UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2018

(Argued: February 8, 2019 Final Submission: September 23, 2019
Decided: July 20, 2020)

Docket No. 18-2583-cv

UNITEDHEALTHCARE OF NEW YORK, INC., OXFORD HEALTH INSURANCE, INC.,

Plaintiffs-Appellants,

v.

LINDA A. LACEWELL, IN HER OFFICIAL CAPACITY AS SUPERINTENDENT OF FINANCIAL SERVICES OF THE STATE OF NEW YORK,

Defendant-Appellee.

Before:

POOLER, LOHIER, and CARNEY, *Circuit Judges*.

The plaintiffs are healthcare insurers in the New York insurance market who expected to receive significant payments in 2017 under the Patient Protection and Affordable Care Act (ACA) using a federal risk adjustment program developed by the United States Department of Health and Human Services (HHS). The plaintiffs challenged an emergency regulation promulgated in 2017 by New York's Superintendent of the Department of Financial Services that would have significantly reduced the amount of risk adjustment funding to which the plaintiffs were entitled in 2017 and subsequent years using HHS's federal methodology. The plaintiffs principally argue that the New York

regulation is preempted by the ACA's risk adjustment provisions and HHS's implementing regulations requiring that any deviation by a State from the federal risk adjustment methodology must be approved by HHS. The primary question on appeal is whether New York's emergency regulation was preempted by the ACA and HHS's regulations, or whether it was approved by HHS as required under section 18041(b) of the ACA and HHS's risk adjustment regulations, 45 C.F.R. § 153.320(a). The United States District Court for the Southern District of New York (Koeltl, J.) held that the emergency regulation was not preempted and was approved by HHS, and it therefore dismissed the plaintiffs' complaint. We **REVERSE** the District Court's judgment dismissing the preemption claim, and **VACATE** its judgment and **REMAND** as to the plaintiffs' remaining claims.

NEAL KUMAL KATYAL, Hogan Lovells US LLP (Eugene A. Sokoloff, Hogan Lovells US LLP, Steven Rosenbaum, Covington & Burling LLP, *on the brief*), Washington, D.C., *for Plaintiffs-Appellants* UnitedHealthcare of New York, Inc. and Oxford Health Insurance, Inc.

STEVEN C. WU, Deputy Solicitor General (Matthew W. Grieco, Assistant Solicitor General of Counsel, *on the brief*), *for* Letitia James, Attorney General, State of New York, New York, NY, *for Defendant-Appellee* Linda A. Lacewell, Superintendent of Financial Services of the State of New York.

LOHIER, Circuit Judge:

The Patient Protection and Affordable Care Act (ACA) was designed to expand coverage in individual health insurance markets nationwide. See Pub. L. No. 111-148, 124 Stat. 119 (2010), amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010). The ACA directed the United States Department of Health and Human Services (HHS), which administers the ACA, to issue regulations that establish standards and a

federal methodology for a risk adjustment program. Under the federal program, amounts collected from insurers whose plans have lower-risk enrollees (that is, enrollees who are healthier than average) are used to fund payments to insurers whose plans have higher-risk enrollees. See 42 U.S.C. § 18041(a); id. § 18063.

The plaintiffs UnitedHealthcare of New York and Oxford Health Insurance are healthcare insurers in the New York insurance market that expected to receive significant payments in 2017 using the federal risk adjustment program. The plaintiffs challenged an emergency regulation promulgated in 2017 by New York's Superintendent of the Department of Financial Services (DFS) that would significantly reduce the amount of risk adjustment funding to which they are entitled in 2017 and subsequent years using HHS's federal methodology. The plaintiffs principally argue that the New York regulation is preempted by the ACA's risk adjustment provisions and HHS's implementing regulations requiring, among other things, that any deviation by a State from the federal risk adjustment methodology must be approved by HHS.[1]

[1] The plaintiffs also alleged that unlawfully requiring them to remit the funds they received for the 2017 plan year pursuant to the HHS risk adjustment methodology effected an unconstitutional taking or exaction.

The primary question on appeal is whether New York's emergency regulation was preempted by the ACA and HHS's regulations, or whether it was approved by HHS as required under § 1321(b) of the ACA, 42 U.S.C. § 18041(b), and HHS's risk adjustment regulations, 45 C.F.R. § 153.320(a). The United States District Court for the Southern District of New York (Koeltl, J.) held that the emergency regulation was not preempted, and it therefore denied the plaintiffs' motion for summary judgment and dismissed their complaint. We granted the plaintiffs' motion to enjoin enforcement of the New York regulation pending appeal. After receiving the views of HHS relating to its regulations and approval process, we reverse the District Court's judgment and remand with instructions to grant the plaintiffs' motion for summary judgment as to the claim of preemption. In doing so, we recognize that the very able and distinguished District Judge unsuccessfully sought HHS's views regarding this dispositive question. We also vacate the District Court's dismissal of the plaintiffs' remaining claims under the Takings Clause of the Fifth Amendment and remand for further proceedings as to those claims.

BACKGROUND

I. Statutory Background

A. Relevant Preemption and Risk Adjustment Provisions

In 2010 Congress directed the Secretary of HHS to "issue regulations setting standards" for "the establishment of . . . risk adjustment programs," 42 U.S.C. § 18041(a)(1), (a)(1)(C), and to "establish criteria and methods to be used in carrying out . . . risk adjustment activities," 42 U.S.C. § 18063(b). In general, risk adjustment in health insurance markets is designed to "foster a stable marketplace" by "provid[ing] payments to health insurance issuers that cover higher-risk populations and to more evenly spread the financial risk borne by issuers."[2] Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, 76 Fed. Reg. 41,930, 41,931 (proposed July 15, 2011) [hereinafter "Proposed Standards"]. The ACA therefore mandates that "each State shall assess a charge on health plans and health insurance issuers . . . if the actuarial risk of the enrollees of such plans or coverage . . . is less than the average actuarial risk of all enrollees in all plans or coverage in [the] State." 42 U.S.C.

[2] The purpose of a risk adjustment program is to spread the risk associated with sicker enrollees and thereby disincentivize issuers from avoiding those enrollees or raising premiums.

§ 18063(a)(1) (emphases added). In turn, "each State shall provide a payment to health plans and health insurance issuers . . . if the actuarial risk of the enrollees of such plans or coverage . . . is greater than the average actuarial risk of all enrollees in all plans and coverage" in the State. Id. § 18063(a)(2) (emphases added). Finally, § 1321 of the ACA provides that "[n]othing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title." Id. § 18041(d).

B. HHS's Federal Risk Adjustment Regulations

In 2012 HHS promulgated regulations for establishing risk adjustment methodologies and programs in the individual and small-group health insurance markets. The regulations define "risk adjustment methodology" as "the risk adjustment model, the calculation of plan average actuarial risk, the calculation of payments and charges, the risk adjustment data collection approach, and the schedule for the risk adjustment program." 45 C.F.R. § 153.20; see Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, 77 Fed. Reg. 17,220, 17,246 (Mar. 23, 2012) [hereinafter "2012 Standards"]. The regulations provide that "[a]ny risk adjustment methodology used by a State, or HHS on behalf of the State, must be a Federally certified risk adjustment methodology." 45 C.F.R.

§ 153.320(a); see 2012 Standards, 77 Fed. Reg. at 17,249. A risk adjustment methodology can become "Federally certified" in one of two ways: it can be "developed by HHS" or "submitted by a State . . . [and] reviewed and certified by HHS."[3] 45 C.F.R. § 153.320(a)(1)–(2); see 2012 Standards, 77 Fed. Reg. at 17,249. Our principal focus in this case is on the latter process for federal certification or approval.

The approval process has a regulatory history stretching back roughly nine years. When HHS first proposed its risk adjustment regulations in 2011, it "interpret[ed] the statutory provision regarding the Secretary's establishment of criteria and methods for risk adjustment . . . to require substantive Federal oversight of the risk adjustment process." Proposed Standards, 76 Fed. Reg. at 41,939 (emphasis added). HHS explained that States would be allowed "to utilize alternate risk adjustment methodologies," but made clear that "States

[3] If a State proposes an alternate risk adjustment methodology, HHS will review the methodology to assess the extent to which the methodology: "(i) Accurately explains the variation in health care costs of a given population; (ii) Links risk factors to daily clinical practice and is clinically meaningful to providers; (iii) Encourages favorable behavior among providers and health plans and discourages unfavorable behavior; (iv) Uses data that is complete, high in quality, and available in a timely fashion; (v) Is easy for stakeholders to understand and implement; (vi) Provides stable risk scores over time and across plans; and (vii) Minimizes administrative costs." 45 C.F.R. § 153.330(a)(2); see also id. § 153.330(b)(1).

taking advantage of this flexibility must submit their proposed alternate risk adjustment methodologies for HHS review and certification." Id. Under the 2012 regulations described above, a State can either operate its own risk adjustment program or let HHS operate the program on its behalf. Any State that elects to operate its own risk adjustment program must apply to HHS for permission to do so. See 45 C.F.R. § 153.310(d). A State that declines to operate its own risk adjustment program, by contrast, "forgo[es] implementation of all State [risk adjustment] functions" under the ACA. Id. § 153.310(a)(2)–(4). In promulgating the 2012 regulations, HHS reaffirmed that States that "wish[ed] to deviate from" the federal risk adjustment methodology developed by HHS would have to "submit an alternate methodology to HHS for approval." 2012 Standards, 77 Fed. Reg. at 17,232.

In 2016 HHS again "encourage[d] States to examine whether any local approaches, under State legal authority, [were] warranted to help ease th[e] transition to new health insurance markets." Amendments to Consumer Operated and Oriented Plan Program (Interim Final Rule), 81 Fed. Reg. 29,146, 29,152 (May 11, 2016). HHS later that year "reiterate[d] that States in which HHS is operating its risk adjustment methodology are not permitted to modify the

methodology, but that States may take temporary, reasonable measures under State authority to mitigate effects under their own authority." Amendments to Consumer Operated and Oriented Plan Program (Final Rule), 81 Fed. Reg. 94,058, 94,159 (Dec. 22, 2016). Similarly, in 2017 HHS proposed a new risk-payment-reduction rule that would "tailor the risk adjustment methodology to particularities of reduced risk selection in a State's small group market" by "permit[ting] States' primary insurance regulators to request a percentage adjustment in the calculation of the risk adjustment transfer amounts in the small group market in their State." HHS Notice of Benefit and Payment Parameters (Proposed Rule), 82 Fed. Reg. 51,052, 51,073 (proposed Nov. 2, 2017) [hereinafter "Proposed Rule"]. In announcing the proposed rule, HHS recognized that its risk adjustment methodology, "which is calibrated on a national dataset, may in some circumstances, overcompensate for risk differences in the small group market for [a] particular State." Id. "In such cases," HHS emphasized, "States have the statutory authority to operate their own State risk adjustment program," but only "under a Federally-certified alternate risk adjustment methodology as they deem fit." Id. (emphasis added).

Likewise, in April 2018, after a notice and comment period, HHS promulgated a new regulation that allowed States to request reductions in "risk adjustment transfers . . . by up to 50 percent in States where HHS operates the risk adjustment program." 45 C.F.R. § 153.320(d); HHS Notice of Benefit and Payment Parameters (Final Rule), 83 Fed. Reg. 16,930, 17,059 (Apr. 17, 2018) [hereinafter "Final Rule"]. Describing the new regulation, HHS asserted that "States are the primary regulators of their insurance markets," and it therefore "encouraged States to examine whether any local approaches under State legal authority [were] warranted to help ease the transition for new entrants to the health insurance markets and mitigate the effects of large risk adjustment charge amounts." Final Rule, 83 Fed. Reg. at 16,956. States have "the statutory authority," HHS said, "to operate their own State risk adjustment program under a Federally certified alternate risk adjustment methodology." Id. "[A]llowing certain State-specific adjustments to the HHS risk adjustment methodology"—including, we presume, reductions in risk adjustment transfers—could "account for the effect of State-specific rules without the necessity for States to undertake operation of their own risk adjustment program." Id. Of course, it remained the case under the new regulation that States that do not administer risk adjustment

programs "will forgo implementation of all State functions," in which case HHS "will carry out all of the provisions [relating to risk adjustment] on behalf of the State." 45 C.F.R. § 153.310(a)(2).

In promulgating the 2018 regulation, which permits reduction requests starting in 2020, HHS acknowledged that reductions could be appropriate where the federal risk adjustment methodology failed to "take into account the effect of State-specific laws and rating rules" tailored to risk differences in a particular State's market. Final Rule, 83 Fed. Reg. at 16,956; see 45 C.F.R. § 153.320(d). As before, however, HHS retained the exclusive discretion to approve, adjust, or deny a State's request for a reduction in risk adjustment transfers. See 45 C.F.R. § 153.320(d)(4).

The 2018 regulation clearly sets out the approval process for a reduction. It says that HHS must determine, "based on the review of the information submitted as part of the State's request, along with other relevant factors . . . and relevant public comments," that a reduction is warranted "to more precisely account for . . . risk differences" due to "State-specific rules" or factors. 45 C.F.R. § 153.320(d)(4)(i). To that end, States that request a reduction must "submit evidence and analysis to HHS identifying the State-specific rules or market

dynamics that warrant an adjustment and demonstrating the actuarial risk differences in plans in the applicable State market are attributable to factors other than systematic risk selection, as well as substantiating the amount of the transfer reduction requested." Final Rule, 83 Fed. Reg. at 16,957; see 45 C.F.R. § 153.320(d)(1).

As described above, HHS's regulations establishing a risk adjustment program provide that any risk adjustment methodology (whether used by a State operating its own risk adjustment program, or by HHS acting on behalf of a State) must be a federally certified risk adjustment methodology. See 45 C.F.R. § 153.320(a). The regulations leave only two avenues to certify a risk adjustment methodology. The methodology must have been either developed by HHS and published in rulemaking in advance of the benefit year, or submitted by the State to HHS, reviewed for compliance with specified regulatory standards, certified by HHS, and published by HHS in the applicable annual rulemaking. See id. § 153.320(a)(1)–(2). Separate state risk adjustment methodologies are rare if not nonexistent. In its amicus brief, HHS tells us that, consistent with 45 C.F.R. § 153.310(a)(2), "since the 2017 benefit year, HHS has been administering the risk-adjustment program in every State, pursuant to the methodology that HHS

develops through annual rulemaking and publishes in advance of the applicable benefit year." HHS Amicus Br. at 4; see also id. § 153.310(a)(3).

II. Factual Background

New York elected to have HHS administer its program using HHS's federal risk adjustment methodology. As a result, New York does not operate its own risk adjustment program and, until this litigation, had not proposed an alternate risk adjustment methodology under the HHS regulations. See Joint App'x at 128; Oral Arg. Tr. at 15; see also 45 C.F.R. § 153.310(a)(3). In 2016, however, the Superintendent of DFS determined that the federal methodology failed to account for certain important features of New York's health insurance markets. In particular, the Superintendent concluded that the HHS program adversely affected New York's small-group market by ignoring the impact of administrative costs and profits on New York carriers and by inadequately addressing "how [New York] counts children in certain" health insurance calculations. 11 N.Y.C.R.R. § 361.9(a)(4); see also id. § 361.9(b)(1).

To remedy these and other problems for the 2017 plan year, the Superintendent promulgated the emergency regulation at issue in this case, which authorized a reduction in the payment transfer calculated under the

federal risk adjustment program. The emergency regulation targeted every health insurance issuer in New York designated to receive a risk adjustment payment under the federal program. The regulation authorized the Superintendent to direct these issuers to remit up to thirty percent of that payment into a State "market stabilization pool." Id. § 361.9(e)(1). The remitted funds in the pool would then be redistributed to those insurers who paid risk adjustment charges under the federal methodology. Id. § 361.9(e)(2)(i). In effect, the Superintendent's emergency regulation proposed to reverse a portion of the risk adjustment payments calculated according to the federal methodology by substantially reducing the amount of payments that the HHS required of certain insurers.

In August 2016, before promulgating the emergency regulation, DFS participated in a call with HHS officials. Second Decl. of John Powell, at 14–15, UnitedHealthcare of N.Y. v. Vullo, 323 F. Supp. 3d 470 (S.D.N.Y. 2018), No. 17-cv-7694, ECF No. 40 [hereinafter "Powell 2d Decl."]. During the call, DFS informed HHS that New York was exploring the possibility of "reducing the magnitude of the [federal risk adjustment] transfers, after HHS had administer the ACA-Risk Adjustment and released final results." Id. at 15. DFS asserts that

HHS officials on the call expressed support for the proposed action. Id. A month later, DFS participated in a second call with HHS, during which DFS summarized for HHS the form and content of the specific emergency regulation (which had not yet been finalized) and the state authority for the proposed regulation. Id. Again, according to DFS, "HHS raised no objection to DFS's regulation and the use of state authority to reduce the magnitude of the transfers caused by ACA-Risk Adjustment." Id. During a final call between DFS and certain HHS officials in October 2017, DFS explained in more detail the structure, purpose, function, and legal basis of the proposed regulation. Id. at 16. There is no dispute that HHS staff expressed some verbal support for the regulation at the end of the call. In fact, shortly after the call, an HHS official wrote an email thanking DFS and saying, "[a]s always, please let us know if anything would be helpful on our end as you operationalize your regulation." Id.

III. Procedural Background

On April 14, 2017, the Superintendent announced that the emergency regulation would go into effect absent extraordinary circumstances, resulting in a thirty percent reduction in transfer payments for the 2017 plan year. The plaintiffs, who expected to be recipients of a federal risk adjustment payment in

that plan year, filed suit, alleging that New York's emergency regulation was preempted by the ACA's risk adjustment provisions and their implementing regulations. The plaintiffs also alleged in the alternative that the regulation effected an unconstitutional taking or exaction by unlawfully requiring them to remit the funds they received for the 2017 plan year pursuant to the federal risk adjustment methodology.

DFS moved to dismiss the complaint, while the plaintiffs cross-moved for summary judgment and for permanent injunctive relief. Although the District Court concluded that the plaintiffs could invoke equity jurisdiction to enjoin the challenged New York regulation as preempted by the ACA, it denied the plaintiffs' motion for summary judgment and granted New York's motion to dismiss the complaint. The District Court determined that New York's regulation was not expressly preempted because it was "complementary" to the federal risk adjustment program and therefore saved by 42 U.S.C. § 18041(d), the ACA provision that preserves state laws that "do[] not prevent the application of [the Act's] provisions." UnitedHealthcare of N.Y., Inc. v. Vullo, 323 F. Supp. 3d 470, 480 (S.D.N.Y. 2018); see 42 U.S.C. § 18041(d). The District Court likewise held that there was no actual conflict between the challenged regulation and the

ACA, explaining that the regulation was intended only "to develop a separate risk adjustment program focused on remedying adverse consequences of the [federal program] in New York." 323 F. Supp. 3d at 482. We have already observed that the District Court unsuccessfully requested the views of HHS as amicus on the issue of preemption. Without the benefit of a response from HHS, the District Court understandably relied on the agency's past statements about the role of the States as the primary regulators of their own insurance markets to reject the plaintiffs' conflict preemption claim.

We enjoined the New York regulation pending appeal. After oral argument, we solicited the views of HHS on a number of issues, including whether the informal calls and emails between HHS officials and the DFS constituted a determination by HHS under 42 U.S.C. § 18041(b)(2) and the HHS risk adjustment regulations, 45 C.F.R. §§ 153.310–.330, that the challenged New York regulation implements the federal standards in New York. In response, HHS explained that its regulations permitted States to request a modification of the federal risk adjustment methodology if HHS administered risk adjustment in the State (as it did in New York). HHS Amicus Br. at 6. HHS also asserted that although the 2018 "state-flexibility regulation" now permits States to seek

approval for prospective reductions, it remains the case that a State "may not modify charge or payment amounts determined under the HHS risk-adjustment methodology—either in advance or on the back end—without obtaining HHS approval under the procedure set out in the state-flexibility regulation." Id. at 14; see 45 C.F.R. § 153.320(d).

DISCUSSION

I. Jurisdiction

DFS first argues that the District Court did not have subject matter jurisdiction over the plaintiffs' preemption claims, or over their claims for declaratory relief on the ground that the challenged state regulation constituted an unlawful taking or exaction under the Takings Clause of the Fifth Amendment.

On de novo review, we first address the District Court's federal equity jurisdiction to enjoin enforcement of preempted state laws. See Friends of the E. Hampton Airport, Inc. v. Town of East Hampton, 841 F.3d 133, 144 (2d Cir. 2016). When a private plaintiff claims that a federal law protects it from state regulation, "the court may issue an injunction upon finding the state regulatory actions preempted." Armstrong v. Exceptional Child Ctr., Inc., 575 U.S. 320, 326

(2015). "In such circumstances, a plaintiff does not ask equity to create a remedy not authorized by the underlying law. Rather, it generally invokes equity preemptively to assert a defense that would be available to it in a state or local enforcement action." Friends of the E. Hampton Airport, 841 F.3d at 144. The plaintiffs' claims fall squarely within this equity jurisdiction.

In Armstrong, the Supreme Court concluded that part of the Medicaid Act prevented healthcare providers from invoking equity to enjoin state officials who wanted to reimburse providers at rates lower than the federal statute required. The Court pointed out that federal statutory authority to withhold Medicaid funding was the "sole remedy" that Congress provided for a State's failure to comply with Medicaid requirements. Armstrong, 575 U.S. at 328. And "even if the existence of" a sole remedy "might not, by itself, preclude the availability of equitable relief, it did so when combined with the judicially unadministrable nature of the statutory text." Friends of the E. Hampton Airport, 841 F.3d at 145 (quotation marks omitted); see Armstrong 135 S. Ct. at 1385 ("It is difficult to imagine a requirement broader and less specific than [the Medicaid Act's] mandate that state plans provide for payments that are consistent with efficiency,

economy, and quality of care, all the while safeguard[ing] against unnecessary utilization of . . . care and services.") (quotation marks omitted).

Neither of the problems identified in Armstrong exists here. As DFS acknowledges, the ACA does not limit HHS to a single remedy, but rather "allows HHS broader power to 'take such actions as are necessary' to bring a State into compliance." Appellee's Br. at 36 (quoting 42 U.S.C. § 18041(c)(1)(B)(ii)(I)). Contrary to DFS's contention, it is irrelevant that the remedies provided by the ACA are agency remedies. See Friends of the E. Hampton Airport, 841 F.3d at 146. Nor are the ACA statutory and regulatory provisions at issue here "judicially unadministrable." Armstrong, 575 U.S. at 328. The District Court had only to determine whether the provisions preclude a State from unilaterally establishing a risk adjustment program or methodology and, if so, whether the state program or methodology was nevertheless authorized by HHS.

The District Court also held that the plaintiffs' takings and exaction claims, brought under 42 U.S.C. § 1983, were ripe at least with respect to the portions of the challenged regulation that apply to the 2017 plan year. We agree substantially for the reasons set forth in the District Court's September 24, 2018

opinion that these claims were ripe. See UnitedHealthcare of N.Y., 323 F. Supp. 3d at 485–86. The District Court nevertheless held that the claims failed on the merits because they were entirely derivative of the plaintiffs' preemption claim, which the District Court had rejected. Because we reverse the District Court's dismissal of the preemption claim, as explained below, we also vacate its dismissal of the takings and exaction claims relating to the 2017 plan year and remand for further proceedings as to those claims in view of our opinion.

II. Preemption

We review de novo the District Court's dismissal of the plaintiffs' preemption claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. See Olagues v. Icahn, 866 F.3d 70, 74 (2d Cir. 2017). In assessing the parties' preemption arguments, we start with the basic principle that "[u]nder the Supremacy Clause of the Constitution, state and local laws that conflict with federal law are without effect." N.Y. SMSA Ltd. P'ship v. Town of Clarkstown, 612 F.3d 97, 103–04 (2d Cir. 2010) (quotation marks omitted). As relevant here, conflict preemption applies when a state law or regulation "is an obstacle to the achievement of federal objectives." Id. at 104; see Marentette v. Abbott Labs., Inc., 886 F.3d 112, 117 (2d Cir. 2018); Steel Inst. of N.Y. v. City of New York, 716

F.3d 31, 36 (2d Cir. 2013); see also Wyeth v. Levine, 555 U.S. 555, 576 (2009) ("[A]n agency regulation with the force of law can pre-empt conflicting state requirements.").

We presume that federal law does not preempt state law. That presumption is especially strong when Congress legislates in a field traditionally occupied by the States.[4] See Wyeth, 555 U.S. at 565; In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig., 725 F.3d 65, 96 (2d Cir. 2013). In this context, we should find preemption only if the conflict between state law and federal policy "is so direct and positive that the two acts cannot be reconciled or consistently stand together." In re MTBE, 725 F.3d at 102 (quotation marks omitted). Under these governing principles and by its own terms, the ACA preempts state law when it is clear that the state law "prevents the application" of the ACA's provisions or its implementing regulations. See 42 U.S.C. § 18041(d).

[4] Because the ACA "specifically relates to the business of insurance," the McCarran–Ferguson Act's special anti-pre-emption rule, which would otherwise require a specific statement of intent to preempt state insurance laws, does not apply. See Barnett Bank of Marion Cty., N.A. v. Nelson, 517 U.S. 25, 37–38 (1996) (quoting 15 U.S.C. § 1012(b)).

As noted, the New York regulation promulgated by the Superintendent would significantly reduce the federal risk adjustment transfers calculated by the federal risk adjustment methodology for the 2017 plan year. On appeal, the plaintiffs argue that the regulation is preempted either expressly or because it conflicts with the applicable provisions of the ACA and HHS's implementing regulations. In response, DFS's core argument is that the plaintiffs' conflict preemption arguments fail in view of what DFS describes as HHS's repeated endorsements of local state approaches to risk adjustment programs under state legal authority in general, and of New York's specific risk adjustment program in particular. DFS also separately responds that neither the ACA nor HHS's regulations expressly preempt New York's actions here. Because we agree with the plaintiffs and the Government that New York's emergency regulation conflicts with the ACA and HHS implementing regulations and, as we explain below, was never approved by HHS, we do not address the issue of express preemption.

We start with the ACA itself. The statute prescribes only two ways to run a risk adjustment program. Either the federal government runs the program, or a state government can elect to run its own program after getting HHS's

approval. 42 U.S.C. §§ 18041(b)–(c). A State that "elect[s]" to run its own risk adjustment program must adopt either "the Federal standards" or analogous standards that HHS "determines implements the standards within the State." Id. § 18041(b). If a State fails to adopt one of these standards, then HHS is required to "take such actions as are necessary to implement" a risk adjustment program in that State. Id. § 18041(c)(1). In any case, HHS must approve whatever program the State chooses to put in place. The "unavoidable implication" of the ACA's risk adjustment framework is "that a State may not enforce its own" risk adjustment methodology "without obtaining [HHS's] approval." Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 99 (1992) (plurality). The ACA does not permit a State to run a risk adjustment program but then modify the federal methodology as it sees fit without first obtaining federal approval. As we explain in more detail below, because the New York emergency regulation purports to modify the federal methodology, it conflicts with the ACA unless DFS obtained HHS's prior approval to do so.

DFS reassures us that HHS viewed New York's regulation as one of the local approaches that "do not generally need HHS approval" because New York is "acting under [its] own State authority and using State resources." Appellee's

Br. at 23 (quoting Final Rule, 83 Fed. Reg. at 16,960). But we note that the challenged New York regulation relies entirely on federal resources, not New York's own resources, to redistribute federal transfers between private insurers. DFS has not pointed us to any state resources that it would tap to reduce the risk adjustment payments that federal law requires and that are at issue in this case. To the contrary, New York's regulation clearly seeks to redeploy federal resources (the federal risk adjustment payments) and redistribute them based on DFS's unilateral assessment. See 11 N.Y.C.R.R. § 361.9(e)(1). This result would reverse the federal government's assessment of how much insurers with higher-risk enrollees should be paid to keep those enrollees. Reallocating funds from an intended recipient back to the intended payor, as DFS proposes, at minimum frustrates the federal regulatory scheme. Cf. Hillman v. Maretta, 569 U.S. 483, 497 (2013) ("[W]here a beneficiary has been duly named, the . . . proceeds she is owed under [federal law] cannot be allocated to another person by operation of state law."). Under these circumstances, we conclude that the New York regulation is in "direct and positive" conflict with the federal risk adjustment

program's regulations governing the small-group and individual health insurance markets.[5] See In re MTBE, 725 F.3d at 102 (quotation marks omitted).

Our view is supported by the preamble to the April 2018 rule that finalized HHS's state-flexibility regulation. As DFS points out, the preamble specifically addressed the "very risk adjustment program at issue here" under New York's regulation. Oral Arg. Tr. at 23. The preamble describes how "[o]ne commenter noted that the New York adjustment could be seen as permitting States to make adjustments without HHS approval and requested clarification that States making adjustments to the risk adjustment formula must first obtain approval from HHS under the risk adjustment program prior to implementing any State-specific adjustments." Final Rule, 83 Fed. Reg. at 16,960. In response to the comment, HHS asserted:

> States are the primary regulators of their insurance markets, and as such, we encourage States to examine whether any local approaches under State legal authority are warranted to help ease the transition

[5] We conclude that HHS's risk adjustment regulations are a reasonable construction of the relevant ACA provisions and are therefore owed Chevron deference. See Wachovia Bank, N.A. v. Burke, 414 F.3d 305, 315 (2d Cir. 2005). Congress directed HHS to "issue regulations setting standards" for "the establishment of . . . risk adjustment programs," 42 U.S.C. § 18041(a)(1), (a)(1)(C), and to "establish criteria and methods to be used in carrying out . . . risk adjustment activities," id. § 18063(b). HHS has done so by establishing standards for federally certified risk adjustment methodologies, for administering risk adjustment, and for collecting and validating data. 45 C.F.R. §§ 153.310–.350.

> for new participants to the health insurance markets. States that take such actions and make adjustments do not generally need HHS approval as these States are acting under their own State authority and using State resources. However, the flexibility finalized in this rule involves a reduction to the risk adjustment transfers calculated by HHS and will require HHS review as outlined above.

Id. (emphasis added). DFS contends that the emphasized language is inapposite because it is not about actions taken by States under their own legal authority and because the language in any event relates to a procedure that is not effective until 2020. But the language relates directly to the federal-risk adjustment regulations and the payment reductions at issue in this case—reductions that undoubtedly reflect "reduction[s] to the risk adjustment transfers calculated by HHS." Id. This only further persuades us that New York could not act unilaterally and under its own authority to effectively reduce the federal risk adjustment transfers required under the federal methodology.

In urging a contrary conclusion, DFS also does not fully grapple with the significant bulk of regulations and HHS statements even before April 2018, as described above, that show that New York's regulation conflicts with federal law. See 45 C.F.R. § 153.310(a)(3) (noting that if a state opts for federal risk adjustment administration, it "will forgo implementation of all State functions""); id. § 153.320(a) (making clear that it is a "[g]eneral requirement" that "[a]ny risk

adjustment methodology used by a State, or HHS on behalf of the State, must be a Federally certified risk adjustment methodology"). HHS's proposed rule published in 2017 reinforced the existence of mandatory federal oversight by requiring federal certification for States that opt for state adjustments to the national methodology. See Proposed Rule, 82 Fed. Reg. at 51,073 (outlining timelines and requirements for submission, public notice and comment, and HHS review and approval of state-requested adjustments).

As the District Court's decision signals, there is some genuine ambiguity in HHS's various prior pronouncements and the regulations themselves about whether States may act as New York did without first getting federal approval. HHS could have been clearer in its statements. But any ambiguity is resolved, in our minds, by the views of HHS as conveyed in its amicus brief. Those views fully confirm our interpretation of the applicable regulations as requiring formal HHS approval in this case. HHS explains that "a reduction to the risk-adjustment transfers is not the type of local approach under State legal authority that a State may implement unilaterally." HHS Amicus Br. at 12 (quotation marks omitted). Instead, HHS tells us, the local approaches referenced in the preamble and elsewhere in the final rule are "modifications to the State's own

insurance regulations" and other actions States could take "acting under their own State authority and using State resources." Id. at 13 (quotation marks omitted). As DFS's own efforts to seek HHS's endorsement suggest, New York needed to have obtained HHS's formal approval before making adjustments to the risk adjustment formula under the New York regulation. Cf. Gade, 505 U.S. at 97–101.

"[A] reasonable agency determination, when advanced in an amicus brief that is not a post hoc rationalization, may be entitled to some deference on account of the specialized experience and information available to the agency." WC Capital Mgmt., LLC v. UBS Sec., LLC, 711 F.3d 322, 331 (2d Cir. 2013) (quotation marks omitted). Here, HHS has provided an interpretation of its regulations in an amicus brief that represents the agency's authoritative or official position and that clearly implicates HHS's substantive expertise in administering the very risk adjustment scheme at issue. Far from pressing a "post hoc rationalization," HHS has, "in response to the Court's request," offered its views in a case in which it has no direct interest. Kisor v. Wilkie, 139 S. Ct. 2400, 2417 & n.6 (2019). Nor do the parties cast any real doubt that HHS's

"interpretation is authoritative, expertise-based, considered, and fair to regulated parties." Id. at 2419.

For these reasons, we award Auer deference to HHS's interpretation. See Auer v. Robbins, 519 U.S. 452, 461 (1997); see also Kisor, 139 S. Ct. at 2416–18; Halo v. Yale Health Plan, Dir. of Benefits & Records Yale Univ., 819 F.3d 42, 53–54 (2d Cir. 2016). In doing so, we note that DFS has long agreed that Auer deference is owed to HHS's interpretation of its own regulations.[6] See Appellee's Reply Br. at 11 n.3.

On appeal, DFS does not genuinely dispute that, having declined to administer its own risk adjustment program, it was required to obtain some form of approval from HHS in order to reduce the federal risk adjustment transfers required under HHS's methodology in the way that the challenged regulation proposes. See Oral Arg. Tr. at 20 ("[A] core predicate of [New York's] argument is HHS's involvement and signoff on what New York has done here."); see also id. at 14–16. This explains why it went to some lengths to confer with and seek

[6] In its letter brief submitted after oral argument, DFS does argue that the views expressed by HHS in its amicus brief conflict with its prior position and therefore are not entitled to deference. But HHS's amicus brief mirrors the position it adopted in the Final Rule, as well as in various regulations and statements that predate that rule. For this reason, we disagree that HHS's amicus brief reflects a radical change in position.

the approval of HHS officials before finalizing the emergency regulation. In addition to citing HHS's past statements in the rulemaking process to argue that HHS effectively pre-authorized New York's attempts to reduce the transfer payments at issue, DFS insists that it obtained HHS's specific approval for the New York emergency regulation in the course of its various contacts with HHS in 2016 and 2017. In response, HHS informs us that it "will approve a state request (in whole or in part) if HHS determines—based on the review of the information submitted as part of the State's request, along with other relevant factors, including the premium impact of the transfer reduction for the state market, and relevant public comments—that a reduction in the transfers is justified or that the requested reduction would have de minimis impact on the premium increase needed to cover the transfers for issuers that would receive reduced transfer payments." HHS Amicus Br. at 6 (citing 45 C.F.R. § 153.320(d)(4)).

To answer whether DFS obtained the approval that the federal regulations require, we turn briefly to DFS's central contention on appeal that the challenged emergency regulation was not preempted by the federal risk adjustment regulations because HHS officials expressly endorsed it during phone calls and

in emails in 2016 and 2017. These informal communications from HHS employees, DFS maintains, constituted a determination under 42 U.S.C. § 18041(b)(2) and the HHS risk adjustment regulations, 45 C.F.R. §§ 153.310–.330, that the challenged New York regulation implements the federal standards in New York. HHS responds that "a State that wishes to run its own risk-adjustment program must show that the alternative methodology meets specified substantive requirements, . . . and, if approved by HHS, that alternative methodology must be published in the applicable annual HHS Notice of Benefit and Payment Parameters." HHS Amicus Br. at 15 (citing 45 C.F.R. §§ 153.320(a)(2), 153.330). Section 153.330 contains a long list of the requirements a State's alternative risk adjustment program must meet. New York does not pretend that it has satisfied any of these specific requirements, let alone that its alternative approach was published as § 153.320(a)(2) contemplates.

An extensive approval and publication regime in this context should come as no surprise. We would marvel if a few casual communications in the guise of informal calls and a staff email constituted an agency's formal position or "determin[ation]" that a state scheme was permissible under the ACA and its implementing regulations. See 42 U.S.C. § 18041(b)(2). We conclude that DFS's

consultations and communications with HHS in 2016 and 2017 fall short of constituting an affirmative formal agency determination by the Secretary of HHS that the state regulation comports with the federal methodology and federal objectives. Nor do DFS's consultations in this case satisfy the approval or certification process that HHS's regulations demand. See 45 C.F.R. §§ 153.310–.330. HHS's amicus brief entirely supports our conclusion that the "informal communications noted [in 2016 and 2017] would not satisfy" the approval and certification requirements contained in its regulations. HHS Amicus Br. at 15–16; see, e.g., Paralyzed Veterans of America v. D.C. Arena L.P., 117 F.3d 579, 587 (D.C. Cir. 1997) (declining to treat a "speech of a mid-level official" as an "authoritative departmental position"); N.Y. State Dep't of Soc. Servs. v. Bowen, 835 F.2d 360, 365–66 (D.C. Cir. 1987) (rejecting the notion that an "informal memorandum" memorializing "a telephone conversation between two mid-level agency employees" could constitute an official agency position).

Apart from the application of the specific HHS regulations at issue in this case, DFS contends more broadly that the challenged state regulation is valid because it seeks to accomplish the ACA's overall objectives by addressing known problems with the federal risk adjustment methodology. But "[a] state law also

is pre-empted if it interferes with the methods by which the federal statute was designed to reach this goal." Int'l Paper Co. v. Ouellette, 479 U.S. 481, 494 (1987) (emphasis added); see also Clean Air Mkts. Grp. v. Pataki, 338 F.3d 82, 87 (2d Cir. 2003) (affirming the same principle "[e]ven where federal and state statutes have a common goal"). As we have detailed above, New York's regulation interferes with, indeed reverses, some of the central "criteria and methods" that HHS, acting within its statutory authority, established for implementing a risk adjustment program and methodology. See 42 U.S.C. § 18063(b).

CONCLUSION

For the foregoing reasons, we reverse the portion of the District Court's judgment that dismissed the plaintiffs' preemption claim and remand with instructions to grant summary judgment in the plaintiffs' favor on that claim. We also vacate the District Court's dismissal of the plaintiffs' takings and exaction claims and remand for further proceedings as to those claims.