18-2583-cv

IN THE

United States Court of Appeals for the Second Circuit

UNITEDHEALTHCARE OF NEW YORK, INC., OXFORD HEALTH INSURANCE, INC.,
Plaintiffs-Appellants,

V.

MARIA T. VULLO, IN HER OFFICIAL CAPACITY AS SUPERINTENDENT OF FINANCIAL SERVICES OF THE STATE OF NEW YORK
Defendant-Appellee.

On Appeal from the United States District Court
for the Southern District of New York, No. 17 Civ. 7694 (JGK)
District Judge John G. Koeltl

BRIEF FOR PLAINTIFFS-APPELLANTS

STEVEN ROSENBAUM
COVINGTON & BURLING LLP
1 CityCenter
850 10th Street, NW
Washington, D.C 20001

NEAL KUMAR KATYAL
EUGENE A. SOKOLOFF
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
neal.katyal@hoganlovells.com

Counsel for Plaintiffs-Appellants

December 10, 2018

CORPORATE DISCLOSURE STATEMENT

Plaintiff UnitedHealthcare of New York, Inc. is a wholly owned subsidiary of UnitedHealth Group, Inc., a publicly traded corporation.

Plaintiff Oxford Health Insurance, Inc. is a wholly owned subsidiary of UnitedHealthcare Services, Inc., which is through corporate intermediaries a wholly owned subsidiary of UnitedHealth Group, Inc., a publicly traded corporation.

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No. 18-2583-cv

UNITEDHEALTHCARE OF NEW YORK, INC., OXFORD HEALTH INSURANCE, INC.,
Plaintiffs-Appellants,

v.

MARIA T. VULLO, IN HER OFFICIAL CAPACITY AS SUPERINTENDENT OF FINANCIAL SERVICES OF THE STATE OF NEW YORK
Defendant-Appellee.

JURISDICTIONAL STATEMENT

Plaintiffs-Appellants UnitedHealthcare of New York, Inc. ("United") and Oxford Health Insurance, Inc. ("Oxford") brought this suit to enjoin the enforcement of a New York regulation that authorizes the State's Superintendent of Financial Services, Defendant-Appellee Maria T. Vullo (the "Superintendent"), to confiscate funds to which Plaintiffs are entitled under the risk-adjustment provisions of the Affordable Care Act (ACA), 42 U.S.C. § 18063(a).

The district court (Koeltl, J.) had subject-matter jurisdiction under 28 U.S.C. § 1331. *See Friends of the E. Hampton Airport, Inc. v. Town of E. Hampton*, 841 F.3d 133, 144 (2d Cir. 2016), *cert. denied*, 137 S. Ct. 2295 (2017); *Ex parte Young*, 209 U.S. 123 (1908). On August 11, 2018, the district court denied Plaintiffs' motion for summary judgment and granted the Superintendent's motion to dismiss

under Rule 12(b)(6). The district court entered judgment on August 13. Plaintiffs filed a timely notice of appeal on August 28, 2018.

INTRODUCTION

The Affordable Care Act (ACA) establishes a federal risk-adjustment program in every State's individual and small-group health insurance markets. Congress mandated that program as an essential complement to the ACA's ban on health insurance plans that either deny coverage or charge higher premiums based on an enrollee's preexisting conditions or medical history. To counteract the risk that health insurance issuers would be incentivized to seek out healthier enrollees, limit coverage, or increase premiums, the program spreads the cost of covering higher-risk enrollees over all participants in a given market. The program works by assessing a charge on plans with relatively low risks and then using the proceeds of that charge to shore up plans with higher risks.

Out of respect for the States' traditional role as the primary regulators of their insurance markets, the ACA and its implementing regulations give States the flexibility to administer these risk-adjustment programs for themselves. But that flexibility is bounded. To ensure that this crucial program operates effectively nationwide, the ACA directs the Secretary of Health and Human Services ("Secretary") to develop uniform standards that every risk-adjustment program must apply, regardless of who runs it. Any deviation from those standards requires federal

approval, and States that opt out or fail to meet the Act's requirements must stand aside and let the Secretary operate the program in their markets.

New York wanted it both ways. The State declined to operate its own risk-adjustment program, leaving it to the Secretary to implement the ACA's risk-adjustment provisions. Apparently dissatisfied with the federal program's allocation of credits and charges, but unwilling to take responsibility for administering the program under federal law, the Superintendent promulgated a regulation in 2017 that unilaterally supplants the federal allocation. What the State candidly refers to as "New York's adjustment to federal risk adjustment," JA190, confiscates a portion of the money the federal program directs to higher-risk plans in the State's individual and small-group markets and returns that money to the same lower-risk plans required to contribute to the federal program.

The district court erred in holding that New York's unilateral confiscation of federal transfers is not preempted by federal law. By its own express terms, the challenged regulation takes what federal law has given and gives what federal law has taken—all without federal oversight or approval. By reversing the federal allocation of payments and charges this way, the challenged regulation nullifies the federal program. The Supremacy Clause commands the opposite result: "*state* law is nullified" in the event of a conflict. *See Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-153 (1982). This Court should reverse.

ISSUES PRESENTED

1. Whether the text and structure of the ACA preempt the challenged regulation in light of Congress's manifest intent to preclude state laws that parallel the Act's requirements without federal permission.

2. Whether the challenged regulation is preempted because it conflicts impermissibly with the ACA and its implementing regulations where (a) the challenged regulation effectively supplants the federal risk-adjustment program, thus preventing the Secretary from fully applying the ACA's provisions in New York; (b) the challenged regulation subverts the important regulatory objective of providing substantive federal oversight of risk-adjustment programs in markets regulated by the ACA; and (c) the challenged regulation redirects funds that belong to Plaintiffs under federal law.

3. Whether the district court had subject-matter jurisdiction to entertain Plaintiffs' claims for injunctive and declaratory relief barring the Superintendent from enforcing a regulation preempted by the ACA.

STATEMENT OF THE CASE

A. The Affordable Care Act's Risk-Adjustment Provisions.

The Affordable Care Act requires health insurance issuers in the individual and small group markets to use a "single risk pool" when developing premium rates. Pooling risk allows issuers to develop an average premium rate for their plans based on the aggregate risk profile of the enrollees in a given market. But setting premiums in this manner is not foolproof; if a plan attracts a disproportionate share of higher-risk enrollees, then the average premium rate will fail to reflect the plan's true risks. Absent other measures, issuers thus may be incentivized to offset this risk by avoiding less-healthy enrollees, narrowing their provider networks, or raising premiums higher than necessary—all to the enrollees' detriment. *See* Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, 77 Fed. Reg. 17,220, 17,221 (Mar. 23, 2012) [hereinafter, "2012 Standards"].

To counter this phenomenon, Congress established a comprehensive risk-adjustment program in each State's individual and small-group health insurance markets. *See* 42 U.S.C. § 18063. The program works by assessing a charge on plans with relatively low-risk enrollees and using that charge to fund corresponding payments to plans with relatively higher-risk enrollees, thereby spreading the

cost of insuring sicker enrollees across all issuers in a given market. *See id.* § 18063(a).

To ensure that the program achieves its objectives in each State, the ACA vests the Secretary of Health and Human Services with significant oversight authority. The Act directs the Secretary to establish uniform "standards for meeting the [Act's] requirements," 42 U.S.C. § 18041(a)(1), including "the establishment of the . . . risk adjustment program[]," *id.* § 18041(a)(1)(C), and the "criteria and methods to be used in carrying out . . . risk adjustment activities," *id.* § 18063(b). These rules must be crafted "in consultation with States," *id.*, and with input from "the National Association of Insurance Commissioners and its members and with health insurance issuers, consumer organizations, and such other individuals as the Secretary selects." *Id.* § 18041(a)(2).

The Department of Health and Human Services (HHS) currently administers the risk adjustment programs in effect in all 50 States and the District of Columbia. *See* JA128. But States may elect to run their own risk-adjustment programs if they "adopt and have in effect" either "the Federal standards established" by the Secretary, or "a State law or regulation that the Secretary determines implements the standards within the State." 42 U.S.C. § 18041(b). If the State opts out, fails to enact appropriate standards, or fails to satisfy the Secretary that it is taking actions necessary to implement the federal requirements, then "the Secretary shall take

such actions as are necessary to implement" the Act's requirements himself. *Id.* § 18041(c), (c)(1)(A).

B. The Federal Risk-Adjustment Regulations.

The HHS Secretary has "interpret[ed] the statutory provision regarding the Secretary's establishment of criteria and methods for risk adjustment under section [18063](b) to require substantive Federal oversight of the risk adjustment process." Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, 76 Fed. Reg. 41,930, 41,939 (July 15, 2011) [hereinafter, "2011 Standards"]. To implement that oversight requirement, the Secretary has promulgated rules prescribing when and how a State may implement the Act's risk-adjustment program in its markets.

The rules require States to apply to HHS for permission to administer a risk-adjustment program for each benefit year. 45 C.F.R. § 153.310(d). A State that seeks re-approval for a subsequent benefit year must publish a detailed summary of its risk-adjustment activities and, after the first three years, a "programmatic and financial audit" for HHS and public review. *Id.* § 153.310(d)(3)-(4). Like the statute, the regulations provide that any State that fails to secure HHS approval must "forgo implementation of all [risk-adjustment] functions" under the rules. *Id.* § 153.310(a)(2)-(4).

The regulations also impose tight controls on the development and approval of each program's risk-adjustment methodology. That methodology comprises the "actuarial tool used to predict health care costs" of covered plans, "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." *Id.* § 153.20. In short, the methodology determines which issuers must contribute to the risk-adjustment program, which issuers are entitled to receive risk-adjustment payments, and how much they must contribute or receive.

In recognition of the central role played by any risk-adjustment program's methodology, the rules require 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." *Id.* § 153.320(a) (emphases added). To be certified, a methodology must either be "developed by HHS" or "reviewed and certified by HHS" in accordance with strict criteria. *Id.* § 153.320(a)(1)-(2).

In States where HHS runs the risk-adjustment program, "HHS will specify" which "Federally certified risk adjustment methodology" applies. *Id.* at § 153.320(c). As of 2018, HHS applied its own methodology in all 50 States and the District of Columbia. JA128. But if a State elects to operate its own risk-adjustment program, it may submit an "alternate risk adjustment methodology" for HHS approval. 45 C.F.R. § 153.320(a)(2). The process for obtaining that approval

is demanding. The State must provide a detailed justification that addresses, among other things, "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." *Id.* § 153.330(a)(2). HHS scrutinizes these explanations and will certify the State's proposal only if it is satisfied that the alternate methodology is justified, coherent, and compliant with the federal risk-adjustment regulations as a whole. *Id.* § 153.330(b). Those regulations prohibit States from making any changes to an approved methodology without HHS approval. *See id.* § 153.330(c).

In the seven years since it first issued proposed risk-adjustment rules, HHS consistently has rejected requests to allow States to make changes to the risk-adjustment methodology without federal review and approval. In the 2012 rulemaking that first promulgated the risk-adjustment regulations, commenters argued that "HHS approval of State methodologies was unnecessary, and that any State alternate methodology should be deemed certified and available to all States." 2012 Standards, 77 Fed. Reg. 17,232. HHS rejected that proposal, agreeing in-

stead with commenters who advocated for requiring States to "submit a rationale for their proposed alternate methodology." *Id.* at 17,232. Indeed, HHS clarified that States were required to seek approval for "*any* alteration" to their certified methodologies." *Id.* at 17,233 (emphasis added).

HHS has not shrunk from its duty to provide substantive oversight even as it has acknowledged complaints about the program's "unintended consequences." Beginning in 2016, HHS "had a number of discussions with issuers and State regulators" concerning "the effects of unanticipated risk adjustment charge amounts." Patient Protection and Affordable Care Act; Amendments to Special Enrollment Periods and the Consumer Operated and Oriented Plan Program, 81 Fed. Reg. 29,146, 29,152 (May 11, 2016). HHS recognized that "States are the primary regulators of their insurance markets" and invited them to develop independent approaches "to help ease this transition to new health insurance markets." *Id.* But HHS was clear that it would retain control of the risk adjustment methodology. *See id.* ("[W]e will also continue to seek ways to improve the risk adjustment methodology."). Likewise, in 2017, HHS invited any "State that wishes to make an adjustment *for* the magnitude of these transfers in the individual and small group markets may take temporary, reasonable measures under State authority to mitigate *effects* under their own authority." Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019, 82 Fed. Reg.

51,052, 51,073 (Nov. 2, 2017) (emphases added). But the agency was clear that any changes *to* the amount of the federal transfers themselves would require careful HHS scrutiny. *Id.* In other words, States may develop their own initiatives to compensate for the effects of federal transfers, but they may not alter the amounts of the transfers themselves.

Consistent with that view, HHS announced in 2018 that it would "provide States the flexibility to *request* a reduction to the otherwise applicable risk adjustment transfers . . . by up to 50 percent," starting in the 2020 plan year. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019, 83 Fed. Reg. 16,930, 16,956 (Apr. 17, 2018) [hereinafter, "2019 Payment Parameters"] (emphasis added). The requirements of this new program are demanding. To obtain a reduction, States 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." *Id.* at 16,957. Although HHS again recognized that States "do not generally need HHS approval" for measures that "ease the transition for new participants to the health insurance markets," it made clear that "the flexibility finalized in this rule involves a reduc-

tion to the risk adjustment transfers calculated by HHS and will require HHS review" and approval. *Id*. at 16,960.

C. New York's Unilateral "Adjustment" To The Federal Program.

New York has not sought approval to administer a risk-adjustment program or to certify an alternate methodology. In a June 2016 letter to the HHS Secretary and the Administrator of the Centers for Medicare and Medicaid Services (CMS), the Superintendent admitted that this means New York is "unable to change" the federally administered program's "parameters or alter issuers' associated liabilities." Letter from Maria T. Vullo, Superintendent, N.Y. State Dep't of Fin. Servs., to Hon. Sylvia M. Burwell, Sec'y, HHS, and Hon. Andrew Slavitt, Acting Adm'r, CMS, at 2 (June 28, 2016), ECF No. 29-17; *see* JA70. Nevertheless, in 2017, the Superintendent promulgated a regulation that does exactly that.

The regulation provides that the Superintendent will "review the impact of the Federal Risk Adjustment Program established pursuant to 42 U.S.C. [§] 18063" and then take steps to undo a portion of the federal allocation of risk-adjustment payments and charges if the Superintendent "determines"—in her sole discretion—"that the Federal Risk Adjustment Program has adversely impacted" the relevant markets. 11 N.Y.C.R.R. §§ 361.9(b)(2), (d) (for 2017); 361.10(b)(2), (e) (for 2018 forward).

For the 2017 benefit year, the challenged regulation exacts a fixed percentage contribution from "every carrier in the small group health insurance market that is designated as a receiver of a payment transfer from the Federal Risk Adjustment Program." 11 N.Y.C.R.R. § 361.9(e)(1). The regulation then directs the Superintendent to redistribute those federal disbursements to "every carrier in the small group health insurance market that is designated as a payor of a payment transfer into the Federal Risk Adjustment Program." *Id.* § 361.9(e)(2)(i). The program thereby directly reverses the federally mandated distribution. For the 2018 and later plan years, the challenged regulation applies to both the individual and small-group markets—the very same markets covered by the federal program. *Compare id.* § 361.10, *with* 42 U.S.C. § 18063(c).

New York's unilateral "adjustment" is based on the Superintendent's own, undisclosed methodology, determined with no mandatory consultative or public process. *Cf.* 42 U.S.C. §§ 18041(a)(2), 18063(b) (requiring consultation with States, the National Association of Insurance Commissioners, issuers, consumer groups, and other interested parties). The challenged regulation provides only that the Department will confiscate a "uniform percentage" of the funds paid under the federal program, to "be calculated as the percentage necessary to correct any one or more of" several enumerated "adverse market impact factors" and "determined by the superintendent based on reasonable actuarial assumptions." 11 N.Y.C.R.R.

§§ 361.9(e)(1), 361.10(g)(1). That percentage is capped at 30 percent for the 2017 benefit year and 26 percent for the 2018 benefit year. *Id.* §§ 361.9(e)(1), 361.10(g)(1)(i).

D. Plaintiffs' Lawsuit And The Decision Below.

Applying the federal risk-adjustment methodology, the Secretary of Health and Human Services has determined that Plaintiffs are entitled to substantial risk-adjustment payments for the 2017 benefit year.[1] For her part, "the Superintendent has determined that a 30% uniform percentage adjustment will, absent extraordinary circumstances, be used in applying the market stabilization mechanism for the 2017 plan year." JA72.

Threatened with the seizure of up to 30 percent of their federal entitlements for the 2017 benefit year, Plaintiffs filed suit to declare unlawful and enjoin enforcement of the challenged regulation. JA16-60. Plaintiffs alleged that the regulation is preempted by the ACA's risk-adjustment provisions and their implementing regulations and that, by unlawfully confiscating Plaintiffs' risk-adjustment

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[1] Oxford is to receive $216,646,628.89 in connection with its 2017 activities in the small group market, making it liable for $64,993,988.67 under the challenged regulation. JA134; *see* JA72. United's 2017 credit of over $11.5 million relates to its activities in the individual market, which is not subject to the challenged regulation until the 2018 benefit year. *See supra* p. 13; *see also* 11 N.Y.C.R.R. § 361.10(g)(1)(i) (for the 2018 plan year, the "uniform percentage adjustment for the individual and small group health insurance markets is expected to be . . . 26 percent.").

transfers, the regulation would effect an unconstitutional taking or exaction. *See* JA18-19, 47-52. The Superintendent moved to dismiss Plaintiffs' complaint and Plaintiffs cross-moved for summary judgment and permanent injunctive relief.

On August 11, 2018, the district court (Koeltl, J.) denied Plaintiffs' motion and granted the Superintendent's cross-motion to dismiss in part. The court began by rejecting the Superintendent's argument that Plaintiffs lacked a cause of action. JA155. The court found that "with respect to risk adjustment, the ACA does not strip private citizens of their long-standing right under *Ex Parte Young* to invoke federal jurisdiction to enjoin a state entity from subjecting them to a local law enacted in alleged violation of federal requirements." JA159. The court also rejected the Superintendent's position that the court should abstain from exercising its jurisdiction under *Burford v. Sun Oil Co*., 319 U.S. 315 (1943). JA177.

On the merits, the district court rejected Plaintiffs' preemption arguments. The court concluded that the challenged regulation is not expressly preempted because New York's program "is a complementary provision to the" federal risk-adjustment program and therefore saved by 42 U.S.C. § 18041(d), which preserves state laws that "do[] not prevent the application of [the Act's] provisions." JA159-160. The court found no field preemption on the grounds that Congress's reservation of some state authority was inconsistent with an intent to occupy the field of risk adjustment. JA162-163. Finally, the court found no conflict between the chal-

lenged regulation and the ACA's provisions requiring States to seek federal approval before operating a risk adjustment program under the Act or varying from HHS's methodology. The court reasoned that the challenged regulation "does not seek to implement the [federal program], but rather seeks to develop a separate risk adjustment program focused on remedying adverse consequences of the [federal program] in New York." JA166. The court also relied heavily on statements HHS made in connection with various rulemakings, in which the agency recognized the States' role as the primary regulators of their own insurance markets, and encouraged States to consider independent state-law approaches to mitigate any unintended effects of the federal risk-adjustment program. JA166-169.

The district court also briefly addressed Plaintiffs' facial takings and exaction claims, brought under 42 U.S.C. § 1983. The court found that Plaintiffs' challenge with respect to the 2017 benefit year was ripe for review, but it agreed with the Superintendent that it was too early to address the 2018 benefit year. JA172-174. The district court recognized that Plaintiffs' takings and exaction claims rested on the argument that the ACA precludes the State from seizing their risk adjustment payments, and so dismissed them for the same reasons as Plaintiffs' standalone preemption claims. JA176.

Disbursements under the federal risk-adjustment program were scheduled to begin in October 2018, with payments under the challenged regulation due soon

thereafter. Accordingly, Plaintiffs promptly filed a motion in the district court seeking to enjoin the 2017 regulation pending appeal. When the district court denied that motion, Plaintiffs immediately sought an injunction in this Court. On October 10, 2018, Judge Cabranes granted Plaintiffs' motion pending a decision by a three-judge panel. *See* Doc. 45. That panel granted Plaintiffs' motion on November 19, 2018, and set the case for expedited briefing. *See* Doc. 54.

STANDARD OF REVIEW

This Court exercises *de novo* review of a district court's decisions whether to dismiss a complaint and grant summary judgment. *See Marcel Fashions Grp., Inc. v. Lucky Brand Dungarees, Inc.*, 898 F.3d 232, 236 (2d Cir. 2018) (dismissal); *Coregis Ins. Co. v. Am. Health Found., Inc.*, 241 F.3d 123, 127 (2d Cir. 2001) (summary judgment). This Court may remand with instructions to enter summary judgment in the appellant's favor if it determines "that the undisputed material facts require judgment as a matter of law." *16 Casa Duse, LLC v. Merkin*, 791 F.3d 247, 261, 264-265 (2d Cir. 2015); *see also, e.g.*, *Coregis*, 241 F.3d at 124. This Court also exercises *de novo* review of a district court's jurisdictional rulings. *E. Hampton Airport*, 841 F.3d at 144.

SUMMARY OF ARGUMENT

I. The Supremacy Clause commands that "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Free v. Bland*, 369 U.S. 663, 666 (1962) (citing *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 210-211 (1824)). The regulation challenged here does both: it defies Congress's intent to require federal authorization for state laws that duplicate the Act's requirements, and it sharply conflicts with the Act and its implementing regulations in multiple respects, any one of which is sufficient to compel reversal and remand with instructions to enter judgment for Plaintiffs on their preemption claims. And because the ACA bars the State from seizing their risk adjustment payments, Plaintiffs are also entitled to judgment on their takings and exaction claims.

A. The ACA erects a comprehensive federal regulatory scheme that conditions state participation on federal oversight and approval. Examining a nearly identical statutory scheme, the Supreme Court held that this combination of provisions "unquestionably pre-empts" even complementary state regulations enacted without federal authorization. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 97 (1992) (O'Connor, J., plurality op.) (internal quotation marks omitted); *accord id.* at 112-113 (Kennedy, J., concurring). That reasoning resolves this case.

Risk adjustment is a core requirement of the ACA, and the Secretary has promulgated extensive regulations to ensure that the program works effectively in every State. Yet the challenged regulation purports to apply the same type of regulation to the same issuers in the same markets, without adopting these standards or seeking federal approval. The text and structure of the ACA forbid such "supplement[ation]" of the Act's requirements, even "with ostensibly nonconflicting" regulations. *Id.* at 103 (O'Connor, J., plurality op.). The challenged regulation is plainly preempted.

B. Even if Congress's preemptive intent was not obvious on the statute's face, the problems with New York's so-called "adjustment to federal risk adjustment" run deeper than the ACA's plain text and structure. JA190.

First, the challenged regulation impermissibly prevents the Secretary from fulfilling his responsibility to apply the Act's provisions in New York. *See* 42 U.S.C. § 18041(c)-(d). The district court perceived no conflict here because the challenged regulation applies after federal authorities complete their risk-adjustment transfers. But that is the essence of the problem. By reallocating the federal payments and charges, the challenged regulation leaves the allocation where *New York* would have it, canceling out the federal program altogether. "[T]he Framers of our Constitution provided that the *federal* law must prevail" in the face of such a conflict. *Resolution Tr. Corp. v. Diamond*, 45 F.3d 665, 675 (2d

Cir. 1995) (quoting *de la Cuesta*, 458 U.S. at 153) (emphasis added). The challenged regulation cannot stand.

Second, the challenged regulation "interferes with the methods" Congress and the Secretary chose to achieve the statute's aims by flouting the mandatory process for developing and implementing risk-adjustment programs. *Id.* at 674 (quoting *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987)). The conflict is particularly stark in light of HHS's repeated refusal to permit unilateral adjustments to the federal program's methodology, even after considering the same arguments New York now claims justify the regulation. Whatever the Superintendent's reasons for circumventing federal procedures, the Constitution dictates that the federal approach controls "[e]ven where federal and state statutes have a common goal." *Clean Air Mkts. Grp. v. Pataki*, 338 F.3d 82, 87 (2d Cir. 2003).

Third, by confiscating funds the Secretary has determined must go to issuers such as Plaintiffs, the challenged regulation "frustrates the deliberate purpose of Congress to ensure that" issuers get what they have coming to them under a *federally* approved risk-adjustment methodology. *Hillman v. Maretta*, 569 U.S. 483, 494 (2013) (internal quotation marks omitted). That not only usurps the Secretary's authority, it also threatens the close coordination HHS has found is needed between risk adjustment and other ACA-mandated programs. The Supremacy Clause does not countenance that kind of interference.

C. The Superintendent's principal response to these insuperable problems is to claim that HHS somehow has authorized the challenged regulation. It has not, and it could not. The ACA requires the Secretary to implement a risk-adjustment program in New York according to *federal* "criteria and methods." That unambiguous command is not subject to interpretation—let alone in commentary sprinkled through preambles in rulemaking notices. *See Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1979 (2016). Nor has the Superintendent identified the kind of reasoned explanation that would be required before HHS could depart from its long-held view that the ACA requires substantive Federal oversight of the risk adjustment process. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016). And even if the statute's text did not foreclose the Superintendent's argument, the extensive procedural and substantive requirements for implementing risk-adjustment methodologies cannot reasonably be construed to sanction New York's program. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012). So even if the Secretary had approved the challenged regulation—and he has not—that approval would be due no deference in this Court.

II. Finally, the district court unquestionably had subject-matter jurisdiction over Plaintiffs' claims. This Court has long recognized that a private right of action is not needed to invoke a federal court's equity jurisdiction to enjoin enforcement of preempted state regulations. *NextG Networks of NY, Inc. v. City of New*

York, 513 F.3d 49, 53 n.4 (2d Cir. 2008); *see E. Hampton Airport*, 841 F.3d at 144; *Ex parte Young*, 209 U.S. at 155-156. The variety of enforcement mechanisms in the ACA—from the power to reject a State's request to run a risk-adjustment program or to certify a methodology, to civil penalties and sanctions—and the Act's straightforward requirements, refute any suggestion that Congress meant to limit that authority. And even if there could be any doubt, Plaintiffs' facial takings and exaction claims, brought under 42 U.S.C. § 1983, independently assured the district court's jurisdiction. *See Yee v. City of Escondido*, 503 U.S. 519, 534 (1992).

ARGUMENT

I. NEW YORK'S RISK-ADJUSTMENT PROGRAM IS PREEMPTED.

"It is basic that the supremacy clause of the Constitution 'invalidates state laws that interfere with or are contrary to, the laws of congress . . . .' " *Resolution Tr.*, 45 F.3d at 674 (quoting *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981)). "[T]he question whether a certain state action is preempted by federal law is one of congressional intent." *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 208 (1985). Preemption "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *de la Cuesta*, 458 U.S. at 152-153. "Even where Congress has not completely displaced state regulation in a specific area, state law is nulli-

fied to the extent that it actually conflicts with federal law." *Id.* at 153. Those principles decide this case.[2]

A. The ACA Preempts State Laws That Parallel The Act's Requirements Without Federal Permission.

As Plaintiffs explained below, the ACA expressly preempts state efforts to implement *any* risk-adjustment program absent federal approval. Congress made that clear in the exception in the statute's saving clause for laws that "prevent the application of the [ACA's] provisions" and the requirement that the Secretary implement the Act's requirements if no state program is approved. 42 U.S.C. § 18041(d); *see id.* § 18041(c)(1). The district court mistakenly assumed that "complementary" state regulations do not implicate these strictures. In fact, the statute's text and structure evince an unmistakable intent to preempt even ostensibly nonconflicting state laws that parrot the Act's requirements without federal permission.

This should be beyond debate. The Supreme Court analyzed a nearly identical statutory scheme in *Gade v. National Solid Wastes Management Association*

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[2] The district court correctly recognized that Plaintiffs' takings and exaction claims are premised on their argument that the ACA precludes the State from seizing their risk adjustment payments. JA176; *see infra*, Pt. II.C.3. And the Superintendent did not dispute that Plaintiffs would be entitled to judgment on the merits of those claims if the court agreed with Plaintiffs' preemption arguments. *See* ECF No. 39, at 30-32. The preemption arguments made throughout this brief therefore apply to both sets of claims equally.

and held that the scheme "unquestionably" preempted even "supplement[al]" state regulation. 505 U.S. at 97 (O'Connor, J., plurality op.) (internal quotation marks omitted); *accord id.* at 112-113 (Kennedy, J., concurring); *see Steel Inst. of New York v. City of New York*, 716 F.3d 31, 36-38 (2d Cir. 2013). *Gade* involved the federal Occupational Safety and Health Act (OSH Act), which "authorizes the Secretary of Labor to promulgate federal occupational safety and health standards." 505 U.S. at 92. The statute invites any State that wishes to "assume responsibility for development and enforcement" of its own, state-law rules regarding issues covered by federal standards to "submit a State plan for the development of such standards and their enforcement" for federal approval. 29 U.S.C. § 667(b).

Like the Superintendent here, the petitioner in *Gade* claimed that a State was not required to seek permission for state laws that merely "supplement" the federal standards, without taking responsibility for enforcement. 505 U.S. at 99 (O'Connor, J., plurality op.). The Court rejected that contention, holding that the Act " 'unquestionably' pre-empts" state efforts to regulate in areas subject to federal standards without federal permission, even when those efforts parallel federal enforcement. *Id.* at 97 (O'Connor, J., plurality op.); *accord id.* at 112-113 (Kennedy, J., concurring).

"The principal indication that Congress intended to preempt state law" was the requirement that "a State 'shall' submit a plan if it wishes to 'assume responsi-

bility' for" a particular issue. *Id.* at 99 (O'Connor, J., plurality op.). "The unavoidable implication of" that requirement, the Court concluded, "is that a State may not enforce its own . . . standards without obtaining the Secretary's approval." *Id.*; *accord id.* at 112-113 (Kennedy, J., concurring). "To allow a State selectively to 'supplement' certain federal regulations with ostensibly nonconflicting standards," the Court explained, "would be inconsistent with this federal scheme of establishing uniform federal standards, on the one hand, and encouraging States to assume full responsibility for development and enforcement of their own OSH programs, on the other." *Id.* at 103 (O'Connor, J., plurality op.).

The indicia of preemptive intent are, if anything, stronger with the ACA. First, the ACA *requires* the HHS Secretary to promulgate rules that implement the Act's provisions. *See* 42 U.S.C. § 18041(a)(1). Unlike with the OSH Act, there is no aspect of the ACA's requirements "as to which no federal standard is in effect." *Gade*, 505 U.S. at 100 (O'Connor, J., plurality op.). Second, rather than inviting States to develop their own standards once they assume jurisdiction over one of those requirements, the ACA requires States to "adopt and have in effect" either "the Federal standards established" by the Secretary, or a state law that "implements *th[ose] standards*" to the Secretary's satisfaction. 42 U.S.C. § 18041(b) (emphasis added). If a State fails to secure approval for its standards or otherwise conform to the regulations, "the Secretary shall take such actions as are necessary

to implement [the ACA's] requirements," *id.* at § 18041(c)(1), and the State must "forgo implementation of all State functions" set forth in the risk-adjustment regulations. 45 C.F.R. § 153.310(a)(2)-(4).

Gade teaches that the "unavoidable implication" of such statutory language is that States may not implement their own standards with respect to matters regulated by the ACA "without obtaining the Secretary's approval"—even if they stop short of taking on the task of running a risk-adjustment program. *Gade*, 505 U.S. at 99 (O'Connor, J., plurality op.); *accord id.* at 112-113 (Kennedy, J., concurring); *see also Boyes v. Shell Oil Prods. Co.*, 199 F.3d 1260, 1268 (11th Cir. 2000) (applying *Gade*'s reasoning to the Resource Conservation and Recovery Act, 42 U.S.C. § 6991c(d)(2)).

The *Gade* Court found confirmation for its reading of the OSH Act in that statute's saving clause, which preserves state jurisdiction over "any . . . issue with respect to which *no* [federal] standard is in effect." 29 U.S.C. § 667(a) (emphasis added). The Court explained that this "preservation of state authority in the absence of a federal standard *presupposes a background pre-emption* of all state occupational safety and health standards whenever a federal standard governing the same issue *is* in effect." *Gade*, 505 U.S. at 100 (O'Connor, J., plurality op.) (emphases added); *accord id.* at 112-113 (Kennedy, J., concurring).

Once again, the ACA's provisions compel the same inference. The Act saves "any State law that does not prevent the application of the provisions of this title." 42 U.S.C. § 18041(d). Because States may not "apply the [ACA's] requirements" without federal authorization, *id.* § 18041(b); *see* 45 C.F.R. § 153.310(a)(2)-(4), the statute's reservation of state authority to act on matters not covered by the ACA's provisions necessarily presupposes a background preemption of state laws that parallel the Act's requirements without federal approval, just as *Gade* held.

The *Gade* Court also found persuasive the fact that the OSH Act imposed requirements on the development of the federal regulations against which state laws are assessed. The ACA is no different. If, for example, States could impose parallel regulations that did not exactly replicate the standards developed through the Act's mandatory consultation process, "the protections that [the ACA] offers" to key stakeholders such as issuers and consumers "would easily be undercut." *Gade*, 505 U.S. at 100-101 (O'Connor, J., plurality op.); *accord id.* at 113 (Kennedy, J., concurring); *see* 42 U.S.C. §§ 18041(a)(2), 18063(b). Likewise, the Secretary's authority to reject a State's request to carry out a risk-adjustment program would mean little if a State could simply ignore the Secretary's determination and proceed with its own program. *See* 42 U.S.C. § 18041(c); *cf. Gade*, 505 U.S. at 101; *accord id.* at 113 (Kennedy, J., concurring). "Statutory enactments should"

always "be read so as to give effect, if possible, to every clause and word of a statute." *United States v. Kozeny*, 541 F.3d 166, 171 (2d Cir. 2008) (internal quotation marks omitted). Reading the ACA to permit unauthorized state "complements" to the federal standards would violate that basic principle.

Gade's reasoning controls this case. It is undisputed that New York has not sought to assume jurisdiction over the risk-adjustment program required by the ACA. *See* 42 U.S.C. § 18041(b). The State has not "adopt[ed]" and it does not "ha[ve] in force" either the federal risk-adjustment standards developed by the Secretary or any "State law or regulation that the Secretary [has] determine[d] implements the standards within the State." *Id.* Yet New York's risk-adjustment regulation purports to do exactly what the ACA requires: it subjects ACA-covered health insurance plans to a risk-adjustment program. The challenged regulation applies to the *same* issuers in the *same* individual and small-group health insurance markets as the federal program does. *Compare* 42 U.S.C. § 18063(c), *with* 11 N.Y.C.R.R. §§ 361.9(a)(5), 361.10(a)(1). Even setting aside the unavoidable conflict between the programs, *see infra* Pt. II.B, the challenged regulation cannot stand.

To be sure, the *Gade* majority could not agree whether the "unavoidable implication" of the OSH Act's text and structure gave rise to "express" or "implied" preemption. *See Gade*, 505 U.S. at 99, 104 n.2 (O'Connor, J., plurality op.); *accord id.* at 112-113 (Kennedy, J., concurring). But the majority was united in the

view that this distinction made no difference. Although "[f]requently, the pre-emptive 'label' we choose will carry with it substantive implications for the scope of preemption," Justice O'Connor's plurality opinion explained that the "disagreement . . . as to whether the OSH Act's pre-emptive effect is labeled 'express' or 'implied' is less important than our agreement that the implications of the text of the statute evince a congressional intent to pre-empt nonapproved state regulations when a federal standard is in effect." *Id.* at 104 n.2 (O'Connor, J., plurality op.).[3] So too here.

Just as in *Gade*, the ACA's text and structure prohibit States from selectively supplementing the Act's comprehensive scheme with "ostensibly nonconflicting standards" unless they first seek federal permission. *Id.* at 103 (O'Connor, J., plurality op.). That prohibition is sufficiently obvious on the statute's face to find express preemption. After all, courts "do not require Congress to employ a particular linguistic formulation when preempting state law." *Coventry Health Care of Missouri, Inc., v, Nevils*, 137 S. Ct. 1190, 1199 (2017); *see Gade*, 505 U.S. at 112 (Kennedy, J., concurring) ("[W]e have never required any particular magic words in our express pre-emption cases."). The combination of the ACA's comprehen-

[3] Justice O'Connor quipped that "[t]he Court's previous observation that our pre-emption categories are not 'rigidly distinct,' is proved true by this case." *Gade*, 505 U.S. at 104 n.2 (O'Connor, J., plurality op.) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79, n.5 (1990)).

sive regulatory scheme, its demanding requirements for state participation, and its saving clause plainly "manifests [Congress's] intent to preempt state law." *Nevils*, 137 S. Ct. at 1199. But even if there was some ambiguity, the statutory text is indisputably sufficient to support implied preemption. Either way, the result is the same and compels reversal and remand with instructions to enter judgment on all of Plaintiffs' claims.

B. The Challenged Regulation Impermissibly Conflicts With The Federal Risk-Adjustment Program.

Even if *Gade* did not decide this case, "state law is nullified to the extent that it actually conflicts with federal law." *de la Cuesta*, 458 U.S. at 153. That can happen "when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," or when a state law "interferes with the methods by which the federal statute was designed to reach its goal." *Resolution Tr.*, 45 F.3d at 674 (internal quotation marks and brackets omitted). This case presents both problems.

To discern a conflict, courts "consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written." *Jones v. Rath Packing Co.*, 430 U.S. 519, 526 (1977). As Judge Friendly put it, courts "must . . . examine not only the precise language of the [statute] but also the regulations issued and actions taken thereunder to determine whether an irreconcilable conflict has arisen." *Swift & Co. v. Wickham*, 230 F. Supp. 398, 408

(S.D.N.Y. 1964), *aff'd*, 364 F.2d 241 (2d Cir. 1966). Although courts are "more deferential where a state is exercising its traditional police powers," the " 'relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of our Constitution provided that the federal law must prevail.' " *Resolution Tr. Corp.*, 45 F.3d at 675 (quoting *de la Cuesta*, 458 U.S. at 153).[4]

The challenged regulation conflicts with the ACA and its implementing regulations in three distinct ways, each of which independently warrants reversing the district court's judgment and remanding with instructions to enter judgment on Plaintiffs' behalf on all claims. *First*, by effectively replacing the federal risk-adjustment program with an unauthorized state alternative, the challenged regulation prevents the HHS Secretary from carrying out his statutory responsibility to implement the Act's requirements in New York. *Second,* the challenged regulation

[4] Relying on *United States Department of Treasury v. Fabe*, 508 U.S. 491 (1993), this Court has said that state insurance laws "do not yield to conflicting federal statutes unless a federal statute specifically requires otherwise." *Wadsworth v. Allied Prof'ls Ins. Co.*, 748 F.3d 100, 105 (2d Cir. 2014) (quoting *Fabe*, 508 U.S. at 507). But the clear-statement rule *Fabe* cited was the McCarran-Ferguson Act's exception for federal laws that "specifically relate[] to the business of insurance"—the Court did not suggest any additional preemption hurdle for such laws. 15 U.S.C. § 1012(b). Because there can be no serious dispute that the ACA is such a law, the *Fabe* standard has no application here. *Barnett Bank of Marion Cty., N.A. v. Nelson*, 517 U.S. 25, 41 (1996) (noting that McCarran-Ferguson does not apply where the federal law "refers specifically to insurance," and "[i]ts state regulatory implications are not surprising," or "inadvertent").

frustrates Congress's objective to ensure substantive federal oversight of risk-adjustment programs in the States' individual and small-group insurance markets. *Third*, by taking funds away from those issuers entitled to them under a federally approved methodology, the challenged regulation impermissibly reallocates a benefit Congress intended those issuers to receive.

1. The Challenged Regulation Prevents The Secretary From Applying The ACA's Provisions.

In States, such as New York, that have not sought and obtained federal approval to operate a risk-adjustment program, the Secretary is responsible not only for developing the risk-adjustment methodology and rules, but for applying them, as well. *See* 42 U.S.C. § 18041(c); 45 C.F.R. § 153.310(a)(3)-(4). The challenged regulation thwarts the Secretary's exercise of that statutory duty by effectively replacing the program with an unauthorized state-law alternative. Because the ACA preempts state laws that "prevent the application of [the Act's] provisions," it plainly bars the challenged regulation. 42 U.S.C. § 18041(d).

The district court thought that the challenged regulation posed no conflict with the ACA because it was "a separate risk adjustment program." JA166. There is no such thing. When two or more risk-adjustment programs apply to the same players in the same market, the one that applies last in time is the only one that matters. That is because risk adjustment spreads the cost of insuring less-healthy

enrollees by adjusting each insurer's bottom line. At the end of the day, the figure on that bottom line will represent whichever payments or charges were levied last.

The district court acknowledged that the challenged regulation "operates after the [federal program] has determined the adjustments to be made and after the payments are made using the federal methodology." JA165. But the court failed to appreciate that, by partially reversing the federal allocation of payments and charges in a particular market, the challenged regulation leaves the allocation where *New York* would have it, thereby nullifying the federal program. Indeed, under the district court's reasoning, New York would be free to reverse *all* of the federal distribution, making it as though Congress's mandate had never been carried out at all. The Supremacy Clause forbids that result. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000).

That conflict would be fatal even if the challenged regulation could somehow be read to fit within the ACA's saving clause. The Supreme Court "has repeatedly declined to give broad effect to savings clauses where doing so would upset the careful regulatory scheme established by federal law." *Id.* at 870 (internal quotation marks and brackets omitted) (collecting cases). It is highly unlikely that "Congress intended to undermine this carefully drawn statute through a general saving clause." *Ouellette*, 479 U.S. at 494. And Congress' express exception for state laws that "prevent the application of the [ACA's] provisions" strongly sug-

gests that it did not intend to save state laws that undercut the purposes of the Act. 42 U.S.C. § 18041(d).

2. The Challenged Regulation Frustrates Federal Oversight Of Risk Adjustment In ACA-Covered Markets.

The challenged regulation also "interferes with the methods" Congress and the Secretary selected to ensure an effective risk-adjustment program in every State's individual and small-group insurance markets. *See Resolution Tr. Corp.*, 45 F.3d at 674 (quoting *Ouellette*, 479 U.S. at 494); *de la Cuesta*, 458 U.S. at 153 ("[R]egulations have no less pre-emptive effect than federal statutes . . . .").

The centerpiece of any risk-adjustment program is its methodology—the complex set of formulas, assumptions, and policy judgments that determine the credits and liabilities of issuers in a given market. *See* 45 C.F.R. § 153.20. As part of the Secretary's statutory responsibility to provide "substantive Federal oversight of the risk adjustment process," 2011 Standards, 76 Fed. Reg. 41,939, the Secretary has determined 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) (emphasis added). The HHS-developed methodology that currently applies in New York's markets was initially formulated over nearly two years of extensive consultation with States and other stakeholders, including health insurance companies, providers, consumer and industry advocacy groups, employers, state agencies, and individuals. *See* JA63-64. HHS explains

that its methodology "is based on the premise that premiums should reflect the differences in plan benefits, quality, and efficiency – not the health status of the enrolled population." JA128. A State concerned that this methodology does not fully account for local variations may submit "[a]n alternate risk adjustment methodology" for approval. 45 C.F.R. § 153.320(a)(1)-(2). But HHS subjects such alternative proposals to searching scrutiny in light of its technical expertise and the Act's broader policies. *See supra* pp. 8-9.

The express purpose and effect of the challenged regulation is to dispense entirely with this carefully reticulated scheme. The challenged regulation claims that "the calculations for the Federal Risk Adjustment Program do not take into account certain factors, resulting in unintended consequences." 11 N.Y.C.R.R. § 361.9(a)(2). But rather than proposing an alternative methodology for HHS approval in accordance with the procedures designed for that purpose, New York has chosen to reallocate the payments and charges determined under HHS's methodology, based on a percentage "determined by the Superintendent" unilaterally. *Id.* § 361.9(e)(1).

New York's end-run around the requirement of federal certification impermissibly obstructs two different and "important means-related federal objectives." *Geier*, 529 U.S. at 881. *First*, it frustrates the statutory objective of addressing the problem of adverse selection in state markets for individual and small-group health

insurance pursuant to uniform "criteria and methods" developed through stakeholder consultation and notice-and-comment rulemaking, "thereby upsetting the balance of public and private interests so carefully addressed by the Act." *Ouellette*, 479 U.S. at 494. Indeed, the challenged regulation has no provision for public consultation at all and does not even disclose (to the Secretary or anyone else) the Superintendent's methodology.

Second, the challenged regulation "circumvent[s]" the comprehensive regulatory procedures for vetting and approving a risk-adjustment methodology. *Id.* By "adjusting" the federal risk-adjustment program unilaterally, the challenged regulation bypasses the process established by the Secretary for ensuring that the methodology used to adjust risks in these markets is supported by data and carefully vetted by experts at HHS.

The Superintendent has suggested that she satisfied the ACA's procedures by discussing the challenged regulation with HHS personnel. *See, e.g.*, Doc. 41, at 9-10, 14. That is clearly not sufficient. The federal rules set forth a process for making changes to a risk-adjustment methodology and it is indisputable that New York has not followed them. Indeed, the Superintendent's briefing below conceded that "the Emergency Regulation was adopted wholly outside of the ACA-Risk Adjustment Program." Def.'s Opp. to Cross-Mot. for Summ. J., ECF No. 39, at 27-28.

Similarly misplaced is the Superintendent's contention that the challenged regulation "supports the ultimate purpose" of the ACA by addressing perceived shortcomings in the federally certified methodology—a claim Plaintiffs vigorously dispute. *Clean Air Mkts. Grp.*, 338 F.3d at 87. "Even where federal and state statutes have a common goal, a state law will be preempted 'if it interferes with the *methods* by which the federal statute was designed to reach this goal.' " *Id.* (quoting *Ouellette*, 479 U.S. at 494). Whatever the "reasons to favor a different policy," what matters is "the judgment *Congress* made." *Hillman*, 569 U.S. at 494-495 (emphasis added).

The extent of the conflict is confirmed here by the fact that HHS has expressly addressed the very same concerns the Superintendent claims justify the challenged regulation and rejected New York's proposed solution. As explained above, the agency has acknowledged complaints from "[c]ertain States" that the federal risk-adjustment methodology "does not take into account the effect of State-specific laws and rating rules," and "in some circumstances may not precisely account for risk differences for their particular State"—the very same claims the Superintendent makes now. *See* 2019 Payment Parameters, 83 Fed. Reg. 16,956.

Rather than open the door to a patchwork of unilateral adjustments and exceptions to its carefully calibrated risk-adjustment methodology, however, HHS implemented a solution that steadfastly maintains its policy of demanding federal

scrutiny. Under that solution, beginning in 2020, the agency will let States "*request* a reduction to the otherwise applicable risk adjustment transfers" of "up to 50 percent," even if they have not elected to operate their own risk-adjustment programs. *Id.* (emphasis added). To qualify, States will need to provide "evidence and analysis demonstrating the State-specific factors that warrant an adjustment." 45 C.F.R. § 153.320(d)(1)(i). HHS will not defer to the States' contrary assessment of factors already "addressed by the current HHS risk adjustment methodology." 2019 Payment Parameters, 83 Fed. Reg. at 16,958. And the agency retains exclusive discretion to approve, adjust, or deny a requested reduction. 45 C.F.R. § 153.320(d)(4).

The Secretary's deliberate choice to require HHS scrutiny and approval even while granting States limited additional flexibility confirms yet again that the intricate requirements for federal certification are central to the regulatory scheme and to the Secretary's understanding of his statutory duty. New York may not undercut "the accomplishment of [such] a significant federal regulatory objective." *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 330 (2011) (internal quotation marks omitted).

3. The Challenged Regulation Unilaterally Displaces The ACA's Risk-Adjustment Allocation.

In addition to usurping the Secretary's supervisory authority, the challenged regulation also conflicts with the federal risk-adjustment program in a more basic

way. Applying the methodology HHS developed through notice-and-comment rulemaking in consultation with key stakeholders, the Secretary has determined and published the amount that each insurer in New York's individual and small-group health insurance markets must pay or is entitled to receive for the 2017 benefit year. *See, e.g.*, JA134-135. The challenged regulation "interferes with Congress' scheme, because it directs that" these risk-adjustment payments "actually 'belong' to someone other than" the issuers HHS's federally certified risk-adjustment methodology has determined must receive them. *Hillman*, 569 U.S. at 494.

The challenged regulation directs "every carrier in the small group health insurance market that is designated as a receiver of a payment transfer from the Federal Risk Adjustment Program [to] remit" a "percentage of that payment transfer" to the Superintendent. 11 N.Y.C.R.R. § 361.9(e)(1). It then directs the Superintendent to return that money to "every carrier in the small group health insurance market that is designated as a payor of a payment transfer into the Federal Risk Adjustment Program." *Id.* at § 361.9(e)(2)(i). The end result is that issuers the Secretary has determined need a particular sum in order to counter the effects of adverse selection will, in fact, receive some fraction of that amount—70% for the 2017 plan year and 74% for 2018. *See* 11 N.Y.C.R.R. §§ 361.9(e)(1), 361.10(g)(1)(i).

The Supreme Court has held time and again that States may not reduce or redirect federally conferred benefits in this way. In *Hillman*, for example, the Court held that proceeds owed to a beneficiary named under the Federal Employee Group Life Insurance Act (FEGLIA) "cannot be allocated to another person by operation of state law." 569 U.S. at 497.[5] The Virginia statute challenged in that case provided that a divorce or annulment revoked any life-insurance beneficiary designation in favor of the insured's former spouse. *Id.* at 488. In the event that revocation was preempted, the statute made the named beneficiary personally liable to the insured's state-law heirs for the amount of any insurance proceeds.

The Court explained that FEGLIA's procedures for naming a beneficiary and distributing benefits to that person meant Congress intended "that the proceeds *belong* to the named beneficiary and no other." *Id.* at 494 (internal quotation marks omitted). The Court recognized the strong presumption against preemption

[5] *See also, e.g.*, *Boggs v. Boggs*, 520 U.S. 833, 843 (1997) (Louisiana testamentary transfer conflicted with "ERISA's solicitude for the economic security of surviving spouses"); *McCarty v. McCarty*, 453 U.S. 210, 233 (1981) (California community property law impermissibly "diminish[ed]" military retirement "benefit Congress has said should go to the retired service member alone") (internal quotation marks and brackets omitted); *Ridgway v. Ridgway*, 454 U.S. 46, 56 (1981) (Maine constructive trust conflicted with "the breadth of the freedom of choice accorded the service member under the [Servicemen's Group Life Insurance Act]" to select a beneficiary); *Wissner v. Wissner*, 338 U.S. 655, 658 (1950) (California community property law conflicted with aim of "affording a uniform and comprehensive system of life insurance for members and veterans of the armed forces" under National Service Life Insurance Act of 1940)

that applies to state laws regarding domestic relations. *See id.* at 491. But it had no trouble concluding that the Virginia law impermissibly "interfere[d] with Congress' scheme, because it direct[ed] that the proceeds actually 'belong' to someone other than the named beneficiary." *Id.* at 494. "It ma[de] no difference" whether Virginia required the transfer of the proceeds or created a cause of action for their recovery. *Id.* "In either case, state law displaces" the person federal law entitles to the proceeds. *Id.* Just so here.

Through the authority vested in the HHS Secretary under the ACA, Congress has directed that risk-adjustment payments "belong" to the issuers identified through a federally approved risk-adjustment methodology. Just like the Virginia statute in *Hillman*, the challenged regulation "frustrates the deliberate purpose of Congress to ensure that" the issuers receive the transfers to which they are entitled under federal law. *Id.* (internal quotation marks omitted). And, just as in *Hillman*, it makes no difference that New York confiscates the federal risk-adjustment payments from issuers after HHS has made them. *See id.*; *Boggs*, 520 U.S. at 842 (rejecting the argument that state-law claims did not implicate ERISA because they "affect[ed] only the disposition of plan proceeds after they have been disbursed"). Nor does it matter that New York intends to confiscate only a portion of the payment to which the ACA entitles certain plans. *See Boggs*, 520 U.S. at 844. The point is that "States are not free to change [the ACA's] structure and balance." *Id.*

If anything, the conflict here is even more direct for two reasons. *First*, the challenged regulation displaces an expert designation made by a federal agency with mandatory input from key stakeholders and the public—not just a private designation made through federal procedures, as in *Hillman*.

Second, the consequences of New York's unilateral reallocation have far broader implications than who gets the proceeds of a life insurance policy. The allocation of credits and liabilities under the federal risk-adjustment program has secondary effects that interfere with other aspects of the statutory scheme. Thus, for example, HHS has found that "risk adjustment must be coordinated with reinsurance and risk corridors"—two other ACA programs that address adverse selection—"to help stabilize the individual and small group markets and ensure the viability of the Exchanges." 2011 Standards, 76 Fed. Reg. 41,938. And it has noted that "risk adjustments affect calculations of both risk corridors and the rebates specified under [42 USC § 300gg-18]." *Id.* The challenged regulation impermissibly disrupts the careful balance Congress and the Secretary have established. That is a textbook example of an irreconcilable conflict.

C. HHS Has Not Authorized And Could Not Authorize New York's Unilateral Confiscation Of Federal Disbursements

The Superintendent also has claimed that there is no preemptive conflict because HHS approved New York's unilateral "adjustment to federal risk adjustment," JA190, in various statements encouraging States to adopt their own solu-

tions to any unintended consequences of the federal program. The Superintendent is mistaken. Although HHS has said that States need not seek federal approval to compensate for the *effects* of transfers made under the federal risk-adjustment methodology, it has expressly rejected calls to let States unilaterally alter the amounts of those transfers. *See supra* pp. 9-12.

The Secretary's consistent position is not only good policy, it is compelled by law. "Even assuming, *arguendo,* that the preamble to [an] agency's rulemaking could be owed *Chevron* deference," courts "do not defer to the agency when the statute is unambiguous." *Kingdomware*, 136 S. Ct. at 1979. There is no dispute in this case that the statute obligates the Secretary to "take such actions as are necessary to implement" a risk-adjustment program in New York in accordance with federal "criteria and methods." 42 U.S.C. §§ 18041(c)(1), (a)(1)(D); 18063(b). And there is no reasonable interpretation of that congressional command that would allow the Secretary effectively to cede the implementation of a risk-adjustment program in New York's individual and small-group insurance markets to the Superintendent with no supervision, in blatant disregard of those criteria and methods. So even if the Secretary himself had urged this Court to accept the Superintendent's claim—and he has not—that argument would be entitled to no deference.

Nor can the Superintendent's claim be squared with the Secretary's interpretation of the statute "to require *substantive* Federal oversight of the risk adjustment process." 2011 Standards, 76 Fed. Reg. 41,939 (emphasis added). Agencies may not alter their existing policies with no "reasoned explanation for the change." *Encino Motorcars*, 136 S. Ct. at 2125 (internal quotation marks and brackets omitted). "[A]n unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice" that "receives no *Chevron* deference." *Id.* at 2126 (internal quotation marks and brackets omitted). There is no reasonable understanding of the Secretary's prior interpretation of the ACA that could countenance giving the Superintendent *carte blanche* to develop her own methodology—with no input from anyone—and use it to roll back the allocation required by the federal methodology. So even if the Secretary were to approve New York's program—and, again, he has not—that would be an about-face from the agency's prior position. Without a coherent explanation for such a radical change, the Superintendent's preferred interpretation would be due no deference.

Even setting aside the statutory text and the Secretary's prior interpretations of it, the federal risk-adjustment regulations are themselves unequivocal: they require 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) (emphasis added). And they impose a raft of procedural and substantive constraints on obtaining certification for alternative methodologies. The challenged regulation bypasses those constraints to impose the Superintendent's own methodology on New York's markets, to the exclusion of the federal methodology. It would make no sense for the Secretary to promulgate detailed procedures for obtaining federal approval for alternative risk-adjustment methodologies while simultaneously encouraging States to flout those procedures by making the very same kinds of modifications unilaterally. An interpretation that allowed such an obvious conflict would be so plainly "inconsistent with the regulation" that deference would "undoubtedly" be "inappropriate." *SmithKline Beecham*, 567 U.S. at 155 (internal quotation marks omitted).

In any event, the Superintendent reads too much into the commentary on which she relies. The Superintendent leans heavily on HHS's answer to a comment on the rule discussed above that will permit States to seek limited reductions in the amount of the risk-adjustment transfers in certain markets starting in 2020, subject to HHS review and approval. *See supra* pp. 10-12, 37-38. "A few commenters noted that New York ha[d] already taken action to reduce transfers under the State's authority," in the form of the challenged regulation. 2019 Payment Parameters, 83 Fed. Reg. 16,960. "One commenter noted that the New York adjustment could be seen as permitting States to make adjustments without HHS approv-

al 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." *Id.* HHS responded that:

> 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 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. (emphases added).

The district court thought that this passage expressed an endorsement of New York's program. But neither the wording of that statement nor its context supports that interpretation. That is not surprising; agencies do not normally make preemption determinations in passing responses to comments in a rulemaking prooceding. What HHS's comment actually says is that, although "local approaches under State legal authority" that "help ease the transition for new participants to the health insurance markets" do not need approval, "the flexibility finalized in this rule [*i.e.*, the federal rule being finalized in that notice] involves a reduction to the risk adjustment transfers calculated by HHS and will require HHS review" and approval. *Id.* Understood in light of the agency's longstanding requirement of "substantive Federal oversight," 2011 Standards, 76 Fed. Reg. 41,939, that passage

clarifies that reductions to the risk-adjustment transfers calculated by HHS require federal approval.

II. THE DISTRICT COURT HAD SUBJECT-MATTER JURISDICTION OVER PLAINTIFFS' CLAIMS.

Although the district court misapplied the preemption doctrines that control the merits of this case, it properly concluded that it had subject-matter jurisdiction over Plaintiffs' claims. The Superintendent has nevertheless persisted in contending that Plaintiffs lack a "private right of action" here. *See, e.g.*, Doc. 41 at 19-21. That argument ignores controlling principles of federal jurisdiction. This suit falls in the heartland of federal courts' long-recognized equity jurisdiction to enjoin enforcement of preempted state laws, and nothing in the ACA suggests that Congress meant to take the grave step of limiting federal courts' authority to hear such claims. And, in any event, Plaintiffs' takings and exaction claims provided a free-standing ground for jurisdiction over Plaintiffs' challenge.

A. Plaintiffs' Suit Falls Squarely Within Federal Equity Jurisdiction.

"The ability to sue to enjoin unconstitutional actions by state and federal officers is the creation of courts of equity, and reflects a long history of judicial review of illegal executive action, tracing back to England." *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1384 (2015). It has nothing to do with private rights of action. To the contrary, this Court has long recognized that "a private right of action is *not required* where a party seeks to enjoin the enforcement of

a local rule or regulation on the ground that the regulation is preempted by federal law." *NextG Networks of NY*, 513 F.3d at 53 n.4 (emphasis added); *see Ex parte Young*, 209 U.S. at 155-156. That is because "[a] claim under the Supremacy Clause that a federal law preempts a state regulation is distinct from a claim for enforcement of that federal law." *W. Air Lines, Inc. v. Port Auth. of N.Y. & N.J.*, 817 F.2d 222, 225 (2d Cir. 1987).

"A claim under the Supremacy Clause simply asserts that a federal statute has taken away local authority to regulate a certain activity." *Id.* "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." *E. Hampton Airport*, 841 F.3d at 144. That is just what happened here.

Plaintiffs are threatened with the confiscation of a portion of the risk-adjustment payments to which they are entitled under federal law. They "seek to enjoin enforcement" of the challenged regulation on the grounds that it violates the text, structure, and purposes of the ACA and its implementing regulations. *Id.* at 144-145. "Such a claim falls squarely within federal equity jurisdiction . . . ." *Id.* at 145.

B. The ACA Does Not Limit Federal Courts' Equity Jurisdiction.

To be sure, a federal court's equitable jurisdiction to enjoin state laws on preemption grounds "is subject to express and implied statutory limitations." *Armstrong*, 135 S. Ct. at 1385; *see also E. Hampton Airport*, 841 F.3d at 144-145. But the Superintendent does not—and cannot—contend that Congress expressly barred health insurance issuers from asserting preemption as a defense to state regulations that subvert the ACA's purposes. Nor does the ACA implicitly foreclose this suit, as the district court correctly found.

The Supreme Court's decision in *Armstrong* is not to the contrary. In that case, the Court found that Congress did not intend private parties to enforce the reimbursement rates for medical service providers required under the Medicaid Act. "The Court located Congress's intent to foreclose such equitable relief in two aspects of the statute." *E. Hampton Airport*, 841 F.3d at 145. "First, federal statutory authority to withhold Medicaid funding was the sole remedy Congress provided for a State's failure to comply with Medicaid requirements." *Id.* (internal quotation marks omitted). "Second, even if the existence of" such 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." *Id.* (internal quotation marks and brackets omitted). The ACA does not raise either problem, let alone both.

Unlike the Medicaid Act, the ACA contains a range of administrative remedies for violations of the Act's requirements. As the district court observed, the ACA gives the HHS Secretary the authority to impose civil monetary penalties on plans or issuers. JA156-157; *see, e.g.*, 42 U.S.C. §§ 18041(c)(2); 300gg–22(b). The ACA also gives the Secretary the authority to disapprove a State's request to operate a risk-adjustment program or to refuse to certify a State's alternative methodology. *See* 42 U.S.C. § 18041(b)-(c); 45 C.F.R. § 153.310(d). That the ACA and regulations confer this authority on the Secretary, "and not on private parties, does not imply" that Congress intended to "bar such parties from invoking federal jurisdiction where, as here, they do so *not* to enforce federal law themselves, but to preclude a [state] entity from subjecting them to" preempted state regulation. *E. Hampton Airport*, 841 F.3d at 146 (emphasis added); *see* JA156-157. To the contrary, the statutory remedies are entirely consistent with Plaintiffs' request for an injunction barring New York's implementation of an unauthorized risk-adjustment program.

Nor are the relevant requirements here intricate or complex; "[t]he plaintiffs in this case are not asking the Court to evaluate New York State's risk adjustment program but simply to determine whether the [challenged regulation] is preempted by the ACA." JA158. The district court correctly concluded that the regulations "provide clear direction for a court" faced with that task. *Id.* The ACA plainly

sets forth the Secretary's exclusive authority to promulgate risk-adjustment standards and his obligation to administer the Act's requirements in non-electing States. *See* 42 U.S.C. § 18041(a), (c). The regulations are similarly straightforward in their requirement that States seek approval before operating a risk-adjustment program or applying a methodology other than the one designed by HHS. *See* 45 C.F.R. §§ 153.310(a), (d); 153.320; 153.330. Those are exactly the kinds of "simple rule[s]" this Court has held do not suggest that Congress intended to preclude private enforcement. *E. Hampton Airport*, 841 F.3d at 146.

C. In Any Event, Plaintiffs' Takings And Exaction Claims Assured The District Court's Jurisdiction.

Even if there could be any doubt that the ACA preserves courts' equitable jurisdiction to hear pre-enforcement challenges to preempted regulations, this Court has long recognized "the clear availability of declaratory relief for asserted Takings Clause violations." *In re Chateaugay Corp.*, 53 F.3d 478, 493 (2d Cir. 1995). The Declaratory Judgment Act "allows individuals threatened with a taking to seek a declaration of the constitutionality of the disputed governmental action before potentially uncompensable damages are sustained." *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 71 n.15 (1978); *see also, e.g.*, *Eastern Enters. v. Apfel*, 524 U.S. 498, 520-522 (1998) (O'Connor, J., plurality op.).

The district court found that Plaintiffs' takings and exaction claims, brought under 42 U.S.C. § 1983, were ripe at least with respect to the portions of the chal-

lenged regulation that apply to the 2017 plan year. JA171-174. That conclusion was correct. To be sure, a regulatory takings claim is ordinarily not ripe before the plaintiff "has both received a 'final decision regarding the application of the [challenged] regulations . . .' from 'the government entity charged with implementing the regulations' and sought 'compensation through the procedures the State has provided for doing so.' " *Suitum v. Tahoe Reg'l Planning Agency*, 520 U.S. 725, 734 (1997) (quoting *Williamson Cty. Reg'l Planning Comm'n v. Hamilton Bank of Johnson City*, 473 U.S. 172, 186, 194 (1985)). But that test does not apply to *facial* challenges to state laws, "which by their nature request[] relief distinct from the provision of 'just compensation.' " *San Remo Hotel, L.P. v. City & Cty. of San Francisco*, 545 U.S. 323, 345-346 (2005) (observing that such challenges may be brought "directly in federal court"); *see Yee*, 503 U.S. at 534.

Plaintiffs' preemption challenge easily fits the facial-claim exception. Plaintiffs' argument "does not depend on the extent to which [they] are deprived of" their federal funds "or the extent to which [Plaintiffs] are compensated." *Yee*, 503 U.S. at 534; *see, e.g.*, *Int'l Union of Operating Eng'rs Local 139 v. Schimel*, 863 F.3d 674, 679 (7th Cir. 2017) (applying the facial-claim exception); *Richardson v. City & Cty. of Honolulu*, 124 F.3d 1150, 1165 (9th Cir. 1997) (same).[6] Rather,

[6] Even if the "just compensation" prong applied to Plaintiffs' claims, this Court has explained in the analogous federal context that "where the challenged statute

Plaintiffs' argument is that *any* interference with the federal risk-adjustment program "goes too far" because the Supremacy Clause nullifies conflicting state laws. *See de la Cuesta*, 458 U.S. at 153. And the injunction Plaintiffs seek would bar the Superintendent from enforcing the challenged regulation altogether. *See John Doe No. 1 v. Reed*, 561 U.S. 186, 194 (2010) (a claim is "facial" where "it is not limited to plaintiffs' particular case, but challenges application of the law more broadly"). The takings and exaction claims thus clear *Williamson*'s "prudential hurdles" and offer an independent source of subject-matter jurisdiction. *Suitum*, 520 U.S. at 733-734.

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requires a person or entity to pay money to the government, it must be presumed that Congress had no intention of providing compensation for the deprivation." *Chateaugay*, 53 F.3d at 493. The same presumption applies here. And even if New York's procedures did apply, forcing Plaintiffs to pursue them before challenging a regulation that "requires a direct transfer of funds . . . would entail an utterly pointless set of activities." *Apfel*, 524 U.S. at 521 (O'Connor, J., plurality op.) (internal quotation marks omitted).

CONCLUSION

For the foregoing reasons, this Court should reverse the portion of the district court's decision granting the Superintendent's motion to dismiss and remand with instructions to grant summary judgment in Plaintiffs' favor on all claims, permanently enjoin the Superintendent from enforcing the challenged regulation, and award reasonable costs and attorneys' fees pursuant to 42 U.S.C. § 1988.

Respectfully submitted,

/s/ Neal Kumar Katyal
NEAL KUMAR KATYAL
EUGENE A. SOKOLOFF
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
neal.katyal@hoganlovells.com

Counsel for Plaintiffs-Appellants

STEVEN ROSENBAUM
COVINGTON & BURLING LLP
1 CityCenter
850 10th Street, NW
Washington, D.C 20001

December 10, 2018

ADDENDUM

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42 U.S.C. § 18041

§ 18041. State flexibility in operation and enforcement of Exchanges and related requirements

(a) Establishment of standards

(1) In general

The Secretary shall, as soon as practicable after March 23, 2010, issue regulations setting standards for meeting the requirements under this title, and the amendments made by this title, with respect to—

(A) the establishment and operation of Exchanges (including SHOP Exchanges);

(B) the offering of qualified health plans through such Exchanges;

(C) the establishment of the reinsurance and risk adjustment programs under part E; and

(D) such other requirements as the Secretary determines appropriate. The preceding sentence shall not apply to standards for requirements under subtitles A and C (and the amendments made by such subtitles) for which the Secretary issues regulations under the Public Health Service Act [42 U.S.C. 201 et seq.].

(2) Consultation

In issuing the regulations under paragraph (1), the Secretary shall consult with the National Association of Insurance Commissioners and its members and with health insurance issuers, consumer organizations, and such other individuals as the Secretary selects in a manner designed to ensure balanced representation among interested parties.

(b) State action

Each State that elects, at such time and in such manner as the Secretary may prescribe, to apply the requirements described in subsection (a) shall, not later than January 1, 2014, adopt and have in effect—

(1) the Federal standards established under subsection (a); or

(2) a State law or regulation that the Secretary determines implements the standards within the State.

(c) Failure to establish Exchange or implement requirements

(1) In general

If—

(A) a State is not an electing State under subsection (b); or

(B) the Secretary determines, on or before January 1, 2013, that an electing State—

(i) will not have any required Exchange operational by January 1, 2014; or

(ii) has not taken the actions the Secretary determines necessary to implement—

(I) the other requirements set forth in the standards under subsection (a); or

(II) the requirements set forth in subtitles A and C and the amendments made by such subtitles; the Secretary shall (directly or through agreement with a not-for-profit entity) establish and operate such Exchange within the State and the Secretary shall take such actions as are necessary to implement such other requirements.

(2) Enforcement authority

The provisions of section 2736(b) of the Public Health Services Act [42 U.S.C. 300gg–22(b)] shall apply to the enforcement under paragraph (1) of requirements of subsection (a)(1) (without regard to any limitation on the application of those provisions to group health plans).

(d) No interference with State regulatory authority

Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title.

(e) Presumption for certain State-operated Exchanges

(1) In general

In the case of a State operating an Exchange before January 1, 2010, and which has insured a percentage of its population not less than the percentage of the population projected to be covered nationally after the implementation of this Act, that seeks to operate an Exchange under this section, the Secretary shall presume that such Exchange meets the standards under this section unless the Secretary determines, after completion of the process established under paragraph (2), that the Exchange does not comply with such standards.

(2) Process

The Secretary shall establish a process to work with a State described in paragraph (1) to provide assistance necessary to assist the State's Exchange in coming into compliance with the standards for approval under this section.

42 U.S.C. § 18063

§ 18063. Risk adjustment

(a) In general

(1) Low actuarial risk plans

Using the criteria and methods developed under subsection (b), each State shall assess a charge on health plans and health insurance issuers (with respect to health insurance coverage) described in subsection (c) if the actuarial risk of the enrollees of such plans or coverage for a year is less than the average actuarial risk of all enrollees in all plans or coverage in such State for such year that are not self-insured group health plans (which are subject to the provisions of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1001 et seq.]).

(2) High actuarial risk plans

Using the criteria and methods developed under subsection (b), each State shall provide a payment to health plans and health insurance issuers (with respect to health insurance coverage) described in subsection (c) if the actuarial risk of the enrollees of such plans or coverage for a year is greater than the average actuarial risk of all enrollees in all plans and coverage in such State for such year that are not self-insured group health plans (which are subject to the provisions of the Employee Retirement Income Security Act of 1974).

(b) Criteria and methods

The Secretary, in consultation with States, shall establish criteria and methods to be used in carrying out the risk adjustment activities under this section. The Secretary may utilize criteria and methods similar to the criteria and methods utilized under part C or D of title XVIII of the Social Security Act [42 U.S.C. 1395w–21 et seq., 1395w–101 et seq.]. Such criteria and methods shall be included in the standards and requirements the Secretary prescribes under section 18041 of this title.

(c) Scope

A health plan or a health insurance issuer is described in this subsection if such health plan or health insurance issuer provides coverage in the individual or small group market within the State. This subsection shall not apply to a grandfathered health plan or the issuer of a grandfathered health plan with respect to that plan.

45 C.F.R. § 153.310

§ 153.310 Risk adjustment administration.

(a) *State eligibility to establish a risk adjustment program*. (1) A State that elects to operate an Exchange is eligible to establish a risk adjustment program.

(2) Any State that does not elect to operate an Exchange, or that HHS has not approved to operate an Exchange, will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

(3) Any State that elects to operate an Exchange but does not elect to administer risk adjustment will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

(4) Beginning in 2015, any State that is approved to operate an Exchange and elects to operate risk adjustment but has not been approved by HHS to operate risk adjustment prior to publication of its State notice of benefit and payment parameters for the applicable benefit year, will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

(b) *Entities eligible to carry out risk adjustment activities*. If a State is operating a risk adjustment program, the State may elect to have an entity other than the Exchange perform the State functions of this subpart, provided that the entity meets the standards promulgated by HHS to be an entity eligible to carry out Exchange functions.

(c) *State responsibility for risk adjustment*. (1) A State operating a risk adjustment program for a benefit year must administer the applicable Federally certified risk adjustment methodology through an entity that—

(i) Is operationally ready to implement the applicable Federally certified risk adjustment methodology and process the resulting payments and charges; and

(ii) Has experience relevant to operating the risk adjustment program.

(2) The State must ensure that the risk adjustment entity complies with all applicable provisions of subpart D of this part in the administration of the applicable Federally certified risk adjustment methodology.

(3) The State must conduct oversight and monitoring of its risk adjustment program.

(4) *Maintenance of records*. A State operating a risk adjustment program must maintain documents and records relating to the risk adjustment program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of the State-operated risk adjustment program's compliance with Federal standards. A State operating a risk adjustment program must also ensure that its contractors, subcontractors, and agents similarly maintain and make relevant documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity.

(d) *Approval for a State to operate risk adjustment*. (1) To be approved by HHS to operate risk adjustment under a particular Federally certified risk adjustment methodology for a benefit year, a State must establish that it and its risk adjustment entity meet the standards set forth in paragraph (c) of this section.

(2) To obtain such approval, the State must submit to HHS, in a form and manner specified by HHS, evidence that its risk adjustment entity meets these standards.

(3) In addition to requirements set forth in paragraphs (d)(1) and (2) of this section, to obtain re-approval from HHS to operate risk adjustment for a third benefit year, the State must, in the first benefit year for which it operates risk adjustment, provide to HHS an interim report, in a manner specified by HHS, including a detailed summary of its risk adjustment activities in the first 10 months of the benefit year, no later than December 31 of the applicable benefit year.

(4) To obtain re-approval from HHS to operate risk adjustment for each benefit year after the third benefit year, each State operating a risk adjustment program must submit to HHS and make public a detailed summary of its risk adjustment program operations for the most recent benefit year for which risk adjustment operations have been completed, in the manner and timeframe specified by HHS.

(i) The summary must include the results of a programmatic and financial audit for each benefit year of the State-operated risk adjustment program conducted by an independent qualified auditing entity in accordance with generally accepted auditing standards (GAAS).

(ii) The summary must identify any material weakness or significant deficiency identified in the audit and address how the State intends to correct any such material weakness or significant deficiency.

(e) *Timeframes*. A State, or HHS on behalf of the State, must implement risk adjustment for the 2014 benefit year and every benefit year thereafter. For each

benefit year, a State, or HHS on behalf of the State, must notify issuers of risk adjustment payments due or charges owed annually by June 30 of the year following the benefit year.

45 C.F.R. § 153.320

§ 153.320 Federally certified risk adjustment methodology.

(a) *General requirement*. Any risk adjustment methodology used by a State, or HHS on behalf of the State, must be a Federally certified risk adjustment methodology. A risk adjustment methodology may become Federally certified by one of the following processes:

(1) The risk adjustment methodology is developed by HHS and published in the applicable annual HHS notice of benefit and payment parameters; or

(2) An alternate risk adjustment methodology is submitted by a State in accordance with § 153.330, reviewed and certified by HHS, and published in the applicable annual HHS notice of benefit and payment parameters.

(b) *Publication of methodology in notices*. The publication of a risk adjustment methodology by HHS in an annual HHS notice of benefit and payment parameters or by a State in an annual State notice of benefit and payment parameters described in subpart B of this part must include:

(1) A complete description of the risk adjustment model, including—

(i) Factors to be employed in the model, including but not limited to demographic factors, diagnostic factors, and utilization factors, if any;

(ii) The qualifying criteria for establishing that an individual is eligible for a specific factor;

(iii) Weights assigned to each factor; and

(iv) The schedule for the calculation of individual risk scores.

(2) A complete description of the calculation of plan average actuarial risk.

(3) A complete description of the calculation of payments and charges.

(4) A complete description of the risk adjustment data collection approach.

(5) The schedule for the risk adjustment program.

(c) *Use of methodology for States that do not operate a risk adjustment program*. HHS will specify in the annual HHS notice of benefit and payment parameters for the applicable year the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

45 C.F.R. § 153.330

§ 153.330 State alternate risk adjustment methodology.

(a) *State request for alternate methodology certification*. (1) A State request to HHS for the certification of an alternate risk adjustment methodology must include:

(i) The elements specified in § 153.320(b);

(ii) The calibration methodology and frequency of calibration; and

(iii) The statistical performance metrics specified by HHS.

(2) The request must include 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.

(b) *Evaluation criteria for alternate risk adjustment methodology*. An alternate risk adjustment methodology will be certified by HHS as a Federally certified risk adjustment methodology based on the following criteria:

(1) The criteria listed in paragraph (a)(2) of this section;

(2) Whether the methodology complies with the requirements of this subpart D;

(3) Whether the methodology accounts for risk selection across metal levels; and

(4) Whether each of the elements of the methodology are aligned.

(c) *State renewal of alternate methodology*. If a State is operating a risk adjustment program, the State may not implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology without first obtaining HHS certification.

(1) Recalibration of the risk adjustment model must be performed at least as frequently as described in paragraph (a)(1)(ii) of this section;

(2) A State request to implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology must include any changes to the parameters described in paragraph (a)(1) of this section.

11 N.Y.C.R.R. § 361.9

§ 361.9. Market stabilization pools for the small group health insurance market for the 2017 plan year.

(a) (1) The superintendent has been assessing the Federal Risk Adjustment Program developed under the Federal Affordable Care Act and its impact on the health insurance market in this State. In its simplest terms, the Federal Risk Adjustment Program requires that carriers whose insureds or members have relatively better loss experience pay into the risk adjustment pool and those with relatively worse experience receive payment from that pool. The broad purpose of the risk adjustment program is to balance out the experience of all carriers.

(2) In certain respects, however, the calculations for the Federal Risk Adjustment Program do not take into account certain factors, resulting in unintended consequences. The department has been working cooperatively with the Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS) on risk adjustment. Recently, CMS has announced certain changes to the methodology. CMS has also stated that it will continue to review the methodology in the future.

(3) The Federal Risk Adjustment Program has led to a situation in which some carriers in this State are receiving large payments out of the risk adjustment program that are paid by other carriers. For many of these other carriers, the millions to be paid represent a significant portion of their revenue. The money transfers among carriers in this State under the Federal Risk Adjustment Program have been among the largest in the nation.

(4) CMS's changes and planned reviews are much appreciated and anticipated. The superintendent will continue to work with CMS and hopes that over time the Federal Risk Adjustment Program will be improved so that it fully meets its intended purposes. The Federal risk adjustment methodology as applied in this State does not yet adequately address the impact of administrative costs and profit of the carriers and how this State counts children in certain calculations. These two factors are identifiable, quantifiable and remediable for the 2017 plan year.

(5) This section applies only to risk adjustment experience in the small group health insurance market for the 2017 plan year to be applied to payments and receipts in 2018. The department will continue its review of the Federal Risk Adjustment Program and its impact on the individual and small group health

insurance markets in this State. Among other issues, the department will continue to examine whether Federal risk adjustment adequately accounts for demographic regional diversity in this State, as well as whether Federal risk adjustment dissuades carriers from using networks and plan designs that seek to integrate care and deliver value. The superintendent will take all necessary and appropriate action to address the impact on both markets in the future.

(b) (1) The superintendent anticipates that the Federal Risk Adjustment Program will adversely impact the small group health insurance market in this State in 2017 to such a degree as to require a remedy. Several factors are expected to cause the adverse impact, including:

(i) the Federal Risk Adjustment Program results in inflated risk scores and payment transfers in this State because the calculation is based in part upon a medical loss ratio computation that includes administrative expenses, profits and claims rather than only using claims; and

(ii) the Federal Risk Adjustment Program results in inflated risk scores and payment transfers in this State because the program does not appropriately address this State's rating tier structure. For this State, the Federal Risk Adjustment Program alters the definition of billable member months to include a maximum of one child per contract in the billable member month count. This understatement of billable member month counts:

(a) lowers the denominator of the calculation used to determine the statewide average premium and plan liability risk scores;

(b) results in the artificial inflation of both the statewide average premium and plan liability risk scores; and

(c) further results in inflated payments transfers through the Federal Risk Adjustment Program.

(2) Accordingly, if, for the 2017 plan year, the superintendent determines that the Federal Risk Adjustment Program has adversely impacted the small group health insurance market in the State and that amelioration is necessary, the superintendent shall implement a market stabilization pool for carriers participating in the small group health insurance market, other than for Medicare supplement insurance, pursuant to subdivision (e) of this section to ameliorate the disproportionate impact that the Federal Risk Adjustment Program may have on carriers, to address the unique aspects of the small group health insurance market in this State, and to prevent unnecessary instability for carriers

participating in the small group health insurance market in this State, other than for Medicare supplement insurance.

(c) As used in this section, *small group health insurance market* means all policies and contracts providing hospital, medical or surgical expense insurance, other than Medicare supplement insurance, covering 1 to 100 employees.

(d) Following the annual release of the Federal risk adjustment results for the 2017 plan year, the superintendent shall review the impact of the Federal Risk Adjustment Program established pursuant to 42 U.S.C. section 18063 on the small group health insurance market in this State for that plan year.

(e) If, after reviewing the impact of the Federal Risk Adjustment Program on the small group health insurance market in this State for the 2017 plan year, including payment transfers, the statewide average premiums, and the ratio of claims to premiums, the superintendent determines that a market stabilization mechanism is a necessary amelioration, the superintendent shall implement a market stabilization pool in such market as follows:

(1) every carrier in the small group health insurance market that is designated as a receiver of a payment transfer from the Federal Risk Adjustment Program shall remit to the superintendent an amount equal to a uniform percentage of that payment transfer for the market stabilization pool. The uniform percentage shall be calculated as the percentage necessary to correct any one or more of the adverse market impact factors specified in paragraph (b)(1) of this section. The uniform percentage shall be determined by the superintendent based on reasonable actuarial assumptions and shall not exceed 30 percent of the amount to be received from the Federal Risk Adjustment Program:

(i) the superintendent shall send a billing invoice to each carrier required to make a payment into the market stabilization pool after the federal risk adjustment results are released pursuant to 45 CFR section 153.310(e);

(ii) each carrier shall remit its payment to the superintendent within 10 business days of the later of its receipt of the invoice from the superintendent or receipt of its risk adjustment payment from the Secretary of the United States Department of Health and Human Services pursuant to 42 U.S.C. section 18063; and

(iii) payments remitted by a carrier after the due date shall include the amount due plus compound interest at the rate of one percent per month, or portion thereof, beyond the date the payment was due; and

(2) for the 2017 plan year:

(i) every carrier in the small group health insurance market that is designated as a payor of a payment transfer into the Federal Risk Adjustment Program shall receive from the superintendent an amount equal to the uniform percentage of that payment transfer, referenced in paragraph (1) of this subdivision, from the market stabilization pool;

(ii) the superintendent shall send notification to each carrier of the amount the carrier will receive as a distribution from the market stabilization pool after the federal risk adjustment results are released; and

(iii) the superintendent shall make a distribution to each carrier after receiving all payments from payors. However, nothing in this section shall preclude the superintendent from making a distribution prior to receiving all payments from payors.

(f) The superintendent may modify the amounts determined in subdivision (e) of this section to reflect any adjustments resulting from audits required under 45 CFR section 153.630.

(g) In the event the payments received by the superintendent pursuant to paragraph (e)(1) of this section are less than the amounts payable pursuant to paragraph (e)(2) of this section, the amount payable to each carrier pursuant to this section shall be reduced proportionally to match the funds available in the pool.

11 N.Y.C.R.R. § 361.10

§ 361.10. Market stabilization pools for the individual and small group health insurance markets for plan years 2018 and thereafter.

(a) (1) This section applies to risk adjustment experience in the individual and small group health insurance markets for plan years 2018 and thereafter.

(b) (1) The superintendent anticipates that the Federal risk adjustment program will adversely impact the individual and small group health insurance markets in this State for plan years 2018 and thereafter to such a degree as to require a remedy. Several factors are expected to cause the adverse impact, including:

(i) the Federal risk adjustment program results in inflated risk scores and payment transfers in this State because the calculation is based in part upon a medical loss ratio computation that includes administrative expenses, profits and claims rather than only using claims;

(ii) the Federal risk adjustment program results in inflated risk scores and payment transfers in this State because the program does not appropriately address this State's rating tier structure. For this State, the Federal risk adjustment program alters the definition of billable member months to include a maximum of one child per contract in the billable member month count. This understatement of billable member month counts:

(a) lowers the denominator of the calculation used to determine the statewide average premium and plan liability risk scores;

(b) results in the artificial inflation of both the statewide average premium and plan liability risk scores; and

(c) further results in inflated payments transfers through the Federal risk adjustment program; and

(iii) other factors, including, without limitation, the disparate impact of the Federal risk adjustment program on this State, this State's demographic diversity and geographic rating, carriers' networks and plan designs, carriers' solvency and financial conditions, and market stability.

(2) Accordingly, if, for plan years 2018 and thereafter, the superintendent determines that the Federal risk adjustment program has adversely impacted the individual health insurance market in this State and that amelioration is necessary, then the superintendent shall implement a market stabilization pool for carriers participating in the individual health insurance mar-

ket, other than for Medicare supplement insurance, pursuant to subdivision (g) of this section. The market stabilization pool shall:

(i) ameliorate the disproportionate impact that the Federal risk adjustment program may have on carriers;

(ii) address the unique aspects of the individual health insurance market in this State; and

(iii) prevent unnecessary instability for carriers participating in the individual health insurance market in this State, other than for Medicare supplement insurance.

(3) Similarly, if, for plan years 2018 and thereafter, the superintendent determines that the Federal risk adjustment program has adversely impacted the small group health insurance market in the State and that amelioration is necessary, then the superintendent shall implement a market stabilization pool for carriers participating in the small group health insurance market, other than for Medicare supplement insurance, pursuant to subdivision (g) of this section. The market stabilization pool shall:

(i) ameliorate the disproportionate impact that the Federal risk adjustment program may have on carriers;

(ii) address the unique aspects of the small group health insurance market in this State; and

(iii) prevent unnecessary instability for carriers participating in the small group health insurance market in this State, other than for Medicare supplement insurance.

(c) As used in this section, *individual health insurance market* means all policies and contracts providing hospital, medical or surgical expense insurance, other than Medicare supplement insurance, issued directly to an individual.

(d) As used in this section, *small group health insurance market* means all policies and contracts providing hospital, medical or surgical expense insurance, other than Medicare supplement insurance, covering one to 100 employees.

(e) Following the annual release of the Federal risk adjustment results for the applicable plan year, the superintendent shall review the impact of the Federal risk adjustment program established pursuant to 42 U.S.C. section 18063 on the individual and small group health insurance markets in this State for that plan year.

(f) If, after reviewing the impact of the Federal risk adjustment program on the individual and small group health insurance markets in this State for the appli-

cable plan year, including payment transfers, the statewide average premiums, the ratio of claims to premiums, Federal risk adjustment results for previous plan years, and carriers' risk adjustment assumptions included in the premium rates approved by the superintendent for the applicable plan year, the superintendent determines that a market stabilization mechanism is a necessary amelioration in the individual health insurance or small group health insurance market, then the superintendent shall implement a separate market stabilization pool pursuant to the procedures set forth in subdivision (g) of this section.

(g) (1) For each year that the superintendent determines that a market stabilization mechanism is a necessary amelioration in the individual health insurance or small group health insurance market, the superintendent shall determine the uniform percentage adjustment that should be used in administering the market stabilization pool for such market. The uniform percentage adjustment for the applicable market shall be calculated as the percentage necessary to correct any one or more of the adverse market impact factors specified in subdivision (b)(1) of this section. The uniform percentage for the applicable market shall be determined by the superintendent based on reasonable actuarial assumptions.

(i) For plan year 2018, the uniform percentage adjustment for the individual and small group health insurance markets is expected to be, but shall not exceed, 26 percent of the amount to be received from the Federal risk adjustment program prior to the 14 percent adjustment described in the following sentence. The uniform percentage shall be in addition to the 14 percent adjustment due to the Federal government's removal of non-claims-based administrative expenses from the Federal risk adjustment calculation. (The department's market stabilization for the small group market for plan year 2017 (section 361.91 of this Part) authorizes adjustments to the Federal risk adjustment transfers up to 30 percent. The 14 percent adjustment due to the Center for Medicaid and Medicare Services's removal of non-claims based administrative expenses from the Federal risk adjustment calculation is not applicable to the 2017 plan year.)

(ii) For plan year 2019 and beyond, the superintendent will provide guidance to carriers, within a reasonable time before the date on which rate applications shall be submitted to the department, as to the assumptions for the Federal risk adjustment program they should include in developing premium rates for the applicable plan year. The guidance may also specify the relevant uniform percentage adjustment for the individual health insurance or small group health insurance market.

(2) For each year that the superintendent determines that a market stabilization mechanism is a necessary amelioration in the individual health insurance or small group health insurance market, every carrier that is designated as a receiver of a payment transfer from the Federal risk adjustment program for the applicable market shall remit to the superintendent an amount equal to the uniform percentage of that payment transfer for the applicable market stabilization pool as follows:

(i) the superintendent shall send a billing invoice to each carrier required to make a payment into the applicable market stabilization pool after the federal risk adjustment results are released pursuant to 45 CFR section 153.310(c);

(ii) each carrier shall remit its payment to the superintendent within 10 business days of the later of its receipt of the invoice from the superintendent or receipt of its risk adjustment payment from the Secretary of the United States Department of Health and Human Services pursuant to 42 U.S.C. section 18063; and

(iii) payments remitted by a carrier after the due date shall include the amount due plus compound interest at the rate of one percent per month, or portion thereof, beyond the date the payment was due; and

(3) (i) for each year that the superintendent determines that a market stabilization mechanism is a necessary amelioration in the individual health insurance or small group health insurance market, every carrier that is designated as a payor of a payment transfer into the Federal risk adjustment program for the applicable market shall receive from the superintendent an amount equal to the uniform percentage of that payment transfer for the applicable market stabilization pool as follows:

(a) the superintendent shall send notification to each carrier of the amount the carrier will receive as a distribution from the applicable market stabilization pool after the Federal risk adjustment results are released; and

(b) the superintendent shall make a distribution to each carrier after receiving all payments from payors pursuant to paragraph (2) of this subdivision. However, nothing in this section shall preclude the superintendent from making a distribution prior to receiving all payments from payors.

(ii) In the event the payments received by the superintendent pursuant to subdivision (h) of this section are less than the amounts payable pursu-

ant to this paragraph, the amount payable to each carrier pursuant to this section shall be reduced proportionally to match the funds available in the applicable pool.

(h) The superintendent may modify the amounts determined in subdivision (g) of this section to reflect any adjustment resulting from audits required under 45 CFR section 153.630.

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limits of Fed. R. App. P. 32(a)(7) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 12,016 words.

2. This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman.

/s/ Neal Kumar Katyal
Neal Kumar Katyal

CERTIFICATE OF SERVICE

I hereby certify that the foregoing was filed with the Clerk using the appellate CM/ECF system on December 10, 2018. All counsel of record are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

/s/ Neal Kumar Katyal
Neal Kumar Katyal