Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELI LILLY AND COMPANY, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR., *et al.*, Defendants.	Case No. 1:24-cv-03220-DLF

BRIEF OF STATE AND REGIONAL HOSPITAL ASSOCIATIONS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS

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CORPORATE DISCLOSURE STATEMENT

Amici curiae are non-profit organizations. They have no corporate parents and are not owned in whole or in part by any publicly held corporation.

STATEMENT OF INTEREST[1]

Amici curiae are 37 state and regional hospital associations.[2] They represent thousands of hospitals and health systems across the United States. *Amici*'s members participate in the 340B drug discount program (the "340B Program"), which is essential to supporting hospitals in their service to their communities through the delivery of high-quality, efficient, and accessible health care.

Hospitals participating in the 340B Program "perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). Eli Lilly and Company's ("Lilly's") unlawful proposal to provide discounted pricing under the 340B Program through rebates ("rebate proposal") would increase costs for 340B hospitals and make it more difficult for them to serve their patients and communities. *Amici* therefore have a strong interest in ensuring that Lilly cannot implement the rebate proposal and that their members can continue to access the benefit of the 340B Program as Congress intended.

INTRODUCTION

Lilly's rebate proposal is an unlawful attempt to self-police the 340B Program and increase costs for 340B Program providers ("covered entities"). It is fundamentally incompatible with the text and structure of the 340B statute and the purpose of the Program. *See Univ. Med. Ctr. of S.*

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[1] No party's counsel authored any part of this brief. No one, apart from the *amici curiae* and their counsel, contributed money intended to fund the brief's preparation or submission.

[2] A complete list of the *amici curiae* can be found in the appendix hereto.

Nev. v. Shalala, 173 F.3d 438, 439 (D.C. Cir. 1999) (Congress was "concerned that many federally funded hospital facilities serving low-income patients were incurring high prices for drugs."); *see also NextEra Energy Res., LLC v. FERC*, 118 F.4th 361, 371 (D.C. Cir. 2024) ("[C]ourts should prefer textually permissible readings that would advance statutory or regulatory goals over ones that would frustrate them. These are bedrock principles of statutory construction." (internal citations omitted)). We do not address those statutory arguments here and instead refer the court to the *amici curiae* brief filed by other 340B hospital groups. *See* AHA Amicus Br., ECF No. 34; *see also* Intervenors' Memo. Supp. Cross. Mot. Summ. Judg., ECF No. 36-1, at 18-24. If the Court agrees with those statutory arguments, the case can end because the Health Resources and Services Administration ("HRSA") did not have the authority to approve Lilly's rebate model in the first place, as HRSA explained in its September 17, 2024, letter to Johnson & Johnson ("J&J") and in its December 13, 2024, letter to Sanofi-Aventis U.S. LLC ("Sanofi"). *See* Letter from Carole Johnson, Administrator, HRSA, to Joaquin Duato, Chairman and Chief Executive Officer, Johnson & Johnson, at 2, Sep. 17, 2024, https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-17-2024-hrsa-letter-johnson-johnson.pdf (hereinafter "J&J Letter") (noting that requiring covered entities to purchase drugs at prices that exceed the 340B ceiling price "violates Section 340B(a)(1) of the PHS Act"); Letter from Carole Johnson, Administrator, HRSA, to Paul Hudson, Chief Executive Officer, Sanofi-Aventis U.S. LLC, at 2, Dec. 13, 2024, https://www.hrsa.gov/sites/default/files/hrsa/opa/dec-13-2024-hrsa-letter-sanofi.pdf (hereinafter "Sanofi Letter") (noting that requiring covered entities to purchase drugs at prices that exceed the 340B ceiling price "violates Section 340B(a)(1) of the PHSA"). Instead, *amici* submit this brief to respond to Lilly's many mischaracterizations of how the 340B Program works. Once those

inaccuracies are corrected, it becomes clear that HRSA's decision to reject Lilly's rebate proposal was not arbitrary and capricious.

In particular, Lilly alleges that HRSA's rejection of the rebate proposal was arbitrary and capricious because the rebate proposal is similar to the replenishment models covered entities already use for 340B Program inventory management. But Lilly fails to recognize critical differences between replenishment models and the rebate proposal that justify HRSA's rejection of the proposal. Lilly also alleges that HRSA's rejection of the rebate proposal was arbitrary and capricious because HRSA failed to explain why it approved rebates in other circumstances for certain types of AIDS Drug Assistance Programs ("ADAPs"), a narrow category of covered entities, and not Lilly's rebate proposal. But Lilly ignores the detailed record explaining the unique circumstances faced by ADAPs and how they differ from other 340B covered entities. And Lilly incorrectly claims that manufacturers can only comply with their obligations under the Inflation Reduction Act ("IRA") by providing 340B pricing through rebates. But Lilly disregards several other mechanisms that could allow manufacturers to meet their IRA obligations without using 340B rebates in violation of the 340B statute.

Lilly's failure to grapple with these meaningful distinctions is a distraction from Lilly's true motive behind its rebate proposal—a desire to evade its obligation under the 340B statute to offer discounted pricing to covered entities and obtain access to sensitive claims data that it could later use to attack 340B hospitals. Allowing manufacturers to unilaterally implement 340B rebate models would transfer enforcement power from HRSA to drug companies, permitting them to make their own determinations about whether covered entities are entitled to 340B pricing. Providing 340B pricing through rebates would increase covered entity costs, in contradiction of the purpose of the 340B Program, and require covered entities to advance millions of dollars to

cover increased drug costs while waiting for the manufacturer to decide in its sole discretion whether to grant a 340B rebate. 340B hospitals should not be forced to submit purchase data to Lilly and hope for the best. Lilly should be forced to follow the law, just as HRSA did when it rejected Lilly's illegal rebate model.

For these reasons, among others, *amici* believe the Court should reject Lilly's effort to destabilize the 340B Program for its own financial benefit and grant summary judgment for the government.

ARGUMENT

I. 340B Rebate Models are Different than Virtual Inventory Replenishment Models.

Lilly alleges that HRSA's rejection of Lilly's rebate proposal was arbitrary and capricious because the rebate proposal is similar to the replenishment models covered entities already use for 340B inventory management. *See* Lilly Memo. Supp. Mot. Summ. Judg., ECF No. 15-1, at 31-33. As acknowledged in HRSA's September 17, 2024, letter to J&J, however, rebate models differ from virtual inventory replenishment models ("replenishment models") in several important ways. *See* J&J Letter at 2. That explanation of the obvious (*i.e.*, replenishment models are fundamentally different from rebate models) was more than sufficient under well-established D.C. Circuit precedent. *See, e.g.*, *Inv. Co. Inst. v. CFTC*, 720 F.3d 370, 372-373 (D.C. Cir. 2013) ("So long as CFTC provided a reasoned explanation for its regulation, and the reviewing court can reasonably ... discern[] the agency's path, we must uphold the regulation, even if the agency's decision has less than ideal clarity.… CFTC's regulation clears this low bar." (internal quotation marks omitted)); *see also* AHA Amicus Br., ECF No. 34, at 11 n.7 (collecting cases).

Replenishment models are longstanding systems used by pharmacies to manage different drug inventories, both in the 340B Program context and outside of the 340B Program. They are fundamentally different from the rebate model that Lilly suddenly attempted to impose last

summer. The distinctions between the replenishment inventory management system and Lilly's rebate model payment system provide a rational and sound basis for treating the two differently, demonstrating that HRSA's rejection of the rebate proposal was far from arbitrary and capricious.

A. Pharmacies have used virtual inventory replenishment models for decades, including for reasons unrelated to the 340B Program, and longstanding HRSA guidance confirms covered entities can use them without prior approval.

Hospitals have relied on replenishment models to meet their inventory management and compliance obligations under the 340B statute for decades—indeed, since the very start of the 340B Program. HRSA first addressed the use of replenishment models in 1994 guidance published two years after the 340B Program's enactment. *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110 (May 13, 1994). In that guidance, HRSA discussed the statutory prohibition against diversion, which forbids covered entities from reselling or otherwise transferring 340B drugs to individuals who are not covered entity patients. To comply with the prohibition, HRSA recognized that covered entities treating both 340B-eligible and ineligible patients "must develop and institute adequate safeguards to prevent [diversion] (e.g., separate purchasing accounts and dispensing records)." *Id.* at 25112; *see also* 42 U.S.C. § 256b(a)(5)(B). HRSA described the safeguards needed to prevent diversion as "tracking each discounted drug through the purchasing and dispensing process." 59 Fed. Reg. at 25113 (noting that covered entities can develop alternative systems to demonstrate compliance "short of tracking each discounted drug through the purchasing and dispensing process," confirming that tracking each drug through the purchasing and dispensing process is the standard system covered entities must use to demonstrate compliance).

Of course, one possible way that covered entities *could* track each drug through the process would be to maintain physically separate inventories of 340B-purchased drugs and non-340B purchased drugs, so that an entity could verify that it provided 340B drugs only to eligible patients.

But that is not the only possible way. For many covered entities, physical separation is impractical. After all, maintaining two separate physical inventories of the same drugs purchased at different prices is duplicative, causes waste, increases administrative costs, and takes up considerable physical warehousing space that covered entities may not have to store the drugs. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549, 43554 (Aug. 23, 1996) ("A separate inventory is a wasteful concept with respect to time, space and money. Further, it provides little if any additional security, as a separate inventory only speaks to what is currently on the shelf and not what should be on the shelf.") These issues could make it difficult for covered entities to stock needed drugs, which could create patient access issues.

To avoid the challenges associated with maintaining physically separate inventories, covered entities have adopted an inventory replenishment process that uses a single drug inventory that includes drugs purchased through different accounts and is tracked virtually.

Replenishment models are not unique to the 340B Program, and pharmacies have used them to manage drug inventories in other contexts for decades. *See, e.g.*, *Abbott Labs. v. Portland Retail Druggists Ass'n, Inc.*, 425 U.S. 1, 19-20 (1976) (confirming that a hospital pharmacy can segregate two different types of drug inventories virtually using a "recordkeeping procedure that segregates the nonexempt use from the exempt use" and is "supplemented by the hospital's submission to its supplier of an appropriate accounting followed by the price adjustment that is indicated"); Fed. Trade Comm'n, University of Michigan Advisory Opinion Letter to Dykema Gossett (Apr. 9, 2010), https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf (approving a hospital's use of a "GPO replenishment-based drug benefit program" under which a pharmacy would fill

prescriptions using its own inventory and, later, if it is determined that certain dispenses were eligible for different pricing, the hospital would place an order through a different purchasing account to replace or replenish drugs that were previously dispensed by the pharmacy); Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70624 (Nov. 22, 2005) (noting that "[s]ome [Patient Assistance Programs] offer assistance directly to patients, while others replenish drugs furnished by pharmacies, clinics, hospitals, and other entities to eligible patients whose drugs are not covered by an insurance program").

Early in the 340B Program's history, HRSA confirmed that covered entities may use replenishment models to meet program compliance rules. 59 Fed. Reg. at 25111 ("There is no requirement for separate inventories."); 61 Fed. Reg. at 43554 ("However, the requirement for a separate inventory of 340B drugs is unnecessary, because the covered entity is required to monitor dispensing and inventory records. In addition, these records are also subject to Department and manufacturer audits."). And that guidance remains in force today. For instance, HRSA's technical assistance contractor, Apexus, maintains an FAQ reiterating that covered entities do not have to use separate inventories, so long as covered entities "have fully auditable purchasing and dispensing records that document compliance with all 340B requirements." Apexus FAQ 1343 (Nov. 10, 2014), https://www.340bpvp.com/search#q=1343&tab=faq (last accessed Mar. 7, 2025). When commenters asked HRSA to require pre-approval of all "safeguard systems" used by covered entities to prevent diversion, HRSA confirmed that "procedures in these areas need no prior approval." 59 Fed. Reg. at 25111. HRSA's consistent approval of this inventory management system from the very beginning of the 340B Program is entitled to "great weight." *Loper Bright*

Enters. v. Raimondo, 603 U.S. 369, 388 (2024); *see generally* AHA Amicus Br., ECF No. 34, at 14-16.

