United States Court of Appeals
For the First Circuit

No. 25-2236

AMERICAN HOSPITAL ASSOCIATION; ST. MARY'S REGIONAL MEDICAL CENTER; MAINE HOSPITAL ASSOCIATION; NATHAN LITTAUER HOSPITAL AND NURSING HOME; UNITY MEDICAL CENTER; DALLAS COUNTY MEDICAL CENTER,

Plaintiffs, Appellees,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services; THOMAS J. ENGELS, Administrator Health Resources and Services Administration; HEALTH RESOURCES AND SERVICES ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES,

Defendants, Appellants.

Before

Gelpí, Montecalvo, and Rikelman, Circuit Judges.

ORDER OF COURT

Entered: January 7, 2026

In 2025, the federal government instituted a new program that benefits drug manufacturers by upending a decades-long practice of providing safety-net hospitals -- which serve rural and low-income communities -- with upfront discounts to purchase prescription drugs. A group of hospitals and hospital organizations filed suit in the U.S. District Court for the District of Maine challenging the new program under the Administrative Procedure Act (APA) and requested a preliminary injunction. In a careful and thorough decision, the district court granted the preliminary injunction. It determined that the federal government had failed to consider the hospitals' reliance interests and other important aspects of the problem in enacting the new program and that the hospitals would face irreparable harm, including potential closure, without an injunction during the course of the litigation. It then denied the federal government's request for a stay pending appeal. The federal government has now moved for an emergency stay from our court. We conclude that the federal government has failed to carry its burden of "ma[king] a strong showing that [it is] likely to succeed on the merits" in this appeal and thus deny its stay request. Nken v. Holder, 556 U.S. 418, 434 (2009).

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In 1992, Congress enacted Section 340B of the Public Health Service Act to assist safety-net hospitals that serve vulnerable populations by alleviating their prescription drug acquisition costs. Pub. L. No. 102-585, § 602 (1992). Under Section 340B, drug manufacturers enter into pricing agreements with the Secretary of the U.S. Department of Health and Human Services (HHS) so that their drugs may be covered by Medicaid and Medicare Part B. 42 U.S.C. § 1396r-8(a)(1); id. § 256b(a). Since Section 340B's enactment, the pricing agreements have required manufacturers to provide discounts to safety-net hospitals at the time of sale in order "to stretch scarce federal resources as far as possible." Although drug manufacturers have previously proposed a switch to a rebate model in which safety-net hospitals would pay higher upfront costs and receive reimbursements later, HHS has historically rejected such proposals as both inferior to Section 340B's current upfront-discount model and disruptive to safety-net hospitals.

On July 31, 2025, however, the Health Resources and Services Administration (HRSA) announced the 340B Rebate Model Pilot Program (the "Rebate Program") to allow nine drug manufacturers to charge safety-net hospitals upfront the wholesale prices for certain drugs and provide a rebate later to achieve the statutorily required discount price. Although the district court concluded that the administrative record is devoid of any explanation or reasoning for the change in policy, the apparent purpose of the Rebate Program is to address a "duplication" issue that can arise from the complex interplay of various federal drug-pricing laws. Put simply, between Section 340B's upfront discount and other subsidies offered through different federal healthcare programs, drug manufacturers have at times been subjected to duplicative pricing concessions when selling drugs to safety-net hospitals (although manufacturers do have alternative methods to address the double-discount issue). To avoid this duplication problem, the Rebate Program requires safety-net hospitals to pay to the drug manufacturers upfront prices far exceeding the amounts that they actually owe -- essentially functioning as an interest-free loan from the hospitals to the manufacturers -- and then wait for a rebate.

On December 1, 2025, multiple hospitals and hospital organizations sued the Secretary of HHS and other federal agencies and officials, alleging that the establishment and implementation of the Rebate Program violated the APA. Specifically, the hospitals maintain that the federal government acted arbitrarily and capriciously by failing to consider their significant reliance interests -- based, again, on more than thirty years of established practice -- and the hundreds of millions of dollars' worth of new costs that safety-net hospitals would incur under the Rebate Program. The hospitals sought immediate injunctive relief and a declaratory judgment establishing that the Rebate Program contravenes Section 706 of the APA. 5 U.S.C. § 706.

In evaluating the motion for a preliminary injunction, the district court began by considering the hospitals' likelihood of success on the merits of their APA claims, noting the "paucity" of the administrative record, including the lack of any explanation by the federal government for the change in decades-long practice. Indeed, the court concluded that the administrative record affirmatively demonstrated that the federal government had failed to consider important aspects of the problem, all in violation of the APA. The court also declined to rely on a declaration by Chantelle Britton, Director of the Office of Pharmacy Affairs, which, along with a limited range of other documents, the federal government had offered as a preview

of the operative administrative record, because the declaration "largely presents post hoc rationalizations" that may not be considered in an APA challenge.

Next, the district court determined that the hospitals would suffer irreparable harm under the Rebate Program absent a preliminary injunction, including by "floating the upfront costs . . ., hiring additional staff to process and track rebate claims, and cutting back or altogether abandoning certain programs and services." In support, the district court pointed to unrebutted evidence submitted by the hospitals that many of them operate with less than eleven days' worth of cash on hand and that the Rebate Program would cause them to lose hundreds of millions of dollars per year that they could not recoup, thus threatening to close several hospitals. After concluding that the remaining factors also weighed in the hospitals' favor, the district court granted a preliminary injunction preserving the status quo and barring the federal government from implementing the Rebate Program during the course of this litigation. It then denied the federal government's request for a stay of its order pending appeal.

The federal government has now moved for a stay in our court.[1] "'A stay is not a matter of right.'" Nken, 556 U.S. at 433 (quoting Virginian R. Co. v. United States, 272 U.S. 658, 672 (1926)). "The party requesting a stay bears the burden of showing that the circumstances justify" a stay. Id. at 433-34. When deciding whether to exercise our discretion to grant a stay pending appeal, we consider the following four factors:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits [of the appeal]; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Id. at 434 (quoting Hilton v. Braunskill, 481 U.S. 770, 776 (1987)). "The first two factors . . . are the most critical." Id.

The federal government has not carried its burden to justify a stay. To begin, we agree with the district court that the administrative record previewed below is devoid of evidence that the federal government considered the hospitals' significant reliance interests -- a critical factor in the analysis of an arbitrary-and-capricious claim. "An agency's decision is arbitrary and capricious if the agency relied on improper factors, disregarded 'an important aspect of the problem, offered an explanation that runs counter to the evidence,' or when a reasonable explanation for the agency's decision cannot be discerned." Gulluni v. Levy, 85 F.4th 76, 82 (1st Cir. 2023) (quoting Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983)). Further, an agency must provide "a more detailed justification" for a new policy "when its prior policy has engendered serious reliance interests that must be taken into account." FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009). The agency must "assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." DHS v. Regents of the Univ. of Cal., 591

[1] The federal government also filed a motion for an administrative stay in our court. We denied that motion by order entered on December 31, 2025, and requested additional briefing as to the merits of the stay request. The parties have since submitted that additional briefing.

U.S. 1, 33 (2020).

As the district court determined, the preview of the administrative record submitted by the federal government is threadbare. It does not contain any evidence showing that the federal government considered the hospitals' reliance interests, which all parties agree are significant. At best, the federal government identifies a sentence in the record acknowledging that "rebate models could fundamentally shift how the 340B Program has operated for over 30 years." Though unquestionably true, that statement does not demonstrate that the federal government considered whether and to what extent such a "shift" would impact the hospitals, whose financial survival relies on the upfront discounts that they have long received. And similarly, the administrative record does not reveal any prior consideration of the significant costs that safety-net hospitals will incur under the Rebate Program. Indeed, in its briefing to the lower court, the federal government conceded that it was "currently examining" the hospitals' increased administrative costs from the Rebate Program. Thus, the federal government has failed to identify any likely error in the district court's conclusion, based on the portions of the administrative record provided thus far, that the agency failed to consider an "important aspect of the problem," in violation of the APA. Gulluni, 85 F.4th at 82 (citation omitted).

To overcome the deficiencies in the previewed administrative record, the federal government points to Britton's declaration, which the district court described as a post hoc rationalization submitted to "fill the yawning void in th[e] administrative 'record.'" The federal government contends that the district court erred by not supplementing the administrative record with Britton's declaration, which it avers "illuminat[es] . . . the reasons for agency action." When considered in full, it argues, Britton's declaration indicates that the agency fulfilled its duty under the APA to sufficiently consider the relevant interests and costs.

The federal government has failed to make a strong showing that the district court likely erred with respect to its analysis of the Britton declaration. "Judicial review of agency action is limited to the grounds that the agency invoked when it took the action." Regents of the Univ. of Cal., 591 U.S. at 20 (citation modified). "[A]n agency must stand by the reasons it provided at the time of its decision and cannot rely on post-hoc rationalizations developed and presented during litigation." In re Fin. Oversight & Mgmt. Bd. for P.R., 37 F.4th 746, 761 (1st Cir. 2022). Although agencies may later "elaborate" on the reasons initially provided to justify agency action, they may not provide altogether new reasons after-the-fact. See Regents of the Univ. of Cal., 591 U.S. at 21.

As the district court pointed out, the preview of the administrative record contains almost no contemporaneous explanation for the Rebate Program. In the absence of any such explanation, there is nothing upon which Britton's declaration could "elaborate." Instead, the declaration appears to present new information in an attempt to justify the Rebate Program retroactively.

The federal government does cite several cases in contending that the declaration is not an impermissible post hoc rationalization but rather "an explanation for the agency's action submitted by the officer who had the authority to act." But the cases that the federal government cites do not support its argument. For example, the federal government in part relies on Sierra Club v.

Marsh, but that case is inapposite. See 976 F.2d 763, 770-75 (1st Cir. 1992) (finding that the supplemental "affidavits d[id] not contain any 'facts' about the proposed project that [were] not also included in the . . . administrative record"); see also, e.g., Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 419-21 (1971) (remanding at summary judgment because the whole administrative record was not before the court, and contemplating a limited circumstance in which something like a post hoc rationalization from an agency would be permissible on that record and at that stage); Camp v. Pitts, 411 U.S. 138, 142-43 (1973) (remanding at summary judgment when the agency failed to sufficiently explain its action, but explaining that the agency's explanation on remand would need to comport with the contemporaneous (yet insufficient) explanation already provided by the agency). Thus, the federal government has not carried its heavy burden of showing that the district court likely erred in its treatment of the Britton declaration.

As an alternative argument, the federal government suggests that "the APA does not specifically require [it] to explain its decision[s]" because the Rebate Program is an informal adjudication. That argument, however, is waived because the federal government did not develop it before the district court and instead argued the opposite position. See New Jersey v. Trump, 131 F.4th 27, 43 (1st Cir. 2025) (declining to consider arguments different from those pressed during "the preliminary injunction proceedings themselves"); Rhode Island v. Trump, 155 F.4th 35, 46-47 (1st Cir. 2025) (declining to consider argument not raised in motion to stay in the district court); see also Carrozza v. CVS Pharmacy, Inc., 992 F.3d 44, 59 (1st Cir. 2021) ("[A]ppellants cannot raise an argument on appeal that was not 'squarely and timely raised in the trial court.'" (quoting Thomas v. Rhode Island, 542 F.3d 944, 949 (1st Cir. 2008))).

In its brief opposing the motion for a preliminary injunction before the district court, the federal government referenced informal adjudications twice, but neither reference presented the argument that it now offers on appeal. First, in distinguishing the types of decisions that are justiciable, the federal government maintained that its 340B rebate decisions constitute "informal agency adjudications," which it conceded are "final agency actions" that may be challenged under the APA. It said nothing, however, about the APA's requirement to explain informal adjudications. At most, it included a passing citation to Izaak Walton League of Am. v. Marsh with an explanatory quotation describing informal adjudication as a type of agency action "that need not be conducted through 'on the record' hearings." See 655 F.2d 346, 361 n.37 (D.C. Cir. 1981). But the federal government did not leverage that quote to argue that it had no obligation to explain its decision; instead, it cited Izaak Walton League merely to support the proposition that informal adjudications are a species of final agency action that may be challenged under the APA.

Next, the federal government referenced the claimed informal-adjudication status of the Rebate Program as part of its argument that its decision satisfied the arbitrary-and-capricious standard of the APA. But again, its passing mention of "the context of informal agency adjudications" did not buttress a broader argument that it need not explain its decisions. Indeed, in the same passage, the federal government claimed the opposite: "[t]o comply with the arbitrary and capricious standard, the agency must examine the relevant data and articulate a satisfactory explanation for its action."[2] (Emphasis added.) See United States v. Chen, 998 F.3d 1, 6 (1st

[2] The federal government repeated this point at the preliminary-injunction hearing below,

Cir. 2021) (explaining that a party waives an issue by "purposefully abandon[ing] it, either expressly or by taking a contrary position" in the district court (emphasis added)). Further, the federal government cited Royal Siam Corp. v. Chertoff for the APA standard of review for informal adjudications; that case, however, does not suggest that an agency need not explain an informal adjudication. See 484 F.3d 139, 148 (1st Cir. 2007). In fact, our court observed there that the "record reveal[ed] that [the agency] considered all the relevant facts and produced a closely reasoned judgment as to the nature of [its decision]." Id. (emphasis added).

Even in its motion for a stay in the district court, the federal government repeatedly acknowledged its burden to "provide[] . . . adequate explanation for [its] action[s]." In its view, Britton's declaration satisfied that burden. But for the reasons we have set forth above, the federal government has not demonstrated at this stage that the district court likely erred in its treatment of the declaration. And the federal government did not argue below that, absent Britton's declaration, it had no duty under the APA to explain the change in policy. Rather, it consistently recognized that the opposite is true. See Chen, 998 F.3d at 6. Thus, the federal government has waived its argument that the APA does not require agencies to explain informal adjudications. See New Jersey, 131 F.4th at 41 (declining to consider arguments not developed in motion to stay in the district court); see also Rhode Island, 155 F.4th 46-47 (emphasizing the same).

Relatedly, on appeal, the federal government suggests that "experimental programs" -- like the Rebate Program -- "require less justification than permanent changes." But none of its briefing below mentioned a reduced obligation to justify "experimental" or "pilot" programs. In its argument to the district court, the federal government primarily leaned on the "pilot" designation of the Rebate Program to explain why the hospitals' injury would be limited in scope, and to explain the information-gathering nature of the program. At no point, however, did the federal government argue that the "experimental" nature of the program reduces its obligation to justify its decisions under the APA. It has therefore forfeited that argument as well. See New Jersey, 131 F.4th at 43; Rhode Island, 155 F.4th 46-47.

The hospitals pointed out these waiver and forfeiture issues in their response to the stay motion, yet the federal government did not address these arguments in its reply -- even though it did address a different waiver argument asserted by the hospitals. Instead, in contending that the district court erred in declining to consider Britton's declaration, the federal government doubled down on its position that administrative records for informal adjudications are often permissibly "silent" on the decision-making process. But again, it did not argue to the district court that it need not explain its decision to institute the new program.[3] See New Jersey, 131 F.4th at 41, 43.

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conceding that "agencies have to provide some explanation for their decision," even when engaging in informal adjudications.

[3] As a point of clarification, we note that the federal government asserted a related, but distinct argument to the district court: that it had no obligation to "respond to the comments received on the notice." The district court agreed with the federal government on this point because the agencies were not engaging in rulemaking. Nevertheless, that argument is different from the one that the federal government pursues on appeal. Although agencies may not have an obligation to respond to public comments as part of an informal-adjudication process, the federal

Beyond its failure to make a strong showing that it is likely to succeed on the merits of its appeal, the federal government has not shown that it would be "irreparably injured absent a stay." Nken, 556 U.S. at 434 (citation omitted). Indeed, the preliminary injunction simply preserves the status quo that has existed for more than three decades. The federal government has not demonstrated that it would expend any unrecoverable funds absent a stay, nor has it demonstrated that a delay in the roll-out of the Rebate Program would cause it to suffer any other irreparable injury. Rather, the primary cost of any delay appears to run to the drug manufacturers, not the federal government. Finally, the federal government has indicated that manufacturers have alternative methods to address the previously described duplication issue, further underscoring the lack of any substantial injury in the absence of a stay.[4]

For these reasons, the federal government has not demonstrated that it is entitled to stay relief. The motion for a stay pending appeal is thus **DENIED**.[5]

No later than Monday, January 12, 2026, at 1:00 p.m., the parties shall jointly propose an expedited briefing schedule. In the event that the parties cannot arrive at a joint proposal, individual proposals may be submitted by the same deadline set out above. The court intends to resolve the appeal without undue delay.

cc:
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government now suggests that it need not "explain its decision[s]" at all. As discussed, it did not develop that argument in the district court, and it is therefore waived. See New Jersey, 131 F.4th at 43.

[4] Neither of the remaining Nken factors outweigh the first two, which are the "most critical." Nken, 556 U.S. at 434.

[5] In our discretion, we have accepted the proposed amicus brief from 340B Health, America's Essential Hospitals, American Society of Health-System Pharmacists, Association of American Medical Colleges, and National Association of Children's Hospitals. We have considered the amicus brief only insofar as it addresses legal issues and positions raised by the parties. See Ryan v. U.S. Immigr. & Customs Enf't, 974 F.3d 9, 33 n.10 (1st Cir. 2020).