UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

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

and

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

Plaintiffs,

v.

XAVIER BECERRA,
in his official capacity as Secretary of HHS
Office of the Secretary
200 Independence Avenue, S.W.
Washington, D.C. 20201,

DANIEL J. BARRY,
in his official capacity
as Acting General Counsel of HHS
Office of the General Counsel
200 Independence Avenue, S.W.
Washington, D.C. 20201,

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

DIANA ESPINOSA,
in her official capacity as
Acting Administrator of HRSA
5600 Fishers Lane
Rockville, MD 20852,

and

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

Defendants.

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

Document Electronically Filed

PLAINTIFFS' BRIEFING MEMORANDUM IN SUPPORT OF TEMPORARY RESTRAINING ORDER

Plaintiffs submit this briefing memorandum as a summary of their memorandum in support of Plaintiffs' motion for a preliminary injunction and TRO, *see* Dkts. 94-95, filed on May 20, 2021.

BACKGROUND

1. On December 30, 2020, Defendants issued an "Advisory Opinion" announcing for the first time, and contrary to Defendants' many prior pronouncements on the issue, that pharmaceutical manufacturers participating in the 29-year-old 340B drug pricing program must provide steep discounts for their products on sales made by an unlimited number of contract pharmacies, or else face civil monetary penalties and potential expulsion from parts of Medicare and Medicaid. *See* ADVOP_1-8. In response to the imposition of that new obligation, Lilly filed this lawsuit, which alleges, among other things, that the December 30 Decision is in fact an invalid legislative rule and that Defendants lack statutory or constitutional authority to impose such a requirement. Dkt. 1. In other words, the core question this case presents is whether HHS and HRSA can lawfully require manufacturers to provide 340B discounts on contract pharmacy sales.

Lilly filed an amended complaint shortly thereafter adding claims challenging HHS's separate 340B ADR Rule. Dkt. 17. Lilly also filed a motion for preliminary injunction seeking to prevent Defendants from enforcing the ADR Rule against Lilly. Dkt. 18. After briefing and oral argument relating solely to the ADR Rule, the Court granted Lilly's motion. Dkts. 81-82.

The case then proceeded to dispositive briefing on both sets of claims. On April 20, the government filed a motion to dismiss Lilly's claims challenging the December 30 Decision and for summary judgment on all of Lilly's claims. Dkt. 88 ("MTD/MSJ"). On May 10, Lilly filed an opposition and cross-motion for summary judgment on all of its claims. Dkt. 89 ("Lilly MSJ").

2. Consistent with the briefing schedule the parties agreed to and this Court entered, *see* Dkt. 85, Lilly expected that the next it heard from Defendants would be on June 1 when they filed their reply brief. Instead, Defendants sent Lilly a letter on May 17—just five days after

Secretary Becerra was confronted by multiple members of Congress about the contract pharmacy issue—declaring that they expect Lilly to capitulate to the government's interpretation of the statute by June 1. The letter announces that "HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute," and demands that "Lilly must ***immediately*** begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements" and must "credit or refund all covered entities for overcharges that have resulted from Lilly's policy"—under which Lilly offers all covered entities all 340B discounts, but will not as a matter of course provide discounts to contract pharmacies. Exh. A at 1-2 (emphasis added). The letter goes on to warn that "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies" will "result in CMPs" (which "would be in addition to repayment") unless Defendant HHS is sufficiently satisfied with "Lilly's willingness to comply with" Defendants' view of Lilly's "obligations under section 340B[.]" *Id.* And it concludes by "request[ing] that Lilly provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by **June 1, 2021**." *Id.* at 2.

3. Faced with that June 1 deadline, Lilly filed a motion for a preliminary injunction on May 21 to prevent Defendants, pending final resolution of this case, from requiring Lilly to provide 340B discounts on contract pharmacy sales or penalizing it for refusing to do so; Lilly also requested a TRO to the same effect pending resolution of its motion. Dkt. 94. Lilly also filed an accompanying memorandum explaining its entitlement to such relief. Dkt. 95 ("Lilly PI/TRO").

ARGUMENT

I. The May 17 Letter Rises And Falls With The December 30 Contract-Pharmacy Decision.

The May 17 letter implicates the same fundamental issue already before the Court: whether Defendants have the statutory and/or constitutional authority to obligate manufacturers to provide

340B discounts on contract pharmacy sales. Resolution of that question in favor of Lilly would preclude Defendants from carrying out their May 17 threats. After all, Lilly's claim in this case is that the December 30 Decision is in fact an improper legislative rule that imposes new, extra-statutory obligations on manufacturers without notice and comment or statutory authority. If that is correct (and Lilly is likely to succeed in showing that it is), then the May 17 letter is simply the government's first application of that invalid rule; and because the rule must fall, so must the May 17 "determination" that Lilly has violated it. That is why this Court can resolve Lilly's TRO motion without waiting for a new amended complaint. *See Habitat Educ. Ctr., Inc. v. Kimbell*, 250 F.R.D. 397, 400-01 (E.D. Wis. 2008) ("Defendants cite no authority, and I have found none, that would require a plaintiff to file a fresh lawsuit to challenge a final agency action when the action is no more than the latest iteration of an earlier action that is the subject of a pending suit.").

To be clear, Lilly of course is ready and willing to file an amended complaint if that is what this Court determines is required. But no such amendment is necessary to support a temporary restraining order. Lilly's current complaint—*i.e.*, the subject of the already-on-file motion to dismiss and already-on-file cross-motions for summary judgment—alleges that:

- Defendants lack statutory authority to require, on pain of penalty, that manufacturers provide 340B discounts on drugs dispensed by contract pharmacies (Count II);
- even if Defendants have such authority, given their repeated pronouncements to the contrary, they cannot impose that obligation without notice and comment (Count I);
- the December 30, 2020 "Advisory Opinion" is arbitrary and capricious for a number of reasons, including that it fails to acknowledge Defendants' prior pronouncements, let alone to explain the basis for their change in position (Count III); and
- the Constitution precludes Defendants from putting manufacturers to the Hobson's choice of giving discounts to an unlimited number of contract pharmacies or else face sanctions that include potential expulsion from pervasive federal programs (Count IV).

Should Lilly prevail on any of these counts, it will follow that Defendants cannot carry out their threat to impose penalties and irreparable injury on Lilly if it does not begin providing

discounts to an unlimited number of contract pharmacies—*i.e.*, precisely the same thing Lilly's complaint argues HHS and HRSA have no authority to do. Nevertheless, if the Court prefers or finds it necessary, Lilly will promptly submit an amended complaint addressing the letter, which will include counts that are substantially similar to current Counts I-IV. *See* Lilly PI/TRO 11 n.1.

II. The May 17 Letter Confirms That Lilly Is Likely To Succeed On Its Pending Claims.

A. The May 17 Letter Confirms that the December 30 Decision Constitutes a Final, Legislative Rule That Lilly Has Properly Challenged.

It is clear on the face of the Decision itself that the December 30 Decision is a legislative rule properly subject to immediate challenge in this Court. *See* Lilly MSJ 12-19. Agency action constitutes a legislative rule if it has binding effect, *i.e.*, if it imposes a new legal obligation on private parties and binds the agency to that position. *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 357 (D.C. Cir. 2017). That is exactly what the December 30 Decision does. Before December 30, 2020, HRSA was on record in declaring that it lacked authority to impose penalties on manufacturers that declined to provide 340B discounts on drugs dispensed by contract pharmacies. *See* Lilly MSJ 16-17. The December 30 Decision departs from those pronouncements and imposes just that obligation. *See* ADVOP_1. And the May 17 letter removes any doubt about whether legal consequences will flow from this new legal obligation. *See* Exh. A (threatening Lilly with penalties if it fails to comply with the obligation). The imposition of this new, penalty-backed obligation—after years of saying that Defendants lacked authority to do so—constitutes a legislative rule, and at the very least is final agency action subject to immediate challenge. *See Sackett v. EPA*, 566 U.S. 120, 126 & n.2 (2012); *see also* Lilly MSJ 18-22; Lilly PI/TRO 12-14.

The May 17 letter also confirms that the government's statute of limitations argument is meritless. *See* Lilly MSJ 18-19. In explaining what statutory language HRSA believes creates the obligation to deliver discounted drugs to an unlimited number of contract pharmacies, the May 17

letter cites only the "must offer" provision, which ***was not in the statute*** when HRSA issued its prior contract pharmacy guidance. *See* Exh. A at 1; *see also* Lilly MSJ 14-15. The government's suggestion that the statute of limitations extinguished Lilly's cause of action before the agency took any action based on this new language, and indeed before it existed, is absurd. Nor did things suddenly change after 2010. All the way up until the December 30 Decision, HRSA and HHS clung to the ***opposite*** position to the one they take now; they said they could not compel manufacturers to provide 340B discounts on drugs dispensed through contract pharmacies. In short, Lilly could not have sued before December 30 alleging that Defendants cannot obligate it to provide 340B discounts on drugs dispensed by contract pharmacies. *See* Lilly PI/TRO 14-16.

B. The May 17 Letter Confirms that Lilly Is Likely to Succeed in Showing that Defendants' Interpretation of the 340B Statute is Contrary to Law.

1. Nothing in the 340B statute requires manufacturers to deliver discounted drugs to contract pharmacies or to give pharmacies after-the-fact 340B discounts when they "replenish" their stores, and nothing in the statute authorizes Defendants to impose such an obligation. The statute requires manufacturers participating in the program to offer discounts to "each covered entity"—no less, but no more. *See* 42 U.S.C. § 256b(a)(1). The statute further authorizes the HHS Secretary to penalize "any manufacturer with an agreement under this section that knowingly and intentionally charges a ***covered entity*** a price for purchase of a drug that exceeds" the 340B ceiling price. *Id.* § 256b(d)(1)(B)(vi)(III) (emphasis added). If a healthcare provider or other business is not a covered entity, it is not entitled to 340B discounts—period. *See* Lilly PI/TRO 16-17.

Because contract pharmacies are not covered entities, Defendants cannot require Lilly (or other manufacturers) to provide 340B discounts on contract pharmacy sales. The statute sets up an intricate program and precisely defines the 15 kinds of covered entities that are entitled to participate in and claim discounts through the program. Congress's conscious omission of contract

pharmacies—and any for-profit enterprises remotely like them—should be the end of the matter. The *expressio unius* carries particular force when "the items expressed are members of an 'associated group or series,' justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence." *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003). And here, whereas the entities Congress defined to be covered entities are all safety-net providers that serve the needy as a matter of mission, contract pharmacies are big businesses that serve their shareholders and profit off manufacturer discounts. *See* Lilly MSJ 24-27. Stretching the text to include for-profit retailers like contract pharmacies would thus result not in "a construction of [the] statute, but, in effect, an enlargement of it." *Lamie v. United States Tr.*, 540 U.S. 526, 538 (2004).

In the December 30 Decision, HHS declared that it did not matter that contract pharmacies are not included in the statute, or that they are fundamentally unlike the safety-net providers that Congress did include, so long as they act as covered entities' agents. *See* ADVOP_1-8. As Lilly's summary judgment brief explained (at 27-31), that position cannot be correct because (1) it flouts the statute's limitation of permissible "agency" arrangements to three categories that do not include contract pharmacies, *see* 42 U.S.C. § 256b(d)(1)(B)(v), (2)(B)(iv), and (3)(B)(vi); (2) it undercuts the statute's goal of ensuring that the 340B program actually serves to benefit needy patients, as opposed to diverting funds into the pockets of for-profit intermediaries; (3) the statute forbids arrangements under which covered entities join hands with outside enterprises to spread the wealth generated on the backs of manufacturer discounts, *see id.* § 256b(a)(5)(A)); and (4) the statute explicitly limits Defendants' regulatory authority to establishing an ADR process, creating a methodology for calculating ceiling prices, and doling out CMPs, *see id.* § 256b(d)(1)(B)(vi).

Nor can the statute be construed to mean that a drug delivered to a contract pharmacy under the now-prevailing "replenishment model" is one "purchased by" a covered entity. The way

contract pharmacies work in practice is through a so-called "replenishment model," under which the contract pharmacies "identif[y] 340B eligibility after the prescription has been dispensed to the patient and reimbursed by the payer" and then seek after-the-fact discounts from manufacturers. Dkt. 92-1 (Vandervelde Amicus Br.), at 16. This "represent[s] a sizeable shift from how contract pharmacy arrangements were administered prior to the 2010 guidance," and it has "turned 340B eligibility determination and inventory management into an accounting exercise that allow[s] … enhanced profitability" for pharmacies. *Id.* at 13-14. More to the point, "replenishment" purchases cuts covered entities out of the "purchase" that ostensibly triggers manufacturers' obligation to offer covered outpatient drugs at the ceiling price. In sum, the statute cannot reasonably be read to allow Defendants to require manufacturers, on pain of penalty, to provide 340B discounts on sales made by an unlimited number of contract pharmacies. *See* Lilly PI/TRO 16-18.

2. Even if the statute could be read to allow Defendants to impose such an obligation, the constitutional avoidance canon would foreclose adopting that construction. Requiring Lilly to give discounts to contract pharmacies—which typically do not pass on discounts to patients (in part because they are not required to)—would be tantamount to "a naked transfer of property from private party *A* to *B* solely for *B*'s private use and benefit," *Carole Media LLC v. N.J. Transit Corp.*, 550 F.3d 302, 311 (3d Cir. 2008), which is the classic form of an unconstitutional taking, *see Kelo v. City of New London Conn.*, 545 U.S. 469, 477-78 (2005). And putting manufacturers to the Hobson's choice of complying with that obligation or face civil monetary penalties and potential expulsion from multiple, pervasive federal programs is the classic form of an unconstitutional condition. The May 17 letter makes it even clearer that Lilly is likely to succeed on this claim, as the letter specifically warns that HRSA believes Lilly will be in violation of its PPA unless it capitulates to HRSA's view of the statute, and the penalties for violating a PPA

include expulsion from the 340B program (***and*** Medicare and Medicaid). *See* Lilly MSJ 35-37; Lilly PI/TRO 18-19.

The government's principal defense has been to say that because Lilly's participation in the 340B program is nominally voluntary, Lilly cannot complain about the conditions imposed on that participation. *See, e.g.*, MTD/MSJ 30-32. But the new conditions HHS and HRSA are trying to impose—give an unlimited number of for-profit businesses discounted product, no questions asked, or else be subjected to crippling penalties and the potential expulsion from some of the largest government programs in existence—were not the terms of the program when Lilly signed its PPA. Imposing these onerous conditions now is more than just a classic bait and switch; it is a textbook unconstitutional condition—"a gun to the head" in the guise of a mere "financial inducement," *NFIB v. Sebelius*, 567 U.S. 519, 581 (2012). *See* Lilly MSJ 35-37; Lilly PI/TRO 19.

3. The May 17 letter also confirms that the December 30 Decision is arbitrary and capricious. The crux of the Decision was the purported "agency relationship" between a covered entity and a contract pharmacy. *See* ADVOP_1, 6. The May 17 letter does away with all of that. Although it reiterates (and makes good on) the Decision's basic conclusion that manufacturers must sell to contract pharmacies at 340B prices or else, not once does the letter mention common-law agency or suggest that Lilly would have an opportunity, before handing over money, to prove that a particular covered entity's relationship with a contract pharmacy did not constitute an agency relationship. Everything the government said in the December 30 Decision (and everything the government said trying to defend the Decision in this Court) is thus out the window now, with one exception—namely, Defendants' insistence not only that the statute ***must*** be read to allow them to compel manufacturers to provide 340B discounts on contract pharmacy sales, but that they have always held that position. *See* Exh. A at 1; ADVOP_4. But as Lilly has already pointed out, the

statutory language Defendants invoke ***was not in the 340B statute back in 1996***. That means that Defendants' position must have changed since 1996, and that they are acting arbitrarily in refusing to acknowledge, much less explain, their change in position. *See* Lilly PI/TRO 19-23.

III. Lilly Will Suffer Irreparable Harm Absent An Injunction, Lilly Has No Adequate Remedy At Law, And The Balance Of Harms And The Public Interest Favor Lilly.

Lilly will suffer irreparable injury without an injunction. Complying with Defendants' demands, to avoid penalties, will result in unrecoverable payments from Lilly to third parties—an injury that is irreparable *per se*. Lilly also stands to suffer reputational injury from a government pronouncement that Lilly is in violation of its legal obligations (not to mention from the imposition of any CMPs). *See* Dkt. 95-5 ¶¶ 27-30. Lilly stands to suffer constitutional injury absent an injunction, too, and "[t]he existence of a continuing constitutional violation constitutes proof of an irreparable harm." *Preston v. Thompson*, 589 F.2d 300, 303 n.3 (7th Cir. 1978). And Lilly has also "shown a likelihood of establishing that [its] procedural right to advance notice and comment was violated"—and "parties suffer actionable harm when they are 'depriv[ed] of a procedural protection to which [they are] entitled.'" Dkt. 81 (ADR PI Op.), at 24. *See* Lilly PI/TRO 25-28.

The balance of harms and public interest favor issuance of the injunction as well. No covered entity will be harmed by an order preventing Defendants from taking action against Lilly premised on the new contract-pharmacy obligation during the pendency of the case. Neither will Defendants. If Defendants ultimately prevail on the statutory question, they will then be able to enforce the statute as they construe it. In the meantime, they will suffer no cognizable harm by having to live with the status quo ante. On the flip side, if Lilly ultimately prevails but no injunction issues in the interim, the money it will have handed over to third parties will be gone forever. That is more than enough to tilt the balance in Lilly's favor. And given the government's effort to hijack these proceedings and force Lilly to submit to its position on the ultimate legal

issue currently being briefed before this Court, an order maintaining the status quo and preventing further efforts to usurp this Court's role is in the public interest. *See* Lilly PI/TRO 28-30.

IV. The May 17 Letter Confirms That The Court Should Resolve The Merits Now.

The May 17 letter also underscores why the Court should decide the merits of Lilly's statutory challenge now, rather than simply vacate the December 30 Decision under the APA and remand to HHS/HRSA. To be sure, "[w]hen an agency commits a legal error, a court 'normally remand[s] … to the agency.'" *Conservation L. Found. v. Pritzker*, 37 F. Supp. 3d 254, 272 (D.D.C. 2014) (first alteration added) (citation omitted). But "*Chenery* does not require … remand" when, as here, "[t]here is not the slightest uncertainty as to the outcome of [an agency] proceeding." *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 n.6 (1969). Defendants have made clear that they are going to treat the 340B statute as obligating manufacturers to deliver discounted drugs to an unlimited number of contract pharmacies. There is no reason to prolong decision on the key question of whether Defendants have authority to do so. *See* Lilly PI/TRO 23-24.

Indeed, Defendants do not have such authority, so no amount of procedure could result in a valid rule that requires manufacturers to deliver discounted product to contract pharmacies. *See NRDC v. EPA*, 643 F.3d 311, 322 (D.C. Cir. 2011). On the flip side, without a decisive ruling, HHS and HRSA will be free to continue trying to coerce Lilly to conform to their view of the statute, which in turn will force Lilly to seek emergency relief yet again. The Court should decide the merits of the statutory question in deciding Lilly's pending claims. *See* Lilly PI/TRO 24-25.

CONCLUSION

Lilly respectfully requests that the Court enter (1) a preliminary injunction on Counts I-IV barring Defendants from taking any action against Lilly based on the contract pharmacy obligation announced in the December 30 Decision, and (2) a temporary restraining order to the same effect until this Court resolves Lilly's request for a preliminary injunction.

Dated: May 26, 2021

Respectfully submitted,

s/ John C. O'Quinn
John C. O'Quinn, P.C.*
Matthew S. Owen*
Matthew D. Rowen*
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue N.W.
Washington, D.C. 20004
(202) 389-5000
john.oquinn@kirkland.com
matt.owen@kirkland.com
matthew.rowen@kirkland.com

Andrew A. Kassof, P.C.*
Diana M. Watral*
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-2000
andrew.kassof@kirkland.com
diana.watral@kirkland.com

* Admitted *pro hac vice*

Andrea Roberts Pierson
Brian J. Paul
Nicholas B. Alford
FAEGRE DRINKER BIDDLE & REATH LLP
300 N. Meridian Street, Suite 2500
Indianapolis, IN 46204
(317) 237-0300
andrea.pierson@faegredrinker.com
brian.paul@faegredrinker.com
nicholas.alford@faegredrinker.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on **May 26, 2021,** a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s/ John C. O'Quinn
John C. O'Quinn

Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 17, 2021

Mr. Derek L. Asay
Senior Director, Government Strategy
Eli Lilly and Company
Lilly Corporate Center
893 Delaware Street
Indianapolis, IN 46285

Dear Mr. Asay:

The Health Resources and Services Administration (HRSA) has completed its review of Eli Lilly and Company's (Lilly) policy that places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. Lilly is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

Lilly purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, Lilly must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. Lilly must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from Lilly's policy. Lilly must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on Lilly's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that Lilly provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

Diana Espinosa

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).