IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELI LILLY AND COMPANY,
Lilly Corporate Center
Indianapolis, Indiana 46285,

and

LILLY USA, LLC,
Lilly Corporate Center
Indianapolis, Indiana 46285,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services,
200 Independence Avenue SW
Washington, D.C. 20201,

The U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, D.C. 20201,

CAROLE JOHNSON, in her official capacity as Administrator of the Health Resources and Services Administration,
5600 Fishers Lane
Rockville, Maryland 20852,

and

The HEALTH RESOURCES AND SERVICES ADMINISTRATION,
5600 Fishers Lane
Rockville, Maryland 20852,

Defendants.

Case No. 1:24-cv-3220

COMPLAINT

1. This case involves the broken federal 340B program; Lilly's attempt to improve the program's integrity, consistent with the law; and the government's unlawful attempt to stop it.

2. The 340B statute requires Lilly to sell its medicines at significantly reduced prices to specific categories of healthcare providers. At issue is *how* Lilly makes the 340B price available. The statute expressly provides for either up-front "discounts" *or* back-end "rebates." The government has never mandated either, and what's predominantly used today is a system of in-kind rebates. That system operates in the shadows, enables widespread abuse, and obstructs Lilly's ability to comply with federal law. To solve these problems, Lilly decided to offer the 340B price by paying cash instead. But the government unlawfully shut Lilly down before it could start—and without ever explaining why.

3. Not all healthcare providers are eligible for 340B pricing. The 340B price is available only to a specific list of providers called "covered entities," which today includes about 60% of hospitals. These entities do not have to pass on the price reductions to their patients. That creates an arbitrage opportunity: covered entities can buy medicines at low prices (sometimes just pennies) and sell them for much more to patients and their insurers, including Medicare and Medicaid. Large hospitals and other covered entities pocket billions in profit from these transactions every year.

4. Recognizing the potential for abuse, Congress imposed several conditions on the availability of 340B pricing. Among them is the duplicate-discount prohibition, which bars covered entities from requesting payment from a state Medicaid program for 340B-priced medicines. 42 U.S.C. § 256b(a)(5)(A)(i). Manufacturers pay state Medicaid programs rebates under a different federal program, so the duplicate-discount prohibition protects manufacturers from giving two significant mandatory price reductions for the same prescription—first by selling

reduced-price medicines to covered entities, and then again by paying a Medicaid rebate—and likely losing money on the sale. Another statutory guardrail prohibits a covered entity from dispensing 340B-priced drugs to individuals who are not their "patients." *Id.* § 256b(a)(5)(B).

5. Early on, covered entities complied with these requirements by keeping their 340B inventory separate from their other inventory. By maintaining separate inventories, covered entities could verify in real time that 340B-priced medicine was *eligible* for dispensing—e.g., that the person receiving the prescription was not a Medicaid beneficiary and was a patient of the 340B provider. This assured manufacturers that dispensations of 340B medicines would comply with federal law.

6. Over time, that assurance disappeared. Maintaining separate inventories was an administrative burden, so 340B providers sought alternatives. What emerged is a system of in-kind rebates called a "product replenishment model." It relies on an elaborate accounting fiction: (1) a package of medicine is purchased at market price; (2) that medicine is often dispensed in smaller quantities; (3) sometime later, covered entities or their vendors determine whether they believe prescriptions were 340B-eligible; (4) after filling enough prescriptions to equal a full package, a "replenishment" package is purchased at the 340B price; (5) the 340B-priced replenishment package is placed in general inventory; (6) that replenishment medicine is dispensed—regardless of whether the person filling the prescription is a patient of the 340B provider; and (7) the cycle begins anew.

7. Only after this series of cumbersome steps and opaque transactions does 340B revenue trickle into the hands of covered entities—after for-profit third parties take their cut. The vast majority of these steps take place behind closed doors; the details of what purportedly triggered the 340B price, who is an eligible "patient," what happens to the "replenishment"

medicine, and who reaps the "spread" between the market price and the 340B price are all largely unknown.

8. If that process sounds ripe for abuse, that's because it is. The Government Accountability Office has noted, for more than a decade, that the current system results in unchecked duplicate discounts. And it has noted that the government agency tasked with overseeing the 340B program, the Health Resources and Services Administration ("HRSA"), has no interest in detecting or stopping illegal duplicates. The agency has refused to issue guidance to covered entities on how to avoid duplicates in the largest part of Medicaid, and its audits of covered entities don't even look for them. Nevertheless, some estimate that illegal duplicates total more than *$2 billion* annually.

9. And the problem is only going to get worse. The recently passed Inflation Reduction Act ("IRA") imposes a so-called Maximum Fair Price ("MFP") on medicines paid for by Medicare and obligates manufacturers to pay additional inflation rebates in Medicare Parts B and D. The new obligations overlap with 340B: manufacturers, by statute, must offer the lower of the MFP and 340B price, and pay inflation rebates only on non-340B-priced medicines. But the government has refused to take responsibility for de-duplicating claims and instead told manufacturers to develop their own de-duplication methods.

10. Responding to that guidance, Lilly has been searching for a solution to these government-created compliance problems.

11. When a prescription's eligibility for a lower price is known only after it is sold, the standard industry practice is to offer that lower price by providing a cash rebate. Indeed, HRSA has authorized the payment of cash rebates to commercial and government payers, including some 340B-covered entities known as AIDS Drug Assistance Programs ("ADAPs"). After careful

consideration and robust testing, Lilly decided to provide 340B pricing to all covered entities through cash payments—a "cash replenishment" model, to replace the unwieldy and opaque "product replenishment" model that prevails today.

12. Lilly has contracted with Kalderos, a healthcare technology company, to implement a process that will efficiently deliver weekly cash replenishments directly to 340B providers. Providers will dispense the medicine and send readily available information to Kalderos; Lilly will put cash into their hands weekly (and without others' hands in the till). And Lilly's program will ensure that manufacturers are not forced to make duplicative price concessions across interlocking provisions of the 340B statute, the Medicaid statute, and the IRA. In this way, Lilly's approach would allow for more accurate—and more efficient—compliance with all statutory requirements. Lilly's *cash* replenishment approach thus represents a tremendous improvement over the *product* replenishment approach.

13. Rather than embrace Lilly's new program, the HRSA has tried to stop it. Through a letter to Lilly on September 18, 2024 (the "September 18 Letter"), and letters to another manufacturer that sought to implement its own version of a rebate-based approach, HRSA has declared such approaches are unlawful and warned manufacturers that implementing cash replenishment approaches will subject them to civil monetary penalties ("CMPs") and removal from not just the 340B program but also Medicaid and Medicare Part B.

14. HRSA's disapproval of Lilly's cash replenishment program contravenes the Administrative Procedure Act several times over.

15. Most importantly, the agency's position conflicts with the 340B statute. The statute requires manufacturers to offer their medicines to covered entities at the reduced price, on commercially reasonable terms. And the statute expressly contemplates that 340B pricing may be

offered through either an up-front "discount" or an after-the-fact "rebate." *See, e.g.*, 42 U.S.C. § 256b(a)(1). Even if HRSA can *require* one or the other, the statute requires HRSA to do so through the Pharmaceutical Pricing Agreement (PPA) manufacturers sign to participate in the program. HRSA has not done so here.

16. Nor has HRSA ever purported to bar cash replenishment (assuming it even could) through notice-and-comment rulemaking. *See* 5 U.S.C. § 553. HRSA is not empowered to freely invent new substantive obligations that bind manufacturers—over and above those that Congress authorized—especially without going through the rulemaking process.

17. The agency has also acted arbitrarily and capriciously in multiple ways. It has arbitrarily permitted an in-kind *product* replenishment model while rejecting Lilly's materially indistinguishable *cash* replenishment model. HRSA has not explained—and cannot—why it allows the former while rejecting the latter.

18. HRSA similarly countenances the cash replenishment approach for ADAP-covered entities but refuses to do so for others. The agency again has not explained why only some covered entities get the benefits of cash replenishment.

19. And at every step, HRSA has offered no meaningful justification for its disapproval. HRSA failed to acknowledge the many advantages that Lilly's cash replenishment model offers—let alone address how those benefits could be outweighed by other unmentioned considerations. Nor did HRSA engage with Lilly's argument that a cash replenishment model is the *only* way to ensure compliance with the 340B statute and interlocking 340B-related provisions of other federal statutes. And HRSA has not said what companies like Lilly should do to satisfy the conflicting obligations that the Centers for Medicare and Medicaid Services ("CMS")—

another component of HRSA's parent agency, the Department of Health and Human Services ("HHS")—has put squarely on their shoulders.

20. HRSA's rationale for prohibiting Lilly's cash replenishment model is flawed from top to bottom.

21. HRSA's September 18, 2024 letter denies Lilly its statutory rights and places Lilly at certain risk of significant penalties for noncompliance if it proceeds to implement its cash replenishment model. That final agency action creates concrete and imminent harm for Lilly. This Court should set aside the letter and declare Lilly's cash replenishment program lawful.

THE PARTIES

22. Plaintiff Eli Lilly and Company is a publicly traded medicine company organized and existing under the laws of the State of Indiana and headquartered in Indianapolis, Indiana. Eli Lilly and Company participates in the 340B program.

23. Plaintiff Lilly USA, LLC is a wholly owned subsidiary of Eli Lilly and Company existing under the laws of the State of Indiana and headquartered in Indianapolis, Indiana.

24. Defendant HHS is an executive branch department in the United States government headquartered in the District of Columbia. HHS oversees the activities of HRSA.

25. Defendant Xavier Becerra, sued in his official capacity only, is secretary of HHS (the "Secretary"). His official address is in the District of Columbia. Secretary Becerra has ultimate responsibility for oversight of the activities of HRSA, including the administration of the 340B program and the actions at issue in this Complaint.

26. Defendant HRSA is an administrative agency within HHS and has been delegated authority for administering the 340B program. HRSA is headquartered in Rockville, Maryland.

27. Defendant Carole Johnson, sued in her official capacity only, is administrator of HRSA. Her official address is in Rockville, Maryland. Administrator Johnson has ultimate responsibility for HRSA's Office of Pharmacy Affairs ("OPA"), which is involved directly in the administration of the 340B program and is directly responsible for the actions at issue in this Complaint.

JURISDICATION AND VENUE

28. Lilly brings this action under the APA, 5 U.S.C. §§ 701–706.

29. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under federal law.

30. Venue is proper in this Court because, among other things, Defendants HHS and Becerra reside in this District. *See* 28 U.S.C. § 1391(e)(1).

31. This Court may grant relief pursuant to 5 U.S.C. §§ 701–706.

32. Lilly challenges "final agency action" within the meaning of 5 U.S.C. § 704.

33. To constitute final agency action, a decision "must [1] mark the 'consummation' of the agency's decision-making process—it must not be of a merely tentative or interlocutory nature" and "[2] be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). (internal citations omitted).

34. HRSA's September 18 Letter reflects the consummation of the agency's decision-making. HRSA has prohibited Lilly from implementing its cash replenishment program, which HRSA claims violates the 340B statute. That creates real-world consequences for Lilly, which must either proceed to implement the model at significant risk to its reputation and ability to participate in Medicare and Medicaid or forgo its statutory rights, its access to the ADR process, and its ability to ensure compliance with the 340B program's statutory prerequisites.

FACTUAL AND LEGAL ALLEGATIONS

The Federal 340B Program

35. Before 340B, manufacturers voluntarily sold reduced-price medicines to the Department of Veterans Affairs and certain other providers, like rural and community health centers. With the enactment of the federal Medicaid Drug Rebate Program of 1990, *see* H.R. Rep. No. 102-384, pt. 2, at 9–10 (1992), manufacturers were forced to offer Medicaid discounts that matched the lowest price they offered to other buyers. As a result, if a manufacturer continued to sell discounted medicines to these providers, it could drastically increase the rebates owed to Medicaid. That dynamic had the unintended consequence of disincentivizing manufacturers from continuing to sell reduced-price medicines to these providers.

36. Congress sought to remedy that disincentive with the 340B program. Congress created the 340B program under the Veterans Health Care Act of 1992, codified as Section 340B of the Public Health Service Act. *See* 42 U.S.C. § 256b; *see also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

37. The program works as follows: as a condition of reimbursing manufacturers under Medicaid and Medicare Part B, the HHS Secretary must "enter into an agreement with [the] manufacturer," 42 U.S.C. § 256b(a)(1), known as a PPA, that "incorporate[s] the statutory obligations and record[s] the manufacturers' agreement to abide by them." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 117–18 (2011).

38. Each PPA provides that the manufacturer "shall offer" its medicines to each covered entity at or below the applicable "ceiling price." 42 U.S.C. § 256b(a)(1); PPA § II. The D.C. Circuit has interpreted this "shall offer" requirement to mean a "bona fide" offer to sell drugs at or below the statutory price. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). The "ceiling price" is calculated using a statutorily prescribed formula that can require

manufacturers to sell their medicines for as little as a penny a unit. 85 Fed. Reg. 45,755 (July 24, 2020).

39. The 340B statute expressly states that the 340B price may be made available to covered entities by either "rebate or discount." Specifically, the statute requires manufacturers to enter into an agreement 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 . . . does not exceed" the ceiling price. 42 U.S.C. § 256b(a)(1).

40. To the extent that the Secretary has discretion to *mandate* either a "discount" approach or a "rebate" approach, he must do so in the PPA. *See id.* The Secretary has not; the PPA is silent in this regard, stating only that the "[m]anufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." PPA add. § 2.

41. The Secretary has also not engaged in any other notice-and-comment proceeding to mandate how manufacturers must make the 340B price available. HRSA's creation of a new substantive requirement under the 340B statute, with a binding effect on manufacturers, constitutes an exercise of legislative authority. The agency cannot mandate use of the product replenishment model—assuming it even has the authority to do so—through positions staked out in letters sent to individual manufacturers. That is a violation of basic procedural requirements under the APA.

42. The 340B statute includes several fundamental guardrails to protect manufacturers from program abuse. Under the duplicate-discount prohibition, a covered entity "shall not request payment" from a state Medicaid program for any "drug that is subject" to the 340B program "if the drug is subject to [a Medicaid rebate]." 42 U.S.C. § 256b(a)(5)(A)(i). This ensures that a manufacturer is not required to sell a medicine at the 340B price *and* issue a Medicaid rebate to the relevant state Medicaid program for the same medicine. The 340B statute also prohibits

"diversion"—that is, the transfer of a 340B-priced unit to a non-patient of the covered entity. *Id.* § 256b(a)(5)(B).

43. If a covered entity violates the prohibition on duplication, the HHS Secretary may require the payment of CMPs. In "systematic and egregious" cases, the agency may "remov[e] the covered entity from the drug discount program" altogether. *Id.* § 256b(d)(2)(B)(v). The Secretary has also established an Administrative Dispute Resolution ("ADR") mechanism to address, in relevant part, claims by manufacturers that covered entities have violated the statutory prohibitions. *Id.* § 256b(d)(1)(B)(v), (d)(3); *see* 89 Fed. Reg. 28643 (Apr. 19, 2024); 42 C.F.R. § 10.21(a).

44. The 340B statute includes procedures for policing unlawful duplication and diversion. Covered entities must, among other things, permit manufacturers to audit a covered entity's records that "directly pertain to the entity's compliance" with those two prohibitions. 42 U.S.C. § 256b(a)(5)(C). Such audits are a prerequisite for a manufacturer's filing of an ADR petition. 42 U.S.C. § 256b(d)(3)(A); *see also* 42 C.F.R. § 10.21(a)(2).

45. To conduct an audit, however, manufacturers need to provide data to HRSA sufficient to establish "reasonable cause" for the audit—meaning evidence that a covered entity has caused the payment of duplicate rebates or diverted 340B medicines to non-patients. HRSA, Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406, 65410 (Dec. 12, 1996).[1]

[1] Lilly reserves all rights on whether "reasonable cause" and other requirements contained in HRSA's Audit Guidelines are properly grounded in the 340B statute. Such issues are beyond the scope of this Complaint.

The "Product Replenishment Model"

46. Today, the dominant method for effectuating the 340B ceiling price is through the "product replenishment model."

47. There are two variations on the model: one for medicines dispensed through contract pharmacies, and another for in-house dispensations at the covered entity. Both rely on up-front purchases of a medicine at the market price followed by a subsequent "replenishment" of that medicine at the 340B price. Ex. 1 (Pedley Decl.) ¶¶ 3, 5 (OPA director explaining that "the contract pharmacy's drug inventory is 'replenished' with a drug purchased directly by a covered entity at the 340B discount after a drug is dispensed").

48. For-profit contract pharmacies deploy software that "compares the information about the dispense with eligibility criteria provided from the covered entity, in order to determine if the patient was eligible for 340B product." *Id.* ¶ 6. Then, the software "notifies the covered entity that it may place a replenishment order for the drug in question" using a covered entity's 340B purchasing account with the relevant wholesaler of the pharmaceutical manufacturer. *Id.* ¶ 7. Covered entities, for their part, conduct the same retrospective 340B eligibility determination for in-house dispensing using their own data.

49. Covered entities use similar software for in-house dispensations. That software collects data about each covered-entity prescription filled from a so-called "neutral" inventory. It then "uses logic based on configurations, chosen by the entity, to separate 340B from non-340B transactions after they occur." Apexus, *340B Split-Billing Software Key Attributes (Jan. 2023)*. When the covered entity has filled enough prescriptions for patients the software deems to be 340B eligible, the software then helps covered entities place replenishment orders at the 340B price.

50. Covered entities and contract pharmacies cannot place a replenishment order for each dispensation; they must wait until they have dispensed the equivalent of a full package of the

medicine. Ex. 1 ¶ 8. When it comes time to place the order, the covered entity, its contract pharmacy, or a third-party administrator places an order using the covered entity's 340B purchasing account. *Id.* ¶ 9. The manufacturer's wholesaler then delivers the 340B-priced medicine to the covered entity or the contract pharmacy, where it is placed on the shelf and becomes "neutral inventory" that "may be dispensed to any subsequent patient," irrespective of whether the recipient is a 340B-eligible patient. *Id.* ¶ 11.

51. Practically speaking then, covered entities and their contract pharmacies often purchase covered outpatient drugs at market price, then replace that product with 340B-priced product on the back end. These back-end orders are referred to as product "replenishment orders." (Hence the name "product replenishment model".)

52. The product replenishment model is a form of a rebate, in which manufacturers provide the 340B price to covered entities in arrears—*after* dispensing product to a customer. *See* Ex. 1 ¶ 3 (Pedley Dec.) (describing that "the contract pharmacy's drug inventory is 'replenished' with a drug purchased directly by a covered entity at the 340B discount after a drug is dispensed").

53. The product replenishment model is not mentioned, much less mandated, in the PPA. Nor has it been subjected to notice-and-comment rulemaking.

54. The HHS Office of the General Counsel has nevertheless acknowledged the prevalence of this arrangement, characterizing the model simply as "inventory-accounting." Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program 6 & n.6 (HHS, Off. of the Gen. Couns. Dec. 30, 2020). The agency has never objected to the product replenishment model.

55. There are numerous drawbacks to the current replenishment model. For one, it is rife with abuse. In the contract pharmacy context, a for-profit contract pharmacy or a third-party

administrator determines, through a black-box algorithm, which dispensations may have been to 340B-eligible patients and therefore trigger a 340B-priced replenishment order. Covered entities and their contract pharmacies are often overinclusive in determining which dispensations should result in a 340B-priced product replenishment: the algorithms sweep in customers who are not in fact "patients" of the covered entity. *See, e.g.*, GAO, GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28 (Sept. 2011). And multiple covered entities and their contract pharmacies may claim the same patient as their own, which can result in duplicative 340B price concessions for the same prescription. *See, e.g.*, Adam J. Fein, *Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market*, Drug Channels (July 11, 2023), https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html.

56. Third-party administrators that service contract pharmacies market their IT abilities as identifying the maximum possible number of 340B-eligible units by reviewing dispensation data and "harvesting" 340B claims, often weeks or months after a prescription is filled. *See* Aaron Vandervelde et al., Berkely Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 5 (Oct. 2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf (describing that "large national and regional [pharmacy] chains turned to sophisticated software algorithms to identify 340B prescriptions and maximize the revenue generated from these discounted fills"). These proprietary algorithms run various profitability scenarios on data that have been harvested and identify 340B eligibility if that is the most financially beneficial outcome to the contract pharmacy or covered entity. *See id*. at 8 ("Contract pharmacy administrators develop and operate the software algorithms that determine 340B eligibility and enable for-profit pharmacies to influence which prescriptions are classified as

340B."); *see also* Neal Masia, Ph.D., All. for Integrity & Reform, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019* 2, https://340breform.org/wp-content/uploads/2021/05/AIR340B-Neal-Masia-Report.pdf (last visited Oct. 12, 2024)

57. The product replenishment model also severs the link the between the 340B-priced product and the covered entity prescription, rendering the entire transaction an unlawful diversion. The 340B-priced replenishment product is treated as if it were bought at the market price and available for dispensing, without regard to whether the person receiving the medicine is a patient of the 340B provider or otherwise eligible for the 340B price.

58. Lastly, the product replenishment model makes it hard for manufacturers to identify and prevent unlawful Medicaid-340B duplicates. *See* 42 U.S.C. § 256b(a)(5)(A)(i). That is because the model makes it difficult to impossible for manufacturers to match a prescription for which a Medicaid agency has submitted a rebate claim with that prescription's 340B-priced replenishment counterpart, the latter of which is sold to the covered entity by a wholesaler in a different transaction, often months later.

59. Manufacturers need timely information about 340B dispensations to prevent duplicate discounts. But under the product replenishment model, covered entities do not even internally identify 340B-eligible dispenses at the time a prescription is filled. Such identification occurs well afterwards—and even then, covered entities typically do not provide any information to manufacturers about the original sale that nominally triggered the discount. Thus, when a state Medicaid program requests a rebate from a manufacturer, it is difficult, if not impossible, for manufacturers to prevent paying a duplicate Medicaid rebate.

60. In all, the product replenishment model method is slow, indirect, and opaque, and undermines the 340B statute's fundamental guardrails.

The Product Replenishment Model Leads to Widespread Violations of 340B's Duplicate-Discount Prohibition.

61. As the product replenishment model has grown in popularity, abuses of the 340B program have skyrocketed. That growth is a direct byproduct of the incentives provided to covered entities and third-party participants to claim an ever-increasing volume of sales as 340B-eligible to expand their own profits.

62. In 2010, the Affordable Care Act expanded the Medicaid Drug Rebate Program to include Medicaid managed care organizations. Since Medicaid managed care accounts for the vast majority of Medicaid utilization, that expansion substantially increased the potential for illegal Medicaid-340B duplicates. GAO, GAO-20-212, *Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* 1 (Jan. 2020) (the "2020 GAO Report").

63. At the same time, covered entities' use of so-called contract pharmacies exploded. Using the product replenishment model, these for-profit contract pharmacies can buy and dispense 340B-priced medicines purportedly on behalf of covered entities. The Office of Inspector General has found that these relationships "create complications in preventing diversion . . . [and] duplicate discounts." U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., No. OEI-05-13-00431, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program* 1, 2 (Feb. 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. Yet, between 2010 and 2019, the number of contract pharmacies increased from about 1,300 to about 23,000. 2020 GAO Report 2.

64. With the Affordable Care Act's expansion of the Medicaid Drug Rebate Program and the increased use of contract pharmacies came increased risks that manufacturers would be subject to illegal Medicaid-340B duplicates. Between 2011 and 2018, total Medicaid rebates more than doubled, from about $15 billion to more than $36 billion. 2020 GAO Report 2. And in 2021 total Medicaid rebates increased to $42.5 billion. Medicaid and CHIP Payment and Access

Comm'n, *High-Cost Drugs and the Medicaid Program: MACPAC Evidence and Recommendations* (Feb. 2024), https://www.macpac.gov/wp-content/uploads/2024/02/Policy-in-Brief-High-Cost-Drugs-FINAL-2.pdf.

65. Notwithstanding the explosive growth in the 340B and Medicaid rebate programs, HRSA has all but given up trying to enforce the duplicate-discount prohibition. "HRSA does not assess whether covered entities are actually following state policies and procedures regarding the use and identification of 340B drugs for Medicaid beneficiaries." 2020 GAO Report 2. And, although Medicaid managed care accounts for approximately 50% of Medicaid utilization, there is currently no system in place to prevent manufacturers from paying Medicaid managed care duplicates.

66. The government's own watchdog, in fact, has concluded that "HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts," leaving "manufacturers at risk of providing duplicate discounts" and "compromis[ing] the integrity of the 340B Program." 2020 GAO Report 1; *see also* GAO, GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 35, 43 (June 2018) (finding "weaknesses in HRSA's audit process compromise its oversight of covered entities").

67. It is now estimated that three to five percent of all Medicaid rebates duplicate 340B pricing, which in 2020 amounted to between ***$1.3 billion*** **and** ***$2.1 billion*** in illegal duplicates. Ashwin Mundra, *The 340B Noncompliance Data Gap Leaves Drug Manufacturers in the Dark,* Drug Channels (Mar. 18, 2022), https://www.drugchannels.net/2022/03/the-340b-noncompliance-data-gap-leaves.html. The amount of illegal duplicates is likely much higher today, since 340B purchases nearly doubled between 2020 and 2023 from ***$38*** **to** ***$66 billion***. Adam J. Fein, *The*

340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions, Drug Channels (Oct. 22, 2024), https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html.

Without Action, the Inflation Reduction Act Will Dramatically Increase the Number of Unlawful Duplicates Paid by Manufacturers.

68. In August 2022, Congress passed, and the president signed, the Inflation Reduction Act. That law created two significant federal drug discount mechanisms that now intertwine with the 340B program. First, the IRA created the Drug Price Negotiation Program, which empowers HHS to fix the prices at which Medicare will purchase certain medicines. Second, the IRA created Medicare Part B and Part D inflation-rebate programs, under which manufacturers are required to pay Medicare rebates on medicines covered under Parts B and D if their prices rise faster than the rate of inflation. Both IRA programs impact manufacturers' 340B obligations.

69. Under the Drug Price Negotiation Program, the HHS Secretary must "enter into agreements with manufacturers of selected [Medicare Part B and Part D] drugs," pursuant to which the Secretary and the manufacturer will negotiate a "maximum fair price" for the selected drug. 42 U.S.C. § 1320f-2(a). The manufacturer must then "provide access to such price" with respect to MFP-eligible individuals. *Id*. § 1320f-2(a)(1).

70. Recognizing the overlap between discounting obligations under the Drug Price Negotiation Program and those under the 340B program, the IRA also provides that manufacturers must offer only the lower of the MFP or the 340B ceiling price—not both—if a prescription is subject to both reduced prices. 42 U.S.C. § 1320f-2(d).

71. CMS, which administers the Drug Price Negotiation Program, reiterates this obligation in guidance, instructing that "manufacturers must ensure that the appropriate price concession is honored, consistent with their obligations under [the IRA], and inclusive of their

agreements under section 340B(a)(1).” CMS, *Medicare Drug Price Negotiation Program: Final Guidance* 230 (Oct. 2, 2024).

72. That is no small task: if manufacturers choose to effectuate the MFP through a rebate model, CMS requires that rebates be issued 14 days after manufacturers receive verified claims data. *Id.* at 196.

73. The Drug Price Negotiation Program, however, lacks mechanisms to avoid duplicate discounts. In CMS’s Final Guidance, the agency disclaimed responsibility for “deduplicating discounts between the 340B ceiling price and [IRA price],” *id.* at 54, instead directing manufacturers to figure out a de-duplication mechanism on their own, *id.* at 56. Although the Final Guidance contemplates that a manufacturer might decline to pay an MFP rebate, *id.* at 230, there is no practical way for manufacturers to first identify potential duplicates and then “provide documentation demonstrating the claim was 340B-eligible,” *id*.

74. Worse still, neither the Drug Price Negotiation Program nor the 340B program provides manufacturers the right to audit covered entities to ensure they are not creating illegal duplicates under the IRA.

75. Medicare Part B and Part D inflation rebates lack the same fundamental protections for manufacturers. Although manufacturers face civil monetary penalties if they fail to pay the appropriate inflation rebate, 42 U.S.C. § 1320f–6(c), CMS has no pathway for fulfilling its statutory obligation to exclude 340B units from its Part D inflation rebate claims, only a vague “plan to explore” a future solution at some point, *see* Medicare and Medicaid Programs, __ Fed. Reg. __, 1724 (anticipated Dec. 9, 2024) (“Inflation Rebate Final Rule”), https://public-inspection.federalregister.gov/2024-25382.pdf. And CMS has not provided for any type of dispute resolution process or other mechanisms to help ensure compliance with the duplicate-discount

obligations for either Part B or Part D drugs. Inflation Rebate Final Rule 1584, 1765. Yet such protections are critical. The government has said that it cannot bill inflation rebates to manufacturers for 340B-priced medicines. But the government will not have any way to identify those prescriptions—and neither will manufacturers.

76. In short, the interplay of the IRA, Medicare Part B, and Part D inflation rebates increases manufacturers' need for timely information about how 340B drugs are distributed, dispensed, and billed—in some cases at the risk of substantial civil penalties.

The Product Replenishment Model Prevents Manufacturers Like Lilly from Participating in 340B ADR Proceedings.

77. The opacity of the current product replenishment model also denies Lilly the information it needs to exercise its statutory audit rights, bring ADR claims against covered entities to recover for violations of the 340B statute, and comply with HRSA's recently revised ADR Rule.

78. The 340B statute requires covered entities to submit to manufacturer audits to ensure covered entities are not causing the payment of duplicate Medicaid rebates or diverting 340B-priced medicines. 42 U.S.C. § 256b(a)(5)(C). Covered entity audits are a key part of maintaining the 340B program's integrity. They are also a prerequisite to filing an ADR claim against covered entities. *Id*. § 256(d)(3)(A).

79. But to conduct an audit, manufacturers first need to provide evidence that a covered entity has caused the payment of duplicative Medicaid rebates or diverted 340B medicines to non-patients. HRSA, Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406, 65410 (Dec. 12, 1996). Because the product replenishment model operates in the shadows, it is difficult for manufacturers to gather the information necessary to show reasonable cause unless covered entities are required to supply it. That lack of access to information makes it harder for Lilly to avail itself of audits and the ADR process.

80. This lack of transparency also makes compliance with HRSA's recently revised ADR rule more difficult for manufacturers—regardless of who initiates the proceeding.

81. HRSA's ADR rule is designed to channel disputes between manufacturers and covered entities regarding overcharges and duplicate discounts, among other issues, through an ADR process. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28634 (Apr. 19, 2024).

82. Under that rule, covered entities may submit information or document requests to the ADR panel, which will then transmit them to the manufacturer. 42 C.F.R. § 10.22(a), (b).

83. A manufacturer "must fully respond" to any such request. *Id.* § 10.22(c). Part of this full-response obligation includes a responsibility for manufacturers to "obtain[] relevant information or documents from any wholesaler or other third party that may facilitate the sale or distribution of its drugs to covered entities." *Id.* § 10.22(c)(1). In other words, HRSA's ADR rule requires manufacturers to produce information that it can only get from third parties that are not required (and may not be inclined) to voluntarily share it. Neither are such third parties under Lilly's control such that it could demand the information.

84. Because the product replenishment model operates behind closed doors, Lilly does not have the information that it could be required to provide in an ADR proceeding and often cannot get such information.

Lilly Identifies a Cash Replenishment Model as a Solution to the Government-Created 340B Compliance Problem.

85. As these problems have worsened—particularly after HHS recently disclaimed any ability to solve them and put that onus on manufacturers—Lilly began searching for a solution. It landed on the cash replenishment model. A cash replenishment model eliminates unlawful duplicates and facilitates participation in the 340B ADR process. And a cash replenishment model

benefits covered entities by speeding up and streamlining effectuation of the 340B price, while preserving—or in many cases improving—their cash flow.

86. Lilly intends to make the 340B price available to all covered entities, for all Lilly products, through a platform offered by Kalderos, a cutting-edge healthcare technology company. Kalderos's platform, Truzo, effectuates cash replenishments to covered entities that make 340B purchases. Covered entities will purchase Lilly products at the market prices and then submit a claim for a cash replenishment to ensure the covered entity pays no more than the 340B price. Lilly's use of the Truzo platform will be consistent with its own standard commercial practices, as well as the types of practices that HRSA has countenanced in the context of the ADAP replenishment model.

87. To get a cash replenishment, covered entities will need to provide only readily available, nonproprietary claims data related to the dispensation and purchase of the eligible Lilly product. Lilly and Kalderos will then evaluate these claims data to either validate the claim and promptly issue a replenishment or flag the claim if it falls into one of the narrow circumstances that warrants denial or further action, such as when a covered entity is not registered as a 340B-covered entity on HRSA's website. Even when a submitted claim is flagged, covered entities will have clear visibility into the underlying reason. They will also be able to ask questions and raise concerns, and to resubmit the claim, if necessary, after corrections are made.

88. This highly efficient, data-driven process is the only way that Lilly can identify and prevent duplication between ***340B and Medicaid*** before it happens. *See* 42 U.S.C. § 256b(a)(5)(A). The claims data that Lilly will collect under its program will enable it to match rebate claims requested by state Medicaid programs to replenishments paid under the 340B program. Lilly will *never* deny a cash replenishment claim from a covered entity because it is

duplicative of a requested Medicaid rebate; instead, Lilly will address any duplication with state Medicaid programs. And there will be no impact whatsoever on patients' access to their medications.

89. The cash replenishment model is also the only way Lilly can ensure nonduplication between the ***340B price and MFP*** when a Lilly product inevitably becomes subject to the Drug Price Negotiation Program. Under the program, manufacturers must provide the lower of the MFP or the 340B ceiling price if a prescription is subject to both programs. 42 U.S.C. § 1320f-2(d). CMS has instructed manufacturers to take responsibility for policing nonduplication. *Medicare Drug Price Negotiation Program: Final Guidance* 231. The claims data that Lilly will collect under its cash replenishment program will enable it to identify claims subject to both an MFP and 340B pricing and adjust the price offered accordingly. Lilly will thus be in a position to prevent duplication, as instructed by CMS, and comply with requirements under both programs.

90. Indeed, CMS's guidance concerning the MFP all but necessitates a 340B cash replenishment program. CMS requires that manufacturers effectuate the MFP within 14 days and "expects" that a manufacturer "will have documented evidence" that the "selected drug is 340B eligible" in order to invoke the nonduplication provision. *Id.* at 61. That instruction necessarily requires manufacturers to be able to accurately and timely identify 340B prescriptions.

91. The cash replenishment model is also the only way Lilly can avoid ***340B-inflation rebate duplication*** and ensure that inflation rebates are correctly invoiced on certain Medicare Part B and Part D drugs. For Part D drugs, CMS initially proposed to loosely estimate, based on admittedly flawed data, the number of 340B units to back out of the inflation rebate calculation. 89 Fed. Reg. 61596, 61969–73 (July 31, 2024). Because that initial proposal was hopelessly flawed, CMS ultimately abandoned the estimation method but did not propose a replacement, only

stating that it would "explore avenues" to implement the statutory prohibition on duplicate discounts. Inflation Rebate Final Rule 1718. At the same time, CMS said it will not "provide claim-level data to manufacturers regarding the 340B Program or other statutory exclusions of units from rebate counts." *Id.* at 1583. And for Part B and Part D drugs, there is no audit or appeal process that would allow manufacturers to confirm that the inflation rebates are calculated correctly. Inflation Rebate Final Rule 1584–85, 1765; CMS, *Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance* 19–20 (Dec. 14, 2023). Instead, CMS will allow a limited "Suggestion of Error process" that is "limited to mathematical steps involved in determining the rebate amount." 89 Fed. Reg. at 61956; *see also* Inflation Rebate Final Rule 1637–38.

92. The claims data Lilly will collect through its cash replenishment program will enable it to determine exactly how many units of a Medicare Part B or Part D product were dispensed under the 340B program. That will ensure that the inflation rebates are accurately calculated for both Part B and Part D drugs and allow Lilly to protect itself from significant civil penalties for failing to do so.

93. Requiring claims data as part of a cash replenishment model is also the only way that Lilly can fully and effectively utilize the ***340B ADR process***. Before a manufacturer may initiate an ADR proceeding, it must conduct an audit—and before it can do that, it must first make a sufficient "reasonable cause" showing. 61 Fed. Reg. 65406, 65409 (Dec. 12, 1996). Claims data enable manufacturers to do just that by helping manufacturers identify unlawful Medicaid-340B duplication.

Cash Replenishment Is an Integral Part of Many Federal Drug Programs, Including 340B.

94. Cash replenishment is not a new concept, even in the 340B program. Decades ago, manufacturers and ADAPs began entering into agreements that allowed manufacturers to offer the

340B price via cash replenishment. Neither manufacturers nor ADAPs sought HRSA's permission before executing these agreements. And HRSA never objected to these arrangements afterward.

95. These voluntary rebate agreements became so pervasive, and presumably desirable, that in 1997 HRSA published a notice proposing to "recognize" a model. The notice provided for cash replenishments to ADAPs, so long as the replenishment amount equaled or exceeded the discount required by the 340B ceiling price. HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45823 (Aug. 29, 1997).

96. The next year, HRSA published a final notice that "recognize[d] *rebates* obtained by the State ADAPs or their components that equal or exceed the 340B discount provided by the statutory ceiling price *as a method of participating in the 340B program.*" 63 Fed. Reg. at 35239 (emphasis added).

97. The agency therefore expressly recognized—without pre-approval—a cash replenishment model implemented by manufacturers. HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35239, 35240 (June 29, 1998) (rebate agreements that predate Notice need not be renegotiated if provisions of Notice already met).

98. In doing so, HRSA made several observations concerning cash replenishments. First, HRSA acknowledged that a cash replenishment is among the options available under the 340B statute for effectuating the 340B ceiling price: "Section 340B has no explicit language as to whether the required reduction in price should be obtained by an initial reduction in the purchase price (i.e., a discount mechanism) or received as a required reduction in cost rebated after purchase, dispensing, and payment are completed (i.e., a rebate option)." 62 Fed. Reg. at 45823.

99. Second, HRSA concluded that a cash replenishment approach does not result in an impermissible overcharge to the covered entity merely based on timing—*i.e.*, by charging market rates before replenishments are applied—provided that manufacturers ultimately offer "at least the minimum statutory discount" and do not otherwise impose "requirements inconsistent with section 340B and published program guidelines." 63 Fed. Reg. at 35240.

100. Third, HRSA acknowledged that requirements that are inherent in a replenishment model are not inconsistent with the 340B program. Covered entities can be "expected to submit claims-level data to a manufacturer in support of each qualified payment to receive a rebate from that manufacturer," which "may" include an "assurance that the claim is not for a drug subject to a Medicaid rebate." *340B Drug Pricing Program Omnibus Guidance*, 80 Fed. Reg. 52300, 52313 (Aug. 28, 2015).

101. Fourth, HRSA justified the creation of the cash replenishment model based on the same dynamics that exist today throughout the 340B program. 62 Fed. Reg. at 45824. ADAPs, like nearly all covered entities today, use a pharmacy network that involves "formal agreements with a network of retail pharmacies," and these entities "submit claims to drug manufacturers for rebates on medications that were purchased through a retail pharmacy network at a price higher than the 340B price." HIV/AIDS Bureau, *AIDS Drug Assistance Program (ADAP) Manual* 42 (June 2023). That "purchasing system" mimics the contract pharmacy and product replenishment models used by virtually every covered entity today.

102. That is not all. The rebate model is an integral part of nearly every federal medicine discount program, including the Medicaid Drug Rebate Program, the Medicare Part D Coverage Gap Discount Program, the Drug Price Negotiation Program, the Medicare inflation rebate programs, and the Tricare Retail Pharmacy Program.

Lilly's Cash Replenishment Model Facilitates Both 340B Price Access and Statutory Compliance.

103. Lilly's cash replenishment model is more efficient, direct, and transparent than the current product replenishment model.

104. Under the model, Lilly will offer cash replenishment for each prescription filled, meaning covered entities will no longer have to wait to accumulate package-level dispensations to receive replenishment product, as they must do under the current model.

105. In addition, Lilly's cash replenishment model puts covered entities in control of their 340B revenue. Instead of waiting for third-party administrators and contract pharmacies to pay them, covered entities will receive direct deposits from Lilly first, which they can in turn distribute as appropriate.

106. Further, Lilly will issue these cash replenishments on a weekly basis, improving covered entities' cash flow. In fact, many covered entities will receive their cash replenishment even before they pay the up-front cost of the medicine itself, depending on a covered entity's billing arrangements with wholesalers and how quickly a covered entity chooses to submit a cash replenishment claim.[2]

107. On top of that, Lilly's new cash replenishment program will be entirely *free* for covered entities. Lilly is funding the implementation of Kalderos's Truzo platform for its entire portfolio of medicines. And Kalderos will provide intensive support to covered entities throughout onboarding and into regular platform use with a dedicated suite of resources.

[2] The Truzo system will permit covered entities to continue to follow a schedule of batch submission of claims if that is their preference, but it will not limit them to such an approach unlike the current model.

108. This highly efficient, data-driven process will give both parties visibility to the same data and prevent duplication, diversion, and other concerns before they happen. These features will in turn lead to fewer good-faith inquiries and disputes and ADR petitions, and reduce the burden on manufacturers, covered entities, and HRSA.

HRSA Purports to Reject Lilly's Cash Replenishment Model.

109. Lilly sought to educate HRSA on the benefits of its cash replenishment model for all program stakeholders. In August, Lilly's vendor, Kalderos, notified HRSA that it had contracted with a manufacturer to implement a cash replenishment model and provided the agency with information about its system.

110. That same month, Lilly requested an in-person meeting with HRSA and previewed in its email the benefits of its cash replenishment model. Ex. 2 (Aug. 30, 2024 Email to HRSA).

111. On September 4, Lilly, Kalderos, and HRSA held a virtual meeting in which Lilly communicated its intent to adopt its cash replenishment model to HRSA. A few days later, Lilly sent HRSA a letter addressing HRSA's questions from the virtual meeting and outlining in further detail the benefits for all stakeholders of its cash replenishment program. Ex. 3 (Sept. 9, 2024 Letter to HRSA).

112. On September 18, HRSA rejected Lilly's proposal. It offered no explanation and did not even acknowledge any aspect of Lilly's cash replenishment model, instead stating only that "implementing such proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval" of HRSA. Ex. 4 at 1 (Sept. 18, 2024 Letter to Lilly).

113. Though HRSA decreed that Lilly could not lawfully implement its new cash replenishment model, it nevertheless included a list of twenty-three additional questions for Lilly. In the spirit of cooperation, Lilly provided written responses to those questions on September 23.

Ex. 5 (Sept. 23, 2024 Letter to HRSA). It also asked for HRSA to tell Lilly by October 7 whether it had changed its position that Lilly's cash replenishment model was unlawful. HRSA never did so.

114. Although HRSA failed to provide any explanation for its rejection of Lilly's cash replenishment model, some semblance of the agency's reasoning can be gleaned from its letters to another manufacturer. Just one day before rejecting Lilly's proposal, on September 17, HRSA issued a letter to Johnson & Johnson (the "J&J Letter") warning J&J to cease implementation of a similar cash replenishment program. HRSA publicly released that document—showing the agency's definitive views on the cash-replenishment approach. HRSA Letter to J&J (Sept. 17, 2024), https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-17-2024-hrsa-letter-johnson-johnson.pdf. In the J&J Letter, HRSA posited three reasons for its disapproval. Each is legally deficient.

115. First, the agency stated that the "Secretary has not 'provided'" that the proposed replenishment model would be appropriate. *Id.* In other words, HRSA purports to require Secretarial *pre-approval* of any cash replenishment model. But nothing in the 340B statute suggests that in-kind product replenishment is the statutory default or that cash replenishment is unlawful unless HRSA pre-approves it.

116. Second, HRSA stated that charging covered entities the market price up front and then offering a cash replenishment violates the 340B statute's mandate that manufacturers not offer drugs that exceed "the maximum price[s] that covered entities may permissibly be required to pay." *Id.* (alteration in original). But again, nothing in the plain language of the statute—or in the PPA—supports this position. It is also contrary to HRSA's decades-old position, articulated

in its ADAP guidance, that initial purchases by covered entities at market prices do *not* result in an overcharge, so long as an appropriate replenishment is issued.

117. Third, HRSA rejected the idea that the cash replenishment model is the same as the prevailing product replenishment model. In HRSA's view, "under a typical replenishment structure, a covered entity generally makes an initial purchase at a higher price, then subsequent, ongoing drug purchases are at the 340B price," while under the proposed cash replenishment model, "covered entities will be forced to pay a higher price point up front." *Id.* But there is no material difference between cash and product replenishment—they both effectuate the 340B price *after* a prescription has been filled. And both models rely on up-front purchases of medicines at list price, followed by a subsequent replenishment. The *only* difference is that, under Lilly's model, covered entities get cash instead of replacement product.

118. HRSA also opined that the product replenishment model is somehow distinct from a cash replenishment model because "covered entities voluntarily choose to use replenishment processes," *id.*, suggesting that covered entities alone get to choose between their preferred replenishment models. The statute and the PPA provide for no such thing.

119. On September 27, 2024, HRSA issued another letter to J&J reiterating that "any rebate mechanism" requires "Secretarial approval" and that, if J&J were to proceed with its cash replenishment model despite HRSA's rejection, it would violate 42 U.S.C. § 256b(a)(1). HRSA Letter to J&J (Sept. 27, 2024), https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-27-24-hrsa-letter-johnson-johnson.pdf.

120. Then came the kicker: HRSA stated that it would "begin the process outlined in J&J's Pharmaceutical Pricing Agreement related to terminating the agreement" and "initiate a

referral to the HHS Office of Inspector General" if J&J did not notify HRSA that it was ceasing implementation of its cash replenishment model by September 30, 2024. *Id.*

121. HRSA has thus invoked the nuclear option of removal from not only the 340B program but also Medicaid and Medicare Part B if manufacturers implement a cash replenishment model. The agency, in other words, would risk depriving seniors and poor patients of life-saving medicines rather than countenance a cash replenishment model.

HRSA's Decision to Ban Lilly's Cash Replenishment Model Is Unlawful.

122. HRSA's rejection of Lilly's cash replenishment program is unlawful, contravenes the plain language of the 340B statute, and is arbitrary and capricious. Lilly's program is consistent with the 340B statute, Lilly's PPA, and other federal laws and regulations—and is not just eminently reasonable but an improvement on the current product replenishment model.

123. To begin, the statute expressly contemplates cash replenishment. It requires manufacturers to agree that "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" does not exceed the statutory ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added). The very next paragraph, which defines the ceiling price, refers to the price concession designed to achieve that price as the "rebate percentage." 42 U.S.C. § 256b(a)(2). And Lilly's PPA provides for dispute resolution mechanisms in case Lilly "believes that a covered entity has violated . . . the prohibition against duplicate discounts or *rebates*." PPA § IV(a) (emphasis added).

124. Nothing in the 340B statute suggests that discounts are the statutory default or that cash replenishments are unlawful unless HRSA pre-approves them. Nor does the statute suggest that the *product* replenishment model is uniquely permissible, to the exclusion of *cash* replenishment. The 340B statute discusses "rebates" (i.e., replenishments) together with

"discounts," without indicating a preference for either or dictating a particular mode of replenishment. *See, e.g.*, 42 U.S.C. § 256b(a)(5), (d)(1)(B)(iv).

125. The legislative history of the 340B statute removes any doubt about the permissibility of cash replenishment. Congress, in passing what would become 42 U.S.C. § 256b, noted that while the bill did not "specify" the "mechanism" by which "'covered entities' would receive these favorable prices," a "manufacturer rebate" was among the available options. H.R. Rep. No. 102-384(II), *16 (1992).

126. To the extent that HRSA can insist on "pre-approval" of a cash replenishment program, it must do so by amending a manufacturer's PPA. *See* 42 U.S.C. § 256b(a)(1). HRSA has not amended Lilly's PPA to incorporate any such requirement.

127. Nor has the agency purported to mandate the use of the product replenishment model through notice-and-comment rulemaking—assuming it can even do that.

128. Given the plain-text support for Lilly's cash replenishment program, HRSA may not prohibit Lilly from implementing it. Nor may it subject Lilly's program to some sort of pre-approval policy, especially in the absence of a provision in the PPA specifying otherwise.

129. HRSA's position also is arbitrary and capricious, for a host of reasons. First, the agency has acted arbitrarily by permitting an in-kind *product* replenishment model—which is materially indistinguishable from Lilly's *cash* replenishment model. The agency has not explained why it allows the former while rejecting the latter. Nor has the agency explained why "pre-approval" is required for a cash replenishment but not for a product replenishment.

130. HRSA has also unlawfully failed to treat similarly situated entities the same: HRSA does not object to cash replenishments when requested by ADAPs, nor did it require pre-approval or suggest that those using that model before HRSA recognized it had been acting unlawfully,

much less threaten to terminate their PPAs. Yet HRSA refuses to allow cash replenishments for any other covered entities or when requested by a manufacturer. The agency has offered no reasoned explanation for such differential treatment.

131. The agency never engaged with Lilly's several independent policy arguments in support of the cash replenishment model. It did not acknowledge the fact that Lilly's replenishment model would facilitate compliance with both the 340B duplicate-discount prohibition and the IRA; indeed, a cash replenishment model arguably is the *only* way to effectuate the requirements of the 340B statute and the interlocking provisions of other federal statutes that guarantee nonduplication of statutorily mandated price concessions.

132. HRSA also failed to consider how the cash replenishment model will help Lilly more meaningfully participate in the ADR process. Claims data help manufacturers identify program abuse. If an audit proceeds to an ADR proceeding, manufacturers must "obtain[] relevant information or documents from any wholesaler or other third party that may facilitate the sale or distribution of its drugs to covered entities." 42 C.F.R. § 10.22(c)(1). Lilly's cash replenishment model enables it to ensure that it has the information it needs to comply with requests from covered entities and the ADR panel in an ADR proceeding.

133. And HRSA failed to acknowledge the many practical programmatic enhancements that Lilly's cash replenishment model brings to the table—let alone address how those benefits could possibly be offset.

CLAIMS FOR RELIEF

COUNT I

(Violation of the Administrative Procedure Act – Unlawful, Contrary to Statute, and in Excess of Statutory Authority)

134. Lilly realleges and incorporates by reference the allegations in all preceding paragraphs of this Complaint.

135. HRSA's position is unlawful, violates the plain language of the 340B statute, and exceeds the agency's statutory authority.

136. The 340B statute requires only that participating manufacturers "shall . . . offer" the 340B price on a drug to qualifying purchasers if the drug "is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1).

137. The 340B statute clearly contemplates that manufacturers may implement the ceiling price via cash replenishment. *See* 42 U.S.C. § 256b(a)(1), (a)(2), (d)(1)(B)(iv) (referencing "rebate").

138. Even in a world where HRSA had authority to dictate whether manufacturers implement the ceiling price by way of cash replenishment or discount, that would have to be effectuated in the PPAs with manufacturers. *See* 42 U.S.C. § 256b(a)(1). Lilly's PPA does not contain a prohibition, explicit or implicit, on a cash replenishment model for effectuating the ceiling price.

139. Nor did HRSA undertake notice-and-comment rulemaking to create what amounts to new substantive standards under 340B that are binding on manufacturers.

140. Because there is no independent statutory basis apart from the PPA for HRSA to prohibit Lilly from adopting a cash replenishment model, and because Lilly's PPA is silent on whether it must implement the ceiling price via cash replenishment or discount, HRSA's

September 18 Letter is contrary to law and in excess of its statutory authority and must be set aside. 5 U.S.C. § 706(2)(A), (C).

COUNT II
(Violation of the Administrative Procedure Act – Arbitrary and Capricious)

141. Lilly realleges and incorporate by reference the allegations in all preceding paragraphs of this Complaint.

142. HRSA's position that Lilly may not implement a cash replenishment model is also arbitrary and capricious. Under the APA, an agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted).

143. HRSA acted arbitrarily because it did not adequately explain why it can now condemn *one* replenishment model, when it has tacitly permitted another replenishment model—*product* replenishment—for years. A replenishment is a replenishment, whether in product or cash. It is arbitrary and capricious to treat the two differently, absent a compelling rationale. HRSA has provided no rationale; nor can it.

144. HRSA also has acted arbitrarily by allowing the cash replenishment approach with respect to ADAPs, but refusing the same approach with respect to any other entity. The agency has offered no reasoned explanation for treating these entities differently.

145. HRSA also failed to consider how the cash replenishment model will help police unlawful duplication and facilitate participation in ADRs. The claims data Lilly collects under its cash replenishment program will also allow it to match claims under Medicaid and the 340B program and, if necessary, address duplication with state Medicaid programs (while ensuring

covered entities receive timely 340B replenishments). HRSA's decision here did not even recognize that concern, much less address it.

146. Similarly, the agency failed to consider how the claims data will enable Lilly to match claims and adjust pricing based on a comparison between the MFP and the 340B ceiling price, providing precisely the "documentation" CMS requires a manufacturer to maintain when invoking the nonduplication protection.

147. Lastly, the agency failed to consider how the cash replenishment model will enable Lilly to participate in the ADR process by allowing manufacturers to "obtain[] relevant information or documents from any wholesaler or other third party that may facilitate the sale or distribution of its drugs to covered entities." 42 C.F.R. § 10.22(c)(1).

148. In short, HRSA's position is arbitrary and capricious and should be set aside.

PRAYER FOR RELIEF

149. Lilly respectfully prays that this Court:

a. Set aside HRSA's position on Lilly's cash replenishment model, including as expressed in the September 18 Letter, on the grounds that it is contrary to law, in excess of HRSA's statutory authority, and arbitrary and capricious under the Administrative Procedure Act;

b. Preliminarily and permanently enjoin HRSA from taking any action to enforce its unlawful position on Lilly's cash replenishment model;

c. Declare that Lilly's cash replenishment model is lawful and can be implemented;

d. Award Plaintiffs costs and reasonable attorneys' fees, as appropriate; and

e. Grant any other relief the Court deems just and appropriate.

Dated: November 14, 2024

Respectfully submitted,

By: /s/ John C. Q'Quinn

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CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS

Eli Lilly and Company; Lilly USA, LLC,

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

DEFENDANTS

Xavier Becerra, Secretary of HHS; Us Dep't of HHS; Carole Johnson, Administrator of HRSA; Health Resources and Servs. Admin.,

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

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Kirkland & Ellis LLP, 1301 Pennsylvania Avenue NW, Washington, D.C. 20004

ATTORNEYS (IF KNOWN)

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

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

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

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

IV. CASE ASSIGNMENT AND NATURE OF SUIT
(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ **A. *Antitrust***

- ☐ 410 Antitrust

○ **B. *Personal Injury/ Malpractice***

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

○ **C. *Administrative Agency Review***

- ☐ 151 Medicare Act

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

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

○ **D. *Temporary Restraining Order/Preliminary Injunction***

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

(If Antitrust, then A governs)

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

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

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

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

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

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

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

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

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

G. *Habeas Corpus/ 2255*	H. *Employment Discrimination*	I. *FOIA/Privacy Act*	J. *Student Loan*
☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	☐ 152 Recovery of Defaulted Student Loan (excluding veterans)

K. *Labor/ERISA (non-employment)*	L. *Other Civil Rights (non-employment)*	M. *Contract*	N. *Three-Judge Court*
☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

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

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

5 U.S.C. § 701

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

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

DATE: 11/14/2024 **SIGNATURE OF ATTORNEY OF RECORD** /s/ John C. O'Quinn

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

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

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

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

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

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

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

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

EXHIBIT 1

DECLARATION OF KRISTA M. PEDLEY

I, Krista M. Pedley, declare as follows pursuant to 28 U.S.C. § 1746:

1. I currently serve as Director of the Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), United States Department of Health and Human Services (HHS). OPA is the component within HRSA with primary responsibility for the day-to-day administration of the 340B Program. I have worked at OPA since 2007 and served as Director since 2010. In my role at OPA, I have acquired deep knowledge of and experience with the functioning of all facets of the 340B Program, including covered entities' use of contract pharmacies.

2. I submit this Declaration to respond to certain factual representations that I understand have been made by drug manufacturers and a consultant for the pharmaceutical industry, Aaron Vandervelde, in litigation involving the issue of contract-pharmacy use. Specifically, Mr. Vandervelde has submitted amicus briefs in various cases that describes the "replenishment model" used in some contract-pharmacy arrangements. *See* Br. of 340B Expert Aaron Vandervelde as Amicus Curiae in Support of Neither Party, *Eli Lilly and Company et al. v. HHS et al.*, 21-cv-81 (S.D. Ind. May 12, 2021), Dkt. 92-1 at 13-14; *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, 21-cv-27 (D. Del. Apr. 16, 2021), Dkt. 46; *Sanofi-Aventis U.S., LLC v. HHS et al.*, 21-cv-634 (D.N.J. May 13, 2021), Dkt. 71-2. The drug manufacturers, in reliance on Mr. Vandervelde's brief, have also made assertions about how contract-pharmacy arrangements work. *See* Tr. of May 27, 2021 Hrg., *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, 21-cv-27 (D. Del.), 10:6-14:6; Tr. of May 27, 2021 Hrg., *Eli Lilly and Company et al. v. HHS et al.*, 21-cv-81 (S.D. Ind.), 20:9-15, 22:21-25, 67:8-14.

3. The following paragraphs describe my understanding of how, in general, contract-pharmacy arrangements work under the replenishment model. Of course, contract-pharmacy arrangements vary, and I cannot speak to the exact details of every existing relationship between a covered entity and contract pharmacy. But at its most basic level, under the replenishment model, to the extent that

an individual is determined to have been a 340B patient of the covered entity, the contract pharmacy's drug inventory is "replenished" with a drug purchased directly by a covered entity at the 340B discount after a drug is dispensed.

4. As an initial matter, for all contract-pharmacy arrangements (replenishment or otherwise), a covered entity may establish a relationship directly with a pharmacy, or it may elect to employ a third-party vendor or administrator (TPA) to facilitate data-capture and reporting in the administration of a covered entity's contract-pharmacy program. In the former situation, the covered entity sends data feeds about its patients' 340B eligibility directly to the contract pharmacy; in the latter, it sends that data to the TPA.

5. The replenishment model proceeds in three steps. First, a contract pharmacy dispenses a certain drug in a certain amount—say, 90 tablets of Amoxicillin—to a patient (the dispense). That patient may present a prescription to the pharmacy, or the dispense may result from "e-prescribing," whereby the covered entity directly transmits the prescription to the pharmacy. Either way, the dispensed drug comes from the contract pharmacy's own inventory.

6. Various 340B-tailored software programs exist to evaluate each dispense. That software compares the information about the dispense with eligibility criteria provided from the covered entity, in order to determine if the patient was eligible for 340B product. The software operates under the oversight of the covered entity, in that each 340B-eligible dispense is recorded and reported to the covered entity. And HRSA audits this process: we obtain a random sample of the drugs dispensed, and the covered entity has to provide auditable records that show each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient. Each year, HRSA audits approximately 200 covered entities, along with any of the covered entities' contract-pharmacy arrangements.

7. Second, the 340B software notifies the covered entity that it may place a replenishment order for the drug in question—90 tablets of Amoxicillin—under the covered entity's 340B account with the relevant wholesaler. The replenishment order has to be an exact 11-digit match under the National Drug Code (NDC) system for the product that was identified by the software. (The NDC for a product identifies (1) the product's labeler, *i.e.* manufacturer or distributor; (2) the identity of the product, *i.e.* strength, dosage form, and formulation of the drug; and (3) the product's package size and type.)

8. The trigger for a replacement order will not usually be a single dispense. Rather, the TPA and/or contract pharmacy will "accumulate" 340B-eligible dispenses of a specific 11-digit NDC product towards a pre-set package size. So, for example, a package may be 270 tablets of Amoxicillin, which means that it would take 3 dispenses of the 90-tablet bottles to accumulate one package and lead to submission of a replenishment order. Covered entities are provided accumulation reports where they can track each accumulation to a specific patient/dispense.

9. As noted, the replenishment order will be placed on a covered entity's 340B account with the relevant wholesaler. The 340B account is in the covered entity's name and reflects its financial payment information. That 340B account reflects a "bill to" address and "ship to" address. The covered entity is reflected as the "bill to" party; the contract pharmacy (or sometimes, its warehouse) is reflected as the "ship to" address. The wholesaler invoice shows the covered entity as the purchaser of the product under the "sold to" field. And so, the covered entity pays for and purchases the drug at the 340B discount price from the wholesaler. If the wholesaler's invoice is not paid, it will seek to collect payment from the covered entity directly—not the contract pharmacy.

10. While it is true that the logistics of placing the replenishment order can vary—for example, sometimes the covered entity places the order, sometimes the contract pharmacy orders it as a purchasing agent of the covered entity, sometimes the order is submitted by the TPA—HRSA

understands that the covered entity is the legal purchaser and authorizes the order. If the replenishment order is sent on behalf of the covered entity, the entity should be aware of the replenishment order; indeed, the order is often approved by the covered entity prior to submission to the wholesaler/distributor to ensure accuracy.

11. Third and finally, the drug in question—90 tablets of Amoxicillin—is shipped to the contract pharmacy, where it is placed on the shelf, becomes "neutral inventory," and may be dispensed to any subsequent patient.

12. When utilizing a replenishment model, covered entities must ensure that appropriate safeguards are in place at the contract pharmacy to ensure that the covered entity is replenishing inventory with 340B drugs only in instances where drugs have been provided to qualified 340B patients. The covered entity must have systems in place to be able to demonstrate that the covered entity is properly accounting for 340B purchases in a replenishment system. HRSA ensures that is the case through the audits mentioned above (¶ 6).

13. OPA maintains the 340B Office of Pharmacy Affairs Information System (OPAIS), a database that assists in the functioning of the 340B Program. When registering on OPAIS, a covered entity must list its contract pharmacy(ies), and that listing must reflect a bill-to/ship-to arrangement. Thus, OPAIS clearly shows that the covered entity, as the bill-to party, is the party that purchases the 340B drugs.

Executed on June 16, 2021, in Frederick, MD.

Krista M. Pedley -S

Digitally signed by Krista M. Pedley -S
Date: 2021.06.16 12:41:17 -04'00'

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

EXHIBIT 2

From: Derek L Asay
Sent: Friday, August 30, 2024 2:24 PM
To: Britton, Chantelle (HRSA) <CBritton@hrsa.gov>
Cc: Josh Tomas O'Harra <oharra_josh_t@lilly.com>; Angie.Franks@kalderos.com; Pedley, Krista (HRSA) <KPedley@hrsa.gov>; Herzog, Michelle (HRSA) <MHerzog@hrsa.gov>
Subject: In-person meeting request - Lilly, Kalderos and HRSA
Importance: High

Dear Ms. Britton:

I am writing to request an in-person meeting with representatives from HRSA, Kalderos, and Lilly to discuss Lilly's intention to use Kalderos's 340B platform as a form of "cash replenishment" beginning in the fourth quarter of this year. We believe this is a highly desirable method for effectuating the 340B ceiling price and honoring our "must offer" obligation.

Current State (Product Replenishment)	Future State (Cash Replenishment)
340B dispensed product not acquired at the 340B price is replenished with 340B priced **product**.	340B dispensed product results in **cash payments** directly.
Entities must wait for an **entire package** to be dispensed before the 340B product is replenished.	Entities can seek cash on **individual units** (not packages) as they are dispensed.
Entities do not control the 340B funds; they receive remuneration from their vendors (e.g., TPAs and contract pharmacies) on their vendors timelines.	**Entities control 340B funds** because they receive deposits from manufacturers, which they divide with or use to pay their vendors.
Entities wait for full-packages to accumulate and for vendors to identify and collect remuneration to ultimately repay entities their own 340B funds.	Entities receive cash **within days** of dispense (Lilly plans to issue payment at least twice monthly, hopefully more often)

This model is consistent with the 340B statute and a highly desirable method of effectuating the 340B ceiling price—for both covered entities and patients. Indeed, the Kalderos cash replenishment model is also the only model currently developed that can address the prohibitions of duplicate discounts on inflation rebates, maximum fair prices, and Managed Medicaid claims. It also permits manufacturers to dispute these duplicates with the *right* party, not just covered entities.

Also, the Kalderos data exchange and interface is the only way for manufacturers to faithfully comply with HRSA's ADR rule, which requires manufacturers to produce data they currently lack access to. Indeed, we are hopeful that the transparency of the Kalderos system – which allows entities and manufacturers to have the same real-time access to the exact same purchase information – could help alleviate the need for the ADR process generally.

The Lilly and Kalderos tech teams have completed extensive testing and validation of the enrollment, processing, and payment operations over the past several months. We want to walk you through these details and answer any questions you may have before the system goes live.

As we intend to announce this change by September 23, we hope that you can make time to meet within in the next week or so.

Many thanks, in advance, for your consideration.
Derek

Derek Asay

Senior Vice President, Government Strategy and Federal Accounts
908.268.8720 (mobile)
derek.asay@lilly.com

Eli Lilly and Company
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www.lilly.com

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EXHIBIT 3

Lilly USA, LLC

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

September 9, 2024

BY ELECTONIC DELIVERY (CBritton@hrsa.gov)

Ms. Chantelle V. Britton
Director, Office of Pharmacy Affairs
Health Resources and Services Administration (HRSA)
Office of Special Health Initiatives
5600 Fishers Lane
Rockville, MD 20857

RE: Lilly 340B Cash Replenishment Program

Dear Director Britton:

As a follow up to our September 4 meeting, I am writing to provide notice to HRSA of Lilly's intention to implement its obligation to offer the 340B ceiling price to covered entities through a rebate via a cash replenishment program, specifically using the Kalderos Truzo™ platform. We intend to make this change in our program effective November 1 with a public announcement on September 23 to allow adequate time for covered entity education and onboarding.[1] As discussed in our meeting last week, we welcome any questions or comments you may have as we proceed toward implementation.

We are optimistic that this approach will result in timelier effectuation of the ceiling price to covered entities and will address covered entity concerns with the current product replenishment rebate model (namely, that their vendors get the 340B value in the first instance and that the covered entities receive replacement product that they might never dispense, instead of a rebate in the form of cash). We also believe this approach is fully compliant with all laws, regulations, guidance, and the Pharmaceutical Pricing Agreement (PPA). Indeed, a cash replenishment model is likely compelled by recent changes made by the Inflation Reduction Act (IRA) and further necessitated by provisions in the final Administrative Dispute Resolution (ADR) rule, among other things.

We hope that HRSA will issue a statement endorsing Lilly's efforts to advance the cause of 340B—and broader government healthcare—program integrity, as new systems are needed to maintain the program's viability and to implement recent laws that prohibit certain duplicate discounts for which there are no established safeguards and for which manufacturers do not have audit rights or administrative remedies.

I. Lilly's Cash Replenishment Program

Under the proposed change to our 340B program, Lilly would make the 340B price available to all eligible covered entities, for all Lilly products, through Kalderos's Truzo™ platform. Covered entities will purchase Lilly products at the usual market rate and then submit a claim for cash replenishment equal to the difference between the acquisition cost and the 340B ceiling price. Lilly will be offering cash replenishment on a unit basis (as opposed to forcing covered entities to accumulate to the package level as they must today) and will make payments on approved claims on a weekly basis. While covered entities are able to submit claims at any time, the Truzo™ system will also allow them to wait and make batch submissions of claims if that is the covered entity's preference. In order to

[1] In the event we encounter any unforeseen issues, this date may change.

receive a cash replenishment, covered entities will only need to provide basic, non-proprietary claims data related to the dispense and purchase of the eligible Lilly product, as laid out in the enclosed addendum from Kalderos. Covered entities are already keeping and providing this same data to their Third Party Administrators (TPAs) and other 340B vendors. Given our experience with existing claims data submission processes, we do not anticipate any issues with the Truzo™ platform's requirements, but as has always been our practice, to the extent any covered entities do encounter problems with the data submission process we would be more than willing to work with them on solutions on a case-by-case basis . Indeed, the D.C. Circuit recently concluded that such data requests are consistent with HRSA's past guidance, part of the "standard information" that manufacturers may ask of covered entities, and carry only a "minimal burden" to provide. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 463 (D.C. Cir. 2024).[2] And of course, covered entities will not be required to pay for the Truzo™ platform as Lilly is covering all costs.

As we explained in our meeting, Lilly will use this basic information to avoid paying duplicate and improper rebates to parties other than covered entities (such as CMS for duplicate Part B and Part D inflation rebates or maximum fair price drugs) that are not consistent with having sold the Lilly product at the 340B ceiling price. This prevention of duplicate discounts should have no bearing on the number of legally appropriate 340B claims made by covered entities. A table listing the five reasons that a claim would not automatically be validated, such as the covered entity is not listed in the HRSA OPAIS database, are included in the enclosed addendum from Kalderos.

This proposed program change has many advantages over the current methods of effectuating 340B pricing. Under the current *product* replenishment model, eligible 340B dispenses are identified after the fact, accumulated on a unit-by-unit basis until they reach the number of units in a package, and then entities get a rebate from a vendor in the form of discounted replacement products. This process is slow, indirect, and opaque. Lilly's new *cash* replenishment model will be fast, direct, and transparent. It will provide cash payments directly to covered entities, while ensuring they still pay no more than the ceiling price. Payments will be made weekly, rather than waiting for product orders to accumulate, and submissions can be made either for individual dispenses or for batches of dispenses, at the covered entity's discretion. It will also provide covered entities, rather than other parties, with direct cash replenishments for 340B medicines they dispense. In that way, Lilly's cash replenishment model will put control back in the hands of the covered entities by empowering them to pay their vendors, rather than wait for vendors to pay them. Indeed, in some cases—depending on a covered entity's billing arrangements with wholesalers and how quickly a covered entity chooses to submit a cash replenishment claim—covered entities will receive the cash replenishment payment *even before* they pay the upfront cost for the drug itself. Importantly, these changes should have no impact on patients, nor should it impact the number of lawful 340B purchases by covered entities. We also believe the transparent nature of the Truzo™ platform will help parties more easily resolve any potential disputes prior to needing HRSA's ADR process.

Working with Kalderos, we have put together a robust communications plan to make this change as seamless as possible for covered entities and ensure patients are not impacted. We will endeavor to contact every covered entity directly, via mail and/or email in advance of implementation and inform wholesalers and other vendors. We will also send a notice to HRSA advising covered entities of this change for posting on your website if you are so inclined.

[2] As discussed at our September 4 meeting, Lilly will continue its contract pharmacy limited distribution program via the Truzo™ platform.

II. The Statute Supports a Cash Replenishment Rebate Program

The first line of the 340B statute clearly states that rebates are a permissible form for offering and effectuating a 340B ceiling price: "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)…does not exceed an amount [describing the 340B ceiling price]…" 42 U.S.C. § 256(a)(1). Indeed, the very next paragraph in the statute, which defines the 340B ceiling price, refers to the price concession designed to achieve that price as the "***rebate*** percentage." 42 U.S.C. § 256(a)(2). Other statutory provisions also strongly suggest that, while not mandatory, Congress likely envisioned the 340B price as a rebate. Notably, the prohibition on duplicate discounts is actually a prohibition on "duplicate discounts or ***rebates***." 42 U.S.C. § 256(a)(5) and the initial version of the statute specified the establishment of an alternative mechanism to "ensure against duplicate discounts or ***rebates***." Thus, as a matter of law, the statutory requirement to offer covered entities covered outpatient drugs at the ceiling price can be effectuated *either* with an upfront discount *or* a post-purchase rebate. Were the law otherwise—despite the plain text requiring taking into account any rebate in determining whether the amount paid exceeds the 340B ceiling price—then the provision of rebates under AIDS Drug Assistance Programs, which HRSA has supported, would be legally impermissible. Likewise, product replenishment—which contemplates that product is initially purchased into general inventory at full price, and then replenished with 340B-priced product—would be impermissible if the statute were wrongly read to always require upfront discounts. Here, with rebates being weekly (perhaps before the covered entity even pays for the purchase of the drug itself), the statutory requirement to offer drugs to covered entities at the ceiling price is plainly satisfied.

The legislative history likewise suggests that Lilly's cash replenishment model is consistent with the 340B Program. While pending in Congress, the bill that would become 42 U.S.C. § 256b was referred to the Committee on Energy and Commerce, which subsequently issued a report recommending that the bill pass. The Committee report indicated that while the bill for the 340B program did not "specify" the "mechanism" by which "'covered entities' would receive these favorable prices," a "manufacturer rebate" was among the available options. H.R. REP. 102-384(II), *16 (1992).

III. Multiple Statutory Provisions, including those in the Inflation Reduction Act, Compel a 340B Cash Replenishment Option

On May 3, 2024, CMS unambiguously announced that it "will not … assume responsibility for deduplicating discounts between the 340B ceiling price and MFP" and that, at most, it will pass along information of potential 340B duplicates, but only "[t]o the extent dispensing entities *choose to voluntarily and proactively* indicate on a submitted claim that the claim is 340B eligible."[3] HRSA has not issued any guidance to covered entities on this topic, let alone issued any legally binding requirements. And our experience is that covered entities will not proactively provide such data.

Practically, then, this regulatory vacuum leaves the responsibility for avoiding duplicates entirely to manufacturers. Absent binding and enforceable agency rules, an alternative to the wholesaler product replenishment model is needed and some form of cash replenishment such as the Kalderos Truzo™ model, is the only workable alternative. This is so for two reasons. First, because

[3] CMS, "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027" (May 4, 2024) at 49. Lilly does not presently market any products subject to the Maximum Fair Price program for IPAY 2026, but we anticipate having products selected in the future.

manufacturers cannot audit for duplicate MFP-340B discounts under either the 340B statute or the IRA, there is simply no way to honor an "upfront" discount in time period "one" only to reverse it or claw it back in time period "two," when – or if – the duplicate is identified. Second, there is no mechanism for manufacturers to compel repayment or refunds from covered entities because no agency or administrative process exists that would contemplate such repayments to manufacturers.

The IRA also created so-called "inflation rebates" for Medicare Part B and Part D utilization that are subject to subject to a similar prohibition against 340B duplicate discounts. With respect to those programs, CMS has, again, effectively disclaimed oversight for ensuring that the statutory command is applied and enforced.

In July 2024, CMS issued the proposed 2025 Physician Fee Schedule rule, in which it addressed the prohibition on 340B duplicate discounts with both Part B and Part D inflation rebates. *See* 89 Fed. Reg. 61596, 61934-84 (July 31, 2024). For Part D, CMS proposes to estimate what percentage of Part D sales are 340B using existing data, and then exclude that number of Part D dispenses from the rebate as presumed 340B duplicates. *Id*. at 61969-73. Besides inaccuracies in the data CMS proposes to use, including undercounting in the Apexus data that HRSA is aware of, this reflects an abdication of regulatory responsibility from CMS similar to the approach taken with MFP deduplication. CMS also proposes, relying on the statutory prohibition on administrative and judicial review in the IRA, to not have any dispute resolution process, and will only receive comments related to mathematical errors. *Id*. at 61979.

In this same proposed rulemaking, CMS also proposes to codify its approach to Part B deduplication that it previously announced in guidance in December 2023. While CMS's guidance directs covered entities to use a 340B claims modifier for Part B claims, CMS failed to address commenters' concerns about the accuracy of such modifiers. CMS also rejected requests to create enforcement mechanisms, a claims clearinghouse, or an audit process, simply saying the agency "expects providers to submit accurate claims and utilize correct modifiers."[4]

For Part B, CMS also rejected calls for a dispute resolution process between Part B inflation rebates and 340B, pointing to the statutory prohibition on administrative or judicial review as preventing such a process and providing that if a manufacturer believes there was a "mathematical error" the issue can be submitted and "CMS may consider [it] at its discretion."[5] In this same guidance CMS also rejected commenters' request that the 340B modifiers be included in the Preliminary Rebate Reports provided to manufacturers.[6]

As such, manufacturers will have no insight into the data used to identify duplicate 340B and Part B or Part D inflation rebates out of the IRA and no recourse when duplicate discounts are paid. Accordingly, the only practical option that Lilly has identified to ensure that the appropriate MFP/340B amounts are paid and to avoid duplicate Part B and Part D inflation rebates is through a rebate operated as a cash replenishment option.

[4] CMS, "Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) of the Social Security Act" (Dec. 14, 2023) at 20.
[5] *Id*. at 25.
[6] *Id.* at 40.

IV. The ADR Regulations Also Necessitate a 340B Cash Replenishment Option

On April 19, 2024, HRSA published a final ADR rule. 89 Fed. Reg. 28643 (Apr. 19, 2024). This rule includes several provisions that necessitate and support a 340B cash replenishment option.

First, 42 C.F.R. § 10.22(c)(1) states that "[a] manufacturer is responsible for obtaining relevant information or documents from any wholesaler or other third party that may facilitate the sale or distribution of its drugs to covered entities." This broad obligation to compel production by a third-party who is not required, and may not be inclined to voluntarily turn over data, documents or records puts manufacturers is a difficult position. They can either "hope" that a third-party furnishes records in a timely way or face potential penalties. Moving to a rebate model effectuated as cash replenishment puts manufacturers in control of the relevant data and information needed to comply with HRSA's ADR requirements.

Second, 42 C.F.R. § 10.22 is broadly styled as "Covered Entity Information and Document Requests" and permits only covered entities to seek and obtain information at will through the ADR process. HRSA expressly declined to provide any parallel opportunity for manufacturers to obtain data that they could use to potentially defend themselves or disprove covered entity claims, absent specific approval by an ADR panel. This access-to-information asymmetry is compounded by the currently pervasive 340B replenishment model, which relies on providing the 340B price on products acquired in arrears (i.e., *after* dispensing product to a customer) through wholesalers, requested by third-party administrators after *post-hoc* eligibility determinations, using black-box accumulator programs and unspecified replenishment logic. A cash replenishment program provides much greater transparency and provides manufacturers with information it is responsible for producing under the ADR rules.

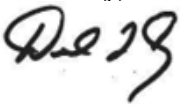
Third, the preamble to the ADR rule recognizes that manufacturer-provided rebates on Managed Medicaid utilization are among the claims permitted under 42 C.F.R. § 10.21. Specifically, HRSA notes that Managed Medicaid utilization is subject to the prohibition on duplicate discounts, under 42 U.S.C. § 256b(a)(5)(C). 89 Fed. Reg. at 28649. This is a welcome development, as many covered entities disclaimed the absolute nature of the statutory prohibition on Medicaid/340B duplicate discounts in comments submitted on the ADR rule, particularly when roughly 85% of Medicaid prescription drug utilization is through Managed Medicaid rather than Medicaid Fee-for-Service. To ensure that manufacturers have the data necessary to develop "reasonable cause" for an audit, and thus the potential to use ADR, a cash replenishment model is needed as that is the only way to "tick-and-tie" Medicaid Managed Care rebate requests to 340B discount requests. Lilly's own recent audit experience demonstrates how deficient the compliance controls related to Managed Medicaid are.

Finally, Lilly still encounters duplicate discounts on Medicaid Fee-for-Service, even though duplicate discounts should be prevented by the so-called "Medicaid Exclusion File" (MEF). Here HRSA has endeavored to create a mechanism to avoid duplicate Medicaid discounts—and we encourage HRSA to do the same for Managed Medicaid— but it only applies to those 15% of Medicaid drug claims covered by "fee-for-service" Medicaid. While duplicate discounts here are generally lower than in the Managed Medicaid context, they still exist. A cash replenishment model improves the compliance environment in this area as well.

***

We appreciate your partnership in this step toward the improved administration of the 340B program. If you have any questions, concerns, please do not hesitate to contact me at your earliest convenience.

Sincerely,



Derek L. Asay
Senior Vice President, Government Strategy, Lilly USA

Addendum A:

Information Provided by Kalderos in Response to HRSA Requests for Additional Information

Covered Entity Experience

Kalderos is committed to the success of covered entities and will be providing white glove support throughout their entire journey via a dedicated success team. From notification, through onboarding, and into regular platform use, we will be supporting the covered entities along the way via a dedicated Customer Success team, on-demand resources, and proactive outreach, all in addition to the easy to use and intuitive Truzo platform.

The Kalderos Customer Success team is aligned to 5 geographic regions. The assigned Customer Success Manager owns the Covered Entity (CE) relationships in their region and will be hand-on to ensure a seamless experience for CEs throughout their journey.

- **Initial Outreach:** Public communication supported by personalized outreach by Kalderos to Authorizing Official and Primary Contact.
- **Enablement:** The Kalderos Truzo Resource Center will include training materials, videos and FAQs. This will be combined with a cadence of CE Webinars and Office Hours.
- **Tailored Support:** Content will be tailored by hospital and non-hospital CE type to provide specific, nuanced support appreciating the different stakeholders profiles, depth of 340B knowledge, resourcing, and retail / acute channel usage across CE types.
- **Monitoring for success:** Proactive monitoring of the CE Onboarding process will occur to ensure CE's have support if needed to get signed up and registered on the Truzo platform.
    - Outreach activities will be tracked to ensure comprehensive coverage across all regions and CE types
    - KPIs to track progress of onboarding by total CEs, regions and types
    - Alerts to call attention to CEs that have stalled in their onboarding process in order to trigger additional outreach
    - The Customer Success Team will review what type of CEs are signing up and if we need to adjust outreach strategy
- **Inbound support:** Covered entities will be directed to the Truzo resource center upon initial outreach and will be able to access the resource center directly from the platform at any time. Covered entities can submit a ticket with any issues or email their assigned customer success manager directly.

The CE platform onboarding process includes the following:

1. **Claiming the profile** - the Authorizing Official claims the profile by confirming their information, reviewing assigned Covered Entities, signing Terms and Conditions, and designating Admins for your Covered Entities.
2. **Connecting a bank account** - the Financial Administrator inputs their bank account information and the platform verifies the connection

3. **Assigning roles to team members -** The administrator can then add other team members requiring access to the Truzo platform and assign the appropriate level of permissions.

After onboarding, covered entities will have enablement resources available to them to ensure they are seeing maximum benefit and success with the platform. The Client Success team will continue to offer proactive support, as well as be available at request of the covered entity. Additionally, we plan to continue our ongoing education through informational content, webinars, and events. These topics include but are not limited to:

- Submitting claims to manufacturers
- Reviewing statuses of their claims and rebates in the platform
- Updating any account information, including contract pharmacy designations
- Requesting discounts for dispenses that occurred prior to cutover but only resulted in a partial accumulations and did not result in a 340B price replenishment
- Understanding reasons for any further inquiries or failed claims

Data Submission Elements

A covered entity requesting a cash replenishment for a 340B dispense will provide the data fields listed below. Each field included can be mapped directly back to one or more of the Payment Confirmation Checks described in the next section. With this routine, easily accessible claim level detail, the platform can effectuate the 340B discount quickly and proactively identify potential duplicate discounts, so they can be mitigated before they happen - ultimately leading to fewer Good Faith Inquiries and decreased burden on CEs and other stakeholders.

Only one set of data elements will be needed per claim, as a claim will either be “Retail” (for medicines that are usually self-administered) or “Medical” (for medicines that are usually administered by healthcare providers).

Retail Claim Fields

Field	Commonly Provided to TPA
Unique Transaction ID	Yes
RX Identifier (RXID)	Yes
Fill Number	Yes
NDC11	Yes
Quantity	Yes
Unit of Measure	Yes
Days Supply	Yes
Ordering Physician NPI	Yes
CE Submitter (340B ID)	Yes
Pharmacy ID (DEA, HIN or NPI)	Yes
Date of Service	Yes
Paid Date	Yes
BIN	Yes
PCN	Yes
GRP	Yes
Claims Modifiers	Yes

Medical Claim Fields

Field	Commonly Provided to TPA
Unique Transaction ID	Yes

Field	Commonly Provided to TPA
NDC11	Yes
Quantity	Yes
Unit of Measure	Yes
Days Supply	Yes
Patient ID (Tokenized)	Yes
Ordering Physician NPI	Yes
CE Submitter (340B ID or NPI)	Yes
CE Administration Location (340B ID)	Yes
CE Administration Location - Medical (NPI)	Yes
Date of Service	Yes
Paid Date	Yes
Insured's Plan Name or Program Name	Yes
Insured's Policy Group or FECA Number	Yes
Claim Modifiers	Yes

** For purposes of comparison, the Medicare Coverage Gap Discount Program requires submission of 19 data elements per claim, which CMS provides to manufacturers; standard rebate agreements with commercial entities typically include up to 83 data elements per claim.*

Payment Confirmation Checks

The following checks are performed in the Truzo platform as part of the payment authorization process. If a request is flagged for further review based on one of these checks, the submitting party will be notified and also:

- Will have clear visibility into the underlying reason;
- Will have access to a dedicated Kalderos customer success representative to ask additional questions or raise any concerns;
- Will have the ability to re-submit the claim (if necessary) once any corrections are made.

Outside of these Kalderos-managed solutions, the covered entity is also encouraged to reach out to Lilly directly. As has always been Lilly's policy, the company is willing to work with covered entities on any issues on a case-by-case basis.

Validation Number	Description
1	**CE Active in OPAIS:** To be eligible to participate in the 340B program, an entity must be validated as an eligible covered entity in HRSA OPAIS database as of the date of service (DOS) of the claim.
2	**Contract Pharmacy Relationship:** Where a contract pharmacy is involved, the CE must have an active affiliation with the contract pharmacy on the DOS in the HRSA OPAIS database and conform with specific manufacturer policies.
3	**Duplicate Claim Submission:** Submitted claim flagged as a duplicate of a previously submitted claim.
4	**Orphan Drug:** CE type is not eligible for 340B prices on orphan drugs.
5	**Claim Submission Timing:** Reasonability check for claim submission relative to DOS.

EXHIBIT 4

HRSA
Health Resources & Services Administration
Office of Special Health Initiatives
5600 Fishers Lane
Rockville, MD 20857

September 18, 2024

BY EMAIL
Lucas Montarce
Executive Vice President and Chief Financial Officer
Eli Lilly and Company
montarce_lucas@lilly.com

Dear Lucas Montarce:

The Health Resources and Services Administration (HRSA) has reviewed the information provided in the September 9, 2024, letter from Eli Lilly and Company (Lilly) regarding Lilly's proposal to implement a 340B rebate model. Lilly indicated that it intends to implement its proposed rebate model on November 1, 2024. The 340B statute states that "[t]he 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" shall not exceed the statutory ceiling price formula. 42 U.S.C. § 256b(a)(1) (emphasis added). To date, the Secretary has not provided for such rebate as proposed by Lilly. Therefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as Lilly has proposed.

In addition, HRSA requests responses to the following questions:

1. Shifting to the rebate model would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase.
    a. Lilly asserts that the rebate model will have no impact on patients. Has Lilly conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected covered entities?
    b. Has Lilly conducted an analysis of the extent of the additional burden and/or costs to the affected covered entities, particularly those that are the sole or primary source of health care in a rural or underserved community?
    c. Lilly indicated that in "some" cases covered entities will receive the cash rebate before paying the upfront cost for the drug itself. Does Lilly have any estimates or has it performed any analysis indicating the proportion of transactions for which this might occur?

2. Lilly states that it will require covered entities to submit rebate claims to the rebate platform.
    a. What other parties, if any, would Lilly share the claims data with?
    b. What protections and safeguards would Lilly plan to implement to ensure such information would be used in support of the 340B Program?
    c. What protections and safeguards would Lilly plan to implement to ensure the privacy and security of such information?
    d. If available, please provide a copy of the Privacy Policy &Terms of Service (or similarly titled agreements) that would govern Kalderos, covered entities, and any other parties in this process.

3. If Lilly identifies a potential 340B duplicate discount, how will the rebate claim be adjudicated?
    a. What is the timeframe that Lilly will process any such adjudication?
    b. What reconsideration or appeals process will Lilly implement?
    c. Will Lilly automatically deny covered entities' 340B rebate claims if Lilly believes a Medicaid rebate was already paid?
    d. Will Lilly automatically deny Medicaid rebate claims if Lilly believes a covered entity's 340B rebate claims have already been paid?

4. Will covered entities receive claim-by-claim information from Lilly regarding which claims were rejected and on what basis?

5. What reconsideration or appeals process will Lilly implement to ensure covered entities receive any 340B discounts that are required by statute?

6. Lilly provided a listing of the data elements that it will collect for the validation of claims. Please indicate how these data elements align with the compliance requirements in the 340B statute. The documentation submitted by Lilly refers to a "reasonability check" for claim submissions relative to the date of service. Please explain what will be involved in this "reasonability check."

7. With respect to the use of pharmacies with which covered entities contract:
    a. Will covered entities need to demonstrate that they purchased individual drugs subject to the rebate claim at wholesale acquisition cost?
    b. Will this process require covered entities to maintain a separate stock of drugs at the contract pharmacy?
    c. If so, how does Lilly plan to ensure this process does not functionally deny covered entities access to the 340B price required by the statute given the additional upfront cost and administrative burden for covered entities, particularly low-margin safety net providers?

8. In 2023, Lilly requested that HRSA post two different refund notices to covered entities on its website as part of standard restatements of 340B drugs. As part of that process, Lilly issued refunds using wholesaler chargeback data. Under this model, how will Lilly operationalize refunds when there are standard restatements in a way that supports the requirement to provide the 340B price?

9. Under this proposal, how would Lilly treat current unreplenished accumulations?

10. Under Lilly's plan, contract pharmacy restrictions would be managed by Kalderos and the 340B ESP model would no longer be used. What transition time will be provided to covered entities that need to designate contract pharmacies in a new system? HRSA has received a number of reports of technical and customer service difficulties with 340B ESP. How would Lilly ensure covered entities could submit claims without technical difficulties or delays and would be able to access customer support without any significant issues under the Kalderos model?

Please send your responses to 340BPricing@hrsa.gov.

Sincerely,

Chantelle V. Britton, M.P.A., M.S.
Director, Office of Pharmacy Affairs

Cc:
Derek Asay, Senior Vice President, Government Strategy and Federal Accounts

EXHIBIT 5

Lilly USA, LLC

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

September 23, 2024

SUBMITTED VIA EMAIL (340BPricing@hrsa.gov)

Dir. Chantelle V. Britton
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
Department of Health and Human Services
5600 Fishers Boulevard
Rockville, MD 20857

RE: HRSA Questions Related to the Kalderos Cash Replenishment Model

Dear Director Britton,

I am writing in response to your letter of September 18, 2024. We are disappointed by HRSA's decision to reject Lilly's cash replenishment model and your determination that implementing a rebate model without affirmative approval would violate the 340B statute. We disagree that the Secretary or HRSA has the statutory authority to reject a cash replenishment model on an ad hoc basis. And here the decision to do so is arbitrary and capricious, especially when HRSA has offered no explanation. It is also inconsistent with the agreed-to Pharmaceutical Pricing Agreement, which imposes no such restriction.

Nevertheless, in the interest of transparency, Lilly is providing HRSA with additional information to help the agency better understand the cash replenishment model. To that end, we reproduce below your questions from your September 18, 2024 letter and provide specific answers. We trust they demonstrate that Lilly is acting in good faith and that any concerns about the cash replenishment model are unfounded. At bottom, the cash replenishment model is not only permitted under the 340B statute, it is faster, more direct, and more transparent than the current product replenishment model. And, unlike that existing model, the cash replenishment model will detect and address illegal claims, ensuring compliance with existing laws and new requirements under the Inflation Reduction Act that have made the need for transparency and oversight even more acute.

1. Shifting to the rebate model would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase.[1]

The cash replenishment model is not going to disrupt any decades-old operation. It instead is designed to replace a far more recent *product* replenishment model—an after-the-fact system of "replenishing" alleged 340B dispenses of non-340B product with 340B-priced product.

In all events, Lilly disagrees that its cash replenishment model would disrupt the operation of the 340B program or strain covered entities' cash flow. To the contrary, Lilly's model will put money in the hands of covered entities sooner than the contorted product-replenishment model that currently prevails. Regardless, Lilly's cash replenishment model is structurally very similar to the prevailing product replenishment model, while protecting against illegal duplicate discounts and diversion, increasing transparency and compliance, and ensuring covered entities are either better off or in the same position from a cash flow perspective.

[1] We note that bolded text in this letter are the questions HRSA posed to Lilly in its September 18, 2024 letter.

Replenishments and rebates are both *post facto* methods for offering a 340B price. The current 340B inventory replenishment models (and there are two: one for contract pharmacies and a different one for in-house dispenses) both rely on upfront purchases of a medicine at the list price followed by a subsequent "replenishment" of that medicine at the 340B price.[2] Similarly, a cash rebate relies on an upfront purchase of the drug at list price and a replacement of the cash expended in excess of the 340B price. The economic effect is the same: 340B pricing is achieved after the fact. But the cash-rebate process is swifter and more efficient.

Under the current contract pharmacy product "replenishment" model, covered entities are billed for units that a contract pharmacy has ordered to replenish a dispense from general inventory. The covered entity must pay that bill up front, and wait a significant period of time for the contract pharmacy to pay the covered entity the amount collected from the patient or the insurer. Under the Kalderos cash replenishment model, covered entities will receive a rebate before having to pay the bill for the contract pharmacy's 340B purchase, which ensures that they get the full benefit of the 340B ceiling price and are equally or better off than under the product replenishment model. And with respect to in-house dispenses, as we discussed during our September 5 meeting and stated in our September 9 letter, cash flow is improved because a cash (as opposed to product) replenishment model puts cash-in-hand every week on a unit-by-unit basis rather than waiting for whole package dispenses. Entities that serve rural and underserved populations should welcome this change, as should all entities.

a. Lilly asserts that the rebate model will have no impact on patients. Has Lilly conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected covered entities?

Yes. To Lilly's disappointment, the 340B program does not directly benefit patients. It is a revenue maximization program for hospitals, many of which are large and profitable, serve affluent communities, and offer less charity care than their non-340B counterparts.[3] That fact has been confirmed both by court filings[4] and Lilly's own studies. Lilly's cash replenishment model will therefore have no impact on patients.

In late 2019 and early 2020, Lilly conducted a survey of contract pharmacy purchases that confirmed patients were not identified at point-of-sale and did not benefit from 340B prices. Nor could they be, given that they are not even identified as 340B patients until after the product is dispensed and the patient has paid for the medication. This has been confirmed over the last four years. Lilly has not received any complaints from patients related to contract pharmacy policies. These findings show that a cash replenishment model will not harm 340B patients that access medicines through a contract pharmacy.

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[2] "[The virtual replenishment] model works by establishing a "neutral" inventory, collecting data about each drug dispensed and administered, and then reordering that drug based on accumulations for 340B eligible patients" *See*, Apexus, "340B Split Billing Software Key Attributes" at 1; *see also* Decl. Of Krista M. Pedley ¶ 11, *Eli Lilly and Co. v. HRSA*, No. 1:21-cv-81 (S.D. Ind. June 25, 2021), ECF No. 125-2 (HRSA official stating that under the replenishment system, contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient").

[3] *See* Neal Masia, Ph.D., *Comparing the Financial Health and Charitable Care of 340B and Non-340B Hospitals* (2023), *available at* https://www.healthcapitalgroup.com/340b-hospitals-and-charity-care-2023.

[4] "[T]he 340B program does not require passing 340B discounts on to patients" and instead covered entities make a profit because they "receive their drugs at a discount and are reimbursed by insurers, including Medicare, at the non-discounted price of the drug." Amicus Brief of 340B Health 2-3, *Genesis Healthcare v. Becerra*, No. 4:19-cv-1531 (D.S.C., Sept. 20, 2023), ECF No. 124-2.

With respect to in-house dispensing, Lilly engaged consultants and experts who advised us on cash flow dynamics for covered entities. Those experts have shared their opinions that covered entities may actually enjoy better cash flow under the cash replenishment model. We also asked Kalderos to conduct a cash flow analysis for in-house dispensing. This analysis was shared with HRSA at our September 4 meeting.

More fundamentally, the cash replenishment model does nothing to discourage or reverse any lawful 340B purchase so should have no effect on patients whatsoever. Indeed, to the extent that any covered entity ever were to pass on a portion of the 340B discount to a patient, the cash replenishment model would enable the covered entity to do so more readily.

b. Has Lilly conducted an analysis of the extent of the additional burden and/or costs to the affected covered entities, particularly those that are the sole or primary source of health care in a rural or underserved community?

There will be no additional burdens or costs to any covered entities, as the data necessary for the cash replenishment model are all readily available and required to be submitted to payors. Covered entities with limited personnel are free to provide access to the Kalderos platform to their vendors. And Lilly will cover all costs associated with the platform.

c. Lilly indicated that in "some" cases covered entities will receive the cash rebate before paying the upfront cost for the drug itself. Does Lilly have any estimates or has it performed any analysis indicating the proportion of transactions for which this might occur?

Based on conversations with outside consultants, Lilly understands that many smaller covered entities, which likely describes those that serve rural or underserved populations, have longer payment terms with wholesalers, commonly 30 days. For those entities, weekly payments under the new cash replenishment model mean that rebates should come before wholesaler bills must be paid, meaning entities can leverage the "float" on the rebates that are in their accounts, a benefit they do not enjoy today.

2. Lilly states that it will require covered entities to submit rebate claims to the rebate platform.

a. What other parties, if any, would Lilly share the claims data with?

Lilly will only share data with State Medicaid Agencies and CMS (or their subcontractors) in limited circumstances: if those entities already possess such claim level data and where Lilly has identified the claim as duplicative of another statutorily prohibited rebate or discount.

b. What protections and safeguards would Lilly plan to implement to ensure such information would be used in support of the 340B Program?

The Kalderos platform is designed to collect only the information that is necessary to process a cash replenishment payment to the covered entity and identify statutorily prohibited duplicate discounts. It therefore *is* the plan to ensure that information is used in support of the 340B program, as the program is improved when integrity is assured, and transparency is increased. To that end, identifying and avoiding unlawful duplication helps all 340B stakeholders.

The data collected via Lilly's cash replenishment model is also necessary for any disputes that may arise under the Administrative Dispute Resolution (ADR) process. HRSA regulations purport to require manufacturers in the ADR process to produce documentation currently in the sole possession of wholesalers due to the unique nature of the current product replenishment model. It is unclear if the wholesalers, who are not a party to any ADR dispute, are willing or able to produce this documentation.

Finally, these data could serve as the basis for establishing "reasonable cause" to support a manufacturer audit—another program integrity enhancement.

c. What protections and safeguards would Lilly plan to implement to ensure the privacy and security of such information?

Lilly, Kalderos, and JP Morgan (the payment processor) employ robust data security and privacy safeguards. Lilly has established a cybersecurity program aligned to industry best practices aligned with the National Institute of Standards and Technology (NIST) Special Publication 800.53. The program includes requirements to conduct comprehensive third-party assessments to verify the cybersecurity controls, policies, and procedures of its third parties. Additionally, Lilly contractually requires vendors to comply with key cyber security controls through its Information Security Standard.

d. If available, please provide a copy of the Privacy Policy &Terms of Service (or similarly titled agreements) that would govern Kalderos, covered entities, and any other parties in this process.

The Kalderos Privacy and Security Policy is available here Kalderos' Privacy Policy. The Lilly Privacy and Security Policy is available here Lilly Supplier Privacy Standards 07.16.24.

3. If Lilly identifies a potential 340B duplicate discount, how will the rebate claim be adjudicated?

Under Lilly's cash replenishment model, neither Lilly nor Kalderos would "adjudicate" a claim (which is a pharmacy concept). Instead, Lilly and Kalderos will evaluate whether the necessary data has been submitted to justify a payment to the covered entity. If there is a problem with the covered entities' data submission, Lilly will engage in good faith discussion with the covered entity to resolve the issue.

To be clear, Lilly's cash replenishment model will not involve the rejection of eligible claims *from covered entities—i.e.*, claims from covered entities listed on the OPAIS database and that are not prohibited from purchasing orphan drugs, that have not already been submitted by a covered entity for a rebate, and that are for quantities of a medicine that could have been dispensed to a patient. Because Lilly will be processing payments weekly, the covered entities' cash replenishment request will be first in right and will be entitled to the 340B price in the first instance. We fully expect that Lilly will withhold or dispute payment with the other party receiving a duplicate discount—*i.e.*, the state Medicaid program or CMS, as appropriate. Covered entities will not have payments withheld for eligible claims.

a. What is the timeframe that Lilly will process any such adjudication?

Lilly will not "adjudicate" any claims. All claims will be evaluated within ten business days of submission by the covered entity or its vendors.

b. What reconsideration or appeals process will Lilly implement?

Lilly and Kalderos are committed to high-customer service and quality so that covered entities will always have a live person to engage with on questions or concerns. Finally, under the ADR Rule, any request for appeal or reconsideration necessarily starts with "good faith" dispute resolution—which is consistent with how Lilly operates today and how it operates with all customers in the supply chain.

c. Will Lilly automatically deny covered entities' 340B rebate claims if Lilly believes a Medicaid rebate was already paid?

No. In that case, we expect that Lilly will withhold or dispute payment with the state Medicaid program. We expect that covered entities will not have payments withheld and, in many cases, need not even know that a duplicate has occurred.

d. Will Lilly automatically deny Medicaid rebate claims if Lilly believes a covered entity's 340B rebate claims have already been paid?

No. Lilly will not deny the Medicaid rebate claim; where appropriate, Lilly will "dispute" the claim in accordance with state and federal Medicaid dispute procedures and work with the states to resolve those disputes, as it does today. This simply provides better data and transparency, which will help make that process more efficient.

4. Will covered entities receive claim-by-claim information from Lilly regarding which claims were rejected and on what basis?

Lilly will not be "rejecting" eligible cash replenishment claims. As we explained and demonstrated at our September 4 meeting, covered entities will see the exact same data—on a claim-by-claim basis—that Lilly will see in the Kalderos platform. We think this represents a significant and meaningful advance over the current opaque product replenishment model in terms of fostering transparency and trust between covered entities and manufacturers.

5. What reconsideration or appeals process will Lilly implement to ensure covered entities receive any 340B discounts that are required by statute?

As discussed at Question 3 above, in the rare event where there is a problem with the covered entities' data submission, Lilly will engage in good faith discussions with covered entities, as we always have, as required by the ADR, and as already happens in the routine course of dealing with all of our customers. This will all be consistent with current practice.

6. Lilly provided a listing of the data elements that it will collect for the validation of claims. Please indicate how these data elements align with the compliance requirements in the 340B statute. The documentation submitted by Lilly refers to a "reasonability check" for claim submissions relative to the date of service. Please explain what will be involved in this "reasonability check."

See Exhibit 1 in response to the request for information related to specific data elements and why they are necessary to comply with the 340B statute and other legal requirements. With respect to the "reasonability check" referenced in the September 9 letter, that related solely to issues around claims submission timing. Claims that are very old or stale may need to be compared against Medicaid or Medicare rebate claims or prior entity submissions from different time periods. Lilly

might also have questions about why such claims took so long to submit, given such submissions are not consistent with ordinary course practice.

7. With respect to the use of pharmacies with which covered entities contract:

a. Will covered entities need to demonstrate that they purchased individual drugs subject to the rebate claim at wholesale acquisition cost?

No. Lilly plans to issue rebates in an amount equal to WAC – 340B.

b. Will this process require covered entities to maintain a separate stock of drugs at the contract pharmacy?

No. Indeed, this process resolves one of the most troubling—and unlawful—elements of the current "product replenishment model," which is the commingling of 340B product and non-340B product in pharmacy stores and dispensing of 340B replenishment product to non-patients, which leads to diversion in violation of the 340B statute.

c. If so, how does Lilly plan to ensure this process does not functionally deny covered entities access to the 340B price required by the statute given the additional upfront cost and administrative burden for covered entities, particularly low-margin safety net providers?

No answer is required here because Lilly's cash replenishment model does not require covered entities to maintain a separate stock of drugs at a contract pharmacy.

8. In 2023, Lilly requested that HRSA post two different refund notices to covered entities on its website as part of standard restatements of 340B drugs. As part of that process, Lilly issued refunds using wholesaler chargeback data. Under this model, how will Lilly operationalize refunds when there are standard restatements in a way that supports the requirement to provide the 340B price?

Today, for routine restatements of Medicaid prices (authorized under 42 C.F.R. 447.510), Lilly generates and sends physical (paper) checks to covered entities via US Mail—some of which go uncashed because of human error. For restatements related to launch product differences, Lilly provides a wholesaler credit, which may not be drawn down or may be drawn down with a lag. The cash replenishment model makes the overcharge refund process (and thus improved compliance with HRSA's rules) much more straightforward. Using Kalderos, Lilly can authorize automatic deposits of any refund amounts directly into covered entity accounts via ACH or wire transfer. Moreover, using Kalderos, Lilly can efficiently issue payments as small as one penny, even though Lilly already leads the industry in its automatic refund method by issuing checks or credits for refunds as low as $1.00 (entities seeking refunds below that can contact Lilly).

9. Under this proposal, how would Lilly treat current unreplenished accumulations?

Covered entities that have unreplenished accumulations can submit for cash replenishment by submitting the unit level claims data to Lilly beginning on the effective date of the program. As the date of dispense will be prior to effective date for providing claim level data, covered entities will be asked to provide a screenshot of their inventory accumulations from their split-billing/virtual inventory system to substantiate the units submitted that have been dispensed prior to go-live that have been accumulated against a saleable package.

10. Under Lilly's plan, contract pharmacy restrictions would be managed by Kalderos and the 340B ESP model would no longer be used. What transition time will be provided to covered entities that need to designate contract pharmacies in a new system? HRSA has received a number of reports of technical and customer service difficulties with 340B ESP. How would Lilly ensure covered entities could submit claims without technical difficulties or delays and would be able to access customer support without any significant issues under the Kalderos model?

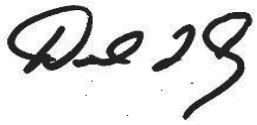
Lilly is planning to seek consent from covered entities to handle, on behalf of the covered entity, the transition of existing contract pharmacy designations from BRG ESP to Kalderos and send confirmation of the transition upon completion, so no action should be needed related to designations when the entity enrolls in Kalderos. However, if the covered entity wishes to terminate their enrollment in the 340B ESP program directly and re-enroll via Kalderos directly, it is also free to do that.

*****

While we disagree that HRSA has the authority to reject (or require approval of) a cash replenishment model on an ad hoc basis, we understand that HRSA has made a determination that Lilly implementing its cash replenishment model would violate the 340B statute. Our hope is that the information provided in this letter has caused HRSA to reconsider or change that decision. If that's the case, please let us know by October 7, 2024. Otherwise, we will assume HRSA stands by the position taken in its September 18, 2024 letter.

We stand ready to work with HRSA to ensure orderly and efficient administration of the 340B program. 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
Senior Vice President, Government Strategy

Exhibit 1:
Response to Question 6
(Note a drug is either retail or medical, not both)

Retail Claims Fields

Field	Purpose/340B Compliance/IRA Compliance
Unique Transaction ID	Allows covered entities to internally track of claims.
RX Identifier (RXID)	Allows Lilly to match claim with Medicaid and Part D Inflation Rebates and Maximum Fair Price claims to identify duplicate discounts.
Fill Number	Allows distinguishing between multiple fills made in the same day by the same patient to reconcile if flagged as a potentially duplicative claim.
NDC11	Necessary to tie the discount request to a specific product and pricing. Allows Lilly to match claim with Medicaid and Part D Inflation Rebates and Maximum Fair Price claims rebate request to identify duplicate discounts.
Quantity	Necessary to calculate the discount amount. Allows Lilly to match claim with Medicaid and Part D Inflation Rebates and Maximum Fair Price claims to identify duplicate discounts.
Unit of Measure	Unit type must match the expected unit type in order to accurately calculate the discount amount (milliliter, tablet, pre-filled pen, etc.).
Days' Supply	Necessary for unit of measure / aberrant quantity validation. Assists in determining if dispense amount is reasonable based on Dosage and Administration as published in FDA label.
Ordering Physician NPI	Allows Lilly to match claim with Medicaid and Part D Inflation Rebates and Maximum Fair Price claims to identify duplicate discounts and necessary to identify duplicate claim identification across different CEs.
CE Submitter (340B ID)	Ensures CE is registered on HRSA OPAIS for the date at issue. Identifies origin of claim submission and ensures that this ID ties back to the appropriate CE account.
Pharmacy ID (DEA, HIN or NPI)	Ensures pharmacy is registered on HRSA OPAIS for the date of service.
Date of Service	Allows Lilly to match claim with Medicaid and Part D Inflation Rebates and Maximum Fair Price claims to identify duplicate discounts and ensures that entity or

Field	Purpose/340B Compliance/IRA Compliance
	pharmacy was 340B eligible based on HRSA database listing.
Paid Date	Allows Kalderos to determine whether adjustments or reversals were made that could identify if two claims were made on the same dispense.
BIN	Allows Lilly to match claim with Managed Medicaid plan rebate requests to identify duplicate discounts.
PCN	Allows Lilly to match claim with Managed Medicaid plan rebate requests to identify duplicate discounts.
GRP	Allows Lilly to match claim with Managed Medicaid plan rebate requests to identify duplicate discounts.
Claims Modifiers	Necessary for reimbursement on "wastage" amounts and to reconcile if flagged as duplicate claim.

Medical Claims Fields

Field	Purpose/340B Compliance/IRA Compliance
Unique Transaction ID	Unique ID helps CE track claim and tie back to a specific dispense / administration in their own EMR. Supports traceability to specific dispense for HRSA Audits.
NDC11	Necessary to tie the discount request to a specific product and pricing. Allows Lilly to match claim with Medicaid rebate request to identify duplicate discounts.
Quantity	Necessary to calculate the discount amount. Allows Lilly to match claim with Medicaid and Part D Inflation Rebates and Maximum Fair Price claims to identify duplicate discounts.
Unit of Measure	Unit type must match the expected unit type in order to accurately calculate the discount amount (milliliter, tablet, pre-filled pen, etc.).
Days' Supply	Necessary for unit of measure / aberrant quantity validation. Assists in determining if dispense amount is reasonable based on Dosage and Administration as published in FDA label.
Patient ID (Tokenized)	Allows for internal tracking of claim as medical claims lack unique identifiers. If CE does not want to tokenize, Kalderos will automatically do so in the Truzo platform.
Ordering Physician NPI	Allows Lilly to match claim with Medicaid and Part D Inflation Rebates and Maximum Fair Price claims to identify duplicate discounts.

Field	Purpose/340B Compliance/IRA Compliance
CE Submitter (340B ID or NPI)	Ensures CE is registered on HRSA OPAIS for the date at issue.
CE Administration Location (340B ID)	Identifies origin of claim submission and ensures that this ID ties back to the appropriate CE account
CE Administration Location - Medical (NPI)	Identifies origin of claim submission.
Date of Service	Allows Lilly to match claim with Medicaid and Part D Inflation Rebates and Maximum Fair Price claims to identify duplicate discounts.
Paid Date	Allows Kalderos to determine whether adjustments or reversals were made that could identify if two claims were made on the same dispense.
Insured's Plan Name or Program Name	Allows Lilly to match claim with Managed Medicaid rebate request to identify duplicate discounts.
Insured's Policy Group or FECA Number	Allows Lilly to match claim with Managed Medicaid rebate request to identify duplicate discounts.
Claim Modifiers	Necessary for reimbursement on “wastage” amounts.

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

UNITED STATES DISTRICT COURT

for the

District of Columbia

ELI LILLY AND COMPANY; LILLY USA, LLC

Plaintiff(s)

v.

XAVIER BECERRA; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CAROLE JOHNSON; HEALTH RESOURCES AND SERVICES ADMINISTRATION

Defendant(s)

Civil Action No. 1:24-cv-3220

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* XAVIER BECERRA,
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: John C. O'Quinn
Kirkland & Ellis LLP
1301 Pennsylvania Avenue, NW
Washington, D.C. 20004

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

ANGELA D. CAESAR, CLERK OF COURT

Date: 11/14/2024

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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

UNITED STATES DISTRICT COURT

for the

District of Columbia

ELI LILLY AND COMPANY; LILLY USA, LLC

Plaintiff(s)

v.

XAVIER BECERRA; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CAROLE JOHNSON; HEALTH RESOURCES AND SERVICES ADMINISTRATION

Defendant(s)

Civil Action No. 1:24-cv-3220

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: John C. O'Quinn
Kirkland & Ellis LLP
1301 Pennsylvania Avenue, NW
Washington, D.C. 20004

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Date: 11/14/2024

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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Date: _____

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Printed name and title

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Server's address

Additional information regarding attempted service, etc:

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UNITED STATES DISTRICT COURT

for the

District of Columbia

ELI LILLY AND COMPANY; LILLY USA, LLC

Plaintiff(s)

v.

XAVIER BECERRA; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CAROLE JOHNSON; HEALTH RESOURCES AND SERVICES ADMINISTRATION

Defendant(s)

Civil Action No. 1:24-cv-3220

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* CAROLE JOHNSON,
Administrator of U.S. Health Resources and Services Administration,
5600 Fishers Lane,
Rockville, MD 20852

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: John C. O'Quinn
Kirkland & Ellis LLP
1301 Pennsylvania Avenue, NW
Washington, D.C. 20004

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

ANGELA D. CAESAR, CLERK OF COURT

Date: 11/14/2024

Signature of Clerk or Deputy Clerk

Civil Action No.

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

Date: _____

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Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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UNITED STATES DISTRICT COURT

for the

District of Columbia

ELI LILLY AND COMPANY; LILLY USA, LLC

Plaintiff(s)

v.

XAVIER BECERRA; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CAROLE JOHNSON; HEALTH RESOURCES AND SERVICES ADMINISTRATION

Defendant(s)

Civil Action No. 1:24-cv-3220

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane,
Rockville, MD 20852

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: John C. O'Quinn
Kirkland & Ellis LLP
1301 Pennsylvania Avenue, NW
Washington, D.C. 20004

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Date: 11/14/2024

Signature of Clerk or Deputy Clerk

Civil Action No.

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

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Date: _____

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Server's signature

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Printed name and title

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Additional information regarding attempted service, etc:

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UNITED STATES DISTRICT COURT

for the

District of Columbia

ELI LILLY AND COMPANY; LILLY USA, LLC

Plaintiff(s)

v.

XAVIER BECERRA; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CAROLE JOHNSON; HEALTH RESOURCES AND SERVICES ADMINISTRATION

Defendant(s)

Civil Action No. 1:24-cv-3220

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Civil Process Clerk
United States Attorney's Office
555 Fourth Street, N.W.
Washington, D.C. 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: John C. O'Quinn
Kirkland & Ellis LLP
1301 Pennsylvania Avenue, NW
Washington, D.C. 20004

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ANGELA D. CAESAR, CLERK OF COURT

Date: 11/14/2024

Signature of Clerk or Deputy Clerk

Civil Action No.

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Additional information regarding attempted service, etc:

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District of Columbia

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Plaintiff(s)

v.

XAVIER BECERRA; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CAROLE JOHNSON; HEALTH RESOURCES AND SERVICES ADMINISTRATION

Defendant(s)

Civil Action No. 1:24-cv-3220

SUMMONS IN A CIVIL ACTION

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

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: John C. O'Quinn
Kirkland & Ellis LLP
1301 Pennsylvania Avenue, NW
Washington, D.C. 20004

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ANGELA D. CAESAR, CLERK OF COURT

Date: 11/14/2024

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