HRSA has acknowledged that a "large number of hospitals use replenishment models to operationalize the 340B Program." Notice, 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300, 52305 (Aug. 28, 2015) (withdrawn Jan. 30, 2017). And HRSA has described the replenishment model as follows:

> Covered entities use replenishment models to *manage drug inventory*, including 340B drugs, which is permissible if the covered entity remains in compliance with all 340B requirements. For example, a 340B covered entity that sees many different types of patients (e.g., inpatients, 340B-eligible outpatients, and other outpatients) would tally the drugs dispensed to each type of patient and then replenish the drugs used by reordering from the appropriate accounts. Some covered entities use software, referred to as accumulators, to track drug use for each patient type. The accumulator software would indicate which drugs are available to reorder on various accounts. In this example, the covered entity counts the units or amounts received by each 340B eligible patient. Once the covered entity has dispensed enough of a certain drug to equal an available package size, the covered entity could reorder that drug at the 340B price. Once drugs are received in inventory, the drugs lose their identity as 340B drugs, inpatient GPO drugs, or outpatient non-340B/non-GPO drugs. Each 340B drug order placed should be supported by auditable records demonstrating prior receipt of that drug by a 340B-eligible patient.

Id. at 52308 (emphasis added).

> To summarize, below are the typical steps under the 340B replenishment model:
>
> 1. Covered entity maintains separate drug purchasing accounts based on different types of pricing available (e.g., 340B account, group purchasing organization ("GPO") account, wholesale acquisition cost ("WAC") account).
>
> 2. Covered entity maintains a drug inventory that includes products purchased through all different accounts mixed in one physical inventory.
>
> 3. Covered entity administers/dispenses drugs to patients using drugs from mixed inventory.
>
> 4. After administering/dispensing to a patient, covered entity identifies the type of pricing the patient is eligible to receive. Covered entity uses "split-billing software" to accumulate drug utilization based on the eligibility determination. For example, administrations/dispenses to outpatients eligible to receive 340B

drugs are accumulated at 340B pricing. Administrations/dispenses to inpatients accumulate at GPO pricing. Administrations/dispenses to outpatients who are ineligible for 340B pricing are accumulated at either GPO or WAC pricing, depending on the type of covered entity (the 340B statute includes a "GPO prohibition" applicable to certain types of hospitals that prevents them from purchasing "covered outpatient drugs" through a GPO. *See* 42 U.S.C. § 256b(a)(4)(L)(iii)); *see also* Apexus, GPO Prohibition Hospitals Sample Policy and Procedure Manual (DSH/PED/CAN), https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-policy-and-procedure-manual-gpo-prohibition-hospitals.docx (last accessed Mar. 7, 2025).

5. Upon accumulating a full package size of a particular drug, the covered entity places a replenishment order through the appropriate account based on eligible accumulations.

6. Covered entity's wholesaler ships the replenishment drugs to the covered entity, and the drugs are incorporated into the virtual inventory to replace the previously dispensed drugs.

Many hospitals using replenishment models have implemented these steps for years. The replenishment model's longstanding recognition as an approved means of 340B Program participation and compliance meaningfully distinguishes it from Lilly's novel rebate proposal, which has nothing to do with inventory management and is instead an effort by drug companies to control whether or when to actually provide covered entities the 340B discounts they are owed under the statute.

B. Replenishment models allow covered entities to make upfront purchases at 340B prices, whereas the rebate proposal would prohibit upfront 340B purchases.

As HRSA noted in its September 17, 2024, letter to J&J, another key difference between replenishment models and the Lilly rebate proposal relates to *when* covered entities are able to access 340B pricing. Under a replenishment model, covered entities can access 340B pricing right away at the point of purchase. The rebate proposal, by contrast, would require delayed access to 340B pricing in every instance. *See* J&J Letter at 2 (noting that "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"). As outlined above, when a covered entity has accumulated enough dispenses/administrations of a drug to 340B-eligible patients, the entity can place a replenishment order for the drug through its 340B pricing account. The entity's wholesaler will then ship the drugs and invoice the entity at the 340B price, allowing the entity to access 340B pricing immediately. Although this purchase occurs after the drug was dispensed or administered to replenish that drug supply, the covered entity's access to 340B pricing is *simultaneous* with the replenishment purchase. In contrast, under Lilly's rebate proposal, a covered entity would not access 340B pricing through a rebate until *after* making a purchase.

Moreover, in cases where a drug is a single dose, the covered entity can place a replenishment order after one single dispense/administration without waiting for additional accumulations. This allows covered entities to place the 340B replenishment order right away after the drug use. The covered entity's access to 340B pricing is effectively simultaneous with the drug dispense/administration, whereas the rebate proposal would create an undetermined delay after the drug use until the manufacturer hopefully approves the rebate.

HRSA also noted another important distinction in its letter to J&J: "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." *Id.* Under the rebate proposal, however, *every* purchase would be at a higher price. Lilly misses this point in its argument and mischaracterizes how the replenishment model works.

In its complaint, Lilly says "there is no material difference" between the rebate proposal and the replenishment model because "both models rely on up-front purchases of medicines at list price, followed by a subsequent replenishment." Compl., ECF No. 1, ¶ 117. But this is not how

the Program functions. Often, hospitals that use a replenishment model rarely purchase at WAC prices and instead primarily purchase at 340B prices, except for the initial purchase.

