

No. 25-2236

**UNITED STATES COURT OF
APPEALS FOR THE FIRST CIRCUIT**

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,
Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., *Secretary of the U.S. Department of Health and Human
Services, et al.*,
Defendants-Appellants,

On appeal from the United States District Court
for the District of Maine
No. 2:25-cv-600-LEW,
Chief Judge Lance E. Walker

**UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF 340B
HEALTH, AMERICAN SOCIETY OF HEALTH-SYSTEM
PHARMACISTS, AMERICA'S ESSENTIAL HOSPITALS,
ASSOCIATION OF AMERICAN MEDICAL COLLEGES, AND
NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS AS *AMICI
CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLEES' OPPOSITION
TO MOTION FOR STAY PENDING APPEAL**

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Pursuant to Federal Rule of Appellate Procedure 29(a)(3), movants 340B Health, American Society of Health-System Pharmacists, America's Essential Hospitals, Association of American Medical Colleges, and National Association of Children's Hospitals respectfully move the Court for leave to file a brief as *amici curiae* in support of Plaintiffs-Appellees' Opposition to Defendants-Appellants' Motion for Stay Pending Appeal. Plaintiffs-Appellees consent to the filing of this *amicus* brief, and Defendants-Appellants take no position regarding the filing of this brief.

I. INTEREST OF MOVANTS

Amici and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The upfront discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in this Court denying Defendants-Appellants' Motion for Stay Pending Appeal, which would allow the district court's preliminary injunction barring implementation of the 340B Rebate Model Pilot Program" (the Rebate Program or the Program) to stand and the status quo to remain in effect.

II. MOVANTS' BRIEF WILL BE USEFUL TO THE COURT'S CONSIDERATION OF DEFENDANTS-APPELLANTS' MOTION.

Movants' brief complies with Federal Rule 29 and contains valuable insight to inform the Court's consideration of Defendants-Appellants' Motion. As

representatives of 340B covered entities and pharmacists serving patients, movants are uniquely positioned to explain the critical role of the upfront discounts provided through the 340B program. Movants are also qualified to explain why a stay of the district court's order would impose onerous burdens on covered entities nationwide and that those covered entities have accrued significant reliance interests for more than 30 years of the 340B program's operation through upfront discounts.

III. CONCLUSION

Based on the foregoing, movants respectfully request that the Court grant this motion for leave to file a brief as *amici curiae* in support of Plaintiffs-Appellees' Opposition and accept for filing the *amicus curiae* brief submitted contemporaneously with this motion.

Date: January 5, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on January 5, 2026, the foregoing Unopposed Motion for Leave to File Brief of 340B Health, American Society of Health-System Pharmacists, America's Essential Hospitals, Association of American Medical Colleges, and National Association of Children's Hospitals as *Amici Curiae* in Support of Plaintiffs-Appellees' Opposition to Motion for Stay Pending Appeal was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

/s/ William B. Schultz
Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 314 words, as counted by Microsoft Word, excluding the parts of the motion excluded by Federal Rule of Appellate Procedure 32(f). This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Word in 14-point Times New Roman font.

/s/ William B. Schultz
Counsel for Amici Curiae

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CORPORATE DISCLOSURE STATEMENT

340B Health is a non-profit organization that does not have a parent corporation.

It does not issue stock.

The American Society of Health-System Pharmacists is a non-profit organization that does not have a parent corporation. It does not issue stock.

America's Essential Hospitals is a non-profit organization that does not have a parent corporation. It does not issue stock.

The Association of American Medical Colleges is a non-profit organization that does not have a parent corporation. It does not issue stock.

The National Association of Children's Hospitals d/b/a Children's Hospital Association is a non-profit organization that does not have a parent corporation. It does not issue stock.

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INTEREST OF AMICI CURIAE¹

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation’s healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education, and professional development, and has served as a steadfast advocate for members and patients.

America’s Essential Hospitals (AEH) is dedicated to high-quality care for all, including those who face social and financial barriers. Consistent with this safety-net mission, AEH’s nearly 400 members provide a disproportionate share of the nation’s uncompensated care, with three-quarters of their patients uninsured or covered by Medicare or Medicaid.

¹ No party’s counsel authored this brief in whole or in part. No one other than *Amici* or their counsel contributed any money to fund its preparation or submission. Plaintiffs-Appellees consent to the filing of this brief, and Defendants-Appellants take no position regarding the filing of this brief.

The **Association of American Medical Colleges (AAMC)** is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 162 U.S. medical schools accredited by the Liaison Committee on Medical Education; nearly 500 academic health systems and teaching hospitals; and more than 70 academic societies. More than 90 per cent of AAMC's member teaching hospitals participate in the 340B Program and rely heavily on the Program's upfront discounts to generate resources that are used to provide critical health care programs for their communities, including vulnerable populations in those communities.

The **National Association of Children's Hospitals, Inc., d/b/a Children's Hospital Association**, is the national voice of more than 220 children's hospitals. It advances child health through innovation in the quality, cost, and delivery of care in children's hospitals.

Amici and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The upfront discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the denial of a stay pending appeal so that the injunction entered by the district court will continue to enjoin Defendants-Appellants from allowing manufacturers to provide

discounts through rebates through the “340B Rebate Model Pilot Program” (the Rebate Program or the Program).

As a result of their strong interest, 340B Health has participated in four cases now pending in the D.C. Circuit involving drug company challenges to Defendants-Appellants’ denial of proposals to implement rebate models before the Rebate Program was announced, *see Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir.), and AEH has filed *amicus* briefs in these cases at the district court level and in the D.C. Circuit.

ARGUMENT

Plaintiffs-Appellees and the district court have both persuasively explained why the Department of Health and Human Services’ Health and Resources and Services Administration (HRSA)’s creation of the Rebate Program was arbitrary and capricious under the Administrative Procedure Act (APA). Accordingly, Defendants-Appellants’ request for a stay pending appeal should be denied because they cannot make the required “strong showing” that they are likely to succeed on appeal. *Nken v. Holder*, 556 U.S. 418, 433–34 (2009). At the appropriate time, *Amici* intend to file a brief on the merits of this appeal to support affirmance of the district court’s order below.

At this expedited stage of the case, *Amici* file this brief solely to explain that Defendants-Appellants misapprehend the applicable standard for evaluating

informal adjudications under the APA. Although HRSA’s decision to allow the Rebate Program to go forward was an informal adjudication (*i.e.*, accomplished without notice-and-comment rulemaking and without a formal hearing), the law is clear that review of a decision made through an informal adjudication is subject to the same substantive arbitrary-and-capricious standard as a rulemaking or formal adjudication. *Neustar, Inc. v. FCC*, 857 F.3d 886, 893 (D.C. Cir. 2017) (“[I]nformal adjudications still must comply with the familiar APA standard banning arbitrary and capricious actions.”); *PharmaEssentia USA Corp. v. Dep’t of Health & Hum. Servs.*, --- F.Supp.3d ----, 2025 WL 2761211, at *5 (D.D.C. Sep. 29, 2025) (While “agencies must satisfy only minimal *procedural* requirements” in undertaking informal adjudications, they “still must comply with the familiar APA standard banning arbitrary and capricious actions.”) (emphasis added) (internal citations omitted).

In each case, to demonstrate that its decision is not arbitrary and capricious, the agency must show that its action is “reasonable and reasonably explained.” *California v. Dep’t of Educ.*, 132 F.4th 92, 98 (1st Cir. 2025) (quoting *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)). This means that—irrespective of whether the agency action is a rule or an adjudication and whether it is formal or informal—the agency must show that it “acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained

the decision.” *Prometheus*, 592 U.S. at 423; *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513–14 (2009).

Defendants-Appellants ask the Court to ignore this basic well-established principle of administrative law because the Rebate Program was created through informal adjudication. But that contention conflates the minimal *procedural* requirements with the *substantive* arbitrary-and-capricious review standard that applies to agencies’ informal adjudications. Defs.-Appellants’ Reply at 7–12. To support their bold proposition, Defendants-Appellants cite three cases that all center on the *procedural* requirements of the APA.² None of these cases disturbs the *substantive* dictates that agencies must satisfy.³

Here, the administrative record (or lack thereof) confirms repeated violations of the APA’s substantive requirements, and the district court correctly concluded that

² *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 653 (1990) (“Finally, we consider the Court of Appeals’ ruling that the agency *procedures* were inadequate in this particular case.”) (emphasis added); *Neighborhood Ass’n of the Back Bay, Inc. v. Federal Transit Admin.*, 463 F.3d 50, 60 (1st Cir. 2006) (addressing Sections 106 and 110 of the National Historic Preservation Act of 1966, which both impose procedural requirements); *Citizens Awareness Network, Inc. v. United States*, 391 F.3d 338, 349 (1st Cir. 2004) (addressing the “procedural safeguards . . . demanded by the APA”).

³ *See generally* Harry T. Edwards & Linda A. Elliott, *FEDERAL STANDARDS OF REVIEW—REVIEW OF DISTRICT COURT DECISIONS AND AGENCY ACTIONS* 167 (2007) (“[T]he arbitrary and capricious standard governs review of all proceedings that are subject to challenge under the APA.”); *see also Consumers Union of U.S., Inc. v. FTC*, 801 F.2d 417, 422 (D.C. Cir. 1986).

Defendants-Appellants acted arbitrarily and capriciously in creating the Rebate Program for multiple reasons. Indeed, the Program Notice contains no explanation, justification, or analysis supporting the implementation of the Program, other than recounting the manufacturers' stated reasons for supporting the rebate model. Add.47–49.

First, Defendants-Appellants “failed to consider an important aspect of the problem,” *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)—specifically, the administrative costs of the Rebate Program, namely the costs of floating the full price of 340B drugs until 340B entities receive their statutorily owed rebate, and the non-economic costs on patients and hospitals. Add.16–18. Defendants-Appellants admit that they are “still evaluating the full magnitude of compliance costs,” Reply at 7, and are “currently examining the comments alleging an under-estimation of administrative costs in the context of the Paperwork Reduction Act[.]” Add.34. Although they argue that the Paperwork Reduction Act supports their approach, Defendants-Appellants do not—and cannot—explain how the provision in that Act allowing agencies additional time to collect information to comply with that law supports their argument that they have complied with the APA, when they acknowledge they have made their decision *before* resolving the clearly important issue of the financial burden of their decision on safety-net hospitals and other 340B providers. This clearly falls short of the APA’s

requirement that Defendants-Appellants “consider an important aspect of the problem” *before* undertaking the relevant agency action. *See State Farm*, 463 U.S. at 43; *DHS v. Regents of the Univ. of Calif.*, 591 U.S. 1, 25–29 (2020) (applying *State Farm* to informal adjudication).

This admission alone is fatal to the Rebate Program, and Defendants-Appellants’ citation to *FCC v. Prometheus Radio Project* undermines—rather than supports—their position. 592 U.S. 414 (2021). In *Prometheus*, the agency “repeatedly asked commenters to submit empirical or statistical studies” regarding the repeal of the rule at issue, but “no commenter produced such evidence.” 592 U.S. at 427. “In the absence of additional data from commenters, the FCC made a reasonable predictive judgment based on the evidence it had.” *Id.* Here, by contrast, HRSA received myriad comments from the American Hospital Association, 340B Health, AAMC, AEH, ASHP, and covered entities providing data regarding the burdensome costs of compliance on covered entities. For example, commenters demonstrated that Defendants-Appellants’ calculation of two hours per week of administrative burden was wildly off the mark. Compl. (Dkt. 1) ¶¶ 73–80, 145. But here, as explained above, Defendants-Appellants did not “reasonably reflect upon

th[is] information contained in the record and grapple with contrary evidence.” *Fred Meyer Stores, Inc. v. NLRB*, 865 F.3d 630, 638 (D.C. Cir. 2017).⁴

Again, Defendants-Appellants *admit* that they did not engage with that evidence before reaching a final decision implementing the Rebate Program. Add.34. It is well-established that “an agency’s refusal to consider evidence bearing on the issue before it constitutes arbitrary agency action within the meaning of § 706.” *Butte Cnty. v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010) (applied in informal adjudication before Department of Interior). This requirement of “[r]easoned decisionmaking is not a procedural requirement” but “stems directly from § 706 of the APA.” *See Hogen*, 613 F.3d at 195.

Second, the district court correctly found that Defendants-Appellants failed to appropriately account for 340B hospitals’ reliance interests or to weigh those reliance interests against any competing policy concerns. Add.12–15; *see Regents*, 591 U.S. at 33; *California v. Dep’t of Educ.*, 132 F.4th at 98. Defendants-Appellants admit (Defs.-Appellants’ Mot. 14) that the only place the Program Notice even mentions reliance interests is in a sentence acknowledging that the Rebate Program would fundamentally change the 340B Program. *See* Add.48. Neither this statement

⁴ *W. Coal Traffic League v. Surface Transp. Bd.*, 998 F.3d 945, 954 (D.C. Cir. 2021) (“[T]he failure to respond to significant comments—which is what Petitioner essentially claims—violates a substantive guarantee of the APA.”).

nor the stray, threadbare comments in the *post hoc* Britton Declaration demonstrate that Defendants-Appellants “determine[d] whether [the reliance interests] were significant, and weigh[ed] any such interests against competing policy concerns,” as HRSA was required to do where it was “not writing on a blank slate.” *Regents*, 591 U.S. at 33.

Third, Defendants-Appellants failed to provide “a reasoned explanation for the Rebate Program, at least in regard to design components.” Add.15; *see* Add.47–49.⁵ While in this Court, Defendants-Appellants take the position that the Rebate Program is necessary to implement the Medicare Drug Price Negotiation Program (DPNP), the manufacturers have made clear in their requests to HRSA that they seek to use the Program for other purposes (such as Medicaid duplicate discounts and diversion). And Defendants-Appellants themselves pointed out in their Motion that “[m]anufacturers have alternate means to deduplicate discounts[.]” Mot. 8. Indeed, as the Britton Declaration repeatedly confirms, Defendants-Appellants apparently base much of the Program design on the “central aim” of determining whether a

⁵ *See also United Airlines, Inc. v. TSA*, 20 F.4th 57, 63–64 (D.C. Cir. 2021) (“Placing the burden on United, however, does not relieve the TSA of its ordinary burden under the Administrative Procedure Act—*i.e.*, its duty to provide a reasoned explanation for its decision. Even when denying an interested party’s request via informal adjudication, an agency cannot merely state a conclusion but rather must ‘articulate a satisfactory explanation’ for its action. In other words, the agency must always adequately explain ‘why it chose to do what it did.’”) (internal citation omitted).

rebate model is feasible—a goal that is independent of the Program Notice’s statement of the manufacturers’ objectives of preventing duplicate discounts under the DPNP and Medicaid as well as diversion of 340B drugs to non-eligible patients. Add.29. The APA demands more of Defendants-Appellants than a mere statement that drug manufacturers are interested in implementing rebate models to justify a sweeping Program, which is mandatory for *all* 340B covered entities, that will impose significant burden and—even by the government’s own inadequate estimate—cost covered entities hundreds of millions of dollars each year.

CONCLUSION

For the foregoing reasons, and those set forth in Plaintiffs-Appellees’ Opposition, this Court should deny Defendants-Appellants’ Motion for Stay Pending Appeal.

Dated: January 5, 2026

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) and Local Rule 32(b) because it contains 2,160 words, excluding the parts of the brief exempted by Rule 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Rule 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in fourteen-point Times New Roman font.

/s/ William B. Schultz
William B. Schultz

CERTIFICATE OF SERVICE

I certify that on January 5, 2026, I caused the foregoing to be served via the Court's ECF filing system on all registered counsel of record.

/s/ William B. Schultz

Counsel for Amici Curiae