Eli Lilly & Co	00002143380	00002143380	TRULICITY 0.75 MG/0.5 ML PEN	dulaglutide	TRULICITY
Eli Lilly & Co	00002143480	00002143480	TRULICITY 1.5 MG/0.5 ML PEN	dulaglutide	TRULICITY
Eli Lilly & Co	00002481554	00002481554	VERZENIO 100 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002533754	00002533754	VERZENIO 150 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002621654	00002621654	VERZENIO 200 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002448354	00002448354	VERZENIO 50 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002411730	00002411730	ZYPREXA 10 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002759701	00002-7597-01	ZYPREXA 10 MG VIAL	olanzapine	ZYPREXA
Eli Lilly & Co	00002441530	00002441530	ZYPREXA 15 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411230	00002411230	ZYPREXA 2.5 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002442030	00002442030	ZYPREXA 20 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411530	00002411530	ZYPREXA 5 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411630	00002411630	ZYPREXA 7.5 MG TABLET	olanzapine	ZYPREXA

VLTR_000395

Eli Lilly & Co	00002763511	00002763511	ZYPREXA RELPREVV 210 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002763611	00002763611	ZYPREXA RELPREVV 300 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002763711	00002763711	ZYPREXA RELPREVV 405 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002445485	00002445485	ZYPREXA ZYDIS 10 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445585	00002445585	ZYPREXA ZYDIS 15 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445685	00002445685	ZYPREXA ZYDIS 20 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445385	00002445385	ZYPREXA ZYDIS 5 MG TABLET	olanzapine	ZYPREXA ZYDIS

VLTR_000396

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

Background Information

Entity Name: St. Vincent Indianapolis - Hospital & Health **340B ID:** DSH150084

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

NDC	Drug Name	Manufacturer	Package Size	Case Package Size	Unit of Measure	CE Wholesaler
	List Attached	Eli Lilly & Co				McKesson

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

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

Table 1: Unavailable at 340B Price

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

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

- ☐ Drug Shortage
- ☐ Drug Subject to limited distribution or specialty pharmacy plan
- ☐ Other (please describe):
- ☐ Unknown

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

- ☐ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)
  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)
- ☐ Other (please describe):

Date issue first observed:

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

Table 2: Incorrect 340B Price

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

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

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

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

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

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

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

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

Date issue first observed: 10/1/2020

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

Signature

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

Contact Name (printed): Jason Ashby **Phone**: 812-454-3218

Email Address: jashby@ascension.org

Contact Role/Organization: 340B Program Director

Contact Signature: **Date:** 2/1/2021

Supplier	NDC	Product Number	Label Name	Generic Name	Brand Description
Eli Lilly & Co	00002764001	00002764001	ALIMTA 100 MG VIAL	pemetrexed disodium	ALIMTA
Eli Lilly & Co	00002762301	0002-7623-01	ALIMTA 500 MG VIAL	pemetrexed disodium	ALIMTA
Eli Lilly & Co	00002120001	00002120001	AMYVID VIAL	florbetapir F-18	AMYVID
Eli Lilly & Co	00002197590	00002197590	AXIRON 30 MG/ACTUATION SOLN	testosterone	AXIRON
Eli Lilly & Co	00002614511	00002614511	BAQSIMI 3 MG SPRAY ONE PACK	glucagon	BAQSIMI
Eli Lilly & Co	00002614527	00002614527	BAQSIMI 3 MG SPRAY TWO PACK	glucagon	BAQSIMI
Eli Lilly & Co	00002771559	00002771559	BASAGLAR 100 UNIT/ML KWIKPEN	insulin glargine,hum.rec.anlog	BASAGLAR KWIKPEN U-100
Eli Lilly & Co	00002446330	00002446330	CIALIS 10 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446534	00002446534	CIALIS 2.5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446430	00002446430	CIALIS 20 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446234	00002446234	CIALIS 5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446230	00002446230	CIALIS 5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002323560	00002323560	CYMBALTA 20 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002324090	00002324090	CYMBALTA 30 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002324030	00002324030	CYMBALTA 30 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002327030	00002327030	CYMBALTA 60 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002327004	00002327004	CYMBALTA 60 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002766901	00002-7669-01	CYRAMZA 100 MG/10 ML VIAL	ramucirumab	CYRAMZA
Eli Lilly & Co	00002767801	00002-7678-01	CYRAMZA 500 MG/50 ML VIAL	ramucirumab	CYRAMZA
Eli Lilly & Co	00002512377	00002512377	EFFIENT 10 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512330	00002512330	EFFIENT 10 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512130	00002512130	EFFIENT 5 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512152	00002512152	EFFIENT 5 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002143611	00002143611	EMGALITY 120 MG/ML PEN	galcanezumab-gnlm	EMGALITY PEN
Eli Lilly & Co	00002237711	00002237711	EMGALITY 120 MG/ML SYRINGE	galcanezumab-gnlm	EMGALITY SYRINGE
Eli Lilly & Co	00002311509	00002311509	EMGALITY 300 MG (100 MG X3SYR)	galcanezumab-gnlm	EMGALITY SYRINGE
Eli Lilly & Co	66733094823	66733094823	ERBITUX 100 MG/50 ML VIAL	cetuximab	ERBITUX
Eli Lilly & Co	66733095823	66733095823	ERBITUX 200 MG/100 ML VIAL	cetuximab	ERBITUX
Eli Lilly & Co	00002418407	00002418407	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002418430	00002418430	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002418402	00002418402	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002840001	00002840001	FORTEO 600 MCG/2.4 ML PEN INJ	teriparatide	FORTEO
Eli Lilly & Co	00002750201	00002750201	GEMZAR 1 GRAM VIAL	gemcitabine HCl	GEMZAR
Eli Lilly & Co	00002750101	00002750101	GEMZAR 200 MG VIAL	gemcitabine HCl	GEMZAR
Eli Lilly & Co	00002803101	0002-8031-01	GLUCAGON 1 MG EMERGENCY KIT	glucagon,human recombinant	GLUCAGON EMERGENCY KIT

VLTR_000685

Eli Lilly & Co	00002751001	00002751001	HUMALOG 100 UNIT/ML VIAL	insulin lispro	HUMALOG
Eli Lilly & Co	00002751017	00002751017	HUMALOG 100 UNIT/ML VIAL	insulin lispro	HUMALOG
Eli Lilly & Co	00002751659	00002751659	HUMALOG 100 UNITS/ML CARTRIDGE	insulin lispro	HUMALOG
Eli Lilly & Co	00002879959	00002879959	HUMALOG 100 UNITS/ML KWIKPEN	insulin lispro	HUMALOG KWIKPEN U-100
Eli Lilly & Co	00002771227	00002771227	HUMALOG 200 UNITS/ML KWIKPEN	insulin lispro	HUMALOG KWIKPEN U-200
Eli Lilly & Co	00002771459	00002771459	HUMALOG JR 100 UNIT/ML KWIKPEN	insulin lispro	HUMALOG JUNIOR KWIKPEN
Eli Lilly & Co	00002879859	00002879859	HUMALOG MIX 50-50 KWIKPEN	insulin lispro protamin/lispro	HUMALOG MIX 50-50 KWIKPEN
Eli Lilly & Co	00002751201	00002751201	HUMALOG MIX 50-50 VIAL	insulin lispro protamin/lispro	HUMALOG MIX 50-50
Eli Lilly & Co	00002879759	00002879759	HUMALOG MIX 75-25 KWIKPEN	insulin lispro protamin/lispro	HUMALOG MIX 75-25 KWIKPEN
Eli Lilly & Co	00002751101	00002751101	HUMALOG MIX 75-25 VIAL	insulin lispro protamin/lispro	HUMALOG MIX 75-25
Eli Lilly & Co	00002814801	00002814801	HUMATROPE 12 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002814901	00002814901	HUMATROPE 24 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002733511	00002733511	HUMATROPE 5 MG VIAL	somatropin	HUMATROPE
Eli Lilly & Co	00002814701	00002814701	HUMATROPE 6 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002871501	00002871501	HUMULIN 70-30 VIAL	insulin NPH hum/reg insulin hm	HUMULIN 70-30
Eli Lilly & Co	00002871517	00002871517	HUMULIN 70-30 VIAL	insulin NPH hum/reg insulin hm	HUMULIN 70-30
Eli Lilly & Co	00002880359	00002880359	HUMULIN 70/30 KWIKPEN	insulin NPH hum/reg insulin hm	HUMULIN 70/30 KWIKPEN
Eli Lilly & Co	00002831501	00002831501	HUMULIN N 100 UNIT/ML VIAL	insulin NPH human isophane	HUMULIN N
Eli Lilly & Co	00002831517	00002831517	HUMULIN N 100 UNIT/ML VIAL	insulin NPH human isophane	HUMULIN N
Eli Lilly & Co	00002880559	00002880559	HUMULIN N 100 UNITS/ML KWIKPEN	insulin NPH human isophane	HUMULIN N KWIKPEN
Eli Lilly & Co	00002821501	00002821501	HUMULIN R 100 UNIT/ML VIAL	insulin regular, human	HUMULIN R
Eli Lilly & Co	00002821517	00002821517	HUMULIN R 100 UNIT/ML VIAL	insulin regular, human	HUMULIN R
Eli Lilly & Co	00002882427	00002882427	HUMULIN R 500 UNITS/ML KWIKPEN	insulin regular, human	HUMULIN R U-500 KWIKPEN
Eli Lilly & Co	00002850101	00002850101	HUMULIN R 500 UNITS/ML VIAL	insulin regular, human	HUMULIN R U-500
Eli Lilly & Co	66733082259	66733082259	INSULIN LISPRO 100 UNIT/ML PEN	insulin lispro	INSULIN LISPRO KWIKPEN U-100
Eli Lilly & Co	00002822259	00002822259	INSULIN LISPRO 100 UNIT/ML PEN	insulin lispro	INSULIN LISPRO KWIKPEN U-100
Eli Lilly & Co	00002773701	00002773701	INSULIN LISPRO 100 UNIT/ML VL	insulin lispro	INSULIN LISPRO
Eli Lilly & Co	66733077301	66733077301	INSULIN LISPRO 100 UNIT/ML VL	insulin lispro	INSULIN LISPRO
Eli Lilly & Co	00002775205	00002775205	INSULIN LISPRO JR 100 UNIT/ML	insulin lispro	INSULIN LISPRO JUNIOR KWIKPEN
Eli Lilly & Co	00002823305	00002823305	INSULIN LISPRO MIX 75-25 KWKPN	insulin lispro protamin/lispro	INSULIN LISPRO PROTAMINE MIX
Eli Lilly & Co	00002719001	0002-7190-01	LARTRUVO 190 MG/19 ML VIAL	olaratumab	LARTRUVO
Eli Lilly & Co	00002892601	00002892601	LARTRUVO 500 MG/50 ML VIAL	olaratumab	LARTRUVO
Eli Lilly & Co	00002473230	00002473230	OLUMIANT 1 MG TABLET	baricitinib	OLUMIANT
Eli Lilly & Co	00002418230	00002418230	OLUMIANT 2 MG TABLET	baricitinib	OLUMIANT
Eli Lilly & Co	00002771601	0002-7716-01	PORTRAZZA 800 MG/50 ML VIAL	necitumumab	PORTRAZZA
Eli Lilly & Co	00777310402	00777310402	PROZAC 10 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310530	00777310530	PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310507	00777310507	PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC

VLTR_000686

Eli Lilly & Co	00777310502	00777310502	PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310730	00777310730	PROZAC 40 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00002140701	0002-1407-01	QUINIDINE GLUC 80 MG/ML VIAL	quinidine gluconate	QUINIDINE GLUCONATE
Eli Lilly & Co	00002714001	00002714001	REOPRO 10 MG/5 ML VIAL	abciximab	REOPRO
Eli Lilly & Co	00002397760	00002397760	RETEVMO 40 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002298026	00002298026	RETEVMO 80 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002298060	00002298060	RETEVMO 80 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002449108	00002449108	REYVOW 100 MG TABLET	lasmiditan succinate	REYVOW
Eli Lilly & Co	00002431208	00002431208	REYVOW 50 MG TABLET	lasmiditan succinate	REYVOW
Eli Lilly & Co	00002322730	00002322730	STRATTERA 10 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002325130	00002325130	STRATTERA 100 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323830	00002323830	STRATTERA 18 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002322830	00002322830	STRATTERA 25 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002322930	00002322930	STRATTERA 40 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323930	00002323930	STRATTERA 60 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002325030	00002325030	STRATTERA 80 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323230	00002323230	SYMBYAX 12-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323430	00002323430	SYMBYAX 12-50 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323030	00002323030	SYMBYAX 3-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323130	00002323130	SYMBYAX 6-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323330	00002323330	SYMBYAX 6-50 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002144527	00002144527	TALTZ 80 MG/ML AUTOINJ (2-PK)	ixekizumab	TALTZ AUTOINJECTOR (2 PACK)
Eli Lilly & Co	00002144509	00002144509	TALTZ 80 MG/ML AUTOINJ (3-PK)	ixekizumab	TALTZ AUTOINJECTOR (3 PACK)
Eli Lilly & Co	00002144511	00002144511	TALTZ 80 MG/ML AUTOINJECTOR	ixekizumab	TALTZ AUTOINJECTOR
Eli Lilly & Co	00002772411	00002772411	TALTZ 80 MG/ML SYRINGE	ixekizumab	TALTZ SYRINGE
Eli Lilly & Co	00002143380	00002143380	TRULICITY 0.75 MG/0.5 ML PEN	dulaglutide	TRULICITY
Eli Lilly & Co	00002143480	00002143480	TRULICITY 1.5 MG/0.5 ML PEN	dulaglutide	TRULICITY
Eli Lilly & Co	00002481554	00002481554	VERZENIO 100 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002533754	00002533754	VERZENIO 150 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002621654	00002621654	VERZENIO 200 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002448354	00002448354	VERZENIO 50 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002411730	00002411730	ZYPREXA 10 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002759701	00002-7597-01	ZYPREXA 10 MG VIAL	olanzapine	ZYPREXA
Eli Lilly & Co	00002441530	00002441530	ZYPREXA 15 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411230	00002411230	ZYPREXA 2.5 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002442030	00002442030	ZYPREXA 20 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411530	00002411530	ZYPREXA 5 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411630	00002411630	ZYPREXA 7.5 MG TABLET	olanzapine	ZYPREXA

VLTR_000687

Eli Lilly & Co	00002763511	00002763511	ZYPREXA RELPREVV 210 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002763611	00002763611	ZYPREXA RELPREVV 300 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002763711	00002763711	ZYPREXA RELPREVV 405 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002445485	00002445485	ZYPREXA ZYDIS 10 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445585	00002445585	ZYPREXA ZYDIS 15 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445685	00002445685	ZYPREXA ZYDIS 20 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445385	00002445385	ZYPREXA ZYDIS 5 MG TABLET	olanzapine	ZYPREXA ZYDIS

VLTR_000688

From: Ernesty, Gwen
To: HRSA HSB 340B Pricing
Subject: 340B Pricing Notices
Date: Monday, October 19, 2020 5:04:26 PM
Attachments: image001.jpg
AstraZeneca 340B Pricing Notice.pdf
Cardinal_ineligible purchases.docx
Lilly 340B Pricing Notice.pdf
McKesson_340b pricing screenshots.docx
Sanofi 340B Pricing Notice.pdf

Hello,
I am submitting the attachments for review of 340B pricing issues related to three manufacturers at our contract pharmacy locations.
Thank you,

GWEN ERNESTY, R.Ph., MBA
Director of Pharmacy

2579 Chimney Rock Road
Hendersonville, NC 28792
828.692.4289 Ext. 3451
gernesty@brchs.com
www.brchs.com

BLUE RIDGE HEALTH

Background Information

Entity Name: ___Blue Ridge Community Health Service, Inc. _____ **340B ID:** __CH040940____

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

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
1. 00186-0370-20	Symbicort Aer 160-4.5	AstraZeneca	10.2		Gram	Cardinal, McKesson
2. 00310-6205-30	Farxiga 5mg	AstraZeneca	30		Tab	Cardinal, McKesson
3. 00186-0372-20	Symbicort Aer 80-4.5	AstraZeneca	10.2		Gram	Cardinal, McKesson
4. 00310-6524-01	Byetta Inj. 10mcg	AstraZeneca	2.4		mL	Cardinal, McKesson
5. 00310-0095-30	Daliresp 500mcg	AstraZeneca	30		Tab	Cardinal, McKesson

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

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

Table 1: Unavailable at 340B Price

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

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

☐Drug shortage

☐Drug subject to limited distribution or specialty pharmacy plan

☒Other (*please describe*): __Manufacturer is refusing to ship to my contract pharmacies___

☐Unknown

BLUE RIDGE HEALTH

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

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

☒Confirmed shortage issues by reviewing validated resources*

☒Contacted wholesaler and/or manufacturer to confirm unavailability

☒Other (*please describe issue*): ___AstraZeneca is refusing to ship to my contract pharmacies at 340B prices. Our covered entity is forced to pay WAC for these products if purchased for the contract pharmacy.

Date issue first observed: October 1, 2020

Date drug last available at 340B price (enter NEVER if has never been available): 9.30.2020

Table 2: Incorrect 340B Price

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

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

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

☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____

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

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

☐Other (*please describe issue*):

BLUE RIDGE HEALTH

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

Date issue first observed: _____

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

Signature

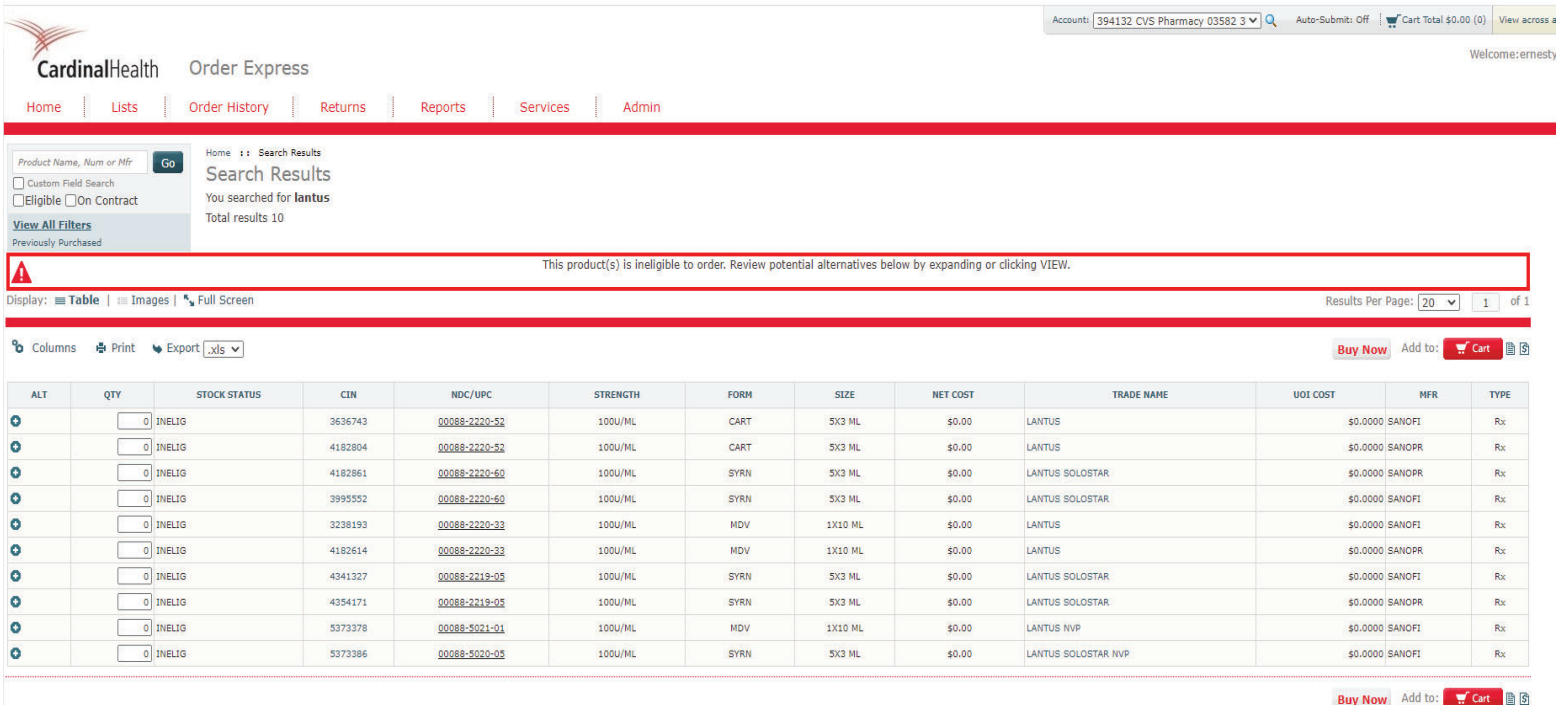
HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): __Gwendolen Ernesty_____ **Phone**: ____828-692-4289 ext. 3451___

Email Address: ___gernesty@brchs.com_____

Contact Role/Organization: Primary Contact and Director of Pharmacy/ Blue Ridge Community Health Services, Inc.

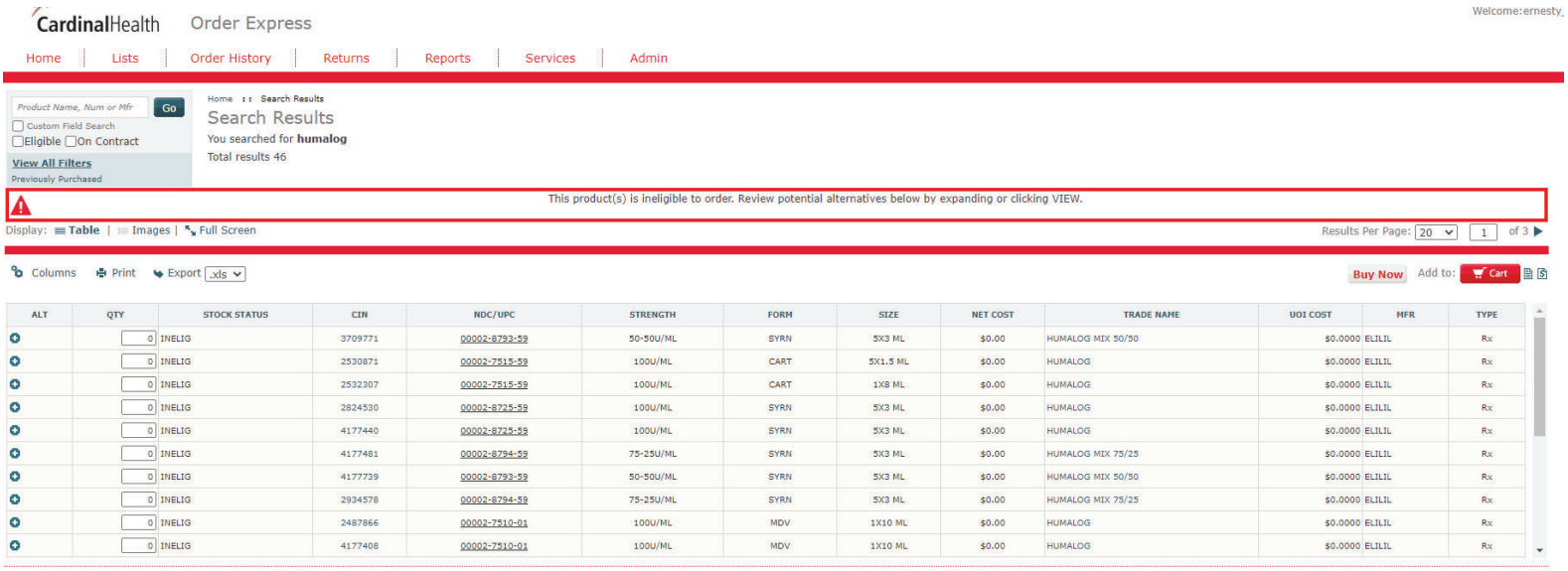
Contact Signature: Gwendolen Ernesty **Date**: 10/19/2020



