UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

BAYLOR ALL SAINTS MEDICAL CENTER, ET AL.,

Plaintiffs,

v.

No. 4:24-cy-00432-P

XAVIER BECERRA,

Defendant.

OPINION & ORDER

Before the Court is Plaintiffs' Motion for Preliminary Injunction (ECF No. 8), which the Court advanced to the case's merits under Federal Rule of Civil Procedure 65. Having considered the briefing and evidence of record, the Court concludes the Motion should be and hereby is **GRANTED** for the reasons below.

BACKGROUND

This is a case about hospital bills. More precisely, it's about how healthcare providers get paid for serving our nation's most vulnerable demographics. Since Medicare and Medicaid were established in 1965, federal, state, and local governments have cooperated to provide low- or

¹ "Plaintiffs" in this case are a plethora of Texas-based hospitals, including: (1) Baylor All Saints Medical Center; (2) Baylor Medical Center at Irving; (3) Baylor Medical Center at Waxahachie; (4) Baylor Scott & White Medical Center – Greater Centennial; (5) Baylor Scott & White Medical Centers – Greater North Texas; (6) Baylor University Medical Center; (7) Covenant Medical Center; (7) El Paso County Hospital District; (8) Hillcrest Baptist Medical Center; (9) Hunt Memorial Hospital District; (10) Lake Pointe Operating Company, L.L.C.; (11) Scott & White Hospital – College Station; (12) Scott & White Hospital – Marble Falls; and (13) Scott & White Memorial Hospital.

no-cost healthcare for persons otherwise unable to afford it.² One way of doing so is a reimbursement system for hospitals that serve Medicare beneficiaries. Medicare reimburses hospitals for covered services via the inpatient prospective payment system ("IPPS"), which is distributed by diagnostic related group ("DRG"). Acronyms aside, the regime is simple: DRGs are unique taxonomies assigned for related diagnoses with a set payment rate. For instance, a certain rate will be more or less appropriate for respiratory infections/inflammations, another for heart failure and shock, and another for kidney and urinary tract infections. The resulting DRG is a guidepost that signals how much Medicare, Medicaid, or insurance should pay for a patient's treatment.

By aggregating anticipated costs by DRG, the IPPS efficiently reimburses hospitals at scale, with payments subject to myriad adjustments. This case involves an adjustment Congress provided when it amended the Medicare statute in 1986. Designed to help hospitals in underprivileged communities, the 1986 amendment gives an adjustment to Disproportionate Share Hospitals ("DSH")—hospitals that serve a "significantly disproportionate number of low-income patients." 42 U.S.C. § 1395ww(d)(5)(F)(i)(I). To provide indigent healthcare for disadvantaged populations, DSHs confront higher costs and generate lower revenues. Enter the adjustment—an offset DSHs receive to lessen this financial burden. Whether a hospital qualifies as a DSH (and the corresponding adjustment it receives) is determined by calculating the hospital's DSH percentage, which functions as a "proxy for the number of low-income patients the hospital serves." This figure

² In his memoirs, President Johnson provides an excellent account of his administration's work with Congress to enact Medicare and Medicaid, endeavoring to provide basic healthcare to those most in need. See Lyndon Baines Johnson, The Vantage Point: Perspectives of the Presidency, 1963–1969, 212–21 (1971). Unfortunately, such instances of effective cooperation are increasingly rare nowadays. Over the last few years, the executive and legislative branches seem to cooperate less and less. As here, in today's America, most "laws" are created through administrative fiat.

determines eligibility for an array of programs, two of which are relevant here.³

At base, the DSH percentage is the sum of two fractions. This case hinges on the "the Medicaid Fraction," a moniker eponymous for the fraction's statutory genesis. As enunciated in the Medicaid statute, the Medicaid Fraction is:

The fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consists of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX [Medicaid], but who were not entitled to benefits under part A of this subchapter, and the denominator of which is the total number of the hospital's patient days for such period.

42 U.S.C. § 1395ww(d)(5)(F)(vi)(II). In other words, the Medicaid Fraction is the ratio of patient days attributable to Medicaid-eligible patients, expressed as a function of treatment days attributable to all inpatients at the hospital.

Congress gave the Medicaid Fraction a facelift in the 2005 Deficit Reduction Act, which adds the following proviso to the calculus:

In determining [the Medicaid fraction,] the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under [Medicaid], the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under title XI.

42 U.S.C. § 1395ww(d)(5)(F)(vi)(II). Under this revamped provision, "the Medicaid fraction's numerator includes both (1) days a hospital treated patients who were Medicaid-eligible, and (2) days a hospital treated patients who are regarded as Medicaid-eligible because they received

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³As is perhaps obvious, the first is the DSH adjustment itself. The second is an ancillary program for DSHs, the 340B Drug Discount (the "340B Program"). Under the 340B Program, qualifying DSHs receive a substantial rebate on many drugs, enabling them to use such drugs at or below a statutory price ceiling. See generally 42 U.S.C. § 256b.

demonstration project benefits." Forrest Gen. Hosp. v. Azar, 926 F.3d 221, 224 (5th Cir. 2019) (emphasis added).

So, what's a demonstration project? As one might guess, the answer requires more acronyms. To obtain federal funds under Medicaid, states submit a "State Plan" for approval by the Centers for Medicare & Medicaid Services ("CMS"). The State Plan lays out who will receive medical assistance, what kind of assistance they'll receive, and other matters of import. If CMS approves the State Plan, that state gets access to federal Medicaid funding. But as noted above, Title XI § 1115 of the Social Security Act authorizes Defendant Becerra, as Secretary of Health and Human Services ("HHS"), to authorize "demonstration projects"—pilot programs that "assist in promoting the objectives of [Medicaid]." 42 U.S.C. § 1315(a). With Mr. Becerra's approval, standard Medicaid requirements are waived for demonstration projects. "In other words, these § 1115 waivers are Congress's green light to the Secretary to relax the usual state-plan-approval requirements." Forrest, 926 F.3d at 224.

A lot hinges on Becerra's approval for demonstration projects: "if the Secretary approves a demonstration project, then [courts] regard patient days involving patients who 'receive benefits under a demonstration project' as if they were patient days attributable to Medicaid-eligible patients (which means those days also go into the numerator)." *Id.* at 228. And the bigger the numerator, the greater the proportion of patient days factored into the DSH percentage, resulting in more money for qualifying DSHs. Why does this matter? Because in 2012, the Supreme Court made Medicaid expansion optional for states. *See Nat. Fed. of Indep. Bus. v. Sebelius*, 567 U.S. 519 (2012). Since then, many states (like Texas) have declined to expand the program, opting to chart their own path and rely upon § 1115 waivers to access federal funding.⁴

⁴ Indeed, as Justice Brandeis aptly recognized, one of the hallmarks of our federal system is that it allows for experimentation and innovation in policymaking at the state level. *See New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

That's why it was a big deal when the Texas Healthcare Transformation and Quality Improvement Program ("THTQIP") got § 1115 approval. Under THTQIP, the Texas Medicaid program provides direct payments to hospitals from Uncompensated Care Cost ("UCC") pools as remuneration for indigent care services. In simple terms, a UCC pool is a bucket of funds reserved for hospitals to cover unmonetized services rendered. If for some reason the bills don't get paid, hospitals can access funds from a UCC pool to help bridge the gap. The Secretary approved this plan in January 2021. This approval was big news for Plaintiffs, who are a group of regional hospitals and healthcare providers (collectively, "the Hospitals"). With approval for THTQIP programming, patients could have their medical costs offset by UCC pool payments and the Hospitals could include those patients in calculating their respective Medicaid Fractions.

Then HHS decided to shake things up. In August 2023, HHS adopted a new regulation the excludes patients receiving UCC pool benefits from the Medicaid Fraction numerator. In relevant part, the new regulation provides that:

Patients whose health care costs, including inpatient hospital services costs, for a given day are claimed for payment by a provider from an uncompensated, undercompensated, or other type of funding pool authorized under section 1115(a) of the Act to fund providers' uncompensated care costs are not regarded as eligible for Medicaid for purposes of [42 C.F.R. § 412.106(b)(4)(ii)]

To stay experimentation [at the states] in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation. It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.

Id.; see also Letter from Thomas Jefferson to Joseph C. Cabell (Feb. 2, 1816), in 12 The Works of Thomas Jefferson (Lipscomb & Bergh, eds., Fed. ed. 1904–05) ("The way to have good and safe government, is not to trust it all to one, but to divide it among the many, distributing to every one exactly the functions he is competent to.").

on that day and the days of such patients may not be included in [the Medicaid Fraction].

88 Fed. Reg. 58,640, 59,332 (Aug. 28, 2023), promulgated at 42 C.F.R. § 412.106(b)(4)(iii) (hereinafter, "the Exclusion Rule").

The Hospitals say the Exclusion Rule conflicts with the clear wording of 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II) and the Fifth Circuit's binding interpretation of the same in Forrest Gen. Hosp. v. Azar, 926 F.3d 221 (5th Cir. 2019). The Hospitals took their concerns to the appropriate administrative body, the Provider Reimbursement Review Board ("PRRB"). The PRRB reviewed and sua sponte dismissed their challenge on jurisdictional grounds, rendering no decision on the underlying legal dispute. The Hospitals sought judicial review in this Court on May 10, 2024, seeking declaratory and injunctive relief. As the material facts are not in dispute, the Court advanced the Hospitals' Motion for Preliminary Injunction (ECF No. 7) to the merits. As explained below, the Fifth Circuit has already rejected HHS's interpretation of the Exclusion Rule, warranting declaratory relief in the Hospitals' favor. Further, considering the Rule's illegitimacy, the Court agrees with the Hospitals that equitable relief is warranted.

LEGAL STANDARD

Summary judgment is proper if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A dispute is "genuine" if the evidence presented would allow a reasonable jury to return a verdict for the nonmovant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 242–43 (1986). A fact is "material" if it would affect a case's outcome. Id. at 248. Generally, the "substantive law will identify which facts are material," and "[f]actual disputes that are irrelevant or unnecessary will not be counted." Id. The Court views evidence in the light most favorable to the non-movant when making this call. Cunningham v. Circle 8 Crane Servs., LLC, 64 F.4th 597, 600 (5th Cir. 2023). The Court may rely on any evidence of record but need only consider materials cited by the parties. FED. R. CIV. P. 56(c)(1)–(3); see generally Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986) (noting summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on

file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law"). But the Court need not mine the record for evidence supporting the nonmovant; the burden falls on the moving party to simply show a lack of evidence supporting the nonmovant's case. *See Malacara v. Garber*, 353 F.3d 393, 404–05 (5th Cir. 2003).

ANALYSIS

The Hospitals say the Exclusion Rule is unlawful, seeking declaratory and injunctive relief. See ECF Nos. 1, 7. Beyond the Rule itself, the Hospitals say the PRRB's dismissal of their administrative appeal was arbitrary and capricious. See ECF No. 1 at 25, 28. HHS pushes back on the merits and on jurisdictional grounds. The Court tackles the jurisdictional dispute first. See United States v. Rodriguez, 33 F.4th 807, 811 (5th Cir. 2022) ("[C]ourts must assess their jurisdiction before turning to the merits.").

A. The Court has continuing jurisdiction over the Hospitals' challenge because remand to the PRRB would be futile.

HHS says the Court lacks jurisdiction because the Hospitals failed to exhaust their administrative remedies as required when suing under the Medicaid statute. See ECF No. 14 at 6. Exhaustion requires the PRRB to make a "final decision" on the Hospitals' administrative challenge, thus entitling them to judicial review. See 42 U.S.C. § 139500(f)(1). The question then lies in what "final decision" means. The Court's analysis on this point is largely framed by precedents interpreting the Social Security Act, which, like Medicaid, requires a "final decision" for judicial review. See Matthews v. Eldridge, 424 U.S. 319, 328 (1976); cf. 42 U.S.C. § 139500(f)(1); 42 U.S.C. § 405(g). As both Acts contain the same requirement, the presumption of consistent usage suggests the term "final decision" would function the same way in both. See Smith v. City of Jackson, 544 U.S. 228, 233 (2005) ("when Congress uses the same language in two statutes having similar purposes . . . it is appropriate to presume that Congress intended that text to have the same meaning in both statutes").

While the Fifth Circuit has not addressed this specific question, the Court agrees with the First, Fourth, Ninth, Eleventh, and D.C. Circuits that Matthews v. Eldridge provides the correct interpretation. See generally Lee Mem'l Hosp. v. Becerra, 10 F.4th 859, 866-67 (D.C. Cir. 2021) (explicating the relevant doctrinal framework). In Matthews, the Supreme Court construed the term "final decision" in 42 U.S.C. § 405(g) to "consist of two elements, only one of which is purely 'jurisdictional'. ..." Matthews, 424 U.S. at 328. The first element, which can't be waived, is that a claim must be "presented to the Secretary." Id. It is undisputed that the Hospitals brought a claim to the PRRB and the PRRB dismissed all claims. See ECF No. 7 (PRRB's findings and dismissal of the Hospitals' challenge). Thus, the Hospitals satisfy the nonwaivable element. See Matthews, 242 U.S. at 328. The next element, which can be waived, is that "the administrative remedies prescribed by the Secretary be exhausted." Id. Exhaustion is waivable when "a claimant's interest in having a particular issue resolved promptly is so great that deference to the agency's judgment is inappropriate." *Id.* at 330.

The Supreme Court reaffirmed this holding in *Smith v. Berryhill* and added that when an agency dismisses a claim and the district court disagrees with the dismissal, "there would be jurisdiction for [the] court to proceed to the merits." 587 U.S. 471, 487 (2019). However, the Court stressed that federal courts cannot use this end-run around jurisdictional dismissals to decide questions expressly delegated to the agency. *See id*.

Here, the PRRB dismissed the Hospitals' challenge on jurisdictional grounds. See ECF No. 7 at 21. When pressed, the PRRB simply said "factual gaps" prevented it from adequately assessing its jurisdiction. Id. at 19. But even accepting that as true, it would then be incumbent upon the Board to seek out the information needed to determine jurisdiction. See 42 C.F.R. § 405.1842(e)(3)(ii). That's the crux of the Hospitals' first and third causes of action. See ECF No. 1 at 25, 28. And they're right: the PRRB was affirmatively required to seek out the information needed to rule on the Hospitals' request for expedited judicial review. 42 C.F.R. § 405.1842(e)(3)(ii). To close the door on their administrative appeal without offering them the chance to provide

further information, the PRRB transgressed its clearly enumerated procedural mandate. *Id*.

While the PRRB's findings are subject to judicial deference, Williamson v. Lee Optical of Okla., 348 U.S. 483, 488–89 (1955), that deference does not give them carte blanche to violate binding rules of procedure. "Procedural perfection in administrative proceedings is not required" as long as "the substantial rights of a party have not been affected." Mays v. Bowen, 837 F.2d 1362, 1364 (5th Cir. 1988). But in this instance, the procedural violation was claim-dispositive. Simply put, the rules governing executive agencies—whether in the APA or otherwise—make the executive stay in its lane. HHS cannot shrug aside 42 C.F.R. § 405.1842(e)(3)(ii) as too burdensome and it cannot give lipservice to compliance by performing a perfunctory factual inquiry.

In any event, the PRRB was wrong. Medical providers are entitled to a PRRB hearing if they are dissatisfied with "a final determination of the Secretary as to the amount of the payment under subsection . . . (d) of section 1395ww," which includes both per-patient payment rates and the DSH adjudgment to those rates. See 42 U.S.C. §§ 1395oo(a)(1)(A)(i)—(ii); 1395ww(d)(1)(A)(iii), (d)(5)(F). That was precisely the issue the Hospitals took to the PRRB here. See ECF 7 at 11. Consequently, the Court finds that PRRB's jurisdictional dismissal was improper.

Having found the PRRB's jurisdictional dismissal was erroneous, the Court must next assess whether deciding the Hospitals' challenge on the merits would usurp the agency's delegated authority. See Berryhill, 587 U.S. at 488. In such situations, the Court must send the claim back to the executive. But that isn't required "when administrative remedies are inadequate." Info Res., Inc. v. United States, 950 F.2d 1122, 1126 (5th Cir. 1992) (cleaned up). And they would be here. While the PRRB has authority over questions arising under the statutory regime, it lacks the Constitutional power to adjudicate the legal question here: whether Exclusion Rule as promulgated violates § 1395ww(d)(5)(F)(vi)(II). See 42 U.S.C. § 1395oo(f)(1). Any PRRB determination apropos of the Hospitals' challenge would have to assume the Exclusion Rule is valid. See 42 C.F.R. § 405.1867 (noting "the Board must comply with all the provisions of Title XVIII of the Act and regulations issued thereunder"). That's where judicial review comes into play. See Sebelius v. Auburn Reg. Med. Ctr., 568 U.S. 145, 157 (2013) ("A court lacks authority to undermine the regime established by the Secretary unless [his] regulation is arbitrary, capricious, or manifestly contrary to the statute." (cleaned up)).

So, sending the Hospitals back to PRRB would be lengthy, costly, and futile. The law does not require such procedural absurdity, so "there is no jurisdictional bar to a court's reaching the merits." *Berryhill*, 587 U.S. at 488. Indeed, "[u]nder bedrock separation-of-powers principles, Article III courts need not—indeed *must* not—outsource their constitutionally assigned interpretive duty to Article II agencies when the Article I Congress has spoken clearly." *Forrest*, 926 F.3d at 228. Moreover, the administrative process should not be used as a weapon to stymy the judicial review of agency action. Having found jurisdiction and assessed the PRRB's dismissal of the Hospitals' claims, the Court now turns to the Exclusion Rule.

B. The Exclusion Rule is unlawful.

This case is simple on the merits. Resolving this dispute doesn't require the judicial skills of Learned Hand or Oliver Wendall Holmes. While HHS may protest, a recent "spotted dog" decision by the Fifth Circuit directly controls the Court's inquiry—and clarifies that the Exclusion Rule contradicts the statute's plain text. See Forrest, 926 F.3d at 228–29. Statutorily, the Medicaid Fraction includes: "patients who . . . were eligible for medical assistance under a State plan approved under [Medicaid]." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II). And since 2005, the Secretary has been empowered to authorize demonstration projects, the beneficiaries of which are to be included in the Medicaid Fraction's numerator:

In determining [the Medicaid fraction,] the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under [Medicaid], the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible

but who are regarded as such because they receive benefits under a demonstration project approved under title XI.

Deficit Reduction Act of 2005, Pub. L. No. 109–171, § 5002(a), 120 Stat. 4 (2006) (codified at 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II)) (emphasis added). And the Fifth Circuit has already rejected the arguments HHS raises here, clarifying that the numerator includes hospital days of Medicaid-eligible patients *and* those treated as such pursuant to a § 1115 waiver. See Forrest, 926 F.3d at 228.

As noted, the Secretary approved UCC pool payments under THTQIP. See ECF No. 6 at 12–13. But the Exclusion Rule swept this approval under the rug, stating the beneficiaries of such pool payments "are not regarded as eligible for Medicaid for purposes of [the Medicaid Fraction] . . . and the days of such patients may not be included in this [] computation." 42 C.F.R. § 412.106(b)(4)(iii). Fifth Circuit precedent roundly rejects this position. Forrest, 926 F.3d at 228. Indeed, the clarity of Forrest General obviates the need for additional analysis vis-à-vis HHS's already-rejected arguments here.

In Forrest, the Fifth Circuit addressed a Mississippi plan, which, like Texas's plan, includes patients not eligible for Medicaid. See Forrest, 926 F.3d at 226. Like the Texas Plan, Mississippi's was also approved by the Secretary. Id. Promulgating a new rule does not change the statutory text or the Fifth Circuit's interpretation, especially when "the governing statutory text is clear." Id. at 228. Section 1395ww(d)(5)(F)(vi)(II) requires HHS to "include days that a hospital treated patients eligible under a Medicaid-approved state plan in the Medicaid fraction's numerator." Id. The only other court to address this question—the D.C. Circuit—agrees. Bethesda Health, Inc. v. Azar, 389 F. Supp. 3d 32, 43—44 (D.C. 2019), aff'd, 980 F.3d 121 (D.C. Cir. 2020). And what the Fifth Circuit has already addressed this Court need not entertain further. See Forrest, 926 F.3d at 226.

As in *Forrest General*, HHS again argues the Secretary has discretion to decide which days go in the calculation. *See* ECF No. 14 at 20–25. But the Fifth Circuit addressed this point in *Forrest General*, noting "[t]he Secretary *may* exercise discretion, and the Secretary did exercise discretion when he authorized the [state plan]." *Forrest*, 926

F.3d at 233 (emphasis added). Thus, the Secretary exercised his discretion when he approved Texas's plan. "No take-backs." *Id*.

To be fair, the Court is not unsympathetic to HHS's statutory interpretation. It's far from an implausible interpretation to read the Deficit Act's proviso as warranting discretion in the eligibility determination itself, as well as in the authorization of a state's plan. See, e.g., 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II) (stating "the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project") (emphasis added). But this Court will not resurrect an argument scotched by the Fifth Circuit. Accordingly, the Court **DECLARES** 42 C.F.R. § 412.106(b)(4)(iii) to be **unlawful** under the statute. See 5 U.S.C. § 706(2)(A) (empowering the court to deem unlawful any agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"). Having granted declaratory relief, the Court now turns to the Hospitals' requests for additional equitable remedies.

C. Vacatur is appropriate but a permanent injunction isn't.

The Hospitals ask the Court to declare the Exclusion Rule unlawful, vacate it, and permanently enjoin its enforcement. ECF No. 1 at 29. Having granted declaratory relief, the Court now turns to their requests for equitable remedies. In doing so, the Court is mindful that "Plaintiffs don't get [injunctive relief] just because they got a declaratory judgment. *Nuziard v. Minority Bus. Dev. Agency*, ---F. Supp. 3rd---, 2024 WL 965299, at *44 (N.D. Tex. Mar. 5, 2024) (Pittman, J.). As explained below, the Hospitals fail to carry their burden in seeking permanent injunctive relief. Nevertheless, considering the Exclusion Rule's manifest impropriety, vacatur is warranted under 5 U.S.C. § 706.

1. The Exclusion Rule should not be permanently enjoined.

The Hospitals want an injunction. See ECF No. 7. But an injunction "is not a remedy which issues as of course." Harrisonville v. W.S. Dickey Clay Mfg. Co., 289 U.S. 334, 337–38 (1933). Indeed, injunctive relief is a "drastic and extraordinary remedy." Monsanto Co. v. Geertson Seed

Farms, 561 U.S. 139, 165 (2010). To get an injunction, the Hospitals must show:

(1) that [they have] suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay, Inc. v. MercExchange, LLC, 547 U.S. 388, 391 (2006). And they must "clearly carry[] the burden of persuasion on all [four] elements." Bluefield Water Ass'n, Inc. v. City of Starkville, Miss., 577 F.3d 250, 253 (5th Cir. 2009). They fail to do so. Specifically, they win on factors two through four, but lose on factor one.

To start with the wins, the Hospitals show inadequacy of legal remedies. See eBay, 547 U.S. at 391. Because they sue the government, money damages are off the table. See Wages & White Lion Invs., LLC v. FDA, 16 F.4th 1130, 1142 (5th Cir. 2021). That's a win for factor two. eBay, 547 U.S. at 391. And factors three and four "merge when the Government is the opposing party." Nken v. Holder, 556 U.S. 418, 435 (2009). As applied to the Parties themselves, the Court "looks to the relative harm to both parties if the injunction is granted or denied." Def. Distrib. v. U.S. Dept' of State, 838 F.3d 451, 460 (5th Cir. 2016). A denied injunction could disqualify the Hospitals from myriad federal programs by operation of an invalid regulation. A granted injunction merely stops HHS from enforcing a single unlawful regulation promulgated last year. That balance clearly favors the Hospitals. Def. Distrib., 838 F.3d at 460.

If the private-interests inquiry favors the Hospitals, the public-interests inquiry does so even more. The Exclusion Rule forces the Hospitals to cut costs and limit services for low-income patients in Texas. See ECF No. 8 at 5. "Such a consequence would harm the public at large." Career Colleges & Sch. of Tex. v. United States Dep't of Educ., 98 F.4th 220, 255 (5th Cir. 2024) (holding the public interest favors an injunction because "a failure to stay the Rule would significantly constrain schools' operations and prevent them from devoting resources to educating their students, upgrading facilities, and constructing new ones."). "But even more fundamentally, the public interest is served

when administrative agencies comply with their obligations under the APA." Carroll Indep. Sch. Dist. v. United States Dep't of Educ., No. 4:24-CV-00461-O, 2024 WL 3381901, at *7 (N.D. Tex. July 11, 2024) (O'Connor, J.). There is generally no public interest in the perpetuation of unlawful agency action. See Wages & White Lion Invs., 16 F.4th at 1143.

Indeed, in most cases, the avoidance of improper laws is "the highest public interest at issue." *Def. Distrib.*, 838 F.3d at 460. That interest is implicated here. But it's the penultimate interest for this case given the significant public-health considerations. *See Roman Catholic Diocese of Brooklyn v. Cuomo*, 492 U.S. 14, 19–20 (2020) (noting public health is paramount in injunctive-relief analyses). Yet despite these decisive victories, the Hospitals must "clearly carry[] the burden of persuasion on all elements" to obtain a permanent injunction. *Bluefield Water Ass'n*, 577 F.3d at 253. And they fail to do so for the first factor: the irreparability of their injury. *eBay*, 547 U.S. at 391.

Without an irreparable injury, you can't get an injunction—full stop. See id. As noted, the Hospitals can't get damages here. See Wages & White Lion Invs., 16 F.4th at 1142. That ordinarily indicates a harm is irreparable. See Sampson v. Murray, 415 U.S. 61, 90 (1974) ("The key word in in this consideration is *irreparable*. Mere injuries, however substantial, . . . are not enough. The possibility that adequate compensatory or other corrective relief will be available at a later date. . . weighs heavily against a claim of irreparable harm."). But what about "other relief"? See id. HHS contends that the Hospitals can seek relief through the established administrative processes, which include the recovery of any underpaid DSH payments with interest, thereby negating the claim of irreparable harm. See ECF No. 14 at 1, 23. Furthermore, HHS argues that not all plaintiffs are likely to succeed on their 340B drug discount claims. See id. at 2. Specifically, some plaintiffs may not be directly impacted by the regulation in a way that would result in irreparable harm, thus undermining their case for injunctive relief. See id. This further demonstrates that the Hospitals have not met their burden of showing irreparable injury, particularly when alternative remedies are available to address any potential financial

harm. Indeed, the Hospitals seem to recognize their 340b arguments are the only viable path to injunctive relief. *See* ECF No. 8 at 22–24.

The record simply cannot carry the day for the Hospitals on this point. William Galinsky's Declaration suggests that only four of the fourteen hospitals may lose 340B eligibility as a result of the challenged rule, indicating that not all plaintiffs would be affirmatively impacted. See ECF No. 8-1. While the Hospitals contend the rule's impact on 340B eligibility will indirectly affect all Plaintiffs by lowering DSH percentages and thereby increasing the risk of disqualification from 340B, see ECF No. 15 at 10, that argument cannot warrant such an "extraordinary and drastic remedy" for all named plaintiffs. Monsanto, 561 U.S. at 165. Although the Court sympathizes with their arguments on this point, case law is clear that the Hospitals must "clearly carry" the burden of persuasion on all [four] elements" to obtain injunctive relief. Bluefield Water Ass'n, 577 F.3d at 253. And while all plaintiffs may face an irreparable injury without an injunction, the Hospitals do not clearly carry their burden on the instant record. See id. Thus, the Court must **DENY** a permanent injunction. Nevertheless, as explained below, vacatur takes some of the sting from the denial.

2. The Exclusion Rule should be vacated.

Having denied a permanent injunction, the Court still has equitable instruments in its toolkit when evaluating an invalid agency action. In deciding which to use, the Court must always consider the "least severe" equitable remedy to resolve a plaintiff's harm. See Nuziard, 2024 WL 965299, at *44–49 (collecting cases); see generally O'Donnell v. Harris Cnty., 892 F.3d 147, 155 (5th Cir. 2018) (noting an equitable remedy must be "narrowly tailored to the injury it is remedying"). And while this Court doubts the APA intended to authorize vacatur, see Nuziard, 2024 WL 965299, at *41–44, the Fifth Circuit's "ordinary practice is to vacate unlawful agency action." Data Mktg. P'ship, LP v. U.S. Dep't of Lab., 45 F.4th 846, 859 (5th Cir. 2022); see also Brown v. U.S. Dep't of Educ., 640 F. Supp. 3d 644, 667 (N.D. Tex. Nov. 10, 2022) (Pittman, J.) (vacated on other grounds). Having considered the briefing and evidence of record, the Court will follow that well-trod path here.

The Exclusion Rule is unlawful. See supra pp. 9–11; see also 5 U.S.C. § 706 (empowering courts to "set aside" unlawful agency actions). Between alternatives, vacatur is less severe on HHS but still remedies the Hospitals' harm. See Texas v. United States, 40 F.4th 205, 219 (5th Cir. 2022) (citing Monsanto, 561 U.S. at 165) ("There are meaningful differences between an injunction, which is a 'drastic and extraordinary remedy,' and vacatur, which is 'a less drastic remedy."). And vacatur is considerably less severe here considering the record's inability to support an injunction, warranting endorsement of the Fifth Circuit's standard practice. See Data Mktg. P'ship, 45 F.4th at 859.

The Hospitals say vacatur is warranted and the Court agrees, especially considering "vacatur does nothing but re-establish the status quo absent unlawful agency action." *Texas*, 40 F.4th at 220. As such, "[a]part from the constitutional or statutory basis on which the court invalidated an agency action, vacatur neither compels nor restrains further agency decision-making." *Id.* Accordingly, while this Court's doubts regarding vacatur under the APA are well known, *see Nuziard*, 2024 WL 965299, at *43–44, the remedy is warranted considering the Exclusion Rule's patