ORAL ARGUMENT NOT YET SCHEDULED
Nos. 25-5177, 25-5179, 25-5220, 25-5221, 25-5236

In the United States Court of Appeals for the District of Columbia Circuit

NOVARTIS PHARMACEUTICALS CORPORATION, *et al.*,
Plaintiffs-Appellants-Cross-Appellees,

v.

ROBERT F. KENNEDY, JR., IN HIS OFFICIAL CAPACITY AS SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,
Defendants-Appellees-Cross-Appellees,

340B HEALTH, *et al.*,
Intervenors-Defendants-Appellees

On Appeal from the United States District Court for the District of Columbia, Nos. 21-cv-2608, 24-cv-3220, 24-cv-3337, 25-cv-117 (Hon. Dabney L. Friedrich), and No. 1:24-cv-3188 (Hon. Rudolph Contreras)

BRIEF OF 37 STATE AND REGIONAL HOSPITAL ASSOCIATIONS AS *AMICI CURIAE* IN SUPPORT OF APPELLEES

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES PURSUANT TO CIRCUIT RULE 28(a)(1)

A. Parties and *Amici*

All parties, intervenors, and *amici* appearing before the district court and in this Court are listed in the Brief for Federal Appellees.

B. Rulings Under Review

References to the rulings at issue appear in the Brief for Federal Appellees.

C. Related Cases

Reference to the only related case of which *amici* are aware appears in the Brief for Federal Appellees.

CORPORATE DISCLOSURE STATEMENT

Amici curiae are non-profit trade associations. They have no parent corporations and do not issue stock. Descriptions of the general purpose and nature of each of the 37 *amicus* associations appears at the Appendix to this brief.

/s/ Scott D. Gallisdorfer
Scott D. Gallisdorfer

RULE 29 STATEMENTS

All parties have consented to the filing of this *amici curiae* brief.

The brief was not authored in whole or in part by a party or its counsel. No party or party's counsel contributed money intended to fund the preparation or filing of this brief; and no person other than the *amici curiae* and their members contributed money intended to fund the preparation or filing of this brief.

Pursuant to Circuit Rule 29(d), *amici* certify that a separate brief is necessary to provide the unique perspective of the *amici* hospital associations and their member hospitals. The member hospitals are the beneficiaries of the 340B Program, and they will be directly impacted by the rebate proposal at issue in this appeal. In light of their shared interests, the 37 *amici* hospital associations have agreed to join in the filing of this single brief to avoid the need for separate briefs by each association.

/s/ Scott D. Gallisdorfer
Scott D. Gallisdorfer

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GLOSSARY

ADAP	AIDS Drug Assistance Program
BMS	Bristol Myers Squibb Company
CMS	Centers for Medicare and Medicaid Services
GPO	Group Purchasing Organization
HRSA	Health Resources and Services Administration
IRA	Inflation Reduction Act
J&J	Johnson & Johnson Health Care Systems, Inc.
JA	Joint Appendix
Lilly	Eli Lilly and Company
MFP	Maximum Fair Price
MTF	Medicare Transaction Facilitator
Novartis	Novartis Pharmaceuticals Corp.
OIG	Department of Health and Human Services Office of Inspector General
WAC	Wholesale Acquisition Cost

STATUTES AND REGULATIONS

The relevant statutes and regulations are reproduced in the addendum to the Brief for Federal Appellees.

INTEREST OF *AMICI CURIAE*

Amici curiae are 37 state and regional hospital associations.[1] Collectively, they represent the interests of thousands of hospitals and health systems across the United States. *Amici*'s members participate in the Section 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). The drug manufacturers' proposals at issue in this appeal—to provide discounted pricing under the 340B Program through rebates, rather than upfront discounts—would increase costs for 340B hospitals and make it more difficult to serve their patients and communities. *Amici* therefore have a strong interest in ensuring that drug manufacturers cannot implement unlawful rebate models, and that their members can continue to access the benefits of the 340B Program as Congress intended.

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[1] The 37 individual associations are identified and described in the Appendix to this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

The rebate proposals put forward by Plaintiffs-Appellants Novartis Pharmaceuticals Corporation ("Novartis"), Bristol Myers Squibb Company ("BMS"), Eli Lilly and Company ("Lilly"), and Johnson & Johnson Health Care Systems, Inc. ("J&J") (collectively, "Plaintiffs") are an unlawful attempt to self-police the 340B Program and increase costs for 340B Program providers ("covered entities"). They are fundamentally incompatible with the text and structure of the 340B statute and the purpose of the Program. *See Univ. Med. Ctr. of S. 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.").

We do not address those statutory arguments here and instead refer the Court to the *amici curiae* brief filed by other 340B hospital groups.[2] If the Court agrees with those statutory arguments, the Court

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[2] *See* Brief of the American Hospital Association, National Association of Children's Hospitals, Inc., d/b/a Children's Hospital Association, Association of American Medical Colleges and America's Essential Hospitals, as *Amici Curiae*.

can affirm because the Health Resources and Services Administration ("HRSA") did not have the authority to approve Plaintiffs' rebate models in the first place. Instead, *amici* submit this brief to respond to Plaintiffs' many mischaracterizations of how the 340B Program works. Once those inaccuracies are corrected, it becomes clear that HRSA's decision to block the rebate proposals was not arbitrary and capricious.

In particular, Plaintiffs contend that HRSA's decision to apply a pre-approval requirement and block the rebate proposals was arbitrary and capricious because the rebate proposals are similar to the replenishment models covered entities already use for 340B Program inventory management. But Plaintiffs fail to recognize critical differences between replenishment models and the rebate proposals that justify HRSA's decision to block the rebate proposals.

Plaintiffs also assert that HRSA's decision to block the rebate proposals was arbitrary and capricious because HRSA failed to explain why it permitted rebates in other circumstances for certain AIDS Drug Assistance Programs ("ADAPs"), a narrow category of covered entities, and not the Plaintiffs' rebate proposals. But Plaintiffs ignore the detailed record explaining the unique circumstances faced by ADAPs and how they differ from other 340B covered entities.

Lastly, Plaintiffs incorrectly claim that manufacturers can only comply with their obligations under the Inflation Reduction Act ("IRA")

by providing 340B pricing through rebates. Yet Plaintiffs disregard several other mechanisms that could allow manufacturers to meet their IRA obligations without using 340B rebates in violation of the 340B statute.

Plaintiffs' failure to grapple with these meaningful distinctions is a distraction from the true motive behind their rebate proposals—a desire to evade their obligation under the 340B statute to offer discounted pricing to covered entities, and to obtain access to sensitive claims data they 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 determine themselves whether covered entities are entitled to 340B pricing. Further, 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 a manufacturer to decide in its sole discretion whether to grant a 340B rebate. 340B hospitals should not be forced to submit purchase data to Plaintiffs and hope for the best. Plaintiffs should be required to follow the law, just as HRSA did when it blocked Plaintiffs' illegal rebate models.

For these reasons, among others, the Court should reject Plaintiffs' efforts to destabilize the 340B Program for their own financial benefit and affirm the district court's grant of summary judgment.

ARGUMENT

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

Plaintiffs allege that HRSA's decision to block the rebate proposals was arbitrary and capricious because the rebate proposals are similar to the virtual inventory replenishment models covered entities already use for 340B inventory management, and HRSA never required preapproval for replenishment models. *See* Pls. Br. at 5, 37. Plaintiffs ask the court to decide "[w]hether HRSA arbitrarily exercised this supposed preapproval power for the first time ever to block Plaintiffs' rebate models while allowing similar models to proceed without preapproval." *Id.* at 6. As acknowledged in HRSA's September 17, 2024, letter to J&J, however, rebate models differ from replenishment models in several important ways. *See* JA454-56. 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)); *Gilbert v. NLRB*, 56 F.3d 1438, 1445 (D.C. Cir. 1995) ("[W]here the circumstances of the prior case 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." (internal quotation marks omitted)).

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 proposals, and these distinctions provide a rational and sound basis for treating the two differently.

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 compliance obligations under the 340B statute for decades—indeed, since the very start of the 340B Program. Plaintiffs are incorrect when they say HRSA never approved replenishment models when they first emerged or that HRSA has not approved replenishment models "to this day." *See* Pls. Br. at 30-31, 37.

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). 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 system[s]" 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. But

that is not the only possible way. For many covered entities, physical separation is impractical. 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.")

Thus, to avoid the challenges associated with 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. 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 K. Reed (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 previously dispensed); 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").

Indeed, 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."). This guidance remains in force today. HRSA's technical assistance contractor, Apexus, maintains an FAQ reiterating that covered entities need not 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 Aug. 8, 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, 394 (2024) ("[C]ourts may—as they have from the start—seek aid from the interpretations of those responsible for implementing particular statutes."). 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).

B. Replenishment models allow covered entities to maintain program compliance and are not used by manufacturers to effectuate the 340B price.

Plaintiffs also incorrectly describe the replenishment model as a model for "effectuating the 340B price," like rebate models, to argue that HRSA can't treat similar models differently. *See* Pls. Br. at 38. But the purpose of the replenishment model is different than the purpose of the rebate models proposed by Plaintiffs. Covered entities use the replenishment model to meet their program compliance requirements,

including to track 340B Program dispenses and ensure they are not provided to ineligible patients. In contrast, Plaintiffs have proposed rebate models to meet their statutory obligation to sell drugs to covered entities at 340B prices. HRSA is justified in treating replenishment models differently than rebate models because they are used by different 340B Program stakeholders to meet different statutory requirements.

C. 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 Plaintiffs' rebate proposals relates to *when* covered entities can access 340B pricing. Under a replenishment model, covered entities can access 340B pricing immediately at the point of purchase. The rebate proposals, by contrast, would delay access to 340B pricing in every instance. *See* JA455 ("[U]nder 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.").

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 Plaintiffs' rebate proposals, 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 dispense/administration without waiting for additional accumulations. This allows covered entities to place the 340B replenishment order immediately after the drug use. The covered entity's access to 340B pricing is effectively simultaneous with the drug dispense/administration, whereas the rebate proposals would create an undetermined delay until the manufacturer hopefully approves the rebate.

HRSA also noted another important distinction: "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 proposals, however, *every* purchase would be at a higher price. Plaintiffs miss this point and mischaracterize how the replenishment model works.

Plaintiffs say the replenishment model is "a type of rebate model" under which "a covered entity first pays the commercial price for covered

outpatient medicines" and covered entities only access 340B prices retroactively. Pls. Br. at 46-47. But this is not how the 340B Program functions. Often, hospitals using a replenishment model rarely purchase at wholesale acquisition cost ("WAC") prices and instead primarily purchase at 340B prices, except for the initial purchase.

For example, HRSA has advised that hospitals using a replenishment model that are subject to the prohibition on using a group purchasing organization ("GPO") to purchase "covered outpatient drugs"[3] 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 at 3, 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 Aug. 8, 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 Plaintiffs lose the thread. Once the hospital maintains a WAC inventory and begins accumulating dispenses/administrations, the hospital may then place

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

replenishment orders at 340B or GPO prices upon achieving sufficient accumulations.

In many cases, particularly when most 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, Plaintiffs' rebate proposal would require the hospital to *always* purchase drugs at WAC prices. Despite Plaintiffs' 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, 1018–19 (9th Cir. 2017).

Lastly, covered entities have certainty under the replenishment model that when they place an order at 340B pricing, they will pay the 340B price. The rebate proposals afford 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 proposals, however, the entity would not know whether the manufacturer will ultimately approve the rebate and 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 Decision to Block the Rebate Proposal Arbitrary and Capricious.

Amici agree with the Intervenor-Appellees that the proposed rebate models are unlawful *per se* and that HRSA lacks authority to approve rebate plans. We do not address those arguments and instead refer the court to the brief filed by the Intervenor-Appellees. But, if the Court finds HRSA may approve a rebate plan, *amici* submit that HRSA's decision to reject Plaintiffs' rebate plans 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 their unique structure. *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.

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

Plaintiffs emphasize in their brief that HRSA "has not explained why Plaintiffs' rebate models needed preapproval but the ADAP cash-rebate model did not." *See* Pls. Br. at 41. 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. 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. HRSA said the rebate option would be accessed by a subset of ADAPs, those that use "decentralized drug purchasing." *Id.* 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 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 Inspector General ("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* OIG, OEI-05-99-00610, AIDS Drug Assistance Program Cost Containment Strategies at 9 (Sep. 2000), 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.* 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 & n.4. The OIG confirmed: "Only ADAPs are eligible to participate in this option." *Id.*

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)).

HRSA provided a detailed and reasoned explanation for why ADAPs are fundamentally different from other 340B covered entities. These ADAPs' unique needs conclusively justify what might otherwise be characterized as any inconsistency in approach. *See, e.g.*, *TransCanada Pipelines Ltd. v. FERC*, 878 F.2d 401, 414-15 (D.C. Cir. 1989) (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." (internal quotation marks omitted)).

B. The rebate proposals differ from the ADAP rebate model in ways that would prevent them from meeting HRSA's ADAP rebate model requirements.

1. *The ADAP rebate model is optional for covered entities, whereas the rebate proposals are mandatory.*

HRSA said manufacturers could meet their statutory obligation to offer 340B prices to ADAPs by providing rebates, but HRSA did not authorize manufacturers to *mandate* the use of rebates as the only mechanism to provide 340B pricing. 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). HRSA confirmed that the ADAP rebate option is an "alternate method of accessing 340B pricing" intended for 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 agreements to address rebate terms and "mutually acceptable solutions." *Id.* at 35241.

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. 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 Plaintiffs' rebate proposals require covered entities to demonstrate eligibility.*

HRSA reminded manufacturers 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* Amicus Br. of Am. Hospital Ass'n, *et al.* at 16 & n.8. If 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, Plaintiffs would not honor a rebate request under their proposals without validating a claim as 340B-eligible based on a review of information submitted by the covered entity. *See, e.g.,* J&J, Notice to 340B End Customers Regarding Purchases of Stelara and Xarelto, Aug. 23, 2024 (updated as of September 30, 2024), at 2,

https://sponsors.aha.org/rs/710-ZLL-651/images/Johnson%20%20Johnson%20Innovative%20Medicine%20340B%20Rebate%20Model%20Policy%20Update%2008-23-2024_FINAL.pdf (last accessed August 8, 2025) (hereinafter "J&J Notice") (noting that J&J would not honor a rebate request under its proposal without validating that "purchases were made by an eligible DSH Covered Entity, units were dispensed from eligible 340B locations, and Rebate Claim Data was submitted in a timely manner").

3. *The ADAP rebate option requires standard business practices, and the requirements under the Plaintiffs' rebate proposals would not meet these standards.*

HRSA also recognized that ADAP rebate models should use "standard business practices." 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, Plaintiffs' proposed rebate models 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 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." *Id.* at 35241. Because Plaintiffs' rebate proposals would require covered entities to submit pharmacy specific data elements such as these, the proposal would not meet HRSA's requirement for ADAP rebate models to be standard business practices. *See e.g.,* J&J Notice at 6-7.

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, the rebate proposals include data submissions that are outside standard business practices. For example, the J&J rebate proposal would require covered entities to submit rebate requests within 45 days of a dispense. J&J Notice at 1.

C. Plaintiffs mischaracterize HRSA's treatment of ADAP rebate models.

Plaintiffs contend HRSA never applied a rebate model pre-approval requirement until now, highlighting that HRSA issued its 1998 guidance *after* manufacturers and ADAPs entered into rebate arrangements. *See* Pls. Br. at 39. Plaintiffs argue HRSA allowed the ADAP rebate model to "go into effect and then evaluate it after it was already being widely used

by manufacturers and ADAPs." *Id.* at 45. But Plaintiffs ignore the fact that, prior to HRSA issuing its 1998 guidance, ADAPs *chose* to enter into voluntary rebate arrangements with manufacturers; manufacturers did not require ADAPs to access 340B pricing via rebates. Because manufacturers did not propose or attempt to impose unilateral rebate models on ADAPs, there were no manufacturer rebate proposals for HRSA to evaluate.

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

Plaintiffs argue the rebate proposals should be permitted because they will allow drug manufacturers 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). Plaintiffs note that BMS and Novartis sell drugs that will be subject to MFP pricing in 2026, and they raise concerns related to duplication of 340B and MFP pricing. They argue the negotiation program "lacks plausible mechanisms for dealing with these [duplication] concerns." *See* Pls. Br. at 15-16. Further, Plaintiffs say the Centers for Medicare and Medicaid Services ("CMS") gives them "only 14 days to pay [the MFP] if the manufacturer effectuates the MFP through a rebate," and they claim manufacturers will not know whether a claim is for a

340B drug within that time period. *See id.* at 11. 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). The IRA requires manufacturers to provide covered entities 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). But the statute does not define how manufacturers must 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, 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.*

Plaintiffs contend that their 340B rebate proposals are needed so they can collect information to identify 340B claims and determine whether to issue an MFP refund, and that this structure is the only way for Plaintiffs to prevent 340B duplication. *See* Pls. Br. at 10-11. However, CMS guidance does not require manufacturers that provide the MFP prospectively to 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. CMS Guidance § 40.4.3.1 at 215-20.

If a manufacturer provided the MFP prospectively, 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, 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 to Meena Seshamani (CMS), July 2, 2024, https://www.340bhealth.org/files/340B-Health-Comments-on-5.3.24-IRA-Draft-Guidance-7_.2.24.pdf (last accessed August 8, 2025) (hereinafter "340B Health Letter to CMS"); Letter from Advocates for Community Health, *et al.* to Meena Seshamani, July 2, 2024, https://www.340bhealth.org/files/Joint-Comments-on-5.3.24-IRA-Draft-Guidance-7_.2.24.pdf (last accessed August 8, 2025) (hereinafter "Covered Entity Joint Letter to CMS"); Letter from Ashley Thompson to Meena Seshamani,, July 2, 2024, https://www.aha.org/system/files/media/file/2024/07/aha-submits-comments-on-cms-guidance-for-medicare-drug-price-negotiation-

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 a manufacturer could issue an MFP refund within 14 days for a claim later determined to be for a 340B-purchased drug and the 340B price is less than the MFP, 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. So, if manufacturers do not implement 340B rebate models to identify 340B claims 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.

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program-letter-7-2-24.pdf (last accessed August 8, 2025) (hereinafter "AHA Letter to CMS July 2024"); Letter from Ashley Thompson to Meena Seshamani, 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 August 8, 2025) (hereinafter "AHA Letter to CMS December 2024").

Systems already exist for covered entities to retrospectively identify 340B claims, as covered entities 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 also 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 Plaintiffs 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. Those other methods, unlike Plaintiffs' models, are actually compliant with the 340B statute.

CONCLUSION

This Court should affirm the district courts' judgments.

August 8, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because it contains 6,481 words, excluding parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Circuit Rule 32(e)(1).

The brief complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Century Schoolbook, a proportionally spaced typeface, using Microsoft Word.

August 8, 2025

/s/ Scott D. Gallisdorfer
Scott D. Gallisdorfer

CERTIFICATE OF SERVICE

I certify that on August 8, 2025, I electronically filed this brief with the Clerk of the Court through the CM/ECF system. All participants in this case are registered CM/ECF users and will be served electronically through that system.

/s/ Scott D. Gallisdorfer
Scott D. Gallisdorfer

APPENDIX

DESCRIPTION AND INTERESTS OF INDIVIDUAL *AMICI*

The Arizona Hospital and Healthcare Association (AzHHA) is Arizona's largest and most influential statewide trade association for hospitals, health systems, and affiliated healthcare organizations. AzHHA's 74 hospital members and 10 healthcare members are united with the common goal of improving the healthcare delivery system in Arizona. AzHHA is a powerful advocate for issues that impact the quality, affordability and accessibility of healthcare for the patients, people, and communities of Arizona.

The Arkansas Hospital Association (ArHA) is a trade association representing over 100 hospitals and related institutions and the more than 45,000 dedicated individuals serving patients within these organizations. For 90 years, ArHA has supported its members in the delivery of high quality, efficient, and accessible healthcare throughout Arkansas. As the state's most trusted authority on health care, ArHA is committed to improving the health system to enhance individual patient care and safeguard the well-being of Arkansas hospitals and the communities they serve.

The California Hospital Association (CHA) is one of the largest hospital trade associations in the nation, serving more than 400 hospitals and health systems and 97 percent of the general acute care and psychiatric acute patient beds in California. CHA's members include all

types of hospitals and health systems: non-profit; children's hospitals; those owned by various public entities, including cities/counties, local health care districts, the University of California, and the Department of Veterans Affairs; as well as investor-owned. The vision of CHA is an "optimally healthy society," and its goal is for every Californian to have equitable access to affordable, safe, high-quality, medically necessary health care. To help achieve this goal, CHA is committed to establishing and maintaining a financial and regulatory environment within which hospitals, health care systems, and other health care providers can offer high-quality patient care. CHA promotes its objectives, in part, by participating as *amicus curiae* in important cases like this one.

The Colorado Hospital Association (CHA) is the leading voice of the Colorado hospital and health system community. Representing more than 100 hospitals and health systems throughout the state, CHA serves as a trusted, credible, and reliable resource on health issues, hospital data, and trends for its members, media, policymakers, and the general public. Through CHA, Colorado's hospitals and health systems work together in their shared commitment to improving health and health care in Colorado.

The Connecticut Hospital Association (CHA) in a not-for-profit membership organization that represents hospitals and health-related organizations. CHA's mission is to advance the health of individuals and communities by leading, representing, and serving hospitals and

healthcare providers across the continuum of care that are accountable to the community and committed to health improvement.

The Florida Hospital Association (FHA) is the leading voice of Florida's hospital community. Founded in 1927, FHA's membership is comprised of more than 200 hospitals. FHA supports the mission of its members to provide the highest quality of care to the patients they serve. To that end, FHA advocates proactively on behalf of hospitals at the state and federal levels on issues that will assist members in their mission of community service and care to patients.

The Georgia Hospital Association is a non-profit trade association made up of member health systems, hospitals, and individuals in administrative and decision-making positions within those institutions. Founded in 1929, the Association serves 150 hospitals in Georgia, which in turn employ thousands of physicians and even more nurses and other healthcare providers. Its purpose is to promote the health and welfare of the public through the development of better hospital care for all of Georgia's citizens. The Association represents its members in legislative matters, as well as in filing *amicus curiae* briefs on matters of great gravity and importance to both the public and to health care providers serving Georgia citizens.

The Healthcare Association of Hawaii (HAH), established in 1939, is a trade association which serves as the leading voice of healthcare on behalf of 170 member organizations who represent almost every aspect

of the healthcare continuum in Hawaii. Members include acute care hospitals, skilled nursing facilities, home health agencies, hospices, assisted living facilities, and durable medical equipment suppliers. In addition to providing access to appropriate affordable, high quality care to all of Hawaii's resident and visitors, our members contribute significantly to Hawaii's economy by employing over 50,000 people statewide. HAH promotes its objectives through a variety of means, including participating as amicus curiae in matters of importance such as this.

The Idaho Hospital Association (IHA), since 1933, has been providing voice, value, and visibility for Idaho's community hospitals. A statewide, nonprofit association, IHA brings hospital and healthcare leaders together in pursuit of quality healthcare across Idaho. IHA strives to offer members valued resources and services in many areas, including: federal and state policy development and advocacy; quality and patient safety; data analytics; and workforce development.

The Illinois Health and Hospital Association (IHA) is a statewide not-for-profit association with a membership of over 200 hospitals and nearly 50 health systems. For over 90 years, the IHA has served as a representative and advocate for its members, addressing the social, economic, political, and legal issues affecting the delivery of high-quality health care in Illinois. As the representative of virtually every hospital in the state, the IHA has a profound interest in this case. The IHA

respectfully offers this *amicus curiae* brief in hopes of providing information not addressed by the litigants that will help the Court evaluate the litigants' arguments more thoroughly.

The Indiana Hospital Association (IHA) is a non-profit organization founded in 1921, and provides leadership, representation, and support to Indiana hospitals to advance a health care delivery system that improves the health and health care of all Hoosiers. IHA's membership of 170 hospitals includes nearly every Indiana hospital. Through its mission, IHA is dedicated to ensuring a health care system that improves quality of care and patient safety for Indiana citizens. IHA represents the collective interests of its members before policymakers, legislators, and regulators and serves as the central voice and advocate in matters of vital concern to its members.

The Iowa Hospital Association (IHA) is a voluntary, nonprofit trade association of 123 hospital and health system members. Established in 1929, its purpose is to reimagine health care in Iowa for life-changing outcomes. IHA provides advocacy, education and data services to its members, and represents and advocates health policy issues benefiting Iowans before the state legislature, U.S. Congress, and regulatory bodies.

The Kansas Hospital Association (KHA) is a voluntary, not-for-profit organization that exists to be the leading advocate and resource for members. KHA membership includes 242 member facilities, of which 124 are full-service community hospitals, including 83 Critical Access

Hospitals. Founded in 1910, KHA's vision is Optimal Health for Kansans and Kansas Hospitals.

The Kentucky Hospital Association (KHA) is a non-profit state association of hospitals, related health care organizations, and integrated health care systems statewide. Membership in KHA is voluntary, and its member entities include 129 hospitals in the Commonwealth of Kentucky. KHA engages in advocacy and representation efforts on behalf of their member hospitals that promote safety, quality, and efficiency in health care. The mission of KHA is to be the leading voice for Kentucky health systems in improving the health of our communities.

The Louisiana Hospital Association (LHA) is a non-profit organization founded in 1926 and incorporated in 1966 for the purpose of promoting the public welfare of the State of Louisiana. The Association's membership is composed of over 150 member institutions, with more than a thousand individual members. Membership consists of hospitals of all kinds, including public, private, non-profit, for-profit, federal, municipal, hospital service district, religious, general, specialty, acute-care, psychiatric, and rehabilitation classifications.

The Massachusetts Health and Hospital Association (MHA), founded in 1936, serves as the unified voice for the commonwealth's hospitals, health systems, and healthcare providers. MHA helps drive change for a healthier commonwealth through public advocacy, education, and collaboration. Its mission is to advance the health of

individuals and communities by helping members provide high-quality, equitable, affordable care – all while pushing the boundaries of healthcare innovation.

The Michigan Health & Hospital Association (MHA) is a statewide advocacy organization representing over 170 Michigan health care facilities providing inpatient care including long-term acute care and rehabilitation facilities as well as other specialty hospitals. Of those, over 130 are community hospitals providing inpatient, outpatient and emergency care 24 hours a day, seven days a week, 365 days a year. MHA membership encompasses large urban trauma centers and teaching hospitals, mid-size community hospitals, and rural Critical Access Hospitals. The MHA represents *all* nonprofit and several for-profit hospitals in the state, advocating on behalf of them and the nearly 10 million people they serve. Established in 1919, the MHA represents the interests of its member hospitals and health systems on key issues and supports their efforts to provide quality, cost-effective and accessible care. The mission of the MHA is to advance the health of individuals and communities. Through its leadership and support of hospitals, health systems and the full care continuum, the MHA is committed to achieving better care for individuals, better health for populations and lower per-capital costs. In addition, the association provides members with essential information and analysis of health care policy and offers relevant education to keep hospital administrators and their staff

current on statewide issues affecting their facilities. Using its collective voice, the MHA advocates for its members before the legislature, government agencies, the media and the public.

The Mississippi Hospital Association (MHA) is a statewide trade association which serves the public by assisting its members in the promotion of excellence in health through education, public information, advocacy, and service.

The Missouri Hospital Association (MHA) members include every acute-care hospital in the state, as well as most of the federal and state hospitals and rehabilitation and psychiatric care facilities. MHA actively serves its members' needs through representation and advocacy on behalf of its members, continuing education programs on current health care topics, and education of the public and media as well as legislative representatives about health care issues.

The New Jersey Hospital Association (NJHA), formed in 1918, has grown to become one of the largest and most influential healthcare organizations in the state. Its mission as a not-for-profit trade organization is to improve the health of the people of New Jersey. NJHA currently has approximately 400 members, including every general acute care hospital in the state, specialty and psychiatric hospitals, health systems, nursing homes, home health agencies, hospice providers, assisted living facilities, healthcare-related businesses and educational institutions, all of which unite through NJHA to promote their common

interests in providing quality, accessible, and affordable healthcare in New Jersey. NJHA provides leadership in advocacy, policy analysis, quality and financial data, education, and community outreach. NJHA regularly appears before all three branches of federal and state government to provide the judiciary as well as elected and appointed decisionmakers with its expertise and industry viewpoint on issues and challenges involving healthcare.

The New Mexico Hospital Association (NMHA) is the trade association for acute and post-acute care hospitals in New Mexico. It advocates for the interests of its members at the state and federal level in the legislative and regulatory arenas. The NMHA represents 48 not-for-profit, investor-owned, and governmental hospitals and health systems from around the state.

The Healthcare Association of New York State (HANYS) is New York's statewide hospital and healthcare system association representing not-for profit and public hospitals, health systems, nursing homes, home health agencies, and other healthcare organizations. HANYS' members cross the spectrum of providers, including rural Critical Access Hospitals, community hospitals, large, urban Academic Medical Centers, and safety net providers. HANYS seeks to advance the health of individuals and communities by providing expertise, leadership, representation, and service to health providers and systems across the entire continuum of care.

The Greater New York Hospital Association (GNYHA) is a Section 501(c)(6) organization that represents the interests of over 200 hospitals and health systems located throughout New York State, New Jersey, Connecticut, and Rhode Island, all of which are not-for-profit, charitable organizations or publicly-sponsored institutions. GNYHA engages in advocacy, education, research, and extensive analysis of health care issues, including finance and reimbursement policy.

The North Carolina Healthcare Association (NCHA) is a statewide trade association representing 136 hospitals and health systems in North Carolina, with the mission of uniting hospitals, health systems, and care providers for healthier communities. NCHA is an advocate before the legislative bodies, the courts, and administrative agencies on issues of interest to hospitals and health systems and the patients they serve.

The North Dakota Hospital Association (NDHA) has been representing hospitals and health-related member organizations for over 80 years. The NDHA is a voluntary, not-for-profit organization comprised of hospitals and health systems, related organizations, and other members with a common interest in promoting the health of the people of North Dakota.

The Ohio Hospital Association (OHA) is a private non-profit trade association established in 1915 as the first state-level hospital association in the United States. For decades the OHA has provided a forum for hospitals to come together to pursue health care policy and

quality improvement opportunities in the best interest of hospitals and their communities. The OHA is comprised of 252 hospitals and 15 health systems, all located in Ohio, and works with its member hospitals across the state to improve the quality, safety, and affordability of health care for all Ohioans. The OHA's mission is to collaborate with member hospitals and health systems to promote a sustainable health care system so Ohioans have access to high-quality hospital care in their communities.

The Oklahoma Hospital Association (OHA) is the voice of hospitals in Oklahoma. Established in 1919, the OHA represents more than 137 hospitals and health systems across the state. OHA's membership is composed of urban, rural and tribal members, including 38 Critical Access Hospitals of which six serve frontier counties. OHA's primary objective is to improve health and healthcare for all Oklahomans through health transformation, workforce and talent development, and strengthening community trust.

The Hospital Association of Oregon, founded in 1934, is a mission-driven, nonprofit trade association representing Oregon's 61 hospitals. Committed to fostering a stronger, safer, more equitable Oregon where all people have access to the high-quality care they need, the hospital association supports Oregon's hospitals so they can support their communities; educates government officials and the public on the state and federal health care landscape, and works collaboratively with

policymakers, community-based organizations, and the health care community to build consensus on and advance health care policy benefiting the state's four million residents. The hospital association joins this amicus curiae filing as part of its commitment to helping vulnerable communities receive the care they need.

The Hospital and Healthsystem Association of Pennsylvania (HAP) is a statewide member services organization that advocates on behalf of Pennsylvania hospitals and health systems to advance high-quality, accessible, and financially sustainable health care. HAP's more than 235 member organizations include the majority of hospitals across the commonwealth. Learn more at www.haponline.org.

The Tennessee Hospital Association (THA) was founded in 1938 and serves as an advocate for hospitals, health systems, and other healthcare organizations across the state. The initiatives of THA support the efforts of Tennessee's hospitals to ensure high-quality care for the patients and communities they serve.

The Texas Hospital Association (THA) is a non-profit trade association representing Texas hospitals. THA advocates for legislative, regulatory, and judicial means to obtain accessible, cost-effective, high-quality health care. THA opposes reductions to 340B Program reimbursement that increase costs for uninsured or low-income patients and reduce hospitals' ability to provide expanded services to patients.

Vermont Association of Hospitals and Health Systems (VAHHS) is a member-owned organization comprised of Vermont's network of not-for-profit hospitals. VAHHS is committed to building a vibrant, healthy Vermont. Its work includes advocacy, policy development, education, and research. Working with partners and stakeholders locally and nationally, VAHHS supports and contributes to policies that meet the association's core principles of making health care more affordable, maintaining high quality care, providing universal access, and preserving the individual's ability to choose their doctor and hospital. VAHHS is deeply committed to health care reforms and policies that help us achieve those principles. Transforming our system to one that focuses on population health and value-based care is essential to improving outcomes for patients and bringing down health care costs over time. The VAHHS Board is comprised of the hospital CEOs of its member institutions, as well as two at-large representatives to include one nurse executive and one health network CEO, one designated clinical trustee, and the President of VAHHS.

Virginia Hospital & Healthcare Association (VHHA) formed in 1926 as a trade association of Virginia hospitals and includes not only rural and urban hospitals, but integrated health care delivery systems and their long-term care facilities and services, ambulatory care sites, home health services, insurance subsidiaries, and other health system-related entities. Collaborating with its members and stakeholders,

VHHA ensures the sustainability of Virginia's hospitals and health systems to improve the health of all Virginians. VHHA currently has 26 member health systems representing 113 community, psychiatric, rehabilitation, and specialty hospitals throughout the Commonwealth.

The Washington State Hospital Association (WSHA) is a non-profit membership organization that represents 107 member hospitals. WSHA works to improve the health of the people of the State by advocating on matters affecting the delivery, quality, accessibility, affordability, and continuity of health care.

The West Virginia Hospital Association (WVHA) is a not-for-profit statewide organization representing 64 hospitals and health systems across the continuum of care. The WVHA supports its members in achieving a strong, healthy West Virginia by providing leadership in health care advocacy, education, information, and technical assistance, and by being a catalyst for effective change through collaboration, consensus building, and a focus on desired outcomes.

The Wisconsin Hospital Association (WHA) is a statewide non-profit association with a membership of more than 130 Wisconsin hospitals and health systems. For 100 years, the Wisconsin Hospital Association has advocated for the ability of its members to lead in the provision of high-quality, affordable, and accessible health care services, resulting in healthier Wisconsin communities.

The Wyoming Hospital Association (WHA) is a member-owned non-profit organization representing Wyoming hospitals. WHA serves as the voice of Wyoming hospitals before local, state, regional and national legislative and regulatory bodies, the media and the general public. WHA also promotes information and education that enables Wyoming hospitals to deliver high quality, adequately financed/cost-effective health care that is universally accessible to all Wyoming citizens.