ALT	QTY	STOCK STATUS	CIN	NDC/UPC	STRENGTH	FORM	SIZE	NET COST	TRADE NAME	UOI COST	MFR	TYPE
	0	INELIG	3636743	00088-2220-52	100U/ML	CART	5X3 ML	$0.00	LANTUS	$0.0000	SANOFI	Rx
	0	INELIG	4182804	00088-2220-52	100U/ML	CART	5X3 ML	$0.00	LANTUS	$0.0000	SANOPR	Rx
	0	INELIG	4182861	00088-2220-60	100U/ML	SYRN	5X3 ML	$0.00	LANTUS SOLOSTAR	$0.0000	SANOPR	Rx
	0	INELIG	3995552	00088-2220-60	100U/ML	SYRN	5X3 ML	$0.00	LANTUS SOLOSTAR	$0.0000	SANOFI	Rx
	0	INELIG	3238193	00088-2220-33	100U/ML	MDV	1X10 ML	$0.00	LANTUS	$0.0000	SANOFI	Rx
	0	INELIG	4182614	00088-2220-33	100U/ML	MDV	1X10 ML	$0.00	LANTUS	$0.0000	SANOPR	Rx
	0	INELIG	4341327	00088-2219-05	100U/ML	SYRN	5X3 ML	$0.00	LANTUS SOLOSTAR	$0.0000	SANOFI	Rx
	0	INELIG	4354171	00088-2219-05	100U/ML	SYRN	5X3 ML	$0.00	LANTUS SOLOSTAR	$0.0000	SANOPR	Rx
	0	INELIG	5373378	00088-5021-01	100U/ML	MDV	1X10 ML	$0.00	LANTUS NVP	$0.0000	SANOFI	Rx
	0	INELIG	5373386	00088-5020-05	100U/ML	SYRN	5X3 ML	$0.00	LANTUS SOLOSTAR NVP	$0.0000	SANOFI	Rx

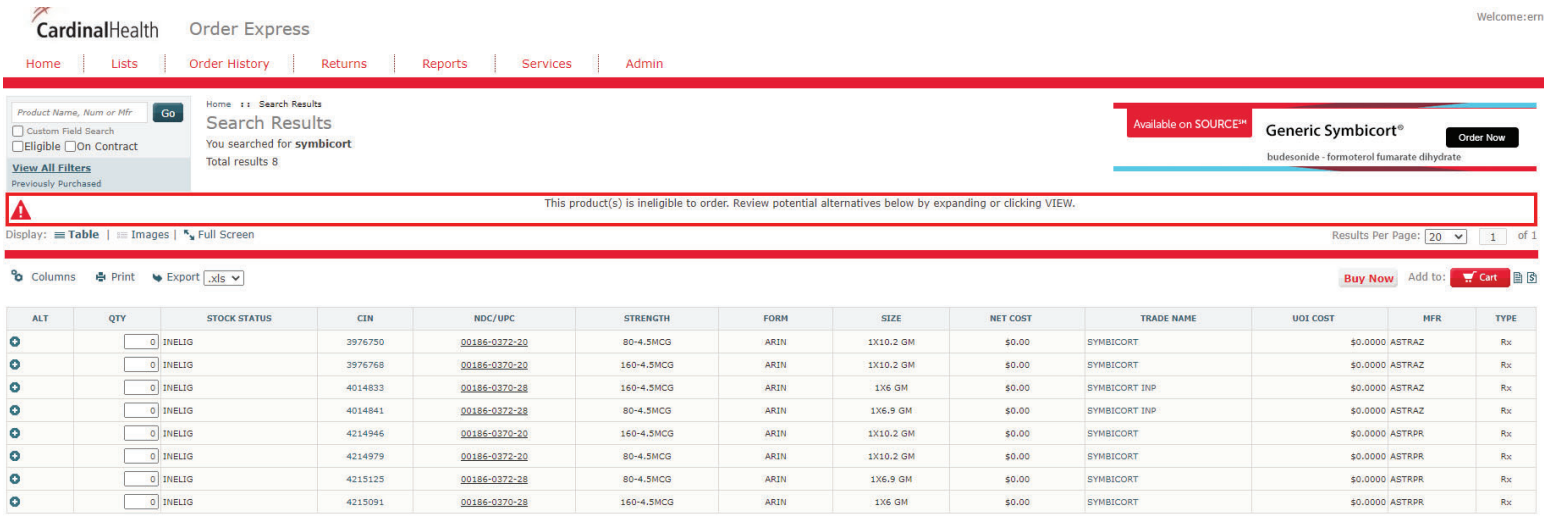
The products from **Sanofi** are marked as “Ineligible” for purchase on the contract pharmacy 340B account due to the removal of the 340B pricing by the manufacturer.

VLTR_001589



The products from **Lilly** are marked as “Ineligible” for purchase on the contract pharmacy 340B account due to the removal of the 340B pricing by the manufacturer.

VLTR_001590



The products from **AstraZeneca** are marked as “Ineligible” for purchase on the contract pharmacy 340B account due to the removal of the 340B pricing by the manufacturer.

VLTR_001591

BLUE RIDGE HEALTH

Background Information

Entity Name: ___Blue Ridge community Health Services, Inc. _____ **340B ID:** __CH040940____

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

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
1. 00002-7510-01	Humalog Inj. 100mg/mL	Lilly	10		mL	Cardinal, McKesson
2. 00002-8215-01	Humulin R Inj. U-100	Lilly	10		mL	Cardinal, McKesson
3. 00002-7510-17	Humalog Inj. 100/mL	Lilly	3		mL	Cardinal, McKesson
4. 00002-1434-80	Trulicity Inj. 1.5/0.5	Lilly	4		ct	Cardinal, McKesson
5. 00002-8031-01	Glucagon Kit 1mg	Lilly	1		Each	Cardinal, McKesson
6. 00002-7715-59	Basaglar Inj.	Lilly	15		mL	Cardinal, McKesson

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

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

Table 1: Unavailable at 340B Price

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

BLUE RIDGE HEALTH

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

☐Drug shortage

☐Drug subject to limited distribution or specialty pharmacy plan

☒Other (*please describe*): __Manufacturer is refusing to ship to my contract pharmacies ____

☐Unknown

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

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

☒Confirmed shortage issues by reviewing validated resources*

☒Contacted wholesaler and/or manufacturer to confirm unavailability

☒Other (*please describe issue*): _Lilly is refusing to ship to my contract pharmacies at 340B prices. My covered entity is forced to pay WAC for these products if purchased for a contract pharmacy.

Date issue first observed: _9/1/2020__

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

Table 2: Incorrect 340B Price

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

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

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

☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____

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

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

☐Other (*please describe issue*):

_____

_____

_____

_____

_____

_____

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

Date issue first observed: _____

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

Signature

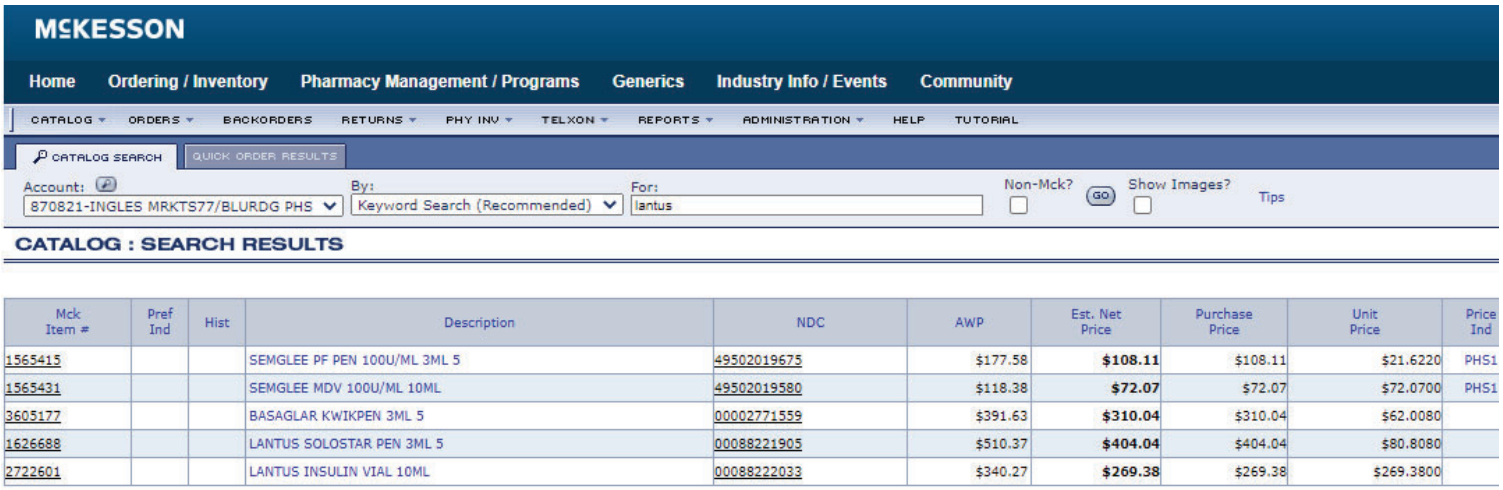
HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): __Gwendolen Ernesty_____ **Phone**: ___828-692-4289 ext. 3451____

Email Address: gernesty@brchs.com _____

Contact Role/Organization: Primary Contact and Director of Pharmacy / Blue Ridge Community Health Services, Inc.