For example, for hospitals subject to the prohibition on using a GPO to purchase "covered outpatient drugs,"[3] HRSA has advised that when they use a replenishment model, they should first "purchase using a non-GPO account and only replenish with 340B drugs once 340B patient eligibility is confirmed and can be documented through auditable records." HRSA 340B Drug Pricing Program Notice, Release No. 2013-1, Statutory Prohibition on Group Purchasing Organization Participation (Feb. 7, 2013), https://www.hrsa.gov/sites/default/files/hrsa/opa/prohibition-gpo-participation-02-07-13.pdf (last accessed Mar. 7, 2025). This means when a hospital subject to the GPO prohibition first orders drug inventory, it must do so at non-340B, non-GPO pricing (often WAC prices). The next purchase, however, is critical—and exactly where Lilly loses the thread. Once the hospital maintains a WAC inventory and begins accumulating dispenses/administrations, the hospital may then place replenishment orders at 340B or GPO prices upon achieving sufficient accumulations. In many cases, particularly when most or nearly all patients in a hospital location are 340B-eligible, the hospital will almost exclusively accumulate dispenses at 340B prices and will generally place replenishment orders at 340B prices. In this scenario, the hospital will nearly always get access to 340B pricing immediately after initially purchasing the inventory at WAC pricing. In contrast, Lilly's rebate proposal would require the hospital to *always* purchase drugs at WAC prices. As such, despite Lilly's best efforts to equate the replenishment model with the rebate proposal, "one of these things is not like the other[]." *Karczewski v. DCH Mission Valley LLC*, 862 F.3d 1006,

[3] *See* 42 U.S.C. § 256b(a)(4)(L)(iii).

1018–19 (9th Cir. 2017) (citing SESAME STREET, *One of These Things (Is Not Like the Others)*, on SESAME STREET BOOK & RECORD (Columbia Records 1970)).

Lastly, the replenishment model is different than the rebate proposal because covered entities have certainty under the replenishment model that when they place an order at 340B pricing, they will be pay the 340B price, whereas the rebate proposal affords no such certainty. The manufacturer plays no role in validating a 340B purchase under the replenishment model, which gives a covered entity confidence that the purchase will generate 340B savings. This certainty permits covered entities to make decisions on their operations, patient care, and use of 340B savings. For example, a covered entity may be able to provide a discounted price to a low-income patient, knowing that the entity was able to acquire the drug at a discounted price. Under the rebate proposal, however, the entity would not know whether the manufacturer will ultimately approve the rebate and, therefore, may not know whether providing a discounted drug price to the patient would be feasible.

II. Even if the Secretary Has Authority to Approve a Rebate Model, HRSA's ADAP Guidance Does Not Make its Rejection of the Rebate Proposal Arbitrary and Capricious.

As outlined by intervenors, *amici* agree that the proposed rebate model is unlawful *per se* and that HRSA lacks authority to approve any rebate plan. *See* Memo. Supp. Cross. Mot. Summ. Judg., ECF No. 36-1, at 18-24. We do not address those arguments here and instead refer the court to the brief filed by the intervenors. But, in the event the court finds HRSA does have authority to approve a rebate plan, *amici* submit that HRSA's denial of Lilly's rebate plan (even though HRSA permitted rebates in the special circumstances of the ADAP programs) was lawful, and certainly not arbitrary and capricious. That HRSA permitted rebates in the special circumstances of the ADAP programs does not change that conclusion.

In 1998, HRSA issued guidance recognizing a 340B rebate option as an alternative method of accessing 340B prices for one specific type of covered entity: ADAPs, due to the unique structure of these covered entities. *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992— Rebate Option, 63 Fed. Reg. 35239 (June 29, 1998). ADAPs provide drugs to low-income individuals living with HIV/AIDS. *See* HRSA, Part B: AIDS Drug Assistance Program (ADAP), https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-adap. Lilly emphasizes in its complaint that HRSA "has offered no reasoned explanation for treating [ADAPs and other covered entities] differently." Compl., ECF No. 1, ¶ 144. However, in its notice recognizing the rebate model for ADAPs, HRSA explained in detail why it recognized the model for ADAPs and not for other covered entities. Moreover, the rebate model proposed by Lilly differs from the ADAP model recognized by HRSA in meaningful ways, particularly given that HRSA envisioned that rebates would be an *option* for ADAPs, not a mechanism *required* by manufacturers.

A. HRSA explained why the ADAP rebate model was needed for ADAPs and not for other covered entities.

There is an extensive record explaining why HRSA recognized a limited rebate model option for ADAPs in 1998 and why HRSA chose not to extend the rebate option to other covered entities. When finalizing the rebate option, HRSA said it developed the option "in response to a clear need by certain State ADAPs which are unable to access [340B] pricing through the direct discount option." 63 Fed. Reg. at 35240. HRSA acknowledged that the rebate option was only available to ADAPs, not to other covered entities, because ADAPs operate differently than other covered entities. Specifically, HRSA said the rebate option would be accessed by a subset of ADAPs, those that use "decentralized drug purchasing." *Id.* In response to HRSA's proposal to allow a limited rebate model for ADAPs, commenters explained that ADAPs are "more like State-

run pharmaceutical benefit programs" and that their support of HRSA's proposal to recognize rebates for ADAPs "would be different if HRSA proposed a rebate program for all covered entities." 63 Fed. Reg. at 35241.The commenters went on to say, "[a]ccordingly, we urge that the rebate mechanism be an option only for meeting the unique needs of the State ADAP programs and that HRSA not consider any further expansion to other categories of entities." *Id.* HRSA agreed with the comments and confirmed the notice "only recognizes a rebate option for the State AIDS Drug Assistance Programs that receive assistance under Title XXVI of the PHS Act." 63 Fed. Reg. at 35241-42.

When proposing the ADAP rebate model option, HRSA explained:

> Initially, HRSA guidance for the section 340B program described only a discount process. Covered entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money. Although the discount system is functioning successfully for most covered entities, most ADAPs have drug purchasing systems that have prevented their participation in the section 340B discount program. The use of a rebate option (in addition to the discount mechanism) should allow these groups to access section 340B pricing.

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45823, 45824 (Aug. 29, 1997).

The Department of Health and Human Services Office of the Inspector General ("HHS OIG") has also addressed the unique needs of certain ADAPs that could benefit from the rebate option, explaining that ADAPs use two purchasing mechanisms: the direct purchase mechanism and the rebate mechanism. *See* HHS OIG, OEI-05-99-00610, AIDS Drug Assistance Program Cost Containment Strategies (Sep. 2000), at 9, https://oig.hhs.gov/documents/evaluation/2127/OEI-05-99-00610-Complete%20Report.pdf (hereinafter "OIG Report"). Under the direct purchase mechanism, the ADAP purchases drugs through a central purchaser or other entities, such as a state pharmacy, purchasing agent, or public agency/hospital. *Id.* Under the rebate mechanism, ADAPs that do not have a central purchaser contract with a pharmacy network or pharmacy

benefits management company to purchase drugs for the ADAP, and the ADAP reimburses the purchasing entity. *Id.* The OIG explained that initially, only ADAPs using the direct purchase mechanism could access 340B pricing, and many ADAPs using a rebate mechanism were unable to participate in 340B until HRSA's guidance recognizing a 340B rebate option for ADAPs. *Id.* at 10. The OIG described the 340B Program as "intended to provide an up-front discount off the purchase price of pharmaceuticals," and noted that HRSA's "340B rebate option was designed to specifically accommodate those ADAPs with a reimbursement structure." *Id.* at 22. The OIG confirmed: "Only ADAPs are eligible to participate in this option." *Id.*

Lilly says "ADAPs are not meaningfully different from other covered entities," but mischaracterizes ADAP operations. *See* Memo. Supp. Mot. Summ. Judg., ECF No. 15-1, at 36. Lilly cites to a HRSA guidance manual for ADAPs that says ADAPs "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." *Id.* (quoting HIV/AIDS Bureau, AIDS Drug Assistance Program (ADAP) Manual, 42 (June 2023) (ADAP Manual), https://targethiv.org/sites/default/files/media/documents/2023-06/adap-manual.pdf). And Lilly goes on to say that is how other entities use the virtual inventory replenishment model. *Id.*

However, that is *not* how other covered entities use the inventory replenishment model. The reference in the ADAP manual to drugs purchased through a "retail pharmacy network" describes how ADAPs using a rebate mechanism contract with a pharmacy network or pharmacy benefits management company to purchase drugs for them, which are later reimbursed by the ADAP. This is a unique purchasing mechanism that applies only to certain ADAPs, and not to other covered entities. Other covered entities may *dispense* drugs though a pharmacy network (e.g.,

contract pharmacies) and replenish them at 340B prices, but they do not *buy* drugs through a pharmacy network like some ADAPs do.

As this extensive record shows, HRSA's decision to permit a rebate option for ADAPs but not for other covered entities is hardly arbitrary or capricious. To be sure, "[w]here an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld." *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005). But a "necessary component of any claim that an agency acted arbitrarily and capriciously in this respect is that the differently treated entities are, in fact, 'similarly situated.'" *Vanda Pharms., Inc. v. Food & Drug Admin.*, 2023 WL 6035663, at *14 (D.D.C. Aug. 2, 2023) (citing *Anna Jacques Hosp. v. Sebelius*, 583 F.3d 1, 7 (D.C. Cir. 2009)).

Here, HRSA has provided a detailed and reasoned explanation for why ADAPs are fundamentally different from other 340B covered entities. As documented in the record, many ADAPs operate through unique purchasing systems that limit their ability to participate in the 340B Program through a discount model. And HRSA's approval of the ADAP rebate option was designed specifically to accommodate ADAPs that employ a reimbursement structure, rather than a direct purchasing structure. These ADAPs' unique needs more than justify what might otherwise be characterized as any inconsistency in approach. *See, e.g.*, *Health Alliance Hospitals, Inc. v. Burwell*, 130 F. Supp. 3d 277, 302 (D.D.C. 2015) (agency action not arbitrary and capricious where activities to which agency applied supposedly disparate rules were "not similarly situated" and agency had "adequately explained the reasons for the disparate treatment"); *TransCanada Pipelines Ltd. v. FERC*, 878 F.2d 401, 414-15 (D.C. Cir. 1989) (noting that different treatment "that is based on relevant, significant facts which are explained would not be arbitrary and

capricious"); *see also Gilbert v. NLRB*, 56 F.3d 1438, 1445 (D.C. Cir. 1995) ("[W]here the circumstances of the prior cases are sufficiently different from those of the case before the court, an agency is justified in declining to follow them, and the court may accept even a laconic explanation as an ample articulation of its reasoning." (quotation marks omitted)).

B. Lilly's rebate proposal differs from the ADAP rebate model in ways that would prevent it from meeting HRSA's ADAP rebate model requirements.

1. The ADAP rebate model is optional for covered entities, whereas the Lilly rebate proposal is mandatory.

In recognizing the ADAP rebate model, HRSA indicated that manufacturers could meet their statutory obligation to offer 340B prices to ADAPs by providing rebates, but HRSA did not authorize manufactures to *mandate* the use of rebates as the only mechanism to make 340B pricing available. Rather, HRSA allowed ADAPs to *choose* whether to access 340B prices via rebates and, in those cases, mandated that manufacturers recognize an ADAP's request for rebates.

For example, HRSA referred to the ADAP 340B model as the "State ADAP Section 340B Rebate ***Option.***" 63 Fed. Reg. at 35242 (emphasis added). Commenters asked HRSA to clarify that the rebate option is an "alternate to" an upfront discount mechanism and that "the ***choice*** of a single mechanism should be made by each State ADAP." *Id.* at 35240 (emphasis added). In response, HRSA confirmed that the ADAP rebate option is an "alternate method of accessing 340B pricing" intended for those state ADAPs unable to access upfront discounts, and in cases where a state ADAP uses both a direct purchase mechanism and a rebate mechanism, some ADAPs "may ***elect*** to access pricing through a rebate mechanism while other ADAP components may develop systems to access a direct discount." *Id.* (emphasis added). HRSA also confirmed that manufacturers and ADAPs could enter into contractual agreements to address rebate terms and "mutually acceptable solutions." *Id.* at 35241. HRSA's responses demonstrate that the use of the

rebate option was a *choice* for ADAPs to make and that HRSA's guidance did not allow manufacturers to *mandate* the use of a 340B rebate model.

HRSA also confirmed that if an ADAP requests a 340B rebate, the manufacturer must provide the rebate, revealing the mandatory nature of the rebate model *as it relates to manufacturers*, not covered entities. *Id.* at 35240-41. HRSA acknowledged that some manufacturers may have previously offered 340B rebates to ADAPs through voluntary rebate agreements, whereas HRSA clarified in the rebate option guidance that the 340B statute *required* manufacturers to offer rebates upon request from an ADAP. The OIG confirmed the mandatory nature of the rebate option with respect to manufacturers, not covered entities, characterizing HRSA's 1998 guidance as allowing states that *select* the rebate option to access the 340B price and "lessening the burden on them to negotiate with individual manufacturer's [sic] for voluntary rebates." OIG Report at 10.

2. The ADAP rebate option prohibits manufacturers from requiring assurances of compliance, whereas the Lilly rebate proposal requires covered entities to demonstrate eligibility.

When finalizing the ADAP rebate option, HRSA reminded manufacturers that prior HRSA guidance regarding manufacturer contract requirements also applies to the ADAP rebate option and that "a manufacturer may not condition a rebate contract or agreement upon an entities' [sic] compliance with the provisions of section 340B." 63 Fed. Reg. at 35239; *see also* AHA Amicus Br., ECF No. 34 at 14 & n.9. In the event that manufacturers had designed voluntary rebate agreements "predicated" on 340B compliance, HRSA instructed them to revise the agreements for purposes of 340B rebate agreements to remove those elements. 63 Fed. Reg. at 35239-40. In contrast, Lilly would not honor a rebate request under its proposal without validating a claim as 340B-eligible based on a review of information submitted by the covered entity. *See* Lilly Memo. Supp. Mot. Summ. Judg., ECF No. 15-1, at 20-21.

3. The ADAP rebate option requires standard business practices, and the requirements under the Lilly rebate proposal would not meet these standards.

HRSA also recognized that "standard business practices" should be used by ADAPs and manufacturers. 63 Fed. Reg. at 35242 (recognizing that standard business practices "are appropriate for the development of rebate contracts and agreements between State ADAPs and manufacturers); *see also id.* at 35240 ("Standard business practices should be utilized by State ADAPs and manufacturers."). However, Lilly's proposed rebate model would not satisfy HRSA's standard business practices requirement.

HRSA noted that manufacturers can use the Medicaid rebate program as a model for development of ADAP rebate agreements and encouraged manufacturers to use the Medicaid claim form as a model because it could be considered a "standard business practice model." *Id.* at 35240. Importantly, HRSA recognized: "Pharmacy specific data (prescription number, date of reimbursement, and similar data elements) are not reported on the initial Medicaid utilization submission and are not considered the standard for initial claim submission." 63 Fed. Reg. at 35241. Because Lilly's rebate proposal would require covered entities to submit pharmacy specific data elements such as these, the proposal would not meet HRSA's requirement for ADAP 340B rebate models to be standard business practices. *See* Compl. Ex. 3, ECF No. 1-4, at 10-11. Similarly, HRSA noted that allowing rebate requests for up to one year would be "within the range of standard business practices." 63 Fed. Reg. at 35241. In contrast, under the Lilly rebate proposal, Lilly's vendor would conduct a "[r]easonability check for claim submission relative to [date of service]," suggesting rebate requests could be rejected if the submission was not close in time to the date of service, which would not be a standard business practice. *See* Compl. Ex. 3, ECF No. 1-4, at 12.

Given the numerous differences between the rebate proposal and the ADAP rebate option, the fact that HRSA permitted rebates in narrow cases for certain types of ADAPs does not mean that HRSA's rejection of Lilly's rebate proposal was arbitrary and capricious.

III. 340B Rebate Models Are Not Necessary to Implement the IRA Medicare Negotiation Program.

In an additional attempt to support its position, Lilly argues the rebate proposal should be permitted because it will allow Lilly to comply with requirements under the IRA to offer covered entities the lower of the 340B price or the maximum fair price ("MFP") (i.e., the discounted price manufacturers must offer under the Medicare drug negotiation program). *See* 42 U.S.C. § 1320f-2(d). Lilly says the rebate proposal "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." Compl., ECF No. 1, ¶ 131. Lilly goes on to claim that the IRA requires Lilly to be able to timely identify 340B prescriptions to meet instructions by the Centers for Medicare and Medicaid Services ("CMS") to provide the MFP within 14 days. Compl., ECF No. 1, ¶ 90. However, neither the IRA nor CMS guidance *mandates* that manufacturers provide the MFP retrospectively, and there are other mechanisms available to effectuate the IRA apart from a 340B rebate model.

A. The IRA does not require 340B rebates.

The IRA requires manufacturers to provide pharmacies and providers with "access to [the MFP]" for drugs selected for negotiation ("selected drugs") that are dispensed to Medicare beneficiaries. 42 U.S.C. § 1320f-2(a)(1). With respect to covered entities, the IRA requires manufacturers to provide the lower of the 340B price or the MFP in a "nonduplicated amount" (referred to as the "340B non-duplication provision"). *Id.* § 1320f-2(d)(2). The non-duplication provision protects manufacturers from providing both the 340B price and the MFP on the same

drug cumulatively. The statute does not define how manufacturers must provide covered entities with access to the MFP or how to prevent 340B duplication, and there is no requirement for manufacturers to use 340B rebate models.

B. CMS guidance recognizes another option for manufacturers to provide the MFP that would prevent 340B duplication and does not require 340B rebates.

CMS issued guidance addressing how manufacturers must provide access to the MFP and acknowledged that they can do so "in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP." CMS, Medicare Drug Price Negotiation Program: Final 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 in 2026 and 2027 (Oct. 2, 2024), § 40.4 at 196, https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf (hereinafter "CMS Guidance"). If manufacturers choose the second option and provide the MFP retrospectively through rebates, they must either provide the rebate within 14 days of receiving information to verify MFP eligibility or explain that they are not providing a rebate because the claim is for a 340B drug and the 340B price is less than the MFP. *Id.*

Lilly appears to be taking the position that its 340B rebate proposal is needed so it can collect information from covered entities to identify 340B claims and determine whether to issue an MFP refund, and that this structure is the only way for Lilly to meet CMS requirements and prevent 340B duplication. *See* Compl., ECF No. 1, ¶ 131. However, CMS guidance does not require manufacturers that provide the MFP prospectively to collect 340B claims data and identify 340B claims within 14 days to prevent 340B duplication. A manufacturer that provides the MFP

prospectively is not required to issue an MFP refund and instead can simply report that it provided the MFP prospectively through an agreement with the dispensing entity. CMS Guidance § 40.4.3.1 at 215-20. If a manufacturer provided the MFP prospectively, covered entities could add a new purchasing account to their existing replenishment systems. Upon dispensing a selected drug to an MFP-eligible Medicare beneficiary, a covered entity would accumulate the dispense at the appropriate pricing. If the entity dispensed the drug to a 340B-eligible Medicare beneficiary and the 340B price was less than the MFP, the drug would accumulate at 340B pricing. If the entity dispensed the drug to a Medicare beneficiary and the MFP was less than the 340B price, the drug would accumulate at MFP pricing. Upon reaching sufficient accumulations, entities would place replenishment orders through the appropriate account. Duplication would not occur because entities can purchase a single drug through only one account; it would not be possible for an entity to purchase a drug at both 340B and MFP pricing. A manufacturer would not issue an MFP refund on a claim that was already purchased at either the 340B or MFP price, because the manufacturer would have agreements in place with covered entities to provide MFP pricing prospectively and would know not to provide MFP refunds on claims billed by covered entities.[4] Covered entities have provided detailed information to CMS on how manufacturers could prevent 340B duplication by making MFP pricing available prospectively.[5]

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[4] With respect to pharmacies that contract with covered entities to dispense 340B drugs on a covered entity's behalf ("contract pharmacies") and bill under the contract pharmacy's billing number, a manufacturer may not know a claim was for a drug purchased by a covered entity at a prospective discount. In these cases, a retrospective process could be used to prevent 340B duplication, as is discussed further below.

[5] *See* Letter from Maureen Testoni, 340B Health, to Meena Seshamani, Department of Health & Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, July 2, 2024, https://www.340bhealth.org/files/340B-Health-Comments-on-5.3.24-IRA-Draft-Guidance-7_.2.24.pdf (last accessed March 7, 2025) (hereinafter "340B Health Letter to CMS"); Letter from Advocates for Community Health, Ryan White Clinics for 340B Access, National Alliance of State & Territorial AIDS Directors, HIV Medicine Association, National Rural Health

C. CMS guidance recognizes a credit/debit ledger system to prevent duplication retrospectively, and there are proven models for covered entities to submit retrospective 340B claim files.

CMS guidance acknowledges there may be situations where a manufacturer issues an MFP refund within 14 days for a claim that is later determined to be for a 340B-purchased drug and the 340B price is less than the MFP, thereby creating duplication. In these cases, a manufacturer may use a "credit/debit ledger system" to reverse the MFP refund and "reconcile the duplicated discounts." CMS Guidance § 40.4.5 at 231. As such, if manufacturers are not able to implement 340B rebate models to identify 340B claims within 14 days and avoid paying MFP refunds, there would be a mechanism available to identify duplication retrospectively and reverse the MFP refund. Similarly, if a manufacturer issues an MFP refund on a claim for a 340B-purchased drug and the MFP is less than the 340B price, the manufacturer could presumably use the credit/debit ledger system to reverse the 340B purchase to avoid duplication.

Systems already exist for covered entities to retrospectively identify claims for selected drugs dispensed to Medicare beneficiaries that were purchased at 340B prices, as covered entities

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Association, America's Essential Hospitals, Association of American Medical Colleges, and 340B Health, to Meena Seshamani, Department of Health & Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, July 2, 2024, https://www.340bhealth.org/files/Joint-Comments-on-5.3.24-IRA-Draft-Guidance-7_.2.24.pdf (last accessed March 7, 2025) (hereinafter "Covered Entity Joint Letter to CMS"); Letter from Ashley Thompson, Senior Vice President, Public Policy Analysis and Development, American Hospital Association, to Meena Seshamani, Deputy Administrator and Director of the Center for Medicare, Centers for Medicare & Medicaid Services, July 2, 2024, https://www.aha.org/system/files/media/file/2024/07/aha-submits-comments-on-cms-guidance-for-medicare-drug-price-negotiation-program-letter-7-2-24.pdf (last accessed March 7, 2025) (hereinafter "AHA Letter to CMS July 2024"); Letter from Ashley Thompson, Senior Vice President, Public Policy Analysis and Development, American Hospital Association, to Meena Seshamani, Deputy Administrator and Director of the Center for Medicare, Centers for Medicare & Medicaid Services, Dec. 26, 2024, https://www.aha.org/system/files/media/file/2024/12/AHA-Letter-to-CMS-on-Medicare-Transaction-Facilitator-and-Drug-Negotiation-Program.pdf (last accessed March 7, 2025) (hereinafter "AHA Letter to CMS December 2024") (hereinafter "AHA Letter to CMS December 2024").

have explained to CMS. *See* 340B Health Letter to CMS; Covered Entity Joint Letter to CMS; AHA Letter to CMS July 2024; and AHA Letter to CMS December 2024. For example, under a longstanding model used by Oregon Medicaid to prevent duplication between 340B discounts and Medicaid rebates, covered entities submit a file to the state's rebate vendor that identifies previously dispensed 340B claims. Oregon Health Authority, Retroactive 340B Claims File Instructions (Jan. 2, 2024), http://www.oregon.gov/oha/HSD/OHP/Tools/340B%20Claims%20File%20Instructions%20and%20Design.docx. The state's rebate vendor uses the information to match 340B claims to claims identified as rebate-eligible to remove 340B claims and ensure the state does not include them in rebate invoices submitted to manufacturers. Covered entities could submit a similar file to the Medicare Transaction Facilitator ("MTF") CMS will use to operationalize the negotiation program. The MTF could match prior 340B dispenses to claims for which manufacturers issued MFP refunds. Manufacturers could then use the credit/debit ledger system to reverse any duplication. None of this would require the use of 340B rebates. Although Lilly may have a preference to provide the MFP via rebates and rely on a 340B rebate model to prevent duplication, there are other methods available to effectuate the IRA. Critically, moreover, those other methods, unlike Lilly's model, are actually compliant with the 340B statute. *See* AHA Amicus Br., ECF No. 34, at 7 & n.4.

Lilly is flat wrong that the only way to comply with both the IRA and the 340B statute is via a rebate model. That is untrue, both because there are multiple ways to comply with both statutes *and* because Lilly's preferred method is "incompatible" with the 340B law. *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011). These inescapable facts are more than enough

to dispose of Lilly's meritless APA claim. Lilly's arguments do not support its claim that HRSA's denial of the proposed rebate model was arbitrary and capricious or otherwise unjustified.

CONCLUSION

Lilly's rebate proposal would increase costs for 340B hospitals and make it more difficult for them to serve their patients and communities. For the reasons above and those stated by Defendants, HRSA was correct to reject Lilly's unlawful rebate proposal, and the Court should deny Lilly's motion for summary judgment.

Dated: March 24, 2025

Respectfully submitted,

/s/ Scott D. Gallisdorfer

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Appendix

Amici Curiae **State and Regional Hospital Associations**

Arizona Hospital and Healthcare Association
2800 N. Central Ave., Suite 1450
Phoenix, AZ 85004
(602) 445-4300
https://www.azhha.org/

Arkansas Hospital Association
419 Natural Resources Dr.
Little Rock, AR 72205
(501) 224-7878
https://www.arkhospitals.org

California Hospital Association
1215 K St., Suite 700
Sacramento, CA 95814
(916) 443-7401
https://calhospital.org

Colorado Hospital Association
1700 Lincoln St., Suite 3030
Denver, CO 80203
(720) 489-1630
https://cha.com

Connecticut Hospital Association
110 Barnes Rd.
Wallingford, CT 06492
(203) 265-7611
https://cthosp.org

Delaware Healthcare Association
1280 S. Governors Ave.
Dover, DE 19904
(302) 674-2853
https://deha.org

Florida Hospital Association
306 E. College Ave.
Tallahassee, FL 32301
(850) 222-9800
https://www.fha.org

Georgia Hospital Association
380 Interstate North Pkwy., Suite 150
Atlanta, GA 30339
(770) 249-4500
https://www.gha.org

Greater New York Hospital Association
555 W. 57th St., Suite 15
New York, NY 10019
(212) 246-7100
https://www.gnyha.org

Healthcare Association of Hawaii
707 Richards St. PH2
Honolulu, HI 96813
(808) 521-8961
https://www.hah.org

Healthcare Association of New York State
1 Empire Dr.
Rensselaer, NY 12144
(518) 431-7600
https://hanys.org

Hospital Association of Oregon
4000 Kruse Way Pl.
Lake Oswego, OR 97035
(503) 636-2204
https://oregonhospitals.org

Idaho Hospital Association
615 N. 7th St.
Boise, ID 83702
(208) 338-5100
https://teamiha.org

Illinois Health and Hospital Association
833 W. Jackson Blvd., Suite 610
Chicago, IL 60607
(312) 906-6000
https://www.team-iha.org

Indiana Hospital Association
500 N. Meridian St., Suite 250
Indianapolis, IN 46204
(317) 633-4870
https://www.ihaconnect.org

Iowa Hospital Association
100 E Grand Ave., Suite 100
Des Moines, IA 50309
(515) 288-1955
https://www.ihaonline.org

Kentucky Hospital Association
2501 Nelson Miller Pkwy.
Louisville, KY 40223
(502) 426-6220
https://www.kyha.com

Louisiana Hospital Association
9521 Brookline Ave.
Baton Rouge, LA 70809
(225) 928-0026
https://ihaonline.org

Massachusetts Health & Hospital Association
500 District Ave.
Burlington, MA 01803
(781) 262-6000
https://www.mhalink.org

Michigan Health & Hospital Association
2112 University Park Dr.
Okemos, MI 48864
(517) 323-3443
https://www.mha.org

Mississippi Hospital Association
116 Woodgreen Crossing
Madison, MS 39110
(601) 982-3251
https://mhanet.org

Missouri Hospital Association
4712 Country Club Dr.
Jefferson City, MO 65109
(573) 893-3700
https://web.mhanet.com

New Jersey Hospital Association
760 Alexander Rd.
Princeton, NJ 08540
(609) 275-4000
https://www.njha.com

New Mexico Hospital Association
7471 Pan American West Fwy. NE
Albuquerque, NM 87109
(505) 343-0010
https://www.nmhospitals.org

North Carolina Healthcare Association
2400 Weston Pkwy.
Cary, NC 27513
(919) 677-2400
https://www.ncha.org

North Dakota Hospital Association
1622 E. Interstate Ave.
Bismarck, ND 58503
(701) 224-9732
https://www.ndha.org

Ohio Hospital Association
155 E. Broad St. Suite 301
Columbus, OH 43215
(614) 221-7614
https://www.ohiohospitals.org

Oklahoma Hospital Association
4000 N. Lincoln Blvd.
Oklahoma City, OK 73105
(405) 427-9537
https://www.okoha.com

Tennessee Hospital Association
5201 Virginia Way
Brentwood, TN 37027
(615) 256-8240
https://www.tha.com

Texas Hospital Association
1108 Lavaca St., Suite 700
Austin, TX 78701
(512) 465-1000
https://www.tha.org

Virginia Hospital & Healthcare Association
4200 Innslake Dr., Suite 203
Glen Allen, VA 23060
(804) 965-1209
https://vhha.com

West Virginia Hospital Association
100 Association Dr.
Charleston, WV 25311
(304) 344-9744
https://wvha.org

Wyoming Hospital Association
2005 Warren Ave.
Cheyenne, WY 82001
(307) 632-9344
https://www.wyohospitals.com

The Hospital and Healthsystem Association of Pennsylvania
30 N. 3rd St., Suite 600
Harrisburg, PA 17101
(717) 564-9200
https://www.haponline.org

Vermont Association of Hospitals and Health Systems
148 Main St.
Montpelier, VT 05602
(802) 223-3461
https://www.vahhs.org

Washington State Hospital Association
999 3rd Ave.
Seattle, WA 98104
(206) 281-7211
https://www.wsha.org

Wisconsin Hospital Association
5510 Research Park Dr.
Fitchburg, WI 53711
(608) 274-1820
https://www.wha.org

CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2025, I electronically filed the above document with the Clerk of Court via the Court's CM/ECF electronic filing system, which will send a notice of electronic filing to all counsel of record identified on the docket.

/s/ *Scott D. Gallisdorfer*
Counsel for Amici Curiae