

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

LIFELINK FOUNDATION, INC., et al.,

Plaintiffs,

v.

Case No. 8:25-cv-2042-KKM-SPF

ROBERT FRANCIS KENNEDY, JR., in
his official capacity, et al.,

Defendants.

ORDER

Organ donor organizations challenge the Centers for Medicare and Medicaid Services' (CMS) Final Rule implementing a competitive ranking system for certification and award of government monopolies over organ procurement services. Although the challenges arise under the Medicare Act and ordinarily require channeling through the agency, the organizations have satisfied the exception by showing that, for certain claims, no opportunity for review exists. But on the merits, the Final Rule does not violate the statute and is not arbitrary and capricious, and CMS reasonably responded to significant comments. So I grant summary judgment in favor of the Secretary.

I. BACKGROUND

Plaintiffs LifeLink Foundation, Inc., OneLegacy, Iowa Donor Network, LifeCenter Northwest, and LifeGift Organ Donation Center are non-profit

corporations that are, or are composed of, organ procurement organizations (OPOs). Compl. (Doc. 1) ¶¶ 23–34. OPOs coordinate “the identification of potential donors, consent and requests for donation, and recovery and transport of donated organs.” *Id.* ¶ 57. OPOs drive community outreach and public education about organ donation. *See id.* They also promote research and innovations that “increase organ donation and recovery rates.” *See id.* Although OPOs “make organs available for transplant, . . . whether an organ is accepted and transplanted is within the discretion and control of transplant surgeons.” *Id.* ¶ 59.

For now, there are more than fifty OPOs across the country, of which the organizations represent seven. *See id.* ¶¶ 23, 25–27, 29, 31, 33, 56. Thus far, with exceptions granted by waiver, each OPO exclusively serves a distinct geographic area, and together they form a nationwide system. *See id.* ¶¶ 5, 43, 54. These geographic areas “are unique and typically composed of a number of counties within one or more states.” *Id.* ¶ 55. “They differ significantly in size and demographics, and they often transcend geographic and political boundaries.” *Id.*

OPOs face “varied challenges.” *Id.* ¶ 58. The “geographic access to transplant centers and the distance between organ donors and their local transplant center” contrast widely among the OPOs. *See id.* ¶ 59. Further, OPOs work in areas that “differ widely in terms of other geographic and

demographic characteristics.” *Id.* ¶ 60. Specifically, “death rates, educational attainment, cultural differences, attitudes towards donation, donor hospital and transplant center performance and concentration, and causes of death and secondary diagnoses (which allow for or prevent donation) . . . influence the number of potential organ donors, and in turn donor and transplantation rates.” *Id.*

Congress established the OPO system when it enacted the National Organ Transplant Act in 1984. In relevant part, the Act grants the Secretary of Health and Human Services authority to promulgate regulations to determine whether an OPO should be certified to receive grants from the Secretary. *See* 42 U.S.C. § 273(b)(1)(D)(ii).

On December 2, 2020, the Secretary promulgated Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. 77,898 (Dec. 2, 2020) (codified at 42 C.F.R. pt. 486), which took effect primarily on February 1, 2021. 85 Fed. Reg. 77,898. Although final tier rankings for the 2022–2026 recertification cycle “[were] expected to issue in mid-2026,” *see* Compl. ¶ 170, the Secretary has not yet announced them. At oral argument in August 2026, the government could not specify when the rankings will be released but stated that they

“presumably” must be released before January 31, 2027, the date that the existing agreements between CMS and the OPOs expire. *See* Tr. 7:6–25.

The organizations challenge the Final Rule’s reliance on two outcome metrics—donation rate and organ transplantation rate—and the Final Rule’s establishment of a tiered ranking system predicated on those two metrics. *See, e.g.,* Compl. ¶¶ 10–11; *see also* 42 C.F.R. § 486.318(d)–(e). “The donation rate is calculated as the number of donors in the [Donation Service Area (DSA)] as a percentage of the donor potential.” 42 C.F.R. § 486.318(d)(1)(i). “The organ transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential” and “is adjusted for the average age of the donor potential.” *Id.* § 486.318(d)(1)(ii). In principle, “[d]onor potential is the number of inpatient deaths within the DSA among patients 75 and younger with a primary cause of death that is consistent with organ donation.” *Id.* § 486.302.

The Final Rule establishes three tiers based on the relative performance—as calculated by using one-sided ninety-five percent confidence intervals—of the OPOs regarding donation rate and organ transplantation rate. *See id.* § 486.318(e)(4)–(6). Tier 1 consists of “OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the” lowest rate among the top twenty-five percent of OPOs nationwide. *See id.* § 486.318(e)(1)(i), (2)(i),

(4). Tier 2 consists of “OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the” median rate among all OPOs but that are not in Tier 1. *See id.* § 486.318(e)(1)(ii), (2)(ii), (5). Tier 3 consists of “OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation or organ transplantation rates that are below the” median rate among all OPOs. *See id.* § 486.318(e)(1)(ii), (2)(ii), (6). All OPOs must also comply with separately promulgated process performance measures. *See id.* §§ 486.316(a)(3)(i) (identifying a lack of compliance with the process performance measures as sufficient grounds for a Tier 3 designation), 486.320–486.360 (Organ Procurement Organization Process Performance Measures).

An OPO’s tier designation “will determine whether the OPO is re-certified [and therefore will avoid competing to retain its DSA] (Tier 1), must compete to retain its DSA (Tier 2), or will receive an initial de-certification determination (Tier 3).” *Id.* § 486.316(a). In other words, for an OPO to remain confidently in business, it must comply with the process performance measures and have donation and organ transplantation rates that are in the top quartile of all OPOs according to the previous year’s data. *See id.* §§ 486.316(a)(1), 486.318(e)(4), (f)(1)–(2); 85 Fed. Reg. 77,914 (“[W]e will be finalizing as proposed that the threshold rates for the donation and organ transplantation rates would be based on the 12-month period immediately prior to the period

being evaluated[.]”). If either (or both) of an OPO’s donation and organ transplantation rates dip below the top quartile, but both remain above the median for all OPOs, the OPOs must “compete to retain its DSA and for any open DSA.” *See* 42 C.F.R. §§ 486.316(a)(2), 486.318(e)(5). Should either of the donation or the organ transplantation rates fall below the median for all OPOs, then the “OPO will receive a notice of de-certification determination.” *See id.* §§ 486.316(a)(3), 486.318(e)(6). Regardless of donation or organ transplantation rates, decertification also occurs if an OPO fails to comply with the process performance measures. *See id.* § 486.316(a)(3)(i). “Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes on or after the effective date of de-certification.” *Id.* § 486.314(k).

OPOs that receive an initial decertification determination (Tier 3) may appeal to CMS. *See id.* §§ 486.314, 486.316(b)(1)–(2). The appeal process first requires reconsideration by CMS based on identified “issues or findings of fact with which the OPO disagrees.” *Id.* § 486.314(b)(1). At this stage, CMS “makes a written reconsidered determination within 10 business days of receipt of the request for reconsideration, affirming, reversing, or modifying the initial determination and the findings on which it was based.” *Id.* § 486.314(b)(3). “An OPO dissatisfied with the CMS reconsideration decision, must file a request for a hearing before a CMS hearing officer.” *Id.* § 486.314(c). Within twenty

business days of the hearing, the presiding officer renders a decision either reversing or upholding the decertification. *See id.* § 486.314(i)(1)–(2).

The hearing officers who adjudicate these appeals have no authority to review the Final Rule for “substantive and procedural legal failures” and “cannot address the arbitrariness of CMS’s Final Rule or CMS’s failure to follow statutory mandates.” Compl. ¶ 177. The appeals are “limited to determining whether CMS correctly applied the 2020 Final Rule, such as determining whether the agency correctly calculated an organ procurement organization’s donor or transplant rate.” *Id.* Thus, the administrative appeals “cannot bring [the organizations] the relief they seek.” *Id.*

Based on interim tier rankings and data released by CMS,¹ most of the organizations expect to be designated Tier 2 or Tier 3. *See id.* ¶¶ 171–73. Iowa Donor Network expects to be designated Tier 1. *Id.* ¶ 174. At oral argument, the Secretary conceded that it is a “near certainty” that “some of the [organizations] will be Tier 2 or Tier 3” and that “at least somebody in the plaintiff side has standing.” *See* Tr. 20:3–15.

The organizations assert three counts. Count I alleges that the Final Rule violates the Administrative Procedure Act (APA) because it is contrary to

¹ The current recertification cycle, which ends in 2026, relies on data from 2024 compared against a threshold rate based on data from 2023. *See* 85 Fed. Reg. 77,916.

law and exceeds CMS’s statutory authority. *See id.* ¶¶ 186–201. Count II asserts that the Final Rule violates the APA because it is arbitrary and capricious. *See id.* ¶¶ 202–217. Count III alleges that the Final Rule violates the APA because it is inadequately reasoned. *See id.* at 79–82. For relief, the organizations seek vacatur of the Final Rule, a declaratory judgment that the Final Rule “is contrary to law” and “arbitrary or capricious,” and “an injunction requiring CMS to comply with the statutory requirements in the National Organ Transplant Act” and to prohibit CMS from enforcing the Final Rule. *Id.* at 82–83 (Prayer for Relief).

Both sides move for summary judgment. Pls.’ MSJ (Doc. 39); Defs.’ Resp. & Cross-MSJ (Defs.’ MSJ) (Doc. 43); Pls.’ Resp. (Doc. 44); Defs.’ Reply (Doc. 46). I directed the parties to file supplemental briefing concerning how the Final Rule applies to Tier 2 OPOs that lose their DSAs and the jurisdictional implications. *See* Briefing Order (Doc. 48); Pls.’ Suppl. Br. (Doc. 50); Defs.’ Suppl. Br. (Doc. 49). In August 2026, I heard oral argument, which focused on whether I have subject-matter jurisdiction over this action in the light of the exception to *Illinois Council’s* broad channeling requirement. *See* Order Granting Mot. for Oral Arg. (Doc. 51); Mins. (Doc. 56).

II. LEGAL STANDARD

Courts properly adjudicate challenges to agency action under the APA on cross motions for summary judgment. *See Mahon v. U.S. Dep’t of Agric.*, 485

F.3d 1247, 1253 (11th Cir. 2007) (citing *Fla. Fruit & Vegetable Ass’n v. Brock*, 771 F.2d 1455, 1459 (11th Cir. 1985)). “[W]hen a party seeks review of agency action under the APA,” “[t]he ‘entire case’ on review is a question of law.” *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (citation omitted). Thus, the substantive standard under Federal Rule of Civil Procedure 56—whether there is a genuine dispute as to any material fact—does not apply. *See Fulbright v. McHugh*, 67 F. Supp. 3d 81, 89 (D.D.C. 2014), *aff’d sub nom. Fulbright v. Murphy*, 650 F. App’x 3 (D.C. Cir. 2016) (per curiam); *cf. Blankenship v. Metro. Life Ins. Co.*, 644 F.3d 1350, 1354 & n.4 (11th Cir. 2011). Instead, summary judgment provides “the mechanism for deciding whether as a matter of law the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review.” *See CS-360, LLC v. U.S. Dep’t of Veterans Affs.*, 101 F. Supp. 3d 29, 32 (D.D.C. 2015) (citation omitted).

Under the APA, a reviewing court must “hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, [] otherwise not in accordance with law[,] . . . [or] in excess of statutory jurisdiction, authority, or limitations[.]” 5 U.S.C. § 706(2)(A), (C). In reaching its determination, “a court reviews legal issues de novo, including by applying its ‘independent judgment’ to statutory-interpretation questions.” *Lopez-Martinez v. U.S. Att’y Gen.*, 149 F.4th 1202,

1207 (11th Cir. 2025) (quoting *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 391–92, 412 (2024)). The challenger to agency action ultimately carries the “heavy burden” to show that such action was arbitrary and capricious. *Legal Env’t Assistance Found., Inc. v. EPA*, 276 F.3d 1253, 1265 (11th Cir. 2001). Lastly, “[a]n agency must consider and respond to significant comments received during the period for public comment.” *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 96 (2015) (citations omitted).

III. ANALYSIS

The organizations advance three APA claims and seek vacatur of the Final Rule. The Secretary argues that the Court lacks jurisdiction to address the claims because the organizations failed to present their claims to the agency before initiating this action, *see* Defs.’ MSJ at 29–34, that the claims fail, *see id.* at 34–59, and that, even if the claims are meritorious, vacatur of the Final Rule is overly broad and unduly disruptive, *see id.* at 59–60.

This order proceeds in three parts. First, I address standing and conclude that Tier 2 and Tier 3 OPOs have standing to challenge the Final Rule. Next, I address the Secretary’s argument that the court lacks subject-matter jurisdiction because the OPOs failed to channel their claims through the administrative review process. Because no review exists for certain claims, the OPOs satisfy the exception to channeling. Lastly, I turn to the merits of the organizations’ APA claims and conclude that they fail.

A. Standing Exists for Tier 2 and Tier 3 OPOs

Although the parties barely address it, courts “are obliged to consider standing sua sponte.” *AT&T Mobility, LLC v. Nat’l Ass’n for Stock Car Auto Racing, Inc.*, 494 F.3d 1356, 1360 (11th Cir. 2007). The party invoking federal jurisdiction bears the burden of proving standing at every stage of litigation. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). The three prerequisites for Article III standing are an injury in fact, traceability from that injury to the challenged action, and redressability by a favorable decision. *See Corbett v. Transp. Sec. Admin.*, 930 F.3d 1225, 1232 (11th Cir. 2019).

Only one of the organizations, Iowa Donor Network, expects a Tier 1 ranking. Compl. ¶ 174. Three organizations expect to be designated Tier 3. *See id.* ¶ 171. Based on “the most recent interim data reported by CMS,” the others anticipate a Tier 2 or Tier 3 ranking. *See id.* ¶¶ 171–73. These anticipated designations based on CMS’s data are neither speculative nor hypothetical, as even the Secretary conceded that at least some of the organizations will end up in Tier 2 or Tier 3 and thus have standing. *See* Tr. 20:3–15.

i. Tier 1 Iowa Donor Network Fails to Establish Standing

As an expected Tier 1 OPO, Iowa Donor Network fails to establish an injury in fact stemming from the Final Rule and therefore lacks standing. Iowa Donor Network asserts a number of injuries. Without evidence, none suffice.

First, the organizations assert that OPOs suffer “significant reputational and operational harms in being labeled Tier 1, Tier 2, or Tier 3, even though those rankings do not accurately reflect their actual performance.” Compl. ¶ 42. Yet they do not explain how being labeled Tier 1 harms an OPO. Elsewhere, the organizations admit that an OPO designated Tier 1 is “deemed” or “ranked as a top performer.” Pls.’ MSJ at 14; Pls.’ Resp. at 18. Aside from the lack of evidence, “common sense” dictates that there is no direct reputational or financial harm from receiving a Tier 1 designation. *See Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100, 118 (2025).

Second, the organizations assert that Tier 1 OPOs have made “significant investments in time and resources to address the immediate disruptions caused by CMS’s Final Rule and the risks that they face imminent decertification or replacement.” Compl. ¶ 42. But “conclusory allegations of injury are not enough to confer standing.” *Tsao v. Captiva MVP Rest. Partners, LLC*, 986 F.3d 1332, 1343 (11th Cir. 2021) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Moreover, each element of standing “must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.” *Lujan*, 504 U.S. at 561. At the summary judgment stage, “the plaintiff can no longer rest on ‘mere allegations,’ but must ‘set forth’ by affidavit or other evidence ‘specific facts,’ . . . which . . . will be taken to be

true.” *Id.* The organizations do not offer evidence on these “significant investments.” *See* Compl. ¶ 42.

Iowa Donor Network specifically alleges that it is harmed by “the threat that CMS’s Final Rule poses to the nation’s organ donation system as a whole, the harms that will be caused to patients and donor families, and the risk that, given CMS’s ‘hunger games’ approach, it will face decertification in future certification cycles regardless of how well it continues to perform.” Compl. ¶ 174; *see generally* Conrad Decl. (Doc. 1-10) (failing to provide further evidence of injury to Iowa Donor Network); *see also* Tr. 56:9–25 (failing to point to evidence beyond the foregoing allegations). These, too, are insufficient conclusory statements. Without more, fears of receiving a Tier 2 or Tier 3 designation in a recertification cycle and being decertified as a result are too remote—the recertification cycles cannot occur more often than every four years—and thus “conjectural and speculative.” *See Corbett*, 930 F.3d at 1233–34; 42 U.S.C. § 273(b)(1)(D)(ii)(I).

Because the organizations fail to establish with evidence that Tier 1 OPOs have or will suffer an injury in fact, they lack standing. Iowa Donor Network’s claims are dismissed without prejudice.

ii. Tier 2 and Tier 3 OPOs Establish Standing

Unlike Tier 1 OPOs, Tier 2 and Tier 3 OPOs have demonstrated an injury in fact stemming from the Final Rule and redressable by a favorable decision. Therefore, Tier 2 and Tier 3 OPOs have standing.

All Tier 2 OPOs must expend resources to compete either to keep their DSA or win another DSA. *See* 42 C.F.R. § 486.316(d)(4) (“An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.”); 85 Fed. Reg. 77,924 (calculating projected costs for OPOs to prepare an application for an open DSA). Thus, even a winning Tier 2 OPO is harmed by the Final Rule’s requirement that it expend resources to retain control of a DSA. *See Fla. State Conf. of NAACP. v. Browning*, 522 F.3d 1153, 1165–66 (11th Cir. 2008) (“An organization suffers an injury in fact when a statute ‘compels’ it to divert more resources to accomplishing its goals. . . . [T]he fact that the added cost has not been estimated and may be slight does not affect standing, which requires only a minimal showing of injury.” (citation modified)); *Louisiana Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998) (“We repeatedly have held that parties suffer constitutional injury in fact when agencies . . . otherwise allow increased competition.”).

Losing Tier 2 OPOs suffer a worse fate. Set adrift without a DSA for the duration of the 2026–2030 recertification cycle, “[o]perationally, a [losing] Tier 2 OPO has to shut down.” Tr. 49:8–9. Although the Secretary noted that some OPOs have other revenue sources, *see id.* 36:8–11, the organizations explained that even tentative Tier 2 designations have already caused OPOs to “start losing [their] employees” and for their existing contracts and business relationships to “get shaken,” *see id.* 49:1–4. By the time a Tier 2 OPO loses its DSA in the competition, it is unable to “operate in the private markets, just as much in the Medicare markets,” *id.* 49:13–14, because without a DSA an OPO faces criminal prosecution should it conduct private organ transplants, *see id.* 53:11–22. By the end of the 2026–2030 recertification cycle, losing Tier 2 OPOs will have “lost all of [their] employees, all of [their] facilities, all of [their] contracts, all of those relationships.” *See id.* 52:2–7. *See also* Pls.’ Suppl. Brief at 10 (indicating that OPOs without a DSA are “shut down” and would expect to lose “essential resources, relationships, and personnel”); Lahrman Decl. (Doc. 1-2) ¶¶ 27, 49, 51 (explaining that if LifeLink of Florida becomes a Tier 2 losing OPO it “would be forced to cease operations and lay off hundreds of employees”); Rabel Decl. (Doc. 1-4) ¶ 51 (explaining that if LifeLink of Georgia “is decertified or loses its contract with CMS it will have to cease operations and lay off hundreds of employees”). The Secretary never disputes these

inevitable harms to Tier 2 losers stemming from the Final Rule or that judicial relief would redress those harms.

As for Tier 3 OPOs, they undisputedly suffer injuries in fact by way of their Tier 3 designation and decertification, which strips them of eligibility for Medicare reimbursement. These harms flow directly from the implementation of the Final Rule, and a judicial order enjoining the Final Rule against them would remedy their harm, at least in part.

Thus, Tier 2 and Tier 3 OPOs have Article III standing.

B. Jurisdiction Exists Because Exhaustion Is Not Required

The Secretary argues that this action is “premature” under both 42 U.S.C. § 405(h) (as incorporated by the Medicare Act, *see* 42 U.S.C. § 1395ii), and the Organ Procurement Organization Certification Act because the organizations failed to present their claims to the agency, as required by those statutes. *See* Defs.’ MSJ at 29. The organizations counter that their claims do not arise under the Medicare Act and therefore channeling is not required, and that the Organ Procurement Organization Certification Act includes no channeling mandate. *See* Pls.’ Resp. at 9–15. But even if channeling were required, the organizations contend that they satisfy the exception because no judicial review exists. *See id.*

Although I agree with the Secretary that these claims arise under the Medicare Act, I conclude that an exception to the channeling requirement applies to the first statute, and none is required in the second.

i. This Action Arises Under the Medicare Act

Section 405(h) “channels most, if not all, Medicare claims through [a] special review system.” *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 8 (2000); *see* 42 U.S.C. § 1395ii (incorporating 42 U.S.C. § 405(h)). Importantly, this provision strips federal courts of jurisdiction to review Medicare claims until a party presents them to the agency. Specifically, Section 405(h) provides, “No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under [the Medicare Act],” except as allowed by Section 405(g). And Section 405(g), as incorporated by 42 U.S.C. § 1395ff(b)(1)(A)), provides for judicial review only after a party concludes the administrative review process. Taken together, Section 405(h) divests federal courts of jurisdiction under 28 U.S.C. § 1331 and § 1346 to hear claims “arising under” the Medicare Act until those claims have been channeled through the Medicare Act’s review provisions. *See Heckler v. Ringer*, 466 U.S. 602, 614–15 (1984); *Am. Acad. of Dermatology v. Dep’t of Health & Hum. Servs.*, 118 F.3d 1495, 1497–99 (11th Cir. 1997). A claim arises under the Medicare Act if it is

“inextricably intertwined” with a claim for benefits under the Act. *Ringer*, 466 U.S. at 614.

The organizations’ claims are “inextricably intertwined” with a claim for benefits, and thus arise under the Medicare Act, because they challenge the Final Rule that controls eligibility for reimbursement. The Final Rule governs how the Secretary assigns tier rankings, which in turn determine certification and bear on assignment of DSAs. Without a DSA, an OPO cannot submit claims for reimbursement. *See* Compl. ¶ 41 (“[The organizations] have standing because CMS’s Final Rule . . . establishes the requirements that [OPOs] (including plaintiffs) must meet to receive payments under the Medicare program for the services they provide.”). Thus, the organizations’ claims must be channeled, absent an exception. *See, e.g., Nat’l Infusion Ctr. Ass’n v. Becerra*, 116 F.4th 488, 506 (5th Cir. 2024) (explaining that “there are two types of claims for which channeling is required: disputes about how reimbursement [from Medicare] is calculated and disputes about whether a particular entity . . . is eligible for reimbursement”).

The organizations admit that none have presented the claims to the Secretary but assert that jurisdiction exists because their action arises under the National Organ Transplant Act, not the Medicare Act. *See* Pls.’ Resp. at 9–10; Compl. ¶ 39. In that way, the organizations contend that they need not satisfy the Medicare Act’s channeling requirement and avoid the jurisdictional

bar of Section 405(h). Specifically, they argue that their claims do not fall within the broad construction of Section 405(h) because they do not seek payment from CMS or challenge a specific determination of eligibility. *See* Pls.’ Resp. at 10. Instead, the organizations consider their challenge to merely “implicate benefits determinations.” *See id.* at 11 (emphasis omitted); *United States v. Blue Cross & Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1109 (11th Cir. 1998). Precedent precludes this theory.

The Supreme Court has “broadly constru[ed]” Section 405(h) to “prevent [parties] from circumventing the administrative process by creatively styling their benefits claims as collateral constitutional or statutory challenges not ‘arising under’ Medicare.” *Blue Cross*, 156 F.3d at 1104. Indeed, Supreme Court and Eleventh Circuit precedent requires channeling here, even though the organizations contend that the Final Rule violates the APA and the National Organ Transplant Act. *See, e.g., Ringer*, 466 U.S. at 622 (rejecting the “old argument” that a plaintiff’s challenge is shielded from channeling because it also arises under legal authority other than the Medicare Act, such as the APA); *Am. Fed’n of Home Health Agencies, Inc. v. Heckler*, 754 F.2d 896, 897–98 (11th Cir. 1984) (concluding that channeling was required because “the claims do eventually seek reimbursement under the Medicare Act” even though the claims were that the regulations were arbitrary and capricious); *accord Weinberger v. Salfi*, 422 U.S. 749, 760–61 (1975) (holding that Section

405(h) still precluded claims arising “under the Constitution”); *Nat’l Infusion Ctr. Ass’n*, 116 F.4th at 506 (recognizing that channeling is required for claims that are “about eligibility for reimbursement” even if the outcome “turned on the interpretation of a provision of the Affordable Care Act”).

As the Supreme Court explained in *Illinois Council*, Section 405(h)’s bar applies “when one who might later seek money or some other benefit from . . . the agency challenges in advance (in a § 1331 action) the lawfulness of a policy, regulation, or statute that *might* later bar recovery of that benefit.” 529 U.S. at 10; *see also id.* at 18–19 (rejecting any “distinction between a dispute about an agency determination in a particular case and a more general dispute about, for example, the agency’s authority to promulgate a set of regulations”). The organizations challenge a regulation that will later bar, through decertification and the loss of DSAs, their ability to receive reimbursement from Medicare.

Seeking to avoid Section 405(h), the organizations contend that channeling is not required because 42 U.S.C. § 1395hh, one of the Final Rule’s cited provisions, does not explicitly require channeling while other provisions do—such as 42 U.S.C. § 1395ff and § 1395oo. *See* Tr. 76:20–77:4; *see also* Pls.’ Suppl. Br. at 17 (pressing a similar argument). But that misses the point. The relevant inquiry is whether the claims are “inextricably intertwined” with a claim for entitlement to benefits, not whether every subsection cited by the Final Rule requires channeling. *See Tenet Healthsystem GB, Inc. v. Care*

Improvement Plus S. Cent. Ins. Co., 875 F.3d 584, 588, 591 (11th Cir. 2017); *Woods v. Sec’y, U.S. Dep’t of Health & Hum. Servs.*, No. 24-11815, 2025 WL 80284, at *1 (11th Cir. Jan. 13, 2025) (per curiam) (citing *Ringer*, 466 U.S. at 614–15); *Bober v. Safe Guard Servs., LLC*, No. 21-11529, 2021 WL 4817714, at *1 (11th Cir. Oct. 15, 2021) (per curiam) (citing *Ringer*, 466 U.S. at 615).

Moreover, the organizations’ claims go well beyond merely implicating benefits determinations. They attack the Final Rule that “establishes the requirements that [OPOs] must meet to receive payments under the Medicare program for the services they provide.” Compl. ¶ 41. The scheme set up by the Final Rule will determine which OPOs are recertified, and which are decertified. Decertification is a “death penalty” for an OPO because without certification an OPO cannot “provide organ procurement services, and neither Medicare nor Medicaid will pay for other services provided by that organization.” Pls.’ MSJ at 18; Compl. ¶ 71; *see* 42 C.F.R. § 486.314(k). For that reason, they are, in fact, disputing ultimate eligibility for reimbursement.

Lastly, the organizations argue that their attack on the Final Rule “does not raise any issues that could be resolved or illuminated through the applicable administrative appeals process.” Pls.’ Resp. at 12. That might be so but matters not for channeling. The Supreme Court holds it irrelevant if the administrative review process is unable to consider the claims or provide the requested remedy. *See Illinois Council*, 529 U.S. at 23 (“The fact that the

agency might not provide a hearing for that particular contention, or may lack the power to provide one, is beside the point because it is the ‘action’ arising under the Medicare Act that must be channeled through the agency.” (citation modified)). Indeed, “[a]fter the action has been so channeled, the court will consider the contention when it later reviews the action. And a court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide, including, where necessary, the authority to develop an evidentiary record.” *Id.* (citation modified); *see also Lifestar Ambulance Serv., Inc. v. United States*, 365 F.3d 1293, 1297–98 (11th Cir. 2004) (“The fact that plaintiffs may not be able to secure the relief they seek at the administrative hearing stage of their claim does not mean that the Act’s remedial structure, which includes plenary judicial review, does not provide an adequate remedy.”).

In sum, the organizations’ claims are jurisdictionally barred under Section 405(h) unless an exception applies.

ii. The *Illinois Council* Exception Applies

Illinois Council provides an exception to the channeling requirement: where channeling would result in “no review at all.” *See* 529 U.S. at 17, 19. As the D.C. Circuit has explained, “[t]he [*Illinois Council*] exception applies not only when administrative regulations foreclose judicial review, but also when roadblocks practically cut off any avenue to federal court.” *Am. Chiropractic*

Ass’n, Inc. v. Leavitt, 431 F.3d 812, 816 (D.C. Cir. 2005). “As to the *latter*, it is not enough that claimants would encounter ‘potentially isolated instances of the inconveniences sometimes associated with the postponement of judicial review,’ or that their claims might not receive adequate administrative attention. The difficulties must be severe enough to render judicial review unavailable as a practical matter.” *Id.* (emphasis added) (quoting *Illinois Council*, 529 U.S. at 22–23 (citation modified)).

1. Under the Final Rule, Tier 2 OPOs Are Barred from Administrative Review

The organizations argue that the exception applies to Tier 2 OPOs because the administrative review process is “entirely unavailable” to them and allows the organizations to pursue this action now. Pls.’ Resp. at 12–13 (emphasis removed). The Secretary does not dispute that OPOs receiving a Tier 2 ranking will suffer harmful final agency action (twice over for those Tier 2 OPOs that also lose their DSAs) and that the Final Rule precludes administrative and thus judicial review for these Tier 2 OPOs. Nor could he.

Each Tier 2 OPO will be forced to compete to retain its DSA or win another DSA. *See* 42 C.F.R. § 486.316(a)(2)(i)–(ii), (c). CMS will designate a winning OPO from among those who compete. *See id.* § 486.316(d). “If a Tier 2 OPO does not win the competition for its DSA and does not win the competition for any other open DSA it competes for, CMS will not renew its agreement with

the OPO. The OPO will not be able to appeal this non-renewal, which is not a de-certification.” 85 Fed. Reg. 77,898, 77,918. The parties agree that—informed by a rule CMS proposed this year—those Tier 2 OPOs would be “forced to cease operations” but remain certified and eligible to compete for any DSA that might open before the end of the next recertification cycle. *See* Pls.’ Suppl. Br. at 9–10 (citing Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage, 91 Fed. Reg. 4,190, 4,208 (Jan. 30, 2026) (to be codified at 42 C.F.R. pt. 486); Defs.’ Suppl. Br. at 6–7 (citing the same). Indeed, the only explicit triggering event for an OPO to seek administrative review is decertification. *See* 42 C.F.R. § 486.314. Neither a Tier 2 ranking nor a loss of a DSA alone equates to decertification.

In other words, CMS regulations deprive Tier 2 OPOs from accessing administrative and eventual judicial review. The Secretary admits as much for losing Tier 2 OPOs: “there is no regulatory mechanism for non-renewed Tier 2 OPOs to administratively appeal the loss of their DSA (absent [separate] decertification).” Defs.’ Suppl. Brief at 13. And the Secretary has never contended that there is review for prevailing Tier 2 OPOs. This deprivation is intentional. *See* Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs), 71 Fed. Reg. 30,982, 30,998 (May 31, 2006) (codified at 42 C.F.R. pts. 413, 441, 486, and 498) (explaining

CMS’s decision to remove access to the administrative appeals process for OPOs who lose in a competition for an open DSA in an earlier Rule because allowing an appeal “would increase uncertainty for the OPO that prevailed,” which “may disrupt the new OPO’s ability to increase organ donation in the [DSA]”). This regulatory per se deprivation of review for all Tier 2 OPOs satisfies the *Illinois Council* exception to channeling because it results in no judicial review at all.

2. Losing Tier 2 OPOs Are Also Practically Barred from Administrative Review

The Secretary contends that Tier 2 OPOs that lose their DSAs will eventually be decertified after the next four-year cycle when they fail to meet the required standards and are deemed Tier 3. Tr. 34:25–35:24. Thus, after languishing without revenue for four years, losing Tier 2 OPOs can seek administrative review after they are deemed Tier 3 and therefore, theoretically, judicial review. *See id.* That chronology blinks reality for all defunct Tier 2 OPOs, which are in law forever precluded from challenging their Tier 2 designation and loss of DSAs. They are also in practice cut off from review from challenging the Final Rule and thus satisfy the *Illinois Council* exception to channeling twice over. And, of course, it also fails to account for the total regulatory deprivation of review by winning Tier 2 OPOs that avoid becoming Tier 3 OPOs altogether.

The fate of losing Tier 2 OPOs confirms why they are practically precluded from all judicial review. At the end of the next recertification cycle in four years, if a losing Tier 2 OPO has not obtained a new DSA, CMS will designate it Tier 3 because the OPO would be unable to meet the necessary outcome metrics. *See* Pls.’ Suppl. Brief at 10; Defs.’ Suppl. Brief at 6–7. The OPO would then be decertified and could finally administratively appeal. Defs.’ Suppl. Brief at 6–7. This appeal would *not* provide “process for the OPO to revisit its 2026 tier ranking and non-renewal [for the 2026–2030 recertification cycle].” Pls.’ Suppl. Brief at 10. Those final agency actions would forever remain immune from administrative and judicial review. Indeed, even if the OPO implausibly survives this four-year period without operations, administratively appeals, and seeks judicial review, a court would likely find that the OPO lacks standing to challenge its loss in 2026 of a DSA and thus eligibility for Medicare reimbursement. The OPO’s harm, which flows from CMS’s decision to reassign the DSA during the 2026–2030 recertification cycle, would long be moot.² *See* 42 C.F.R. §§ 486.302, 486.304(a). As a result, even

² Even if standing existed, the organizations assert that the Final Rule’s tier structure has been harming them since implementation on March 30, 2021, *see* Compl. ¶¶ 41–42; 91 Fed. Reg. 4,208. Thus, soon-to-be Tier 2 OPOs might very well run afoul of the six-year statute of limitations applicable to the APA given the delayed nature of any review—at least for claims seeking to vacate the Final Rule. *See* 28 U.S.C. § 2401(a); *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 809 (2024) (holding “[a] right of action ‘accrues’ when the plaintiff has a ‘complete and present cause of action’—*i.e.*, when she has the right to ‘file suit and obtain relief’” and that the statute of limitations for APA actions runs from the time a plaintiff “suffers an

the “eventual” review by becoming a Tier 3 OPO precludes all review of the most pertinent claims suffered by a losing Tier 2 OPO: the loss of its DSA.

To be sure, this potential review for losing Tier 2 OPOs under the auspices of an eventual Tier 3 designation is not mere delayed review accompanied by “added inconvenience or cost in an isolated, particular case.” *Illinois Council*, 529 U.S. at 22. Rather, this is akin to “hardship likely found in many cases [that] turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review.” *Illinois Council* 529 U.S. at 22–23 (citing *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 496–97 (1991)); *see also Nat’l Ass’n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 38–39 & n.4 (D.D.C. 2000) (concluding that, to require channeling, which would force the plaintiffs to first risk “‘economic suicide’ by termination from Medicare,” was “complete preclusion of judicial review”); *Frontier Health Inc. v. Shalala*, 113 F. Supp. 2d 1192, 1193 (E.D. Tenn. 2000) (concluding the

injury from final agency action” (citation omitted)); *but see id.* at 809 n.2 (leaving open whether one can “bring an as-applied challenge to a rule when the agency relies on that rule in enforcement proceedings against that person, even if more than six years have passed since the rule’s promulgation”).

It might be the case that even OPOs designated as Tier 3 during this cycle would be precluded by the statute of limitations. Depending on how long it takes CMS to announce the final tier rankings and issue notices of decertification, the appeals process, which is permitted to take up to six months, *see* 42 C.F.R. § 486.314, might push beyond March 30, 2027. At oral argument, the Secretary refused to take a position on when the statute of limitations began to run. *See* Tr. 93:10–94:18.

same). As the organizations contend and economic reality confirms, losing Tier 2 OPOs will not survive four years without a DSA. *See* Tr. 49:8–14, 52:2–7, 53:11–22. As a group, then, all losing Tier 2 OPOs are precluded review.

3. The Secretary’s “Proxy” Theory Does Not Cure the Lack of Judicial Review

The conclusion that review is, both in law and in reality, barred for Tier 2 OPOs should end the matter and permit the organizations to bring this action now. But the Secretary urges me to follow a theory adopted in other circuits that bars application of the *Illinois Council* exception where another party might bring the same claim as the plaintiff precluded from administrative review. *See* Defs.’ Suppl. Br. at 10–14. Under this “proxy” theory, so long as a party similarly situated to the plaintiff has access to administrative and judicial review, the *Illinois Council* exception no longer applies. *See Council for Urological Ints. v. Sebelius*, 668 F.3d 704, 708, 711–12 (D.C. Cir. 2011); *Nat’l Athletic Trainers’ Ass’n, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 455 F.3d 500, 504–05 (5th Cir. 2006); *Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 982–84 (9th Cir. 2020); *Retina Grp. of New England, P.C. v. Dynasty Healthcare, LLC*, 72 F.4th 488, 497–99 (2d Cir. 2023).

Here, the Secretary argues, because Tier 3 OPOs will be decertified and can pursue administrative and eventual judicial review, the proxy theory bars the *Illinois Council* exception from applying to Tier 2 OPOs. The Eleventh

Circuit has not had an occasion to consider the proxy theory. After careful review of the Secretary's arguments and the other circuits that have embraced the proxy theory, I decline to adopt it.

Three reasons render the proxy theory unpersuasive. First, this proxy theory is premised on a fundamental misreading of *Illinois Council*. Second, the proxy theory assumes that the party that has access to judicial review can secure relief for the party that does not, ordinarily through vacatur of the challenged action. But in the light of *Trump v. CASA, Inc.*, I have serious concerns about the constitutionality of vacatur, and thus whether a proxy can ever serve as an adequate substitute to a party denied review. Third, because of the monopoly structure of DSAs, vacatur of the Final Rule alone does not provide meaningful relief to the precluded Tier 2 OPOs, and thus a proxy theory is inapplicable here.

a. The Proxy Theory is Not Grounded in *Illinois Council*

The courts that have adopted the proxy theory find support in the below language from *Illinois Council*: “Contrary to what Justice Thomas says [in dissent], we do not hold that an individual party could circumvent § 1395ii’s channeling requirement simply because that party shows that postponement would mean added inconvenience or cost in an isolated, particular case. Rather, the question is whether, as applied generally to those covered by a particular statutory provision, hardship likely found in many cases turns what

appears to be simply a channeling requirement into *complete* preclusion of judicial review.” 529 U.S. at 22–23; see *Council for Urological Ints.*, 668 F.3d at 708, 711–12 (citing this portion of *Illinois Council*); *Nat’l Athletic Trainers’ Ass’n, Inc.*, 455 F.3d at 504–05 (same); *Sensory Neurostimulation, Inc.*, 977 F.3d at 982–83; *Retina Grp.*, 72 F.4th at 497–99.

Contrary to the conclusion reached by other courts, these two sentences do not support a proxy theory in circumstances where a plaintiff is barred from accessing administrative and judicial review by the terms of the regulatory scheme itself. The majority made this statement after expressly assuming that there was no regulatory bar to administrative review. *Ill. Council*, 529 U.S. at 21–22. Within that context, the majority was making the uncontroversial point that mere inconvenience or cost was insufficient to trigger the exception. See *id.* at 22; *Am. Chiropractic Ass’n*, 668 F.3d at 708. Nor are the idiosyncrasies of individual plaintiffs—such as the lack of resources to pursue a lengthy administrative appeal—sufficient to trigger the exception. Rather some sort of structural or practical barrier must exist that could turn the “hardship likely found in many cases” into effectively “complete preclusion of judicial review.” *Illinois Council*, 529 U.S. at 22–23.

The context of the oft-cited language supports this reading. The sentences are found amidst the majority opinion’s analysis of whether the implementation of the regulations by enforcement agencies “den[ied] review in

practice” because they “threaten[ed] termination” of the provider agreement, unless the provider opted to forgo “its opportunity to contest the lawfulness of any remedy-related rules or regulations.” *Id.* at 21; *see* 42 C.F.R. § 488.456. Thus, agency action purportedly “forced [providers] to abandon legitimate challenges to agency regulations[.]” *Illinois Council*, 529 U.S. at 22.³ Even the portions of Justice Thomas’s dissent that the sentences respond to are, in relevant part, concerned with how the majority’s construction of the exception to the bar on judicial review would apply in situations where practical issues, such as a lack of financing or an inability to withstand the costs of waiting for review, preclude plaintiffs from taking action that would trigger administrative review. *See id.* at 42–43, 49–52 (Thomas, J., dissenting) (describing the majority opinion as “peculiar[ly] . . . interpreting a statute to deny judicial review to the poor with the promise that the rich will obtain review in their stead”).

Courts applying the proxy theory eschew *Illinois Council*’s distinction between outright administrative preclusion and practical roadblocks to administrative review. Instead of considering the cause of a plaintiff’s

³ Because the Secretary denied that these practices occurred and the Council provided “no convincing reason to doubt the Secretary’s description,” the Supreme Court did not have to decide whether such agency arm-twisting amounted to “practical equivalent of a total denial of judicial review.” *Illinois Council*, 529 U.S. at 22 (quoting *Haitian Refugee Ctr., Inc.*, 498 U.S. at 497).

preclusion and analyzing whether channeling is required in the light of *Illinois Council*, these courts characterize the issue in terms of whether channeling is required when there is “an avenue for administrative and judicial review of a particular claim . . . but not by the category of affected parties who wish to bring it.” See *Council for Urological Ints.*, 668 F.3d at 708; *Sensory Neurostimulation, Inc.*, 977 F.3d at 983. With this framing, they then misapply the *Illinois Council* majority’s clarification regarding plaintiffs facing practical roadblocks and metastasize the theory to bar all plaintiffs, even those expressly denied administrative review. See, e.g., *Row 1 Inc. v. Becerra*, 92 F.4th 1138, 1147–48 (D.C. Cir.), *cert. denied*, 145 S. Ct. 413 (2024); *RICU LLC v. U.S. Dep’t of Health & Hum. Servs.*, 22 F.4th 1031, 1038–39 (D.C. Cir. 2022); *Sensory Neurostimulation, Inc.*, 977 F.3d at 983–84.

b. Vacatur of Agency Rules is Likely Unconstitutional

The circuit courts that have adopted the proxy theory assume that a proxy sufficiently substitutes for the precluded party if the proxy is willing and able to pursue the same “particular claim” one day in federal court. See, e.g., *Council for Urological Ints.*, 668 F.3d at 712–13; *RICU LLC*, 22 F.4th at 1038; *Row 1 Inc.*, 92 F.4th at 1148 (considering the “alignment in incentives”). Here, no party disputes that a Tier 3 OPO that properly exhausts could raise the same challenges to the Final Rule made in this action or that a Tier 3 OPO

would be adequately incentivized to litigate those claims. Indeed, the organizations include soon-to-be Tier 3 OPOs.

Importantly, the proxy theory rests upon the unstated premise that the relief sought by the proxy will benefit the precluded party—ordinarily through the removal of the unlawful agency action, known as vacatur.⁴ See *RICU LLC*, 22 F.4th at 1038–39; *Council for Urological Ints.*, 668 F.3d at 712–13; *Retina Grp. of New England, P.C. v. Dynasty Healthcare, LLC*, 72 F.4th 488, 497–99 (2d Cir. 2023); *Sensory Neurostimulation, Inc.*, 977 F.3d at 974–77, 983–84; *Row 1 Inc.*, 92 F.4th at 1142–43, 1148; *Sw. Pharmacy Sols., Inc. v. Ctrs. for Medicare & Medicaid Servs.*, 718 F.3d 436, 445–46 (5th Cir. 2013); *Nat’l Athletic Trainers’ Ass’n, Inc.*, 455 F.3d at 505–07. In other words, vacatur of the agency rule or regulation in the ordinary proxy scenario remedies not only the proxy’s harm, but also the harm felt by the judicially precluded party. See, e.g., *Council for Urological Ints.*, 668 F.3d at 708.

Even assuming *Illinois Council* countenanced a proxy theory, what relief a proxy may secure and how it adequately remedies the precluded party’s injury must inform the inquiry into whether the proxy is an adequate substitute. If a proxy cannot obtain relief that would remedy, to some extent,

⁴ A universal injunction—the other form of relief that would similarly benefit precluded parties—is, now clearly, beyond the power of federal courts. See *Trump v. CASA, Inc.*, 606 U.S. 831, 856 (2025). The circuit courts that embraced the proxy theory did so before *CASA*.

the harms of the precluded plaintiff, the proxy must, by definition, be inadequate. Otherwise, the would-be proxy is “ineffective” to represent the interests of the barred plaintiff. *See Regeneron Pharms., Inc. v. United States Dep’t of Health & Hum. Servs.*, 510 F. Supp. 3d 29, 44 (S.D.N.Y. 2020) (finding “no adequate proxies” when potential proxies would likely receive injunctive relief limited to themselves and would not “result in Plaintiff’s sought-after relief”); *Sw. Pharmacy Sols., Inc.*, 718 F.3d at 445 (noting that the plaintiff “has not demonstrated that the [proxies] would be *ineffective* or unwilling proxies” (emphasis added)).

As a result, the proxy theory’s built-in assumption that vacatur renders the proxy an adequate substitute places great weight on the propriety of vacatur. And, because the Secretary argues that the proxy theory precludes application of the *Illinois Council* exception and thus the organizations cannot proceed in federal court, I assess whether vacatur is proper.

I have previously raised questions about whether the “set aside” language in Section 706(2) of the APA created a new universal remedy known as vacatur. *See* K. Mizelle, *To Vacate or Not to Vacate: Some (Still) Unanswered Questions in the APA Vacatur Debate*, 2023 HARV. J. L. & PUB. POL’Y PER CURIAM 1, 14–18 (2023). This statutory question remains open, and both jurists and academics vigorously contest its merits. *Contrast United States v. Texas*, 599 U.S. 670, 693–703 (2023) (Gorsuch, J., concurring in the judgment)

(concluding that whether the APA authorizes vacatur is not “open and shut”), *with Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 603 U.S. 799, 826–43 (2024) (Kavanaugh, J., concurring) (concluding that there is a “longstanding consensus” that “vacatur is an appropriate remedy”).⁵

Yet, the statutory-interpretation debate pales in comparison to the constitutional questions looming behind vacatur of agency rules.⁶ Even if Congress were to enact a law clearly empowering Article III courts to vacate agency rules or regulations and automatically cause their erasure from the Code of Federal Regulations, vacatur would likely still be inconsistent with the limited nature of the judicial power and the non-delegability of core legislative power to the judiciary. As a result, I doubt any amount of tradition, practice,

⁵ Academics have exhaustively debated the meaning of “set aside” in the APA. Contrast J. Harrison, *Section 706 of the Administrative Procedure Act Does Not Call for Universal Injunctions or Other Universal Remedies*, 37 YALE J. ON REGUL. BULL. 37, 42 (2020), J. Harrison, *Vacatur of Rules Under the Administrative Procedure Act*, 40 YALE J. ON REGUL. BULL. 119, 120 (2023), A. Bamzai, *The Path of Administrative Law Remedies*, 98 NOTRE DAME L. REV. 2037, 2041 (2023); W. Baude & S. Bray, Comment, *Proper Parties, Proper Relief*, 137 HARV. L. REV. 153, 180–83 (2023), and I. Wurman, “Set Aside” 7, 50 (Aug. 18, 2026) (unpublished manuscript) <https://ssrn.com/abstract=7301298>; with M. Sohoni, *The Power to Vacate a Rule*, 88 GEO. WASH. L. REV. 1121, 1122 (2020), R. Levin, *Vacatur, Nationwide Injunctions, and the Evolving APA*, 98 NOTRE DAME L. REV. 1997, 2001 (2023), and E. Bremer, *Vacatur Within the Appellate Model of Judicial Review*, 136 YALE L.J. (forthcoming 2026) (manuscript at 8).

⁶ Unless otherwise noted, when I refer to “vacatur,” I mean vacating rules or regulations of general applicability, not other kinds of agency action, such as adjudications, fact findings, party-specific grants, or the like.

or lower-court liquidation can correct the constitutional infirmities of vacatur as currently understood.

Because I am not aware of any court to have addressed the constitutional dimensions of vacatur as opposed to its statutory basis, and I have only gestured at them in the past, *see* K. Mizelle, *To Vacate or Not to Vacate*, at 19–20, I explain my doubts in full. First, I address why vacatur, if considered an equitable remedy, likely transgresses Article III’s grant of judicial power because it has no Founding-era analogue and does not comport with traditional principles of equity. Second, I explain why vacatur, if considered a legal remedy, presents serious separation-of-powers problems. Third, I address why vacatur, when analogized to appellate review, still fails to cure those significant separation-of-powers issues. Finally, I conclude that, consistent with the Constitution, “set aside” in Section 706 is best read as a rule of decision when applied to agency rules.

(1) If Vacatur Is an Equitable Remedy, It Is Likely Unconstitutional

The constitutional concerns of vacatur as an equitable remedy have become more acute in the light of the Supreme Court’s recent decision in *Trump v. CASA, Inc.*, 606 U.S. 831 (2025). In *CASA*, the Supreme Court held that, under the Judiciary Act of 1789, a federal court’s power to grant equitable relief extends only to equitable remedies that are sufficiently analogous to ones

that were available in the English High Court of Chancery at the time of the Founding. 606 U.S. at 841–42 (quoting *Grupo Mexicano de Desarrollo S.A. v. All. Bond Fund, Inc.*, 527 U.S. 308, 318–19 (1999)). Applying that principle to universal injunctions, the Court held that they lack a sufficient analogue in the party-specific equitable remedies that existed in Founding-era courts of equity, and so universal injunctions exceed the Judiciary Act’s grant of equitable power to the federal courts.⁷ *Id.* at 842. But, in reaching this conclusion, the Supreme Court declined to opine on whether Congress may empower courts to grant equitable remedies beyond those available under the Judiciary Act without transgressing Article III’s limitations on the judicial power. *Id.* at 841 n.4. The Court also expressly reserved the “distinct question whether the Administrative Procedure Act authorizes federal courts to vacate federal agency action.” *Id.* at 847 n.10.

Although the Court did not reach those two questions in *CASA*, the reasoning of that opinion casts significant doubt on the constitutionality of vacatur as an equitable remedy. If the Judiciary Act’s grant of equitable authority is coextensive with Article III’s limits on equitable power, and if

⁷ The Court left open a limited exception for “injuries for which it is all but impossible for courts to craft relief that is complete *and* benefits only the named plaintiffs,” for example, “racially gerrymandered congressional maps.” See 606 U.S. at 852 & n.12 (citing *Shaw v. Hunt*, 517 U.S. 899 (1996)). These “indivisible remed[ies]” are “appropriate only when it would be ‘all but impossible’ to devise relief that reaches only the plaintiffs”—a “high bar.” *Id.* at 865 (Thomas, J., concurring).

vacatur is an equitable remedy, then vacatur cannot be constitutional unless it aligns with the principles of equity traditionally exercised by the English High Court of Chancery at the inception of our Country. In other words, vacatur needs a Founding-era analogue.

Start with the premise that vacatur is an equitable remedy. In this circuit, vacatur is “[u]ndeniably” “equitable relief” and the “decision whether to vacate agency action falls within [a court’s] broad equitable discretion.” *Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng’rs*, 781 F.3d 1271, 1290 (11th Cir. 2015) (quoting *Alabama v. Ctrs. for Medicare & Medicaid Servs.*, 674 F.3d 1241, 1244 (11th Cir. 2012) (per curiam)).⁸ Other circuits similarly view vacatur as equitable. *See, e.g., NicQuid, L.L.C. v. Food & Drug Admin.*, No. 24-60272, 2026 WL 2425806, at *6 n.20 (5th Cir. Aug. 19, 2026) (“We view [vacatur] as an equitable remedy.”); *WildEarth Guardians v. U.S. Bureau of Land Mgmt.*, 870 F.3d 1222, 1239 (10th Cir. 2017). Academics, too, describe vacatur alongside equitable remedies. *See, e.g., S. Bray, Multiple*

⁸ Although not addressing its constitutionality, the Eleventh Circuit has said that vacatur is the “ordinary APA remedy,” *Black Warrior Riverkeeper*, 781 F.3d at 1290 (quotation omitted), and I have on one occasion ordered vacatur of an agency rule consistent with that guidance, *see Health Freedom Def. Fund, Inc. v. Biden*, 599 F. Supp. 3d 1144 (M.D. Fla. 2022), *vacated as moot sub nom. Health Freedom Def. Fund v. President of United States*, 71 F.4th 888 (11th Cir. 2023). Even though I expressed “skepticism” regarding vacatur, I ultimately found that such relief “[was] necessary to grant complete relief to [the parties].” *Id.* at 1176–77; *see, e.g., CASA*, 606 U.S. at 852 & n.12 (allowing for nationwide relief where “it is all but impossible for courts to craft relief that is complete *and* benefits only the named plaintiffs”).

Chancellors: Reforming the National Injunction, 131 HARV. L. REV. 417, 421 (2017); A. Bamzai, *The Path of Administrative Law Remedies*, 98 NOTRE DAME L. REV. 2037, 2041 (2023).

Assuming vacatur is an equitable remedy, it must comport with Article III's extension of the "judicial Power" to "Cases, in . . . Equity." U.S. CONST. art. III, § 2, cl. 1. Although *CASA* cabins its reasoning to the Judiciary Act's grant of equity authority, there are compelling reasons to think that Article III does not allow courts to grant equitable remedies that lack a Founding-era analogue and that defy traditional principles of equity. *See CASA*, 606 U.S. at 862 (Thomas, J., concurring) ("[S]erious constitutional questions would arise even if Congress purported to one day allow universal injunctions." (quoting *Trump v. Hawaii*, 585 U.S. 667, 714 n.2 (2018) (Thomas, J., concurring))); *id.* ("In no circumstance can a court award relief beyond that necessary to redress the plaintiffs' injuries. This limitation follows from both Article III and traditional equitable practice." (citation omitted)).

As an initial matter, the full measure of equitable power under Article III likely matches the system of remedies administered by the English Court of Chancery at the time of the Founding, the same equitable power the Judiciary Act bestowed on federal courts. This is true because the "system of judicial remedies . . . had been devised and was being administered by the English Court of Chancery at the time of" the Revolution, *Grupo Mexicano*, 527

U.S. at 318 (quoting *Atlas Life Ins. Co. v. W.I. Southern, Inc.*, 306 U.S. 563, 568 (1939)), and was settled “at the time of the adoption of the Constitution and the enactment of the original Judiciary Act,” *see id.* (quoting A. DOBIE, *HANDBOOK OF FED. JURIS. & PROC.* 660 (1928)). Thus, by the Founding, the principles governing equitable relief had been “reduced to a regular system.” *See* THE FEDERALIST NO. 83, at 569 n.* (J. Cooke ed. 1961). The Constitution and the Judiciary Act then “conferred” this system “en masse upon the national judiciary.” J. POMEROY, *EQUITY AND JURIS.* § 294 (1941). To be sure, the Supreme Court has “repeatedly decided that the equity jurisdiction of the courts of the United States . . . is the same in nature and extent as the equity jurisdiction of England, from which it is derived.” *Dodge v. Woolsey*, 59 U.S. (18 How.) 331, 347 (1855) (citing *Gordan v. Hobart*, 10 F. Cas. 795, 797 (C.C.D. Me. 1836) (Story, Circuit Justice)); *see CASA*, 606 U.S. at 841 (“The equity jurisdiction conferred on the Federal courts is the same that the High Court of Chancery in England possesses.” (quoting *Payne v. Hook*, 74 U.S. (7 Wall.) 425, 430 (1869))).⁹

⁹ The Supreme Court’s early cases do not specify whether they are examining Article III or the Judiciary Act as the limit on courts’ equitable powers. *See* O. Gallogly, *Equity’s Constitutional Source*, 132 YALE L.J. 1213, 1301–07 (2023). Either way, “the Supreme Court typically considers early congressional enactments, and the Judiciary Act in particular, to be weighty evidence of the Constitution’s original meaning. Thus, if early federal judges understood ‘equity’ in section 11 [of the Judiciary Act] to refer to precedent-based Chancery practice, it stands to reason that they would have understood ‘Equity’ in Article III the same way.” *Id.* at 1307–08.

History also rejects any unbounded view of equitable power not so limited “in nature and extent” as the English Court of Chancery’s at the Founding. “The scope of the federal courts’ equitable authority under the Constitution was a point of contention at the founding, and the ‘more limited construction’ of that power prevailed.” *Trump v. Hawaii*, 585 U.S. at 715 (Thomas, J., concurring) (quoting *Missouri v. Jenkins*, 515 U.S. 70, 126 (1995) (Thomas, J., concurring)). As Justice Thomas has explained, the Anti-Federalists worried that Article III’s “mention of equity jurisdiction” was “‘intended to lodge an arbitrary power or discretion in the judges, to decide as their conscience, their opinions, their caprice, or their politics might dictate,’” *Jenkins*, 515 U.S. at 128 (Thomas, J., concurring) (quoting FEDERAL FARMER NO. 15, Jan. 18, 1788, in 2 THE COMPLETE ANTI-FEDERALIST 322 (H. Storing ed. 1981)), which “would result in the growth of federal power and the ‘entire subversion of the legislative, executive and judicial powers of the individual states,’” *id.* (quoting BRUTUS NO. 11, Jan. 31, 1788, in 2 Storing 419). To address those concerns, the Federalists argued that the judicial power would be “bound down by strict rules and precedents, which serve to define and point out their duty in every particular case that comes before them,” *id.* at 129 (quoting THE FEDERALIST NO. 78, at 529 (A. Hamilton) (J. Cooke ed., 1961)), and “emphasized that . . . ‘the principles by which [equitable] relief is governed

are now reduced to a regular system,’ ” *id.* (quoting THE FEDERALIST NO. 83, at 569 n.* (A. Hamilton) (J. Cooke ed., 1961)). Thus, to persuade the public to accept Article III’s framework, the Constitution’s proponents “espous[ed] a narrower interpretation of the equity power.” *Id.* at 126. And, often, “[w]hen an attack on the Constitution is followed by an open Federalist effort to narrow the provision, the appropriate conclusion is that the drafters and ratifiers of the Constitution approved the more limited construction in response.” *Id.* at 126–27 (quoting *McIntyre v. Ohio Elections Comm’n*, 514 U.S. 334, 367 (1995) (Thomas, J., concurring in the judgment)). In the light of this historical backdrop, it would be strange to conclude that the Constitution allows for the creation of sweeping equitable remedies unknown to Founding-era courts of equity.¹⁰ Thus, history strongly supports the view that the Judiciary Act and

¹⁰ There appears to have been little discussion about federal courts’ equity power at the Constitutional Convention itself. During the initial reading of the draft Judiciary article, William Samuel Johnson “suggested that the judicial power ought to extend to equity as well as law—and moved to insert the words ‘both in law and equity’ after the words ‘U.S.’ in the 1st line of sect. 1.” *The 1787 Constitutional Convention 2021 Edition: Monday 27 August 1787 in Convention*, Quill Project, www.quillproject.net/m2/session/6267#674103 (quoting 2 JAMES MADISON’S NOTES OF THE CONSTITUTIONAL CONVENTION 428 (M. Farrand ed., 1911 (accessed Sept. 21, 2026)). George Read “objected to vesting these powers in the same Court,” but the Convention voted to adopt Johnson’s proposal over Read’s objection. *Id.* One reasonable interpretation of this history is that the delegates understood the well-settled difference between legal and equitable powers such that further debate was not needed.

Article III refer to the same “system” of equitable principles. *See also* J. STORY, COMMENTARIES ON EQUITY JURIS. § 57, pp. 64–65 (2d ed., 1839).

The text of Article III and the Judiciary Act likewise support this conclusion. The Constitution and the Judiciary Act both went into effect in 1789, *see* 34 *Journals of the Continental Congress*, 1774–1789, at 523 (Worthington C. Ford ed., 1937) (Sept. 13, 1788) (designating the first Wednesday in March 1789 to be “the place for commencing proceedings under the said constitution”), and they use quite similar language when referring to cases in equity, *compare* U.S. CONST., art. II, § 2, cl. 1 (extending the “judicial Power” to “all Cases[] in . . . Equity”), *with* Judiciary Act of 1789, ch. 20 § 11, 1 Stat. 78 (1789) (granting “circuit courts” “original cognizance” of “suits of a civil nature . . . in equity”); *see* R. Keenan, *Functional Federal Equity*, 74 ALA. L. REV. 879, 904 n.195 (2023) (concluding that Article III and the Judiciary Act’s grants of judicial power are “likely coextensive” based on their similar language and time of enactment).

Vacatur, then, can be constitutional as an equitable remedy—whether contemplated by the Judiciary Act or authorized by the APA—only if it is “sufficiently ‘analogous’ to the relief issued by the High Court of Chancery in England at the time of the adoption of the Constitution.” *CASA*, 606 U.S. at 841–42 (quoting *Grupo Mexicano*, 527 U.S. at 318–19) (internal quotation

marks omitted). But vacatur diverges from traditional equitable principles, and I am aware of no close historical analogue.

Turning first to equity's principles, "[g]enerally, if not universally, equity jurisdiction is exercised in personam, and not in rem." *Hart v. Sansom*, 110 U.S. 151, 154–55 (1884) (emphasis removed); see *Massie v. Watts*, 10 U.S. (6 Cranch) 148, 159 (1810) (Marshall, J.) ("The strict primary decree of a court of equity is . . . *in personam*." (discussing *Penn v. Lord Baltimore* (1750) 27 Eng. Rep. 1132; 1 Ves. Sen. 444 (Ch.)); see also S. BRAY ET AL., REMEDIES: CASES AND MATERIALS 428–36 (4th ed., 2024) (considering equity's in personam nature). This is also true for equitable remedies, which "operate[] *in personam* only." *Hart*, 110 U.S. at 155. A court of equity, "in the ordinary exercise of its jurisdiction," had "no inherent power" to act in rem. *Id.* at 155. So, "in the ordinary exercise of its jurisdiction," a "court of equity" could "compel[] a deed to be executed or canceled by or in behalf of [a] party," but had "no inherent power, by the mere force of its decree, to annul a deed or to establish a title." *Id.*¹¹ Put simply, "suits in equity were brought by and against individual

¹¹ Even critics of the Supreme Court's strict adherence to tracing the judiciary's equitable powers to the Court of Chancery concede that "[t]he hallmark feature of equity's origin story—that it acts on individuals through decrees enforced by contempt sanctions—broadly distinguishes the historic remedial authority of courts of equity from that of courts of common law." J. Pfander & M. Zakowski, *Nonparty Protective Relief in the Early Republic: Judicial Power to Annul Letters Patent*, 120 N.W. UNIV. L. REV. 623, 640–41 (2025). "[C]ourts of equity act on individuals, while courts of law act on property." *Id.* That post-ratification courts of equity (even before the formal merger of law and equity) acted, at times, in rem neither undermines the

parties” and “the ‘general rule in Equity [was] that all persons materially interested [in the suit] [were] to be made parties to it.” *CASA*, 606 U.S. at 842 (quoting STORY § 72, p. 74).

Similarly, equitable relief must be “consistent with the party-specific principles that permeate [the Supreme Court’s] understanding of equity.” *CASA* 606 U.S. at 844. Although the traditional role of equity is “to secure justice where it would not be secured by the ordinary and existing processes of law,” “suits in equity were brought by and against individual parties,” so, in general, an equitable remedy “could not bind one who was not a ‘party to the cause.’” *Id.* (citation omitted).

Unlike traditional equitable remedies, vacatur is not in personam or party specific. Instead, vacatur “has ‘nationwide effect,’ . . . and ‘affects persons in all judicial districts equally.’” *Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930, 951 (5th Cir. 2024), *rev’d and remanded sub nom. Kennedy v. Braidwood Mgmt., Inc.*, 606 U.S. 748 (2025). Vacatur operates directly against the action of a coordinate branch of government “in the abstract,” *id.*, not just refusing to give it effect or enjoining its performance but also removing its legal force wholesale. In that sense, vacatur always operates in rem against the agency

established system of equity at the Founding nor informs the constitutional question of whether vacatur of agency rules and regulations comports with those equitable principles. *Contra id.*

regulation. And vacatur ordinarily causes more disruption to the agency than party-specific remedies while wiping the rule from the books and thus impacting non-parties directly. For these reasons, vacatur appears to violate the traditional principles of equity.

As far as historical analogues, neither a declaratory judgment nor an injunction is like vacatur. These two common forms of equitable relief do not “directly interfere with enforcement of contested statutes or ordinances except with respect to the particular federal plaintiffs.” *CASA*, 606 U.S. at 844 (quoting *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931 (1975)). For the same reason, bills of peace and indivisible remedies likewise fail as apt comparators because those vehicles operate against the named parties, not the law itself, with spill-over effects as a collateral consequence. *See id.* at 847–48 (rejecting the comparison of an injunction with a bill of peace); *id.* at 865 (Thomas, J., concurring) (discussing the limitations on indivisible remedies). Vacatur voids the agency rule or regulation, rendering it a nullity, not simply unenforceable against a party. That legal fiction—of vacating an agency regulation, instead of forbidding its application to a particular plaintiff—creates odd appellate and collateral implications too, such as rendering parallel actions moot when another court “vacates” an agency action. *See Reynoso v. USCIS*, No. 8:26-cv-1314-KKM-NHA, 2026 WL 2191528, at *4 (M.D. Fla. July 30, 2026).

Vacatur as a remedy on a writ of scire facias shares some similarities to vacatur of agency action but fails to support vacatur's historical pedigree as an equitable remedy against agency rules and regulations. *Contra* Pfander & Zakowski, *Nonparty Protective Relief*, at 628 & n.18 (arguing that the writ of scire facias provides a historical basis for nonparty protective relief like APA vacatur). Created in 1285 by the Second Statute of Westminster, T. FOSTER, A TREATISE ON THE WRIT OF SCIRE FACIAS 2 (1851), the writ of scire facias was a claim generally used to compel a judgment debtor to show cause why the execution of a dormant judgment should not issue on the record against him or, as relevant here, to compel a patentholder to show cause why a letter patent should not be repealed based on the record of the patent. *See* FOSTER 2, 12. This latter form was available as an original action brought by or for the Crown “in the Petty-bag Office in Chancery or in the Court of Queen’s Bench.” *Id.* at 12. It reached letters patent issued by the Crown through Chancery, which “were used to confer a broad range of rights, including market charters (monopolies), land grants, offices or commissions, and eventually monopoly rights to market an invention.” Pfander & Zakowski, *Nonparty Protective Relief*, at 647; *see, e.g.*, J. Adams, *A State of the Title of the Massachusetts-Bay, March–May 1774*, Founders Online, Nat’l Archives (explaining the use of scire facias in vacating the Royal Charter of the Massachusetts Bay Colony); R. Berger, *Chilling Judicial Independence: A Scarecrow*, 64 CORNELL L. REV. 822,

831 (1979) (explaining the possible use of scire facias in vacating judicial appointments); S. Prakash & S. Smith, *Removing Federal Judges Without Impeachment*, 116 YALE L.J. 72, 94 (2006) (similar).

Although Chancery issued writs of scire facias, it did so under its common-law jurisdiction; scire facias was a legal, not equitable, action. *See* 3 W. BLACKSTONE, COMMENTARIES *47 (explaining that the Court of Chancery had “two distinct tribunals; the one ordinary, being a court of common law; the other extraordinary, being a court of equity” and that the “ordinary legal court” had “jurisdiction [] to hold a plea upon a scire facias to repeal and cancel the king’s letters patent, when made against law, or upon untrue suggestions”). In accord, if there were disputed factual issues in a scire facias action, Chancery delivered the record to the King’s Bench for a jury trial, after which it would “be remanded into the Chancery, and there judgment [] given.” *In re Lockwood*, 50 F.3d 966, 974 n.9 (Fed. Cir.), *vacated sub nom. Am. Airlines, Inc. v. Lockwood*, 515 U.S. 1182 (1995) (quoting 1 W. HOLDSWORTH, A HISTORY OF ENGLISH LAW 452 (6th ed. 1938)). Although equity subsumed scire facias in the nineteenth century, *see United States v. Stone*, 69 U.S. (2 Wall.) 525, 535 (1865) (“In England [setting aside or annulling a patent] was originally done by *scire facias*, but a bill in chancery is found a more convenient remedy.”), the history is clear that scire facias was a legal action in the English Court of Chancery at the Founding, *see* 3 BLACKSTONE *47 (explaining that scire facias was held in

chancery's common-law tribunal); *see also In re Lockwood*, 50 F.3d at 974 n.9 (“There seems no grounds for the suggestion . . . that there is anything ‘equitable’ about *scire facias*.” (quoting T. PLUCKNETT, A CONCISE HISTORY OF THE COMMON LAW 392 n.2 (5th ed. 1956))).

I am skeptical that vacatur as a remedy in *scire facias* provides a sufficient analogue for vacatur of an agency rule or regulation. As a threshold matter, *scire facias* was legal and neither equitable nor available under “the jurisdiction in equity exercised by the High Court of Chancery in England at the time of the adoption of the Constitution.” *Grupo Mexicano*, 527 U.S. at 318 (citation omitted). More to the point, *scire facias* was brought by or in behalf of the crown to undo a fraudulently or unlawfully procured patent, not against the sovereign. *See* J. Payne & G. Canaparo, *Is Vacatur Unconstitutional?* 12, 34–36 (C. Boyden Gray Ctr. for the Study of the Admin. State, Working Paper No. 02, 2026) (rejecting the analogy between the vacatur for a writ of *scire facias* and vacatur of agency action).¹² And significantly, the writ operated against only letters patent, such as land grants, licenses, offices or commissions, charters, monopolies, patents for inventions, or other individually granted government privileges. *See* Pfander & Zakowsky, *Nonparty Protective Relief*, at 646–47. I am not aware of evidence that vacatur

¹² Available at <https://ssrn.com/abstract=5333468>.

in scire facias ever nullified a rule-like action of the crown, such as a royal proclamation. *See* Payne and Canaparo, *Is Vacatur Unconstitutional?*, at 35. By contrast, vacatur in the administrative context operates directly against the Executive and, at least as applied to agency rulemaking, goes far beyond a particular record by annulling a regulation that has the effect of law.¹³

To conclude, I am aware of no form of equitable relief available in the English High Court of Chancery at the time of the adoption of the Constitution that is analogous to vacatur of rules. Declaratory judgments, injunctions, and bills of peace are inapt because they must be party specific. And, setting aside that scire facias was a legal writ, it fails as an analogy because scire facias could only vacate limited licenses, such as patents or grants, brought in assistance to the Executive, not against it, and not against laws of general applicability. So, if, as many courts and commentators suggest, vacatur is an equitable remedy, it very likely exceeds the “judicial Power” conferred by Article III.

¹³ As stated earlier, my focus is concerned with the constitutional dimensions of vacatur of agency rules and regulations. Thus, I have no occasion to address whether the writ of scire facias provides a historical analogue permitting courts to nullify other kinds of agency actions, such as adjudications, licensing, or permitting. Nor do I address whether the relief procured by the writ of scire facias could be sought in an “applicable form of legal action” under Section 703 of the APA. *See* FED. R. CIV. P. 81(b) (abolishing the writ of scire facias but permitting “[r]elief previously available through [it] . . . by appropriate action or motion”).

(2) If Vacatur Is a Legal Remedy, It Is Likely Unconstitutional

Because treating vacatur as an equitable remedy calls Section 706(2)'s constitutionality into question, *see, e.g., Jennings v. Rodriguez*, 583 U.S. 281, 286 (2018) (discussing the canon of constitutional avoidance), one alternative interpretation is that Section 706(2)'s “set aside” language provides a legal remedy, *see* T. E. Gaiser, M. Sridharan & N. Cordova, *The Truth of Erasure: Universal Remedies for Universal Agency Actions*, U. CHI. L. REV. (Online) (2024) (legal remedy).

If vacatur is a remedy allowed by the APA, it is more likely a legal remedy than an equitable one. “[E]xplicitly authorizing a remedy in a statute’s text’ is generally ‘inconsistent with that remedy’s being rooted in equity,’ as the ‘historical role for equity’ was providing relief where law did not.” *Sripetch v. SEC*, 146 S. Ct. 1403, 1416 (2026) (Thomas, J., concurring) (quoting *SEC v. Hallam*, 42 F.4th 316, 340 (5th Cir. 2022) (Smith, J.)). This is because equity exists to fill “remedial gap[s]” “‘where a plain, adequate, and complete remedy cannot be had’ through law.” *Id.* (quoting 1 STORY § 33). But assuming that the APA authorizes vacatur, it leaves no remedial gap for equity to fill. So, to the extent that Congress created a new “universal remed[y]” in vacatur, it is “legal, not equitable.” Gaiser, Sridharan & Cordova, *supra*.

But classifying vacatur of agency rules and regulations as a legal remedy hardly obviates constitutional concerns. Importantly, it raises the specter of whether Congress can delegate a veto-like legislative power to Article III courts without running afoul of the separation of powers. Payne & Canaparo, *Is Vacatur Unconstitutional?*, at 38–45 (arguing that vacatur is an impermissible delegation to the Judiciary). “[A] court that has ‘set aside’ an agency action has formally vetoed the agency’s work in the same way that a President vetoes a bill.” J. Mitchell, *The Writ-of-Erasure Fallacy*, 104 VA. L. REV. 933, 1015 (2018). Although a presidential veto is part of the lawmaking process, see *INS v. Chadha*, 462 U.S. 919, 947–48 (1983), Congress may not empower itself to veto an executive agency’s action in circumvention of the Constitution’s bicameralism and presentment requirements, see *id.* at 944–59. Nor may Congress extend the President’s veto power to laws that have taken effect. *Clinton v. City of New York*, 524 U.S. 417, 438–40 (1998). To the extent that vacatur’s post-enactment, veto-like nature makes it more like a legislative or executive act than a judicial act, Congress likely cannot delegate that power to courts without transgressing the separation of powers, both by assigning to the judiciary a non-delegable legislative power and by exceeding Article III’s limited judicial power. See, e.g., *Hayburn’s Case*, 2 U.S. 409 (2 Dall.) 410 n.* (1792) (reporting the decisions of several Circuit Courts that Congress cannot assign non-judicial duties to federal courts acting in their judicial capacity);

Nixon v. Admin. of Gen. Servs., 433 U.S. 425, 443 (1977) (“[I]n determining whether [an act] disrupts the proper balance between the coordinate branches, the proper inquiry focuses on the extent to which it prevents the Executive Branch from accomplishing its constitutionally assigned functions.” (citing *United States v. Nixon*, 418 U.S. 683, 711–12 (1974)); cf. *Dep’t of Transp. v. Ass’n of Am. R.R.s*, 575 U.S. 43, 68 (2015) (Thomas, J., concurring) (“When the Government is called upon to perform a function that requires an exercise of legislative, executive, or judicial power, only the vested recipient of that power can perform it.”)).

Classifying vacatur as a legal remedy also upends much of modern APA practice. A plaintiff would not need to show that there is no adequate remedy at law before resorting to vacatur. See *Sripetch v. SEC*, 146 S. Ct. 1403, 1416 (2026) (Thomas, J., concurring) (explaining that equity exists where a complete remedy cannot be had through law). Conversely, the existence of vacatur as a legal remedy would “sharply limit[] the availability of injunctions” and other equitable relief. S. Bray, *The Truth of The Truth of Erasure*, YALE J. REG. NOTICE & COMMENT (Nov. 7, 2024), <https://www.yalejreg.com/nc/the-truth-of-the-truth-of-erasure-by-samuel-l-bray/>. Today, APA plaintiffs routinely seek vacatur along with injunctions, declaratory judgments, and the like. See K. Mizelle, *To Vacate or Not to Vacate*, at 16–18 (detailing high-profile APA

challenges all seeking an assortment of remedies). But if vacatur is legal and injunctive relief unavailable, courts likewise lose their contempt power.¹⁴

(3) If Vacatur is an Appellate Determination of Agency Rules, It is Likely Unconstitutional

Distinct from the above offered justifications, Justice Kavanaugh has argued that “set aside” in Section 706(2) codifies a standalone remedy based on the well-established practice of an appellate court’s vacatur of a lower court’s order. *See Corner Post*, 603 U.S. at 838 (Kavanaugh, J., concurring) (citing M. Sohoni, *The Power to Vacate a Rule*, at 1131–34)). Stated otherwise, Section 706(2) authorizes an “appellate determination” that results in vacating the agency action. *See, e.g., Bremer, Vacatur Within the Appellate Model of Judicial Review*, at 8. But even as an appellate determination, vacatur must still comport with Article III’s limitations on judicial power.

This view reads “set aside” to empower a federal court sitting in review of an agency action to vacate it, much like an appellate court vacates an inferior court’s order. *See Corner Post*, 603 U.S. at 832 (Kavanaugh, J., concurring); *Bremer, Vacatur Within the Appellate Model of Judicial Review*, at 8. When

¹⁴ Professor Bray notes other implications, explaining that “[t]here would likely be a jury trial right in all APA suits for vacatur.” Bray, *The Truth of the Truth of Erasure*. Because I focus only on vacatur of agency rules and not agency actions requiring payment of money, I hesitate to add this consequence to the list. *See* U.S. CONST., amend. VII (“In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved.”); *see also FCC v. AT&T, Inc.*, 608 U.S. 531, 545–46 (2026).

the APA was enacted, “it was common for an appellate court that reversed the decision of a lower court to direct that the lower court’s ‘judgment’ be ‘set aside,’ meaning vacated.” *Corner Post*, 603 U.S. at 829–30 (Kavanaugh, J., concurring) (citing *Shawkee Mfg. Co. v. Hartford-Empire Co.*, 322 U.S. 271, 274 (1944)). The APA thus merely “incorporated that common and contemporaneous meaning of ‘set aside’” when “prescrib[ing]” the “‘set aside’ remedy.” *Corner Post*, 603 U.S. at 830; see Bremer, *Vacatur Within the Appellate Model of Judicial Review*, at 8 (agreeing).

Although Justice Kavanaugh does not specify whether vacatur is equitable or legal, *Corner Post*, 603 U.S. at 832 (calling vacatur a “remedy”), he embraces that the APA provides for vacatur as a remedy against all agency action, *id.* at 829. To the extent that the APA adopted appellate vacatur for judicial review of agency adjudications or enforcement proceedings, that view might be consistent with the history of agency actions at the time of enactment. See J. Harrison, *Section 706 of the Administrative Procedure Act Does Not Call for Universal Injunctions or Other Universal Remedies*, 37 YALE J. REG. BULL. 37, 45 (2020). I am skeptical, though, that vacatur as an appellate determination is a remedy or constitutional vis-à-vis agency rules.

To start, an appellate court’s vacatur of an inferior court’s order, although providing relief from a lower court’s judgment, is not a remedy. “A remedy, in the technical sense, ‘is the end result of a law suit,’ ‘what the court

actually does for, or to the client in the particular case.’” W. Baude & S. Bray, *When the Executive Has Unclean Hands*, at 580 n.83 (quoting BRAY ET AL., REMEDIES: CASES AND MATERIALS 3 (4th ed., 2024)); see *Am. Ass’n of Univ. Profs. v. U.S. Dep’t of Just.*, 175 F.4th 413, 420 n.1 (2d Cir. 2026) (Menashi, J., dissenting) (“‘Remedies . . . do not include judicial actions such as a . . . vacatur of a lower-court opinion.” (citation omitted)). “[V]acatur of a lower-court opinion,” like “a stay of an injunction” or “grant of certiorari before judgment,” operates against a judicial proceeding, not against any particular party. See Baude & Bray, *When the Executive Has Unclean Hands*, at 580 n.83; see also *Nken v. Holder*, 556 U.S. 418, 428 (2009) (contrasting injunctions, which operate in personam, with stays, which “operate[] upon the judicial proceeding itself”). So the appellate-determination model runs counter to vacatur as a remedy of any sort.

The appellate-vacatur model is also an ill-fitted analogy for vacatur of agency rules because the latter operates between different branches of government assigned fundamentally different constitutional powers. Ordinary appellate vacatur occurs between a reviewing court and an inferior court in “one phase of a single unified process” in disposing of a cause “derived from the interrelationship of judicial tribunals forming a hierarchical system.” See *FCC v. Pottsville Broad. Co.*, 309 U.S. 134, 141 (1940) (distinguishing appellate review from a court’s review of an agency action). By contrast, APA vacatur

occurs in separate executive and judicial processes outside the traditional “relationship between lower and upper courts” and annuls the act of a coordinate branch of government. *See id.* at 144. Because the appellate-determination view of vacatur operates to nullify an executive rule and not to set aside a lower court proceeding and is the ultimate relief sought by the ordinary APA plaintiff, an appellate determination model of “set aside” does not lend support for vacatur of agency rules.

Setting aside the mismatch of an appellate-determination model, I doubt that Congress can, consistent with the Constitution, delegate the act of vacating an agency rule to federal courts. In fact, the Framers decisively rejected the notion that a court can sit in review of laws in the abstract. *See Russo v. Secretary of Commerce*, No. 26-10171 2026 WL 2602668, at *10 (11th Cir. Sept. 3, 2026) (Pryor, C.J., concurring) (“Under our constitutional framework, federal courts do not sit as councils of revision. . . .” (quoting *United States v. Rutherford*, 442 U.S. 544, 555 (1979))). At the Founding, New York’s Council of Revision, which comprised the Governor, Chancellor, and New York Supreme Court, had the power to object to laws for constitutional or policy reasons. *See Moody v. NetChoice, LLC*, 603 U.S. 707, 761 (2024) (Thomas, J., concurring in the judgment). The Constitutional Convention considered creating a similar body in the federal government and voted against it “on four different occasions.” *Id.* at 761 (quoting *United States v. Hansen*,

599 U.S. 762, 789 (2023) (Thomas, J., concurring)); *id.* (“No other proposal was considered and rejected so many times.”). To be sure, Founding-era American courts “did not view judicial review in terms of ‘striking down’ laws or regulations.” *Trump v. Hawaii*, 585 U.S. at 718 (Thomas, J., concurring) (quoting *Murphy v. Nat’l Collegiate Athletic Ass’n*, 584 U.S. 453, 488–89 (2018) (Thomas, J., concurring)); *see also* J. Mitchell, *The Writ-of-Erasure Fallacy*, at 936 (“The federal courts have no authority to erase a duly enacted law from the statute books.”).

Judicial vacatur of an agency action adds an additional layer of constitutional concern to even that of the Council of Revision, which vetoed laws *before* enactment. Vacatur as contemplated allows federal courts to dislodge *existing* agency rules, thereby greatly expanding both the nature of the power and the practical effect. Superimposing the federal courts over executive agencies in this way greatly “exaggerates the role of the Judiciary in our constitutional order, allowing individual judges to act more like a legislature by decreeing the rights and duties of people nationwide.” *United States v. Texas*, 599 U.S. at 703 (Gorsuch, J., concurring in the judgment).

To be clear, I share Justice Kavanaugh’s concerns about “the radical consequences for . . . individual liberty” that follow when judicial review is unavailable against agency action. *See Corner Post*, 603 U.S. at 829 (Kavanaugh, J., concurring). But I am not convinced that the legal landscape

absent vacatur is so dire for unregulated parties. When an agency action adversely affects such a party, there are likely non-vacatur options available. For example, that party may seek an injunction against the government agency and, if appropriate, join the regulated party to secure relief. *See* FED. R. CIV. P. 19; *see also Ass’n of Data Proc. Serv. Orgs., Inc. v. Camp*, 406 F.2d 837 (8th Cir. 1969), *rev’d*, 397 U.S. 150 (1970) (seeking injunctive and declaratory relief in suit against Comptroller of Currency and regulated party). And, for reasons already explained, not all agency actions necessarily share the same constitutional concerns as agency rules when subject to vacatur, such as licenses, grants, and development awards. *See Corner Post*, 603 U.S. at 835 (expressing concern about the lack of vacatur for private citizens to challenge agency approval of development projects). But for vacatur of agency rules and regulations, however well intended, courts have no right to provide more relief than Article III permits.

(4) Vacatur As a Rule of Decision

Construing the APA as merely codifying a reviewing court’s prerogative to “disregard” or decline to give effect to an agency rule that is contrary to law avoids all the above-discussed constitutional problems. And it operates in the ordinary way that a court disregards (but does not vacate) an unlawful statute. As Justice Gorsuch has explained, it is also well-supported by the text and structure of the APA. *See, e.g., United States v. Texas*, 599 U.S. at 695

(Gorsuch, J., concurring in the judgment); Harrison, *Section 706 of the Administrative Procedure Act Does Not Call for Universal Injunctions or Other Universal Remedies*, at 37, 45–46. This interpretation likewise comports with the doctrine that Congress must speak clearly if a statute is to create a sweeping new power. *United States v. Texas*, 599 U.S. at 695 (Gorsuch, J., concurring in the judgment) (quoting *Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring)); see A. Klein, *Major Questions Doctrine Jujitsu: Using the Doctrine to Rein in District Court Judges*, 76 ADMIN. L. REV. 327, 346–48 (2023) (“It is . . . timely and appropriate for the Supreme Court to consider whether the principles that underlie the major questions doctrine require the Court to reject the universal vacatur interpretation of ‘set aside.’”). As a result, interpreting “set aside” to mean that the APA instructs courts to disregard an unlawful agency rule or regulation when rendering a decision best comports with the Constitution.

Returning to the proxy inquiry that prompted the extended discussion of vacatur, the point should be obvious to the persevering reader: a nonparty can never adequately represent another’s claim challenging an agency rule because the Constitution likely limits a federal court to disregarding the rule when fashioning individual relief to *that* proxy. With “set aside” properly understood as a rule of decision, that relief never suffices to remedy the injury of the

precluded party who is barred from proceeding in federal court. Thus, although some court someday might opine on the “particular claim” brought by a proxy, any final judgment will almost certainly not inure to the judicially precluded party’s benefit. That is not a sufficient substitute to bar review now to an injured party.

The problem with the proxy theory is that it implicitly relies on the “claim” eventually getting judicial review and, if the “claim” is successful, the court almost certainly awarding vacatur. In so doing, the proxy theory both prioritizes the abstract legal claim at the expense of an individual party’s injury and aggrandizes judicial power against the Executive. I reject that view of judicial review.

c. Vacatur is Ineffective to Address OPOs’ Harm

But assuming vacatur is an available remedy, a court would likely have no occasion in this particular monopoly context to award vacatur to an OPO proxy for two reasons.

First, vacating the Final Rule by which the Secretary evaluates the OPOs and awards DSAs (particularly when he has represented that the agency lacks the requisite data to reinstitute the former scheme), *see* Tr. 16:14–21, 40:25–41:8; Defs.’ MSJ at 50, constitutes the most disruptive remedy imaginable for the agency. It also introduces chaos for both the regulated OPOs and the intended beneficiaries, such as the organ-donor recipients, hospitals,

and transplant providers. Wholesale demolition of a monopoly scheme hardly constitutes the least-burdensome remedy to redress the particular harm of a proxy OPO, so I hesitate to think that a court would impose it when lesser remedies might suffice. *See Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (“[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs.”).

Second, vacatur of the Final Rule, alone, would not necessarily redress a proxy’s injury, so it is unclear a federal court would award it. Only relief preserving or restoring an OPO’s DSA remedies the injury suffered, namely, the decertification and award of the proxy’s DSA to another OPO. Thus, if the proxy ultimately prevails in federal court after receiving emergency injunctive relief forestalling the reassignment of its DSA, the least-disruptive relief would be to make permanent that injunction and direct the Secretary to restore the proxy’s certification. But if the proxy does not receive emergency injunctive relief, CMS will almost certainly reassign its DSA before the action is resolved. *See* Tr. 8:11–18 (noting the competition for open DSAs will take approximately seventy-five days). In this scenario, that proxy’s harm could be remedied only by an injunction directing CMS to recertify the proxy and restore its DSA. Thus, APA vacatur of the entire scheme, without a specific injunction, does little to help to a losing proxy. *See Dep’t of Homeland Sec. v. New York*, 589 U.S. 1173, 1175 (2020) (Gorsuch, J., concurring in the grant of stay) (“Equitable

remedies, like remedies in general, are meant to redress the injuries sustained by a particular plaintiff in a particular lawsuit.”).

Because of the above two problems, an injunction would be the least-disruptive and the most-ameliorating remedy to any proxy. And it stands on firmer constitutional footing. Indeed, vacatur does both more as matter of power against the agency and less as a matter of real remedy to a proxy, contrary to the nature of equity.

Even if, notwithstanding the above, a court vacated the Final Rule at the behest of a proxy, this would not stanch the Tier 2 OPOs’ bleeding. Indeed, Tier 3 OPOs are unable to obtain relief that remedies the chief injury suffered by a losing Tier 2 OPO: the reassignment of its DSA. As noted above, vacatur of the entire regulation creating the ranking system does not undo the reassignments of the DSA monopolies. At oral argument, I inquired how the proxy theory maps onto the present scenario given that each DSA is a government-granted monopoly, which is the mechanism for an OPO to earn revenue and, without one, an OPO falls into financial ruin. *See* Tr. 41:18–42:7, 49:8–14, 52:2–7, 53:11–22, 57:8–59:15; Pls.’ Suppl. Brief at 3; Lahrman Decl. (Doc. 1-2) ¶¶ 27, 49, 51; Rabel Decl. (Doc. 1-4) ¶ 51; *see also* 42 C.F.R. §§ 486.302 (“Designation means CMS assignment of a geographic service area to an OPO.”), 486.304(a) (“Designation is a condition for payment.”); Pls.’ MSJ at 8 (describing decertification as a “death penalty”).

Under the Secretary's view, no jurisdiction exists until the OPO Tier rankings are announced and an OPO receives a Tier 3 decertification, administratively exhausts, and then brings a challenge in federal court. *See* Tr. 18:22–19:25, 20:16–25, 37:8–20, 45:13–19. The Secretary also represented that, ideally, a Tier 3 OPO would secure emergency injunctive relief forestalling the reassignment of *its* DSA before CMS could award it to another OPO. *See id.* 18:13–20, 29:17–30:3. The Secretary also hypothesized that, if the Final Rule was then vacated, all OPAs would revert to the pre-2006 posture with blanket recertification. *See id.* 16:14–17:5. But recertification does not reassign DSAs, it simply makes OPOs *eligible* for assignment. Moreover, the losing Tier 2 OPOs would not have been decertified in the first place and would not be assigned a DSA by dint of the vacatur. *See id.* 40:25–41:8, 42:15–19, 44:6–8. Thus, under the scenario outlined by the Secretary, nothing about the proxy theory remedies the Tier 2 losers' primary harm: the loss of their DSAs, which the agency would have reassigned long before any vacatur. *See* Tr. 8:11–18 (noting the competition for DSAs takes approximately 75 days); *id.* 10:10–14 (describing the time to appeal as taking approximately 95 *business days*); 42 C.F.R. § 486.314 (allowing for up to 145 business days for the administrative appeals process).

Under the organizations' view, this preenforcement action is ripe now because the data conclusively indicates that they will have Tier 2 and Tier 3

designations among them. *See* Tr. 20:3–11, 46:18–47:14, 60:1–17. To remedy that certain, impending harm, including the inevitable reassignment of Tier 2 losers’ DSAs without the ability to administratively exhaust that final agency action, the organizations want vacatur of the Final Rule. *See id.* 59:16–61:4. In their view, vacating the rule is *less* exacting towards the agency than the alternatives of DSA-OPO specific injunctions or, as even the Secretary admitted, the nightmare of reassigning improperly awarded DSAs back to OPOs after a competition concludes. *See id.* 65:12–66:15. Even if feasible, I remain skeptical that Article III courts have the power to oversee the reassignment of government-awarded monopolies writ large. *See Trump v. CASA, Inc.*, 606 U.S. 831, 861 (2025) (“[F]ederal courts do not exercise general oversight of the Executive Branch; they resolve cases and controversies consistent with the authority Congress has given them. When a court concludes that the Executive Branch has acted unlawfully, the answer is not for the court to exceed its power, too.”); *see also Gregory v. Stetson*, 133 U.S. 579, 586 (1890) (“It is an elementary principle that a court cannot adjudicate directly upon a person’s right without having him either actually or constructively before it. This principle is fundamental.”).

When asked what remedy a court could provide if a Tier 3 OPO’s DSA was already reassigned by the time the OPO received judicial review, the Secretary could identify none. Tr. 17:19–18:13; *see also id.* 42:15–19. When

asked the same question, the organizations also could not identify one. *See id.* 57:22–58:10. In the light of these admissions, the parties appear to concede that, if pre-enforcement review of the Final Rule is foreclosed, then Tier 2 losers (and perhaps even Tier 3 OPOs) are left with no ability to secure judicial relief.

In sum, both sides agree that vacating the Final Rule after a would-be proxy OPO reaches federal court would do nothing for the Tier 2 OPOs. *See* Tr. 40:25–45:13, 58:18–60:25. However the proxy rule might operate in other contexts, the dynamic created by the monopoly of the DSAs precludes reliance on the only potential proxies—Tier 3 OPOs. And because courts considering a challenge properly brought by a Tier 3 OPO could not issue injunctive relief remedying the deprivation of a Tier 2 OPO’s DSA that cannot be restored, judicial review must come now to avoid no review at all.

iii. The Organ Procurement Organization Certification Act Does Not Implicitly Require Exhaustion

The Secretary argues that, even if channeling is not required under the Medicare Act, the Organ Procurement Organization Certification Act implicitly precludes pre-enforcement review because the organizations must first bring their claims in the statutory review process found in Section 273 and 42 C.F.R. § 486.314. *See* Defs.’ MSJ at 32–34. At times, Congress may “allocate[] initial review [of final agency actions] to an administrative body,” *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207 (1994), but its intent to do

so must be “fairly discernible in the statutory scheme,” *Ass’n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 157 (1970).

Courts “presume that Congress does not intend to limit district court jurisdiction if” (1) “a finding of preclusion could foreclose all meaningful judicial review”; (2) “the suit is wholly collateral to a statute’s review provisions”; and (3) “the claims are outside the agency’s expertise.” *Elgin v. Dep’t of Treasury*, 567 U.S. 1, 15 (2012) (citation modified). “But the same conclusion might follow if the [three] factors point in different directions. The ultimate question is how best to understand what Congress has done—whether the statutory review scheme, though exclusive where it applies, reaches the claim in question.” *Axon Enter., Inc. v. Fed. Trade Comm’n*, 598 U.S. 175, 186 (2023).

As discussed above, precluding judicial review of the claims in favor of the administrative appeals process would foreclose all meaningful judicial review—at least for Tier 2 OPOs. The claims here are also collateral to Section 273’s review provision, which allows an appeal regarding only a decertification. *See* 42 U.S.C. § 273(b)(1)(D)(ii)(IV); 42 C.F.R. § 486.314. The organizations bring APA challenges to the Final Rule itself; they do not contest a decertification or raise any issue that could be addressed in Section 273’s appeals process. *See Mathews v. Eldridge*, 424 U.S. 319, 330 (1976) (holding that a claim that an agency’s administrative procedures were unconstitutional

was “entirely collateral” to a substantive claim of entitlement to benefits); *cf. Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 490 (2010) (“Petitioners’ general challenge to the Board is ‘collateral’ to any Commission orders or rules from which review might be sought.”). Lastly, the claims here are outside CMS’s expertise as they are “standard questions of administrative law, which the courts are at no disadvantage in answering.” *Free Enter. Fund*, 561 U.S. at 491.

Even if one disagreed with the above factors, the answer to the “ultimate question” of “whether the statutory review scheme . . . reaches the claim in question” is no. *Axon Enter., Inc.*, 598 U.S. at 186. The scheme is limited to allowing only Tier 3 OPOs to appeal one agency action. The administrative process provides no avenue for consideration of the claims here, and serious questions remain as to whether even the Tier 3 OPOs would receive judicial relief by the time the administrative process concludes.

The Organ Procurement Organization Certification Act does not implicitly require the organizations to first exhaust the instant claims in administrative review. Thus, I have jurisdiction to consider the APA claims.

C. The Final Rule Is Lawful

The organizations raise three merits arguments under the APA. First, that the Final Rule contravenes the text of 42 U.S.C. § 273(b)(1)(D). *See* Pls.’ MSJ at 28–43. Second, that the Final Rule is arbitrary and capricious and not

reasonably justified. *See id.* at 43–56. And third, that the Final Rule fails to respond to significant comments regarding consequences for patients and the national donor network. *See id.* at 56–59. None succeed.

i. The Final Rule Does Not Violate the Statute

The organizations contend that the Final Rule violates 42 U.S.C. § 273(b)(1)(D)(ii), which grants the Secretary authority to establish a scheme governing certification and recertification of OPOs. The Secretary’s regulatory scheme must:

- (I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;
- (II) rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations;
- (III) use multiple outcome measures as part of the certification process; and
- (IV) provide for a qualified organ procurement organization to appeal a decertification to the Secretary on substantive and procedural grounds

Id.

The organizations advance three largely atextual reasons for how the Final Rule violates Section 273. First, the scheme purportedly “fails to apply both process and multiple outcome measures.” Pls.’ MSJ at 28. Second, it “decertifies organizations and exposes others to replacement with no evaluation of their actual performance.” *Id.* Third, it “fails to account for

material differences between service areas, which is necessary to accurately evaluate organizations' comparative performance." *Id.*

1. Failure to Apply Process and Multiple Outcome Measures

Because the "Final Rule does not apply any *process* measures when evaluating performance over the four-year recertification period," the organizations argue that it violates Section 273. *Id.* at 31. The organizations' core contentions appear to be that, because the process performance measures are treated by the certification scheme as minimums that all OPOs must meet, while the outcome performance standards are evaluated in comparison to other OPOs, the scheme is not truly relying on the process performance measures. *See* Pls.' Resp. at 16. Further, the organizations take issue with the fact that an OPO is recertified only if it receives passing marks in the process performance measures and in both outcome performance measures. *See id.* The organizations read the statute as requiring CMS to rely on these various measures to the benefit of the OPOs, not to their potential detriment. These arguments are without merit.

Although the Final Rule itself does not implement any new process performance measures for evaluating OPO performance, the Final Rule augments the broader regulatory scheme that has applied process performance measures since 2006. *See* Defs.' MSJ at 36–37; Defs.' Reply at 16–17; 42 C.F.R.

§§ 486.320–486.348 (process performance measures for OPOs). Section 273 requires that the *scheme* for certification and recertification include process performance measures, not that every Final Rule include a specific process performance measure component. In any event, to receive a Tier 1 or Tier 2 designation, an OPO must demonstrate compliance with the process performance measures. *See* 42 C.F.R. § 486.316(a)(1)(i), (2)(i). Additionally, nothing in the statute requires CMS to evaluate all metrics either in a binary pass or fail manner or conversely in a comparative manner across the OPOs. Nor does the statute require CMS to evaluate multiple measures to the benefit of the OPOs such that success in one or more measures excuses failure in another.

The organizations argue that the “Final Rule is also invalid because it does not apply *multiple* outcome measures of performance.” Pls.’ MSJ at 32. The organizations contend that, because the two outcome metrics—donation and transplantation rates—use the same denominator of donor potential, they are “too closely related to qualify as separate measures.” *Id.* The organizations also dispute the use of a transplantation rate as an outcome metric at all, as it is not “a measure of the performance of the [OPOs] themselves” but depends on a variety of factors, including “the performance and judgment of the transplant surgeons.” *Id.* at 33. Both contentions fail.

As the Secretary notes, nothing in the statute requires that the outcome performance metrics be unrelated or independent measures. *See* Defs.’ MSJ at 42. Thus, correlation between the two measures does not violate the statute. Further, although the organizations make take issue with the transplantation rate because OPOs do not control the ultimate decision to transplant any given organ, the OPOs have the ability to “influence . . . transplant hospital practice through OPO advisory boards” and “to place their organs outside of their DSA,” including at the “numerous transplant hospitals throughout the country that successfully transplant ‘less than perfect’ organs.” Organ Procurement Organizations Conditions for Coverage, 84 Fed. Reg. 70,628, 70,632 (Dec. 23, 2019) (codified at 42 C.F.R. pt. 486); *see also* Defs.’ Reply at 21. That the discretion of others impacts, in part, an OPO’s transplantation rate does not render it an invalid outcome performance measure under Section 273, particularly because it correlates with an OPO’s ability to influence key stakeholders and actors in the organ-donation and transplantation arena.

2. Failure to Evaluate Actual Performance

The organizations argue that the Final Rule violates Section 273 because decisions to decertify an OPO or give away its DSA are done “based not on any objective measure of their *actual* performance but instead based only on their *comparative* donation and transplantation rates.” Pls.’ MSJ at 35. The organizations further contend that the Final Rule’s tier-structure and

comparative-rate focus “will inevitably cause consolidation over time and, ultimately, the decertification of all but one organization.” *Id.* Aside from noting that Section 273 requires that CMS establish performance standards and evaluate OPOs against them, *see id.* at 36, the organizations largely ignore Section 273’s text. Instead, they contend that if Congress wanted “such a draconian and disruptive approach, . . . it would have said so.” *Id.* at 35.

Congress delegated to the Secretary the authority to determine how OPOs measure up against the outcome performance metrics. *See* 42 U.S.C. § 273(b)(1) (“A qualified [OPO] . . . is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2)”); *id.* § 273(b)(1)(D)(ii) (“[I]s defined through regulations that are promulgated by the Secretary”); *id.* § 1320b-8(b)(1)(C) (requiring that OPOs meet “performance-related standards prescribed by the Secretary” to be reimbursed); *Baptist Mem’l Hosp. - Golden Triangle, Inc. v. Azar*, 956 F.3d 689, 693 (5th Cir. 2020) (holding that an “as determined by the Secretary” clause “expressly delegates gap-filling authority to the Secretary”); *Children’s Hosp. Ass’n of Texas v. Azar*, 933 F.3d 764, 770 (D.C. Cir. 2019) (same). Nothing in Section 273 prohibits the Secretary from establishing outcome performance measures that turn on relative performance compared to other OPOs. Nor is this a new evolution by the Final Rule. Since 1996, the Secretary has measured outcomes based on the relative performances of OPOs. *See* Conditions of

Coverage for Organ Procurement Organizations, 61 Fed. Reg. 19,722, 19,744 (May 2, 1996) (then-codified at 42 C.F.R. § 486.310(b)); Defs.’ MSJ at 16. Although certainly not dispositive of a text’s meaning, that “consistent” historical practice lends support to reading Section 273 as granting the Secretary discretion to measure performance outcomes of OPOs via comparison. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024) (citation omitted); Defs.’ MSJ at 46. And the use of confidence intervals and the decision to set the threshold rate based on the previous year’s metrics allows for the possibility that all OPOs may achieve outcome performance metrics that qualify them for Tier 1, despite the organizations’ claims otherwise. Defs.’ MSJ at 46–47. According to the Secretary, that was the Final Rule’s goal: to establish a scheme with “both the incentive and opportunity for all OPOs to cluster near the top,” even if “the number of OPOs might initially constrict.” *Id.* at 47 (citation modified).

3. Failure to Measure Performance Based on Empirical Evidence of Other Related Factors

The organizations contend that the Final Rule violates Section 273 because the outcome and process performance measures are not “based on empirical evidence . . . of . . . other related factors in each service area” of qualified OPOs. Pls.’ MSJ at 40 (citation modified); 42 U.S.C. § 273(b)(1)(D)(ii)(II). Because DSAs differ greatly in “the location and distance

between hospitals and transplant centers, and the performance of healthcare providers at those hospitals and transplant centers[,] . . . the occurrence of natural disasters; changes in population size; shifts in the socioeconomic status of populations in the service area; the incidence of chronic disease; and other racial, ethnic, religious, and cultural characteristics,” the organizations argue that Section 273 requires that CMS account for “each [OPO’s] success (or failure) in responding to different challenges in their respective [DSAs].” Pls.’ MSJ at 40–42.

The Secretary responds that the certification scheme includes consideration of “numerous process measures that address factors related to donor potential, like how OPOs should obtain donor consent . . . and evaluate potential donors’ eligibility.” Defs.’ MSJ at 39. The organizations contest this point only to the extent that the certification scheme does not allow excellent process performance metrics to offset a subpar showing in the outcome performance metrics. *See* Pls.’ Resp. at 23. As explained above, nothing in Section 273 requires the Secretary to establish a scheme where good performance on process measures redeems poor outcome measures or vice versa. And, although not required by the statute, the certification scheme allows for an OPO to request a “one-year extension if circumstances ‘beyond the control of the OPOs’ have ‘affected the data of the final assessment period so that it does not accurately capture their performance.’” Defs.’ MSJ at 39

(citing 42 C.F.R. § 486.316(f)). This allows an OPO to identify factors or events unique to its DSA that negatively impacted its performance outcome measures and seek a reprieve.

The Secretary notes that risk-adjusting an OPO's transplantation rate by age and narrowing the definition of donor potential to account for causes of death that are "consistent with organ donation" further adhere to the statute's requirements. *See* Defs.' MSJ at 38–41. The organizations do not contest that these two efforts serve to address, to some extent, the different demographic challenges that OPOs face. Instead, the organizations object that the Secretary must do more. *See* Pls.' Resp. at 22–24. But the text of Section 273 does not require that, *see id.* at 24 (admitting that "Congress did not require CMS to consider 'all' factors or any 'particular' factor"), and I will not read words into a statute that Congress did not enact. *See Romag Fasteners, Inc. v. Fossil, Inc.*, 590 U.S. 212, 215 (2020).

ii. The Final Rule Is Not Arbitrary and Capricious

The organizations contend that the Final Rule is arbitrary and capricious for three reasons. First, that the data that the certification scheme uses is unreliable. Pls.' MSJ at 44. Second, that the outcome metrics do not reasonably or accurately measure performance. *Id.* at 50. And third, that the confidence interval methodology is biased against larger OPOs. *Id.* at 54. The

Final Rule certainly creates a competitive certification scheme, but not an arbitrary or capricious one, thus these arguments fail.

4. Unreliable Data

The organizations press three reasons why flawed data renders the Final Rule arbitrary and capricious. *Id.* at 44–49. First, that the data used to calculate the “donor potential” denominator for both outcome metrics is purportedly based on a dataset with high rates of error and the Secretary justifies this with only a single study showing that adjusting the data would not alter OPO rankings. *Id.* at 44–47. Second, that the Secretary unreasonably “relies on only a 12-month snapshot of data.” *Id.* at 47–48. Third, that the definition of “donor,” which determines which cases are included in the dataset, arbitrarily does not include zero organ donors—those with zero organs transplanted. *See id.* at 48–49.

a. High-Error Rate of the “Donor Potential”

The organizations contend that many comments on the Final Rule explained the problems with using “county-level national mortality data derived from death certificates maintained by the states and territories and aggregated in the Center for Disease Control’s Multiple Cause of Death Mortality Data” to determine the “donor potential” of a DSA. *Id.* at 44. The data includes “large numbers of deaths with absolute contraindications to donation . . . meaning that patients who could never qualify as donors are

counted.” *Id.* The “Final Rule acknowledges these concerns” but relies on purportedly insufficient justifications. *Id.* First, the dataset employs “standardized, reasonable, and objective criteria.” *Id.* at 45 (quoting 85 Fed. Reg. 77,908). Second, the errors “would not vary from [OPO] to [OPO], and the same errors would ‘likely plague other potential data sources.’” *Id.* at 44–45 (quoting 85 Fed. Reg. 77,906). The Secretary supports this latter contention with a “study that it claims shows that adjusting the data . . . to account for ‘cancers, sepsis and ventilator status’ would ‘not alter’ the ranking of [OPOs].” *Id.* at 45 (quoting 85 Fed. Reg. 77,910). The organizations aver that the Secretary mischaracterizes the study, which “states only that the different datasets are ‘correlat[ed]’ and ‘highly concordant in absolute terms.’” *Id.* at 45 (quoting David S. Goldberg et al., *Addressing Critiques of the Proposed CMS Metric of Organ Procurement Organ Performance: More Data Isn’t Better*, 104 TRANSPLANTATION 1662, 1664 (Aug. 2020)).

The organizations also identify “[o]ther studies” that found that adjusting the data “would have dramatic consequences in how [OPOs] are ranked.” Pls.’ MSJ at 46. I do not consider these studies because they were published after the Final Rule and are not in the administrative record, and the organizations do not show bad faith or improper behavior by the government. *See* Defs.’ MSJ at 50 (explaining when the studies published); *Nat’l Min. Ass’n v. Sec’y, U.S. Dep’t of Lab.*, 812 F.3d 843, 875 (11th Cir. 2016)

(explaining that, absent “a strong showing of bad faith or improper behavior by the agency,” “a court does not consider any evidence that was not in the record before the agency at the time that it made the decision or promulgated the regulation”).

The Secretary responds that the decision to use the data was a reasonable choice that CMS sufficiently explained. Defs.’ MSJ at 49. Although the data is not perfect, it allows CMS to evaluate “for itself the correct donor potential number” without having to rely on “potentially self-serving inconsistencies of [the] prior metric that relied on self-reported and unaudited data from OPOs.” *Id.*; see 84 Fed. Reg. 70,630 (explaining stakeholder concerns with self-reported, unaudited data based on inconsistent interpretations of “eligible deaths” across DSAs and OPOs); 85 Fed. Reg. 77,906 (acknowledging the error rates in the data, but concluding that “this data is the most complete information that is readily and publicly available, that can be used for estimating the donor potential at this time,” a position consistent with the views of “[m]any commenters”). Further, the Final Rule explains that the primary error found in the data is a user input error, which “likely plague[s] other potential data sources.” 85 Fed. Reg. 77,906. The Final Rule also considers alternative data sources proposed by some commenters and explained why these data sources “could [not] be obtained by reasonable efforts” as Section 273 requires. *Id.* at 77,907 (noting, for example, that “not all

hospitals have electronic health records that can transmit data” and “not all OPOs have the ability to receive electronic health record transmissions”).

The organizations’ arguments are unavailing. Reliance on imperfect data is common, if not ideal, in agency decisionmaking. *See Fed. Commc’ns Comm’n v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021). And “[t]he APA imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies.” *Id.* The Secretary considered objections and provided reasoned explanations in the Final Rule for use of the particular data.

As for the organizations’ assault on the single study that the Secretary relied on to show that adjusting the data would not alter OPO rankings, the organizations’ out-of-record study admits that this study was the only available one at the time. *See Evaluation of the Stability of Organ Procurement Organization Performance Metrics* (Doc. 1-23) at 3 (“[O]nly 1 [study] addresses the effect of using a CALC-adjusted measure.”). Reliance on the single available study is not arbitrary or capricious. Nor did the Final Rule mischaracterize the study by suggesting that it supports the idea that adjusting the data would not alter the OPO tiers. *See Goldberg et al., Addressing Critiques of the Proposed CMS Metric of Organ Procurement Organ Performance: More Data Isn’t Better*, at 1662–67. “[T]he near-perfect correlation of the [cause of death, age, and location] metric [(CALC)] and the different ‘adjusted’ metrics...shows that these additional qualifiers do not

impact the CALC metric’s utility for capturing *relative* performance over time and between areas.” *Id.* at 1664. That “should provide CMS, and the transplant community, with confidence that the CALC metric using CDC inpatient death data alone does not compromise the proposed CMS metric as a tool to compare OPOs, and that calls to require collection of increased data will not affect the tool’s ability to compare OPOs.” *Id.* at 1667.

b. Twelve-Month Data Window

The organizations next take issue with the Final Rule’s reliance on twelve months of data because Section 273 directs the Secretary to recertify OPOs “not more frequently than once every [four] years,” relying on a twelve-month snapshot deviates from how the Secretary evaluates other healthcare entities, and the twelve-month cutoff fails to account for improvement over the four-year recertification cycle or reflect long-term trends. *See* Pls.’ MSJ at 47–48. The organizations argue that the Secretary did not address these concerns during notice and comment. *See id.* at 48.

The first point, that a twelve-month cutoff is arbitrary because Section 273 mandates a four-year recertification window, amounts to an argument that the Final Rule violates the statute. That argument fails because the statute does not require the Secretary to consider data from the entire four-year window; it only requires that the Secretary not recertify more frequently. *See* 42 U.S.C. § 237(b)(1).

As to the second point, the Secretary explains that the twelve-month cutoff here differs from other healthcare entities because their evaluations have goals different from those of the Final Rule and address different medical procedures. Defs.’ MSJ at 52. It is reasonable to treat such evaluations differently and the organizations do not respond to this point. *See* Pls.’ Resp. at 27.

As for the third point that twelve months of data has too much variability, the Secretary explained that recertification decisions should measure the “current performance of the OPO” and relying on a longer range of data would “mask” that current performance. 85 Fed. Reg. 77,915. Further, relying on data across the four-year cycle would “penalize OPOs who have made the effort to improve performance,” *see id.*, and presumably disincentivize them from continuing to improve at a certain point. Similarly, the anchoring effect of older data would threaten OPOs who are selected to take over a DSA, potentially dooming them to Tier 3 status in that DSA despite substantial improvements. *See id.* The organizations do not engage with these points. *See* Pls.’ MSJ at 47–48; Pls.’ Resp. at 21.

The Final Rule further accounts for the variance by applying confidence intervals and allowing an OPO to seek a one-year extension due to extraordinary circumstances beyond its control. The organizations merely repeat their claims that confidence intervals are biased (I disagree as explained

below) and that the one-year extension is an insufficient remedy. *See* Pls.’ Resp. at 21. Even if there might be a better approach than applying confidence intervals and allowing for one-year extensions, that does not make the Secretary’s choice arbitrary or capricious.

c. “Donor” Excludes “Zero-Organ Donors”

The organizations also argue that the Final Rule is arbitrary and capricious because the donation and transplantation rates are determined by “a large number of factors that are not a reflection of performance by the [OPOs] themselves.” Pls.’ MSJ at 48. Specifically, they object to the exclusion of “zero-organ donors,” who are “donors with zero organs transplanted,” in the definition of “donor” because OPOs cannot control whether a transplant center rejects organs or when certain donor comorbidities arise and cause higher organ discard rates. *See id.* at 49. The organizations characterize the Secretary’s response that OPOs should engage in best practices to reduce the frequency of zero-organ donors as “irrational.” *See id.* Not so.

The Secretary explained that excluding zero-organ donors from “donors” is intended “to incentivize all OPOs to pursue [less than ideal] and marginal donors, even if they may become zero organ donors.” 85 Fed. Reg. 77,903. For support, the Secretary points to an example of an OPO enabling the transplant outside its DSA of kidneys from donors who often were considered “[less than ideal] criteria or marginal donors,” which would otherwise have ended up as

zero-organ donors. *Id.* Lastly, verification of zero-organ donor numbers, which are self-reported, would require “extraordinary effort.” *Id.*

The organizations fail to meet their heavy burden to show that the Final Rule is arbitrary and capricious because of the data upon which it relies.

5. Failure to Provide Adequately Reasoned Responses Regarding Outcome Metrics

The organizations next argue that the Secretary failed to reasonably justify the use of outcome metrics that do not accurately measure performance.

a. Differences in DSAs

First, the organizations argue that the Secretary “has never justified” the failure to “account[] for differences in [OPOs’] assigned [DSAs] that have a material impact on donation and transplantation rates.” Pls.’ MSJ at 50–52. Concurring with comments that the outcome metrics do not account for “material variations” in DSAs, such as “death rates, educational attainment, cultural differences, attitudes towards donation, donor hospital and transplant center performance and concentration, and causes of death and secondary diagnoses,” the organizations argue that the Secretary should have provided better responses explaining why he selected the outcome metrics. *See id.* at 50–51. And the organizations fault the Secretary’s “breezy response” as “suggesting [the agency] did not see how such differences would result in ‘a disadvantage to one OPO compared with other OPOs’ and that making

adjustments for demographic considerations like race could mask poor performance and perpetuate racial stereotypes.” *Id.* at 52 (quoting 85 Fed. Reg. 77,909).

The organizations mischaracterize the Secretary’s response. Acknowledging that the outcome measures do “not control for every variable that can affect OPO performance,” 85 Fed. Reg. 77,928, the Secretary explained that the two metrics “adjust for the geographic differences in the number and causes of death,” and that “[t]he top-performing OPOs are geographically and demographically diverse,” suggesting that geographic and demographic differences are not so determinative of outcome performance. *Id.* at 77,910, 77,927–29. The Secretary “agree[d] with commenters who raise concerns that risk-adjusting for race could mask poorer performance” “in adopting practices that are responsive to the racial/ethnic composition of the DSA served.” *Id.* at 77,910. The Secretary also expressed “concerns that racial risk-adjustments could perpetuate the stereotypes of different racial/ethnic groups and their willingness and ability to be organ donors.” *Id.* The Secretary disagreed that there should be a racial risk-adjustment because such “adjustments reflect the biases and shortcomings of current OPO organ procurement practices” and CMS is “not aware of a biological reason why race, as an independent factor, would affect the decision to be an organ donor or the number of organs transplanted.” *Id.* The Secretary also referred to more recent

studies, explored in greater length in a December 2019 OPO rule, that suggest that “the racial concordance of the OPO requester plays a role in the rate of authorization for organ donation.” *See id.*; 84 Fed. Reg. 70,634.

Further, the Secretary acknowledged that the death-certificate data used to determine cause of death contained some errors, would not account for comorbidities that preclude organ donation, and that there was no perfect risk-adjustment method. *See* 85 Fed. Reg. 77,906–07. Crucially, the Secretary was “not aware of differences in the error rates that would disadvantage one DSA over another DSA.” *Id.* at 77,906. Nor did he “have evidence that the rate of comorbidities associated with these causes of deaths is significantly different from one DSA to another.” *Id.* at 77,907. The Secretary also analyzed whether sicker populations in a DSA influenced outcomes and found no correlation. *See id.* at 77,909. Ultimately, “no commenters have suggested a[n alternate] source of empirical evidence that could be obtained by reasonable effort of organ donor potential in each designated service area sufficient to meet our needs and expectations.” *Id.* at 77,906.

The Secretary also explained that, because even the “highest performing OPOs” have less than “20 percent of potential donors becoming actual donors,” “all OPOs have a pool of potential donors many times higher than the number of donors and organs needed to meet the final rule’s performance standards.” *Id.* at 77,929. Further, while “some OPOs have fewer transplant programs

within their [DSAs] than others,” OPOs are encouraged to place organs outside their DSAs. *Id.* at 77,927. For example, despite “major recent improvements in perfusion techniques” that “extend[s] the time period allowed between donation and transplantation” of kidneys, thereby allowing OPOs to successfully place organs outside their DSAs, not all OPOs have adopted these techniques. *Id.* at 77,929. So, given this, the Secretary adequately explained his decision to use the outcome metrics selected and “reached a conclusion that rests on a rational basis.” *City of Oxford v. F.A.A.*, 428 F.3d 1346, 1352 (11th Cir. 2005).

b. Twenty-Five Percent Cutoff for Tier 1

The organizations argue that the Secretary “provides no reasoned basis for applying an arbitrary 25% cutoff” for Tier 1 OPOs. Pls.’ MSJ at 53–54. The Secretary, according to the organizations, “has articulated no valid statistically based rationale” for the cutoff and “no reason to assume that large numbers of [OPOs] are performing so poorly that they should be decertified.” *Id.* Nor, allegedly, does the Final Rule address “the unsustainability of its approach” caused by “repeated culling of [OPOs] not falling within the top 25%.” *Id.*

Unlike the cases that the organizations cite where an agency did not reasonably justify chosen cutoffs, *see id.* at 53–54 (citing *AARP v. United States Equal Emp. Opportunity Comm’n*, 267 F. Supp. 3d 14, 34 (D.D.C. 2017) and *Bldg. & Const. Trades Dep’t, AFL-CIO v. Martin*, 961 F.2d 269, 277 (D.C. Cir.

1992)), the Secretary reasonably choose the twenty-five percent line here. And unlike other cited cases, *see id.* at 54 (citing *Ass’n of Priv. Colls. & Univs. v. Duncan*, 870 F. Supp. 2d 133, 153–55 (D.D.C. 2012) and *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1317 (Fed. Cir. 2011)), the Secretary, rather than arbitrarily selecting a number, picked the cutoff in conjunction with the presidential directive to improve donation rates and organ-donation data that indicates that the chosen cutoff would represent a meaningful and achievable performance standard.

First, the Secretary analyzed multiple potential thresholds, including thresholds based on the mean or median OPO performer. *See* 84 Fed. Reg. 70,692–96; 85 Fed. Reg. 77,945. In conjunction with Executive Order 13,879, Advancing American Kidney Health, which seeks to increase access to kidney transplants, the Final Rule explains that the twenty-five percent threshold was based on the median rates in part because the Department of Health and Human Services “set a goal to deliver more organs for transplantation and aims to double the number of kidneys available for transplant by 2030.” 84 Fed. Reg. 70,630. The twenty-five percent cutoff supports this goal because the top one-fourths of OPOs achieve “more than double the rates of many lower performing OPOs.” *Id.* 70,644. Further, the OPOs within the top one-fourth “are geographically and demographically diverse, with potential donor pools ranging from about 2,000 deaths a year to almost 10,000 a year.” *Id.* Thus, it

is reasonable for the Secretary to expect that many OPOs can achieve such rates, and that such rates are accurate reflections of OPO performance rather than inexorable results of demographic and geographic factors. And the Secretary's expectation that many OPOs can achieve the cutoff was supported by the "data analyses" included in the Final Rule. *See* 85 Fed. Reg. 77,913.

If anything, the "wide variation in donation rates among OPOs" suggests that "there is significant opportunity, especially among the lower-performing OPOs, to increase their donation rates and . . . transplantation rates." 84 Fed. Reg. 70,635. Had there been a narrower variation in donation rates, the Secretary would have "set a lower threshold rate, such as 30 percent or 40 percent," because there would be less room for improvement. *Id.* But problems with reliance on a mean-based threshold or a threshold determined by standard deviation from the mean prevented the use of other metrics. *See* 85 Fed. Reg. 77,912–13. The mean rate "may not reflect the performance of an actual OPO" and is "affected by extremes in performance." *Id.* at 77,912. A median rate is not affected by extremes and represents "the actual rates performed by one or two OPOs." *Id.* Using the standard deviation method "will always [place] an OPO below the targeted standard deviation from the mean." *Id.* at 77,913. Contrary to the organizations' contention, the twenty-five percent threshold is potentially achievable by all OPOs because of the use of confidence intervals and the fact that the previous year's data determines the

threshold. *See id.* at 77,913–14. Thus, a standard deviation from the mean method might be “unsustainable” but the twenty-five percent cutoff is not.

The Secretary admitted that the twenty-five percent cutoff is “aggressive” and explained that this cutoff would properly incentivize all OPOs, including those in Tier 1, to continually improve “to the benefit of patients.” *See id.* at 77,912. Because OPOs are granted a monopoly by CMS, “it is critical that [CMS] select[s] the most capable OPO” for each DSA. *Id.* at 77,913.

Lastly, the Secretary responded to the comments by creating Tier 2 to avoid automatically decertifying OPOs that “have made substantial changes designed to improve performance and have started to improve their performance.” *Id.* at 77,912. Once again, based on this rationale, the Secretary’s decision to set the twenty-five percent cutoff threshold “rests on a rational basis.” *City of Oxford*, 428 F.3d at 1352.

c. Confidence Intervals Are Biased Against Larger OPOs

The organizations contend that because larger OPOs have smaller confidence intervals, the Final Rule, which applies a ninety-five percent confidence interval when determining the donation and transplantation rates, is mathematically biased against larger OPOs. Pls.’ MSJ at 54–55. Smaller OPOs, the organizations argue, have “greater variability in donation and

transplantation rates owing to their smaller populations, and because that results in relatively larger confidence intervals, they are more likely to achieve a higher tier regardless of actual performance.” *Id.* at 55. The organizations criticize the Secretary’s explanation that the confidence intervals inherently account for the variability in the size of the data samples as an unreasonable “conclusory non-response.” *See id.* Without a reasoned explanation for this portion of its methodology, they argue, the Final Rule is subject to vacatur. *See id.* at 55–56.

The Secretary responds that the organizations misunderstand confidence intervals, which ensure that the differences between an OPO[’s] outcome metrics and the cutoff for Tier 1 or Tier 2 are not “statistically significant.” *See* Defs.’ MSJ at 57; 85 Fed. Reg. 77,911. The use of confidence intervals works to “ensure that an OPO’s rating in a given year reflect actual differences in performance, rather than the random fluctuations in donation and transplantation.” Defs.’ MSJ at 57. They also “ensure that the thresholds do not treat statistically indistinguishable performance differently, so that all similarly performing OPOs achieve the same Tier rating.” *Id.* Naturally, OPOs with larger populations, and thus larger numbers of donations and transplants, will have “tighter confidence intervals than smaller OPOs.” *Id.* But that is the expected result of a larger sample size, not bias hidden within the selection of the confidence interval. *See id.*; 85 Fed. Reg. 77,914. At bottom

then, it is reasonable to conclude that issues unique to larger OPOs are not terminal and that poor outcome metrics are driven by poor performance.

iii. The Secretary Responded to Significant Comments About Patients and the Nation’s Donor Network

When issuing a final rule, agencies ordinarily “must consider and respond to significant [public] comments.” *See Perez*, 575 U.S. at 96. According to the organizations, the Final Rule should be vacated “because CMS failed to respond to objections that its decision to decertify large numbers of organ n procurement[] organizations would destabilize the system, harm patients, and cause untold damage to the nation’s donation system.” Pls.’ MSJ at 56. The organizations repeat many of their previous arguments and contend that the Secretary failed to adequately respond to comments, particularly those suggesting that CMS focus on working with underperforming OPOs rather than decertifying them. *See id.* The organizations also assert that the Secretary “does not attempt to explain how a high-ranking [OPO] serving a comparatively smaller and homogenous [DSA] is equipped to take over a larger and more diverse area without any experience in or connection to that [DSA].” *Id.* at 58.

As an initial matter, the organizations’ argument ignores the Secretary’s responses discussed above on related issues, such as the fact that the use of confidence intervals and setting the cutoffs based on the previous year’s data

establishes a scheme where all OPOs could meet the required metrics and avoid decertification. *See* 85 Fed. Reg. 77,913–14. Separately, although the comments that the organizations identify expressed concerns related to the increased competition caused by the Final Rule, “[m]ost of the commenters, however, wanted more competition than existed under [CMS’s] prior rules and contended that more competition would improve OPO performance.” *Id.* at 77,918.

Additionally, the Secretary responded to the comments suggesting that CMS work with underperforming OPOs rather than decertify them. The Final Rule creates Tier 2, “lower[ing] the level of performance that would lead to an OPO being decertified.” *Id.* The Secretary explained his view that increased competition between OPOs was a worthy tradeoff because “collaboration has not resolved the significant, ongoing disparities that exist in OPO outcomes.” *Id.* at 77,919. With the addition of Tier 2, “[m]any OPOs that would have been de-certified under the proposed outcome measures will be designated in Tier 2 and have the opportunity to compete to retain their DSAs.” *Id.* There still is an incentive for OPOs to cooperate because it can lead to mutual improvements and “increase the number of transplantable organs.” *Id.* Further, by assessing OPO performance annually and releasing the rankings, the Final Rule adopts a version of the plan urged by commenters to work with underperforming OPOs rather than summarily decertify them when their metrics fall below the

desired threshold. *See id.* at 77,912 (“[E]ach OPO will then have an opportunity to improve and receive information about its performance following those improvements. . . . Therefore, OPOs identified as being lower performing at the final assessment period of the agreement cycle would have a history of working with CMS to improve performance . . . in the previous assessment periods.”).

The Secretary also addressed disruptions and the ability of an OPO unfamiliar with a DSA to replace a decertified OPO. The Final Rule explains that the scheme is set up such that all OPOs will have the chance to meet the new requirements. *See id.* at 77,935. And, OPOs should be able to “arrange a friendly merger with another OPO” that limits disruption. *Id.* In cases where an OPO is “decertified and replaced, the newly responsible OPO would presumably arrange a smooth continuation of services in the DSA through negotiations with the outgoing Board of Directors and CEO to retain existing staff. No public comments suggested that any more disruptive outcome would ever be likely.” *Id.* Relying on an admittedly “imperfect” analogy, the Final Rule also pointed to a study that hospital mergers do not adversely impact patient care. *Id.* at 77,941.

As for the concerns about disruptions to patient care, the organizations’ argument, which assumes that the measures are unreliable, amounts “to an argument that the APA requires the Secretary to forgive poor performance.” Defs.’ Reply at 58. As explained in the Final Rule, this approach carries with

it serious patient risks by forcing patients to continue to rely on “poorer performing OPOs . . . if there is a better performing OPO willing and able to service the DSA and provide patients with a higher standard of service.” 85 Fed. Reg. 77,912. In short then, the Secretary adequately and reasonably responded to the significant comments regarding the Final Rule. *See Perez*, 575 U.S. at 96.

IV. CONCLUSION

Because the *Illinois Council* exception applies, I have jurisdiction over this action. But because the Final Rule does not violate Section 273 and is not arbitrary and capricious or otherwise unlawful, I grant summary judgment to the Secretary.

The following is therefore **ORDERED**:

1. Iowa Donor Network’s claims are **DISMISSED without prejudice** for lack of jurisdiction. The Clerk is directed to **TERMINATE** Iowa Donor Network from this case.
2. The Secretary’s motion for summary judgment (Doc. 43) is **GRANTED in part**. Specifically, the Court grants the motion as to the claims brought by all plaintiffs except for Iowa Donor Network. The Secretary’s motion for summary judgment is **DENIED as moot** as to the claims brought by Iowa Donor Network.

3. The organizations' motion for summary judgment (Doc. 39) is **DENIED**.
4. The Clerk is directed to **ENTER JUDGMENT** consistent with this order against the organizations and for the Secretary, and to **CLOSE** this case.

ORDERED in Tampa, Florida, on September 29, 2026.


Kathryn Kimball Mizelle
United States District Judge