Contact Signature: Gwendolen E Ernesty **Date**: 10/19/2020



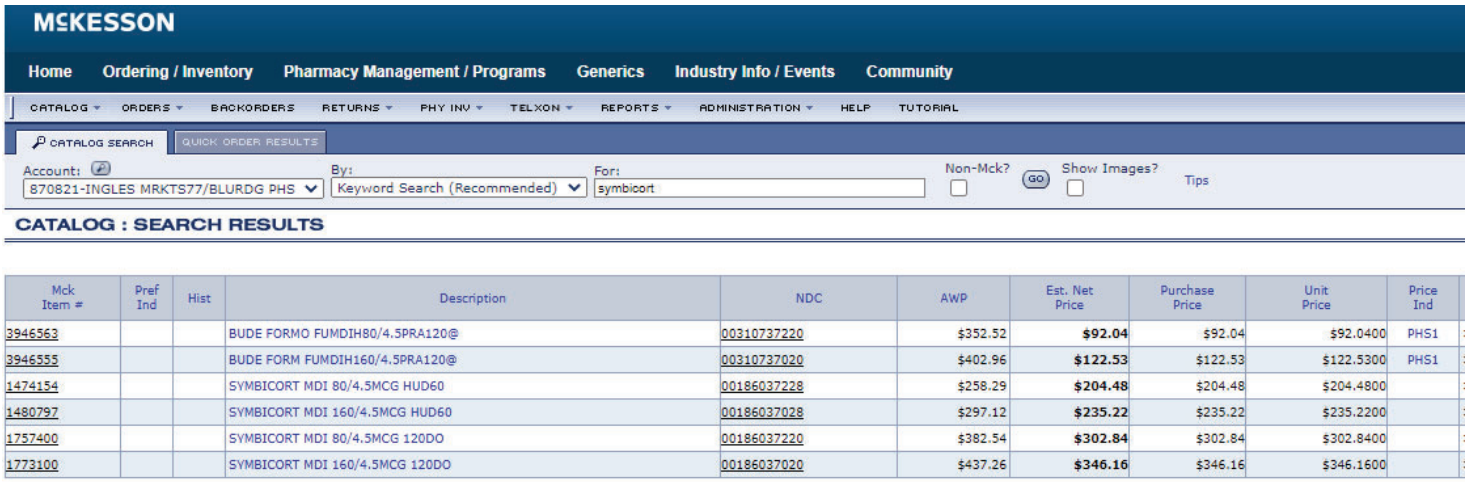
Mck Item #	Pref Ind	Hist	Description	NDC	AWP	Est. Net Price	Purchase Price	Unit Price	Price Ind
1565415			SEMGLEE PF PEN 100U/ML 3ML 5	49502019675	$177.58	**$108.11**	$108.11	$21.6220	PHS1
1565431			SEMGLEE MDV 100U/ML 10ML	49502019580	$118.38	**$72.07**	$72.07	$72.0700	PHS1
3605177			BASAGLAR KWIKPEN 3ML 5	00002771559	$391.63	**$310.04**	$310.04	$62.0080	
1626688			LANTUS SOLOSTAR PEN 3ML 5	00088221905	$510.37	**$404.04**	$404.04	$80.8080	
2722601			LANTUS INSULIN VIAL 10ML	00088222033	$340.27	**$269.38**	$269.38	$269.3800	

Screenshot reflects pricing currently loaded to PHS account for one of our contract pharmacy sites for Sanofi.

340B ceiling price for Lantus (NDC 00088-2219-05) per OPAIS as of 10/19/2020: [redacted]

1

VLTR_001595



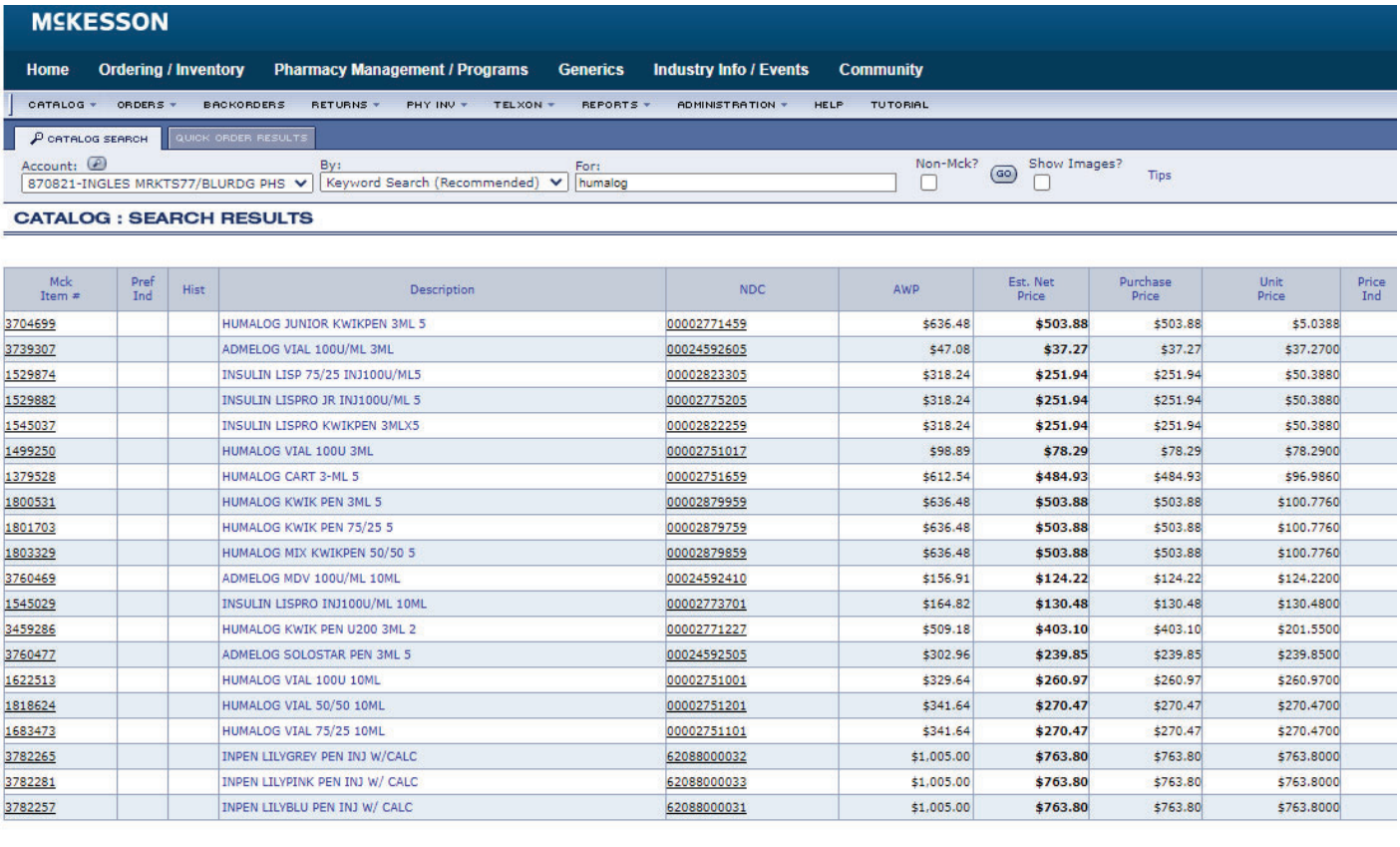
Mck Item #	Pref Ind	Hist	Description	NDC	AWP	Est. Net Price	Purchase Price	Unit Price	Price Ind
3946563			BUDE FORMO FUMDIH80/4.5PRA120@	00310737220	$352.52	**$92.04**	$92.04	$92.0400	PHS1
3946555			BUDE FORM FUMDIH160/4.5PRA120@	00310737020	$402.96	**$122.53**	$122.53	$122.5300	PHS1
1474154			SYMBICORT MDI 80/4.5MCG HUD60	00186037228	$258.29	**$204.48**	$204.48	$204.4800	
1480797			SYMBICORT MDI 160/4.5MCG HUD60	00186037028	$297.12	**$235.22**	$235.22	$235.2200	
1757400			SYMBICORT MDI 80/4.5MCG 120DO	00186037220	$382.54	**$302.84**	$302.84	$302.8400	
1773100			SYMBICORT MDI 160/4.5MCG 120DO	00186037020	$437.26	**$346.16**	$346.16	$346.1600	

Screenshot reflects pricing currently loaded to PHS account for one of our contract pharmacy sites for AstraZeneca.

340B ceiling price for Symbicort (00186-0370-20) per OPAIS as of 10/19/2020: [redacted]

2

VLTR_001596



McKESSON

Home | Ordering / Inventory | Pharmacy Management / Programs | Generics | Industry Info / Events | Community

CATALOG | ORDERS | BACKORDERS | RETURNS | PHY INV | TELXON | REPORTS | ADMINISTRATION | HELP | TUTORIAL

CATALOG SEARCH | QUICK ORDER RESULTS

Account: 870821-INGLES MRKTS77/BLURDG PHS | By: Keyword Search (Recommended) | For: humalog | Non-Mck? | GO | Show Images? | Tips

CATALOG : SEARCH RESULTS

Mck Item #	Pref Ind	Hist	Description	NDC	AWP	Est. Net Price	Purchase Price	Unit Price	Price Ind
3704699			HUMALOG JUNIOR KWIKPEN 3ML 5	00002771459	$636.48	**$503.88**	$503.88	$5.0388	
3739307			ADMELOG VIAL 100U/ML 3ML	00024592605	$47.08	**$37.27**	$37.27	$37.2700	
1529874			INSULIN LISP 75/25 INJ100U/ML5	00002823305	$318.24	**$251.94**	$251.94	$50.3880	
1529882			INSULIN LISPRO JR INJ100U/ML 5	00002775205	$318.24	**$251.94**	$251.94	$50.3880	
1545037			INSULIN LISPRO KWIKPEN 3MLX5	00002822259	$318.24	**$251.94**	$251.94	$50.3880	
1499250			HUMALOG VIAL 100U 3ML	00002751017	$98.89	**$78.29**	$78.29	$78.2900	
1379528			HUMALOG CART 3-ML 5	00002751659	$612.54	**$484.93**	$484.93	$96.9860	
1800531			HUMALOG KWIK PEN 3ML 5	00002879959	$636.48	**$503.88**	$503.88	$100.7760	
1801703			HUMALOG KWIK PEN 75/25 5	00002879759	$636.48	**$503.88**	$503.88	$100.7760	
1803329			HUMALOG MIX KWIKPEN 50/50 5	00002879859	$636.48	**$503.88**	$503.88	$100.7760	
3760469			ADMELOG MDV 100U/ML 10ML	00024592410	$156.91	**$124.22**	$124.22	$124.2200	
1545029			INSULIN LISPRO INJ100U/ML 10ML	00002773701	$164.82	**$130.48**	$130.48	$130.4800	
3459286			HUMALOG KWIK PEN U200 3ML 2	00002771227	$509.18	**$403.10**	$403.10	$201.5500	
3760477			ADMELOG SOLOSTAR PEN 3ML 5	00024592505	$302.96	**$239.85**	$239.85	$239.8500	
1622513			HUMALOG VIAL 100U 10ML	00002751001	$329.64	**$260.97**	$260.97	$260.9700	
1818624			HUMALOG VIAL 50/50 10ML	00002751201	$341.64	**$270.47**	$270.47	$270.4700	
1683473			HUMALOG VIAL 75/25 10ML	00002751101	$341.64	**$270.47**	$270.47	$270.4700	
3782265			INPEN LILYGREY PEN INJ W/CALC	62088000032	$1,005.00	**$763.80**	$763.80	$763.8000	
3782281			INPEN LILYPINK PEN INJ W/ CALC	62088000033	$1,005.00	**$763.80**	$763.80	$763.8000	
3782257			INPEN LILYBLU PEN INJ W/ CALC	62088000031	$1,005.00	**$763.80**	$763.80	$763.8000	

Screenshot reflects pricing currently loaded to PHS account for one of our contract pharmacy sites for Lilly.

340B ceiling price for Humalog (NDC 00002-7510-01) per OPAIS as of 10/19/2020: [redacted]

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

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

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

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

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

Background Information

Entity Name: East Valley **340B ID:** CH099000

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

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	ABC
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	ABC
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	ABC
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	ABC
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	ABC
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	ABC
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	ABC
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	ABC

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

00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	ABC
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	ABC
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	ABC
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	ABC
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	ABC
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	ABC
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	ABC
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	ABC
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	ABC
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	ABC
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	ABC
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	ABC
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	ABC
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	ABC
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	ABC
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	ABC
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	ABC
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	ABC
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	ABC
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	ABC

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

00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	ABC
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	ABC
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	ABC
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	ABC
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	ABC
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	ABC
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	ABC
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	ABC
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	ABC
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	ABC
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	ABC
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	ABC
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	ABC
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	ABC
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	ABC
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	ABC
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	ABC
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	ABC
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	ABC
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	ABC

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

00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	ABC
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	ABC
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	ABC
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	ABC
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	ABC
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	ABC
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	ABC
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	ABC
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	ABC
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	ABC
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	ABC
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	ABC
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	ABC
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	ABC
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	ABC
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	ABC
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	ABC
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	ABC
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	ABC
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	ABC

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

00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	ABC
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	ABC
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	ABC
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	ABC
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	ABC
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	ABC
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	ABC
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	ABC
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	ABC
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	ABC
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	ABC
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	ABC
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	ABC
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	ABC
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	ABC
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	ABC
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	ABC
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	ABC
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	ABC
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	ABC

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

00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	ABC
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	ABC
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	ABC
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	ABC
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	ABC
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	ABC
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	ABC
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	ABC
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	ABC
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	ABC
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	ABC
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	ABC
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	ABC
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	ABC

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

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

Table 1: Unavailable at 340B Price

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

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

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

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

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

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

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

  _____

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

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

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

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

Table 2: Incorrect 340B Price

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

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

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)
  - Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*
- ☒ Validated the ceiling price using the 340B OPAIS pricing system on (date): 10/26/2020
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- ☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

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

Date issue first observed: _____

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

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

Signature

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

Contact Name (printed): Alicia Mardini **Phone**: 626-919-4333 x 2220

Email Address: amardini@evchc.org

Contact Role/Organization: CEO

Contact Signature: Alicia Mardini **Date**: 10/26/2020

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

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

Apexus 340B Prime Vendor PROGRAM

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

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

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

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

Background Information

Entity Name: Life Changers Intervention Services **340B ID:** RWII28470

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

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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

00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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

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

Table 1: Unavailable at 340B Price

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

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

Apexus 340B Prime Vendor PROGRAM

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

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

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

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

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

  _____

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

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

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

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

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price

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

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

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

_____
_____
_____
_____
_____
_____

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

Date issue first observed: _____

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

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

Apexus | 340B Prime Vendor PROGRAM

Signature

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

Contact Name (printed): BEVERLY STANLEY **Phone**: 910-754-7988

Email Address: lifechangersllc@yahoo.com

Contact Role/Organization: CEO/EXECUTIVE DIRECTOR

Contact Signature: [signature] **Date**: 10/29/20

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

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

Apexus 340B Prime Vendor PROGRAM

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

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

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

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

Background Information

Entity Name: MQVN Community Development Corp **340B ID:** CHC26582-00

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

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

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

Apexus 340B Prime Vendor PROGRAM

00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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

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

Table 1: Unavailable at 340B Price

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

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

Apexus 340B Prime Vendor PROGRAM

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

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

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

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

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

  _____

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

  _____

  _____

  _____

  _____

  _____

  _____

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

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

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

Apexus | 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price

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

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

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

_____
_____
_____
_____
_____
_____

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

Date issue first observed: _____

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

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

Apexus 340B Prime Vendor PROGRAM

Signature

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

Contact Name (printed): Diem Nguyen **Phone**: 504-254-2741

Email Address: diemnguyen.mgvncdc@gmail.com

Contact Role/Organization: CEO

Contact Signature: _____ **Date**: 11/2/2020

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

From: Zweerink, Scott
Sent: Thursday, November 05, 2020 1:28 PM
To: Orth, Paul <LINUS.ORTH@tmcmed.org>; 340BPricing@hrsa.gov
Cc: Lamar, Lona M <Lona.Lamar@tmcmed.org>; Hennenfent, Joel A <Joel.Hennenfent@tmcmed.org>
Subject: RE: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer

Ms. Zadecky,

I am circling back on the submission below. Is there any update?

University Health

K. SCOTT ZWEERINK, PharmD
Director of Outpatient Pharmacy Services and 340B Program Compliance
(816) 404-4223 |
Kenneth.Zweerink@tmcmed.org

From: Orth, Paul
Sent: Monday, October 12, 2020 4:41 PM
To: 340BPricing@hrsa.gov
Cc: Zweerink, Scott <Kenneth.Zweerink@tmcmed.org>; Lamar, Lona M <Lona.Lamar@tmcmed.org>; Hennenfent, Joel A <Joel.Hennenfent@tmcmed.org>; Orth, Paul <LINUS.ORTH@tmcmed.org>
Subject: FW: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer

Good Afternoon Ms Zadecky,

In August 2020 Truman Medical Center Lakewood (DSH260102) received notification that Lilly will stop providing 340B pricing on all of their medication with labeler code 00002 when the 340B covered entity (CE) purchasing the drug elects to have it shipped to a 340B contract pharmacy. Since September 1, 2020, when Lilly's policy went into effect, Truman Medical Center (TMC) – Lakewood (DSH260102) has been unable to purchase any medication with labeler code 00002 at the 340B ceiling price for delivery to its contract pharmacy. This action impacts patient care in that it prevents TMC Lakewood's ability to perform its safety net mission by providing 340B pricing discounts directly to vulnerable patients in the communities where they live.

In addition, in August 2020 Truman Medical Center Lakewood (DSH260102) received notification that AstraZeneca will stop providing 340B pricing on all of their medication with labeler code 00186 when the 340B covered entity (CE) purchasing the drug elects to have it shipped to a 340B contract pharmacy. Since October 1, 2020, when AstraZeneca's policy went into effect, Truman Medical Center (TMC) – Lakewood (DSH260102) has been unable to purchase any medication with labeler code 00186 at the 340B ceiling price for delivery to its contract pharmacy. This action impacts patient care in that it prevents TMC Lakewood's ability to perform its safety net mission by providing 340B pricing discounts directly to vulnerable patients in the communities where they live.

In addition, Lilly and AstraZeneca's failure to sell covered outpatient drugs to TMC Lakewood for delivery to TMC Lakewood's contract pharmacies at the 340B ceiling price is contrary to the 340B statute. Under the terms of the statute and the Pharmaceutical Pricing Agreement (PPA) Lilly has entered with HRSA, Lilly and AstraZeneca must charge TMC Lakewood no more than the 340B ceiling price for any covered outpatient drug. *See* section 340B(a)(1). Failure to do so, to the outlet chosen by the hospital, violates the 340B statute and the PPA.

We understand that in response to a request from 340B Health for HRSA's official position on Lilly's notice, on July 8, 2020, HRSA stated that it cannot require Lilly and AstraZeneca to offer the drug at the 340B ceiling price because the 2010 contract pharmacy guidance (75 Fed. Reg. 10272 (March 5, 2010)) is not legally enforceable.

The 340B statute, which HRSA acknowledged in the July 8 statement controls HRSA's decision, however, requires Lilly and AstraZeneca to sell its drugs to TMC Lakewood at the 340B ceiling price, regardless of whether the drug is furnished at the TMC Lakewood's pharmacy or at a pharmacy that has entered into a contract with TMC Lakewood to furnish 340B drugs to TMC Lakewood's patients. The guidance merely described the correct interpretation of the statute, and the statute plainly binds HRSA.

In light of the plain meaning of the statute, TMC Lakewood is asking HRSA to reconsider the formal response it provided to 340B Health and to direct Lilly and AstraZeneca to sell its products to TMC Lakewood through its contract pharmacies at or below the 340B ceiling price and to work in good faith to correct overcharges. Attached are appropriate forms to document the lack pricing availability and overcharge of product.

We look forward to hearing from you. Please reach out if you have any questions.

Sincerely,

Paul Orth

University Health

Paul Orth
340B Compliance Analyst, Pharmacy
(816) 404-4177 | linus.orth@tmcmed.org

From: HRSA HSB 340B Pricing [mailto:340BPricing@hrsa.gov]
Sent: Thursday, September 03, 2020 9:53 AM
To: Zweerink, Scott <Kenneth.Zweerink@tmcmed.org>
Subject: RE: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer

Good morning Mr. Zweerink:

HRSA is aware of the communication you forwarded. HRSA is not posting a letter at this time as HRSA is considering whether manufacturer policies, including Lilly's, violate the 340B statute and whether sanctions may apply. Under section 340B(a)(1) of the Public Health Service Act (PHSA), a manufacturer participating in the 340B Program must offer its covered outpatient drugs for purchase at or below the 340B ceiling price. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B(d)(1)(B)(vi) of the PHSA.

The 340B statute does not specify the mode by which 340B drugs may be dispensed. However, the Agency believes contract pharmacies serve a vital function in covered entities' ability to serve underserved and vulnerable populations, particularly as many covered entities do not operate in-house pharmacies. Without comprehensive regulatory authority, HRSA has only limited ability to issue enforceable regulations to ensure clarity in program requirements across all the interdependent aspects of the 340B Program.

We believe that manufacturers that refuse to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions. To this end, HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements.

Julie Zadecky, Pharm D, BCNP
Office of Pharmacy Affairs
Phone: 301-945-9481

HRSA

From: Zweerink, Scott <Kenneth.Zweerink@tmcmed.org>
Sent: Wednesday, September 2, 2020 1:25 PM
To: HRSA HSB 340B Pricing <340BPricing@hrsa.gov>
Cc: Hoelscher, Marga J <Marga.Hoelscher@tmcmed.org>; Zweerink, Scott <Kenneth.Zweerink@tmcmed.org>
Subject: RE: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer
Importance: High

Ms. Zadecky,

I wanted to confirm that HRSA/OPA was aware of the communications attached. Our 340B team could not find this on the HRSA database under manufacturer communication. Is this communication and stated action approved by HRSA/OPA?

Thank you,

Scott

University Health

K. SCOTT ZWEERINK, PharmD
Director of Outpatient Pharmacy Services and 340B Program Compliance
(816) 404-4223 |
Kenneth.Zweerink@tmcmed.org

From: Zweerink, Scott
Sent: Friday, August 28, 2020 10:27 AM
To: '340bpricing@hrsa.gov' <340bpricing@hrsa.gov>
Subject: FW: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer

Ms. Zadecky,

Please find TMC responses below. We appreciate HRSA/OPA investigation and look forward to your response. Please continue to reach out if further clarification is needed.

Thank you,

Scott

University Health

K. SCOTT ZWEERINK, PharmD
Director of Outpatient Pharmacy Services and 340B Program Compliance
(816) 404-4223 |
Kenneth.Zweerink@tmcmed.org

From: HRSA HSB 340B Pricing [mailto:340BPricing@hrsa.gov]
Sent: Wednesday, August 26, 2020 10:19 AM
To: Zweerink, Scott <Kenneth.Zweerink@tmcmed.org>; HRSA HSB 340B Pricing <340BPricing@hrsa.gov>
Subject: RE: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer

Dear Mr. Zweerink:

As HRSA continues to monitor the Cialis purchasing restrictions at contract pharmacies, HRSA requests some additional information regarding your entity's experience purchasing Cialis. To help us better understand the situations, please answer the following questions:

- **How were you notified that your requests for the 340B ceiling price were denied?** TMC RESPONSE:TMC was notified through Lilly public notice on HRSA database July 1, 2020 that 340B pricing would not be honored at contract pharmacies. TMC monitored purchasing accounts and confirmed 340B pricing was unavailable when replenishment product was ordered and shipped to contract pharmacy after July 1, 2020. TMC worked with wholesaler account manager to confirm pricing is unavailable.
  - **Was a 340B price unavailable in your wholesaler 340B account?** TMC RESPONSE: Yes
  - **What account (e.g. 340B account, WAC account, GPO account) was the product ultimately purchased on?** TMC RESPONSE: 340B account
- **How was the transaction executed?** TMC RESPONSE: 340B eligible patients were dispensed Cialis prior to July 1, 2020. After July 1,2020, the 340B administrator for the contract pharmacy placed a replenishment order and TMC was charged WAC price for the purchases.
  - **Was the entity charged WAC for the purchase?** TMC RESPONSE: Yes
    - **Was the WAC price loaded into the 340B account?** TMC RESPONSE: Yes
  - **Did the contract pharmacy count the transaction as a non-340B commercial dispense?** TMC RESPONSE: No, the dispensations for purchases occurred prior to 340B price being unavailable and 340B eligible patients were dispensed 340B drugs.
- **Please provide any additional information regarding your experience.** TMC RESPONSE: TMC is a good steward of the 340B program and passes 340B savings on to 340B eligible patients. Patients benefiting from discount are most often vulnerable patient populations without prescription "coverage." Any manufacturer who denies 340B pricing to a covered entity within its contract pharmacies is in violation of the 340B statute and is certainly not working in the spirit of 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. Leveraging contract pharmacy agreements is a key element of TMC strategy to provide 340B discounts to 340B eligible patients in the communities where they live.

Thank you for your participation in the 340B Program.

Sincerely,

Julie Zadecky, Pharm D, BCNP
Office of Pharmacy Affairs
Phone: 301-945-9481

HRSA

From: Zweerink, Scott <Kenneth.Zweerink@tmcmed.org>
Sent: Tuesday, August 18, 2020 5:31 PM
To: HRSA HSB 340B Pricing <340BPricing@hrsa.gov>
Subject: Potential SPAM:340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer

August 18, 2020

Via Electronic Mail: 340bpricing@hrsa.gov

Rear Admiral Krista Pedley
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

RE: HRSA's Position on Eli Lilly's Policy for Cialis Products

Dear RADM Pedley:

In June 2020, HRSA posted a notice from Lilly which states that effective July 1, 2020, the company will no longer provide 340B pricing on three formulations of its drug Cialis® when the 340B covered entity (CE) purchasing the drug elects to have it shipped to a 340B contract pharmacy. Since July 1, 2020, when Lilly's policy went into effect, Truman Medical Center (TMC) – Hospital Hill (DSH260048) has been unable to purchase Cialis® at the 340B ceiling price for delivery to its contract pharmacy, and was significantly overcharged on several purchases. This action impacts patient care in that it prevents TMC Hospital Hill's ability to perform its safety net mission by providing 340B pricing discounts directly to vulnerable patients in the communities where they live.

In addition, Lilly's failure to sell Cialis® to TMC Hospital Hill for delivery to TMC Hospital Hill's contract pharmacies at the 340B ceiling price is contrary to the 340B statute. Under the terms of the statute and the Pharmaceutical Pricing Agreement (PPA) Lilly has entered with HRSA, Lilly must charge TMC Hospital Hill no more than the 340B ceiling price for any covered outpatient drug, including Cialis®. *See* section 340B(a)(1). Failure to do so, including the refusal to sell Cialis® to the outlet chosen by the hospital, violates the 340B statute and the PPA.

We understand that in response to a request from 340B Health for HRSA's official position on Lilly's notice, on July 8, 2020, HRSA stated that it cannot require Lilly to offer the drug at the 340B ceiling price because the 2010 contract pharmacy guidance (75 Fed. Reg. 10272 (March 5, 2010)) is not legally enforceable.

The 340B statute, which HRSA acknowledged in the July 8 statement controls HRSA's decision, however, requires Lilly to sell its drugs to TMC Hospital Hill at the 340B ceiling price, regardless of whether the drug is furnished at the TMC Hospital Hill's pharmacy or at a pharmacy that has entered into a contract with TMC

Hospital Hill to furnish 340B drugs to TMC Hospital Hill's patients. The guidance merely described the correct interpretation of the statute, and the statute plainly binds HRSA.

In light of the plain meaning of the statute, TMC Hospital Hill is asking HRSA to reconsider the formal response it provided to 340B Health and to direct Lilly to sell its Cialis® products to TMC Hospital Hill through its contract pharmacies at or below the 340B ceiling price and to work in good faith to correct overcharges. Attached are appropriate forms to document the lack pricing availability and overcharge of product.

We look forward to hearing from you. Please reach out if you have any questions.

Sincerely,

K. Scott Zweerink, PharmD
Director of Outpatient Pharmacy Services and
340B Program Compliance
(816) 404-4223 | Kenneth.Zweerink@tmcmed.org
Truman Medical Center – Hospital Hill (DSH260048)

University Health

K. SCOTT ZWEERINK, PharmD
Director of Outpatient Pharmacy Services and
340B Program Compliance
(816) 404-4223 |
Kenneth.Zweerink@tmcmed.org

The information contained in this communication may be confidential and is intended only for the use of the intended recipient(s). If the reader of this message is not the intended recipient(s), you are hereby notified that any dissemination, distribution, or copying of this communication, or any of its contents, is strictly prohibited. If you have received this communication in error, please return it to the sender immediately and delete any copy of it from your computer system.

- - - - - - - - WARNING: - - - - - - - -
This email originated outside of the TMC email system. If this email came from a sender you trust, then proceed as you normally would. Please do not click on links or open attachments if you don't recognize the sender.

Right click on the sender and use Outlook Junk Mail options to block spam emails you don't want.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. 1:20-cv-03032
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of 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

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 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.

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 Christine Chen

Kimberly Christine Chen
Director of Pharmacy
North Country HealthCare, Inc.

Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

By E-mail (KPedley@hrsa.gov)

August 19, 2020

Rear Admiral Krista M. Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

RE: Availability of 340B-Priced Products to Contract Pharmacies

Dear RADM Pedley:

Eli Lilly and Company (Lilly) is writing to inform the Health Resources and Services Administration (HRSA) that, effective September 1, we have instructed wholesalers to discontinue our practice of voluntarily honoring requests for 340B "contract pharmacies" for orders on all Lilly products except where Lilly has approved an exception that (1) a covered entity does not have an in-house pharmacy and/or (2) for certain insulins, if the 340B discounted price is passed on to the patient. Unless HRSA objects and states that it believes our proposed discontinuation of voluntary contract pharmacy 340B discounts is unlawful by August 31, providing us the reasons for its conclusions, Lilly will no longer honor contract pharmacy-related requests for Lilly products (labeler codes 00002, 00777, and 66173), subject to the exceptions above.

As we explained in our May 18, 2020 letter to you, we believe this action is prudent, reasonable and lawful, particularly in light of the substantial and ongoing expansion of contract pharmacy participation in the 340B program and the now overwhelming evidence demonstrating that contract pharmacy transactions result in 340B duplicate discounts and diversion. Based on these concerns, coupled with the risk that contract pharmacy transactions may be incorrectly considered a basis for Civil Money Penalties or incorrectly subject us to onerous repayment obligations, Lilly feels compelled to take this additional action at this time.

In discussing our plan with respect to the Cialis products, HRSA concluded that its Contract Pharmacy Guidances were non-binding and that our plan did not give rise to any enforceable violation of the 340B statute. Indeed, in our view, contract pharmacy transactions constitute prohibited diversion and lead to duplicate discounts in violation of the statute. We believe that the legal analyses performed previously by HRSA and Lilly apply equally here.

I. The Insulin Exception and Lilly's Commitment to Transparency with HRSA

On July 24, the President signed Executive Order 13,937, "Access to Affordable Life-saving Medications." That order instructs the Secretary of Health and Human Services (HHS) to condition federal grant eligibility for federally qualified health centers (FQHCs) on an FQHC's commitment to pass on the 340B ceiling price to vulnerable patients. Lilly supports this goal. As the Executive Order states, insulin is a critical and lifesaving medication and many insulins "are subject to the

'penny pricing' policy when distributed to FQHCs, meaning FQHCs may purchase the drug at a price of one penny per unit of measure. These steep discounts, however, are not always passed through to low-income Americans at the point of sale. Those with low-incomes can be exposed to high insulin and injectable epinephrine prices…."

We applaud the Administration's concern with how discounts provided by pharmaceutical manufacturers are consumed by intermediaries and are not passed on to patients. And, unlike the Administration, which is legally more constrained than a manufacturer who voluntarily seeks to extend the 340B price through a contract pharmacy, Lilly can apply this HHS policy more broadly.

To that end, and for the reasons set forth below, Lilly will grant an exception to our contract pharmacy limited distribution program for certain Lilly insulin products (NDCs attached) to any 340B contract pharmacy that agrees to the following:

- 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.

    - Rationale: This is consistent with the approach set forth in the recent Executive Order. We appreciate that most contract pharmacies currently may not identify 340B eligible patients at that point-of-sale, choosing instead to identify these patients retrospectively. However, retroactive determinations are inconsistent with HRSA's expectations in both 1996 and 2010 Contract Pharmacy Guidance documents. Both of those guidances suggested that the following "contract provisions" be included in the agreements with the contract pharmacy:

> The pharmacy will dispense Covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient.[1]

While we agree these guidances are not legally binding, we assume that HRSA based its position, at least in part, on the fact that identification of 340B patients at the point-of-sale was, and remains, a critical safeguard to prevent duplicate discounts and diversion. It appears that covered entities and contract pharmacies have ignored this expectation from the outset. Given the growth in contract pharmacies and the well-documented non-compliance referenced in our May 18, 2020 letter, we believe that this is a reasonable condition to qualify for the insulin exception.

[1] 61 Fed. Reg. 43553 (Aug. 23, 1996) and 75 Fed. Reg. 10279 (Mar. 5, 2010); as we also noted in our May 18 letter, HRSA has elsewhere advised against covered entities retroactively reclassifying. *See* HRSA/OPA 340B FAQs, *at* https://www.hrsa.gov/opa/faqs/index.html (last visited August 11, 2020).

- Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing or any administration fee for the Lilly insulin.
    - Rationale: Just as Lilly does not seek to recoup the cost to manufacture or distribute penny priced insulins when they are sold to 340B covered entities, covered entities and their contract pharmacies seeking to obtain this exception we would expect covered entities and contract pharmacies to be willing to dispense the product free of charge.
- No insurer or payer is billed for the Lilly insulin dispensed.
    - Rationale: To avoid overcharges by 340B entities to federal or commercial payers, as well as to facilitate the avoidance of duplicative Medicaid rebates claims, Lilly believes that no third party should be billed for insulins dispensed under this exception.
- The covered entity provides claim-level detail (CLD) for their contract pharmacy(s) to Lilly so that we can validate that the foregoing conditions have been satisfied.
    - Rationale: Several other manufacturers have recently started requesting or requiring CLD from covered entities for their contract pharmacies. As these data should be both readily available and sufficient to confirm that the terms of our voluntary exception have been met, Lilly would seek this documentation.

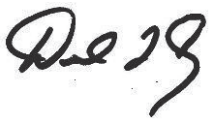
Lilly shares the Administration's goal of ensuring that 340B patients should directly benefit from the significant 340B discounts on Lilly insulins. Lilly will provide quarterly reports (or more frequently, if requested) regarding covered entity use of the two exceptions provided for under our policy.

Attached please find an updated Limited Distribution Notice for posting on the manufacturer notices website on September 1, 2020. Please note that this updated notice is intended to replace the Cialis Limited Distribution Notice which was effective July 1, 2020. If you have questions or comments related to this proposed notice, please do not hesitate to contact me.

***

Please feel free to contact me at derek.asay@lilly.com directly if you have any questions or need any additional information. Thank you for your attention to this very important matter.

Sincerely,

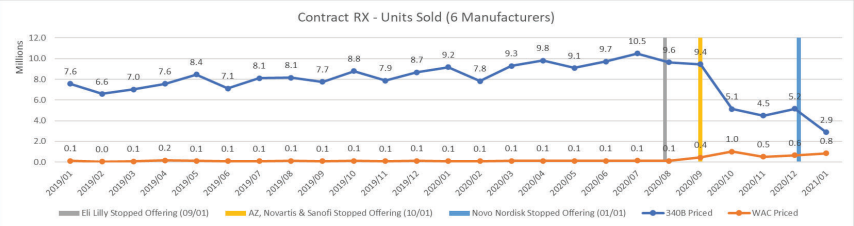


Derek L. Asay
Sr. Director, Government Strategy

Summary and Background

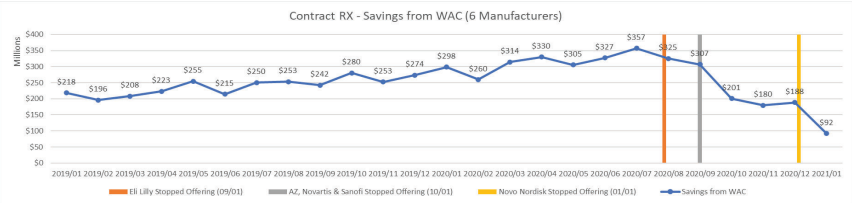
There are 6 manufacturers that have stopped or added limitations to offering 340B price in contract pharmacy arrangements. This analysis attempts to quantify the loss of units sold and savings.
There is not a longterm reciprocal increase in the WAC price purchasing when 340B contract pharmacy pricing is not available. This is because the third party administrator will stop identifying the newly WAC priced products as 340B eligible. There may be a transient spike in WAC purchases initially, but once the entities/software block these products from 340B purchasing, the NDC won't be used moving forward. This analysis demonstrates a decrease in 340B priced units sold from a high of 10.5M prior to the manufacturers' actions in 2020 to 2.9M in January 2021. Annualized this equates to a reduction in 340B units sold of nearly 83M. Note that the "By Units Sold (Contract RX)" tab outlines the consolidated and individual manufactures' units sold, and has units impact on grantees and hospitals.

Figure 1 - Monthly 340B Units Sold Before and After Manufacturers' Actions



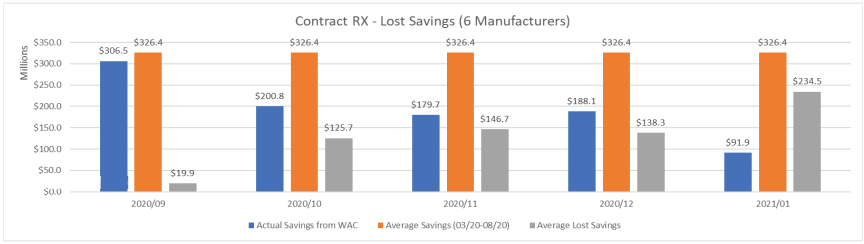
There are two tabs related to savings lost from the manufacturers' actions "Savings from WAC (Contract RX)" and "AverageLostSavings(ContractRX)". The "Savings from WAC (Contract RX)" tab outlines the monthly savings from the 6 manufacturers from January 2019 to January 2021. The highest month of savings before the changes was July 2020 and the savings was $357M with the lowest savings in January 2021, with $92M in savings. The annualized savings lost between the high and low savings months was $3.2B. Figure 2 is a roll up of all 6 manfacturers and the tab has a breakdown by each manufacturer and then by grantee and hospital savings.

Figure 2 - Monthly 340B Contract Pharmacy Savings Before and After 6 Manufacturers' Actions- Lost Annualized Savings = $3.2B



The "AverageLost Savings(ContractRX)" outlines the impact on covered entities in lost savings until January 2021, by comparing the savings from the period of 3/2020-8/2020 as a control to the actual savings in that month. Figure 3 demonstrates the loses from 9/2020 to 1/2021.

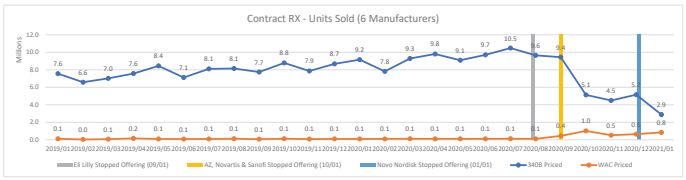
Figure 3 - Lost Savings from 9/2020 to 1/2021



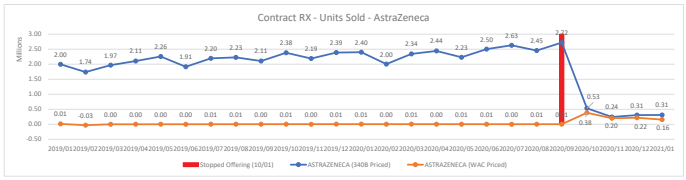
Key to Remaining Tabs

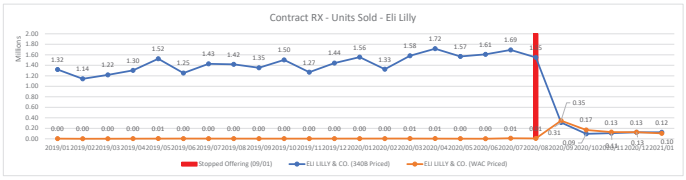
"By Sales (Contract RX)": Provides contract pharmacy sales at 340B and the WAC prices for all 6 manufacturers, for each manufacturer, and then by grantees and hospitals.
"Total Contract RX Sales": Outlines all manufacturers sales to contract pharmacy arrangements.
"By Units Sold (non-Contract RX): Outlines the monthly units sold for the 6 manufacturers rolled up, individually and by grantees and hospitals for all non-contract pharmacy sales.
"By Sales (non-Contract RX): Outlines the monthly sales for the 6 manufacturers rolled up, individually and by grantees and hospitals for all non-contract pharmacy sales.

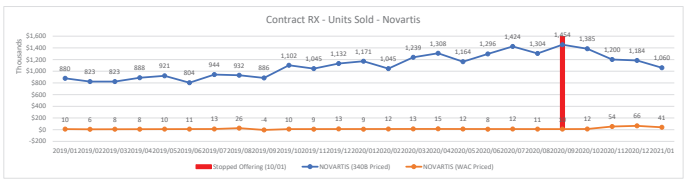
Sale type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B Price	7,552,965	6,580,202	7,015,318	7,571,563	8,448,783	7,119,865	8,111,379	8,146,720	7,740,482	8,790,498	7,859,882	8,681,258	9,158,240	7,824,473	9,295,598	9,805,474	9,088,852	9,706,344	10,482,697	9,648,675	9,446,163	5,131,307	4,494,375	5,150,687	2,882,688
WAC Price	117,257	39,222	72,466	164,015	99,981	84,535	94,210	118,600	75,454	119,954	87,441	110,382	96,657	95,354	115,964	106,877	106,038	108,063	123,102	109,945	445,096	1,015,051	521,761	647,288	845,724
Eli Lilly Stopped Offering (09/01)																				12,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					12,000,000				
Novo Nordisk Stopped Offering (01/01)																								12,000,000	

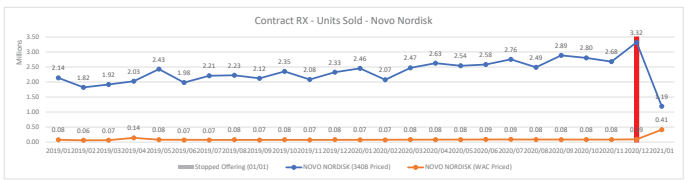


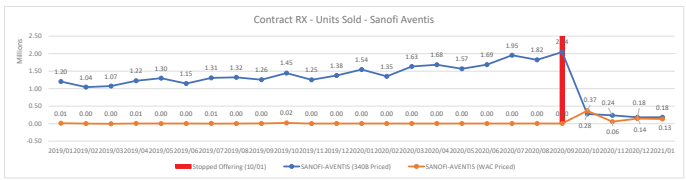
Sale type	Manufacturer	Manufacturer	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B	ASTRAZENEC	ASTRAZENEC	1,998,712	1,739,242	1,968,534	2,107,359	2,257,358	1,913,786	2,196,264	2,226,694	2,105,130	2,381,596	2,188,639	2,387,922	2,401,066	2,003,315	2,340,905	2,441,548	2,228,982	2,501,787	2,629,031	2,452,825	2,719,494	534,773	244,521	306,482	311,210
WAC	ASTRAZENEC	ASTRAZENEC	14,144	-28,444	403	4,553	4,822	2,290	5,273	5,922	3,621	5,241	2,340	6,235	6,195	4,926	8,128	4,028	5,020	5,399	2,401	5,199	5,102	384,787	201,627	217,649	156,204
		Stopped Offering (10/01)																					3,000,000				
340B	ELI LILLY & C	ELI LILLY & C	1,319,983	1,142,145	1,217,714	1,303,748	1,524,679	1,252,729	1,427,013	1,419,225	1,352,628	1,502,821	1,268,730	1,443,154	1,555,998	1,325,501	1,580,931	1,715,723	1,568,058	1,608,907	1,692,781	1,550,370	310,292	94,811	107,136	125,075	124,134
WAC	ELI LILLY & C	ELI LILLY & C	3,512	1,018	2,062	4,019	5,069	3,702	3,154	3,800	3,727	3,410	4,503	3,075	4,311	4,026	6,278	5,170	4,457	2,663	11,102	7,536	345,761	167,380	127,493	126,721	104,215
		Stopped Offering (09/01)																				2,000,000					
340B	NOVARTIS	NOVARTIS (3	879,808	823,276	822,953	888,065	921,269	803,538	943,648	931,998	886,287	1,101,776	1,045,489	1,132,481	1,171,197	1,045,481	1,239,245	1,308,137	1,163,811	1,295,602	1,423,690	1,304,216	1,454,065	1,385,358	1,200,306	#######	#######
WAC	NOVARTIS	NOVARTIS (N	9,518	6,428	7,785	7,884	9,811	10,791	12,547	25,875	-4,058	10,283	8,570	12,860	8,996	12,318	13,412	14,927	11,886	7,729	12,494	10,794	10,214	12,218	53,855	65,653	40,951
		Stopped Offering (10/01)																					1,600,000				
340B	NOVO NORD	NOVO NORD	1,820,302	1,918,451	2,025,451	2,428,105	1,982,299	2,207,817	2,225,149	2,121,566	2,351,448	2,084,486	2,327,073	2,455,256	2,073,740	2,471,838	2,626,907	2,540,323	2,584,100	2,755,221	2,490,662	2,886,577	2,802,020	2,677,460	#######	#######
WAC	NOVO NORD	NOVO NORD	76,755	59,568	65,385	139,512	79,573	67,276	65,784	80,760	68,585	80,252	70,283	84,551	73,697	71,098	84,026	79,293	80,257	89,590	92,902	82,928	80,070	81,983	83,027	92,791	411,585
		Stopped Offering (01/01)																								#######	
340B	SANOFI-AVE	SANOFI-AVE	1,202,433	1,043,040	1,072,812	1,223,742	1,299,603	1,145,878	1,307,758	1,323,118	1,255,091	1,445,102	1,250,943	1,375,718	1,544,893	1,351,079	1,632,413	1,683,305	1,568,555	1,686,781	1,954,766	1,823,862	2,044,945	275,917	237,835	181,832	182,269
WAC	SANOFI-AVE	SANOFI-AVE	13,328	652	-3,169	8,047	707	477	7,452	2,244	3,579	20,767	1,745	3,661	3,459	2,987	4,121	3,461	4,418	2,682	4,203	3,488	3,949	368,683	55,760	144,474	132,769
		Stopped Offering (10/01)																					2,500,000				
340B	UNITED THE	UNITED THE	15,113	12,197	14,856	23,199	17,769	21,634	28,879	20,536	19,781	7,755	21,596	14,911	29,831	25,359	30,268	29,856	19,124	29,168	27,209	26,740	30,790	38,428	27,118	30,102	13,722

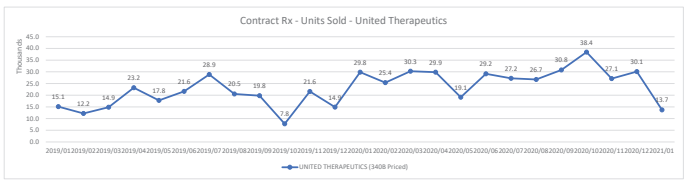




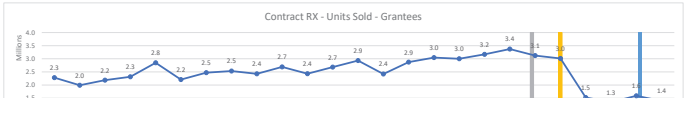


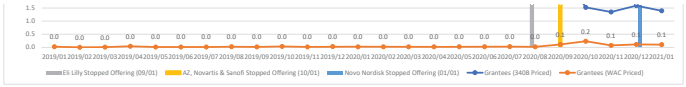


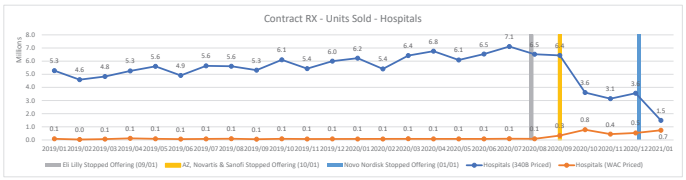




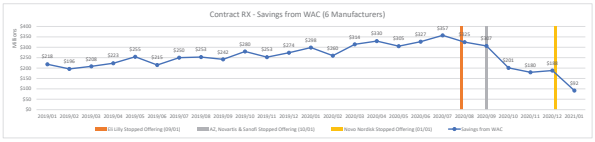
Entity Type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees	2,280,420	1,992,511	2,187,386	2,315,154	2,847,660	2,208,062	2,473,405	2,534,883	2,427,625	2,689,858	2,430,162	2,684,283	2,934,068	2,421,545	2,874,069	3,046,538	3,000,116	3,168,578	3,370,808	3,123,130	3,011,456	1,524,702	1,349,553	1,589,823	1,393,951
Grantees	26,763	2,793	9,522	42,905	14,751	15,947	15,991	26,151	17,299	35,546	16,844	31,726	21,377	21,520	23,042	23,198	26,929	24,515	30,065	20,586	111,574	235,643	77,892	114,771	105,630
Eli Lilly Stopped Offering (09/01)																				4,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					4,000,000				
Novo Nordisk Stopped Offering (01/01)																								4,000,000	
Hospitals	5,272,545	4,587,691	4,827,932	5,256,409	5,601,122	4,911,803	5,637,974	5,611,837	5,312,857	6,100,639	5,429,719	5,996,974	6,224,172	5,402,928	6,421,528	6,758,936	6,088,736	6,537,767	7,111,889	6,525,545	6,434,707	3,606,605	3,144,822	3,560,864	1,488,737
Hospitals	90,495	36,430	62,944	121,110	85,230	68,588	78,219	92,449	58,155	84,408	70,598	78,656	75,280	73,834	92,923	83,679	79,109	83,548	93,037	89,359	333,522	779,408	443,869	532,517	740,094
Eli Lilly Stopped Offering (09/01)																				8,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					8,000,000				
Novo Nordisk Stopped Offering (01/01)																								8,000,000	



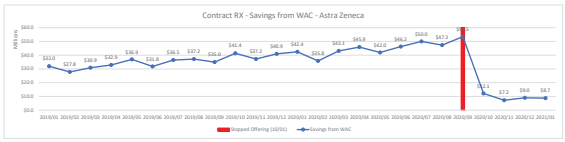

Eli Lilly Stopped Offering (09/01)
AZ, Novartis & Sanofi Stopped Offering (10/01)
Novo Nordisk Stopped Offering (01/01)
Grantees (340B Priced)
Grantees (WAC Priced)

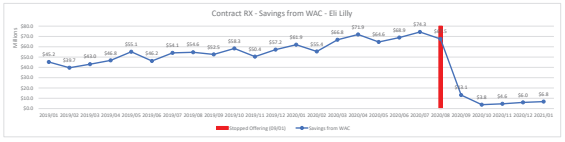

Contract RX - Units Sold - Hospitals
Millions
Eli Lilly Stopped Offering (09/01)
AZ, Novartis & Sanofi Stopped Offering (10/01)
Novo Nordisk Stopped Offering (01/01)
Hospitals (340B Priced)
Hospitals (WAC Priced)

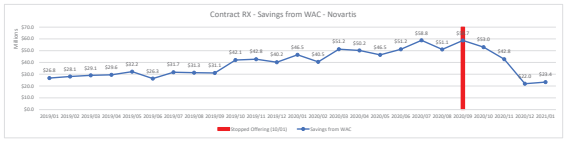
	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Savings from WAC	$218,236,006		$195,997,254	$208,374,595	$223,400,167	$254,509,076	$214,589,045	$250,206,876	$252,895,575	$241,972,098	$280,021,994	$252,600,296	$273,677,477	$298,478,790	$259,595,764	$314,122,762	$329,683,546	$305,324,535	$327,100,735	$357,368,890	$324,970,091	$306,501,169	$200,773,880	$179,701,615	$188,132,591	$91,884,890
Eli Lilly Stopped Offering (09/01)																					$400,000,000				
AZ, Novartis & Sanofi Stopped Offering (10/01)																						$400,000,000			
Novo Nordisk Stopped Offering (01/01)																								$400,000,000	

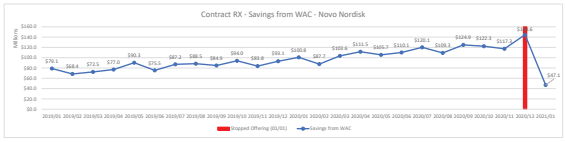


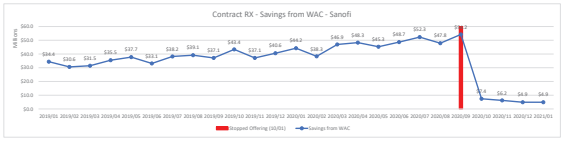
			2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Savings from WAC	ASTRAZENECA	Savings from WAC Stopped Offering (10/01)	$31,987,191	$27,800,118	$30,878,354	$32,879,113	$36,934,324	$31,799,552	$36,471,421	$37,186,394	$34,989,723	$41,396,744	$37,237,664	$40,948,134	$42,443,421	$35,833,551	$43,121,007	$45,902,943	$41,986,004	$46,246,770	$50,028,632	$47,324,434	$53,477,351 $60,000,000	$12,127,989	$7,229,308	$9,001,091	$8,726,284
Savings from WAC	ELI LILLY & CO.	Savings from WAC Stopped Offering (09/01)	$45,172,066	$39,658,299	$43,042,392	$46,776,458	$55,143,309	$46,187,649	$54,078,947	$54,649,521	$52,516,469	$58,309,269	$50,385,315	$57,223,052	$61,944,782	$55,408,635	$66,775,351	$71,893,338	$64,617,091	$68,901,655	$74,307,111	$67,536,605 $80,000,000	$13,089,875	$3,786,056	$4,625,274	$5,972,528	$6,751,854
Savings from WAC	NOVARTIS	Savings from WAC Stopped Offering (10/01)	$26,764,299	$28,095,082	$29,085,099	$29,559,111	$32,207,877	$26,346,691	$31,723,978	$31,131,431	$31,059,207	$42,057,285	$42,773,795	$40,203,100	$46,512,416	$40,497,057	$51,247,026	$50,181,455	$46,464,295	$51,201,738	$58,801,128	$51,087,935 $70,000,000	$58,677,825	$52,996,432	$42,804,901	$21,965,723	$23,361,175
Savings from WAC	NOVO NORDISK	Savings from WAC Stopped Offering (01/01)	$79,050,248	$68,444,521	$72,506,334	$76,982,417	$90,301,290	$75,516,328	$87,164,407	$88,504,526	$84,866,379	$94,014,252	$83,780,413	$93,120,854	$100,774,255	$87,660,395	$103,611,905	$111,528,019	$105,669,572	$110,113,532	$120,128,165	$109,335,765	$124,917,354	$122,288,114	$117,251,750	$144,630,419 $160,000,000	$47,071,806
Savings from WAC	SANOFI-AVENTIS	Savings from WAC Stopped Offering (10/01)	$34,391,418	$30,581,862	$31,479,901	$35,454,878	$37,740,967	$33,122,552	$38,230,409	$39,128,648	$37,127,065	$43,370,426	$37,116,310	$40,569,552	$44,218,810	$38,292,941	$46,931,876	$48,265,295	$45,257,173	$48,654,307	$52,301,943	$47,825,773 $60,000,000	$54,238,892	$7,399,059	$6,209,635	$4,895,540	$4,910,149
Savings from WAC	UNITED THERAP	Savings from WAC	$870,784	$1,417,372	$1,382,516	$1,748,190	$2,181,310	$1,616,273	$2,537,714	$2,095,055	$1,413,254	$874,018	$1,306,800	$1,612,786	$2,585,107	$1,903,186	$2,435,597	$1,912,495	$1,330,400	$1,982,733	$1,801,912	$1,859,578	$2,099,872	$2,176,229	$1,580,747	$1,667,289	$1,063,623

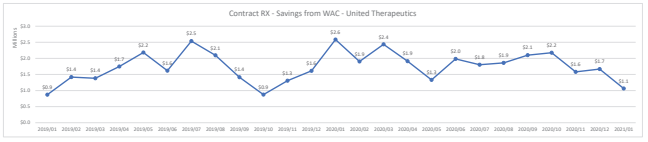




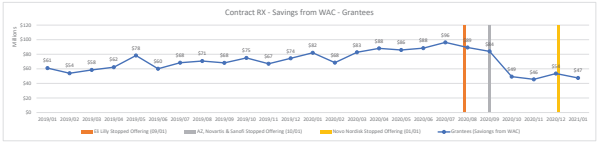


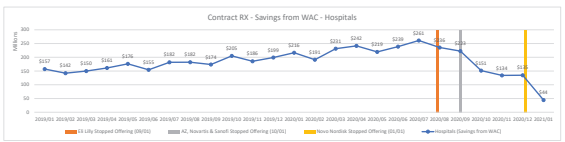






	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees (Savings from WAC)	$60,963,356		$53,894,259	$58,420,019	$62,179,463	$78,310,959	$60,084,096	$68,395,945	$70,737,015	$68,140,115	$74,891,608	$67,004,896	$74,383,384	$82,013,232	$68,497,073	$82,683,472	$88,075,893	$85,870,254	$88,360,046	$96,291,397	$89,320,923	$83,970,126	$49,294,890	$45,578,255	$53,532,159	$47,456,461
Eli Lilly Stopped Offering (09/01)																					$120,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																						$120,000,000				
Novo Nordisk Stopped Offering (01/01)																								$120,000,000	
Hospitals (Savings from WAC)	$157,272,650		$142,102,996	$149,954,575	$161,220,704	$176,198,117	$154,504,949	$181,810,931	$182,158,560	$173,831,984	$205,130,385	$185,595,400	$199,294,093	$216,465,559	$191,098,691	$231,439,290	$241,607,653	$219,454,281	$238,740,689	$261,077,493	$235,649,168 $300,000,000	$222,531,043	$151,478,990	$134,123,361	$134,600,431	$44,428,429
Eli Lilly Stopped Offering (09/01)																						$300,000,000				
AZ, Novartis & Sanofi Stopped Offering (10/01)																										
Novo Nordisk Stopped Offering (01/01)																								$300,000,000	





CERTIFICATE OF SERVICE

I certify that on June 24, 2022, I filed a copy of this supplemental appendix with the Clerk of Court for the Seventh Circuit Court of Appeals through the Court's CM/ECF system, which will serve counsel for all parties.

/s/ Daniel Aguilar
Daniel Aguilar

interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) 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.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term “covered outpatient drug” shall not include a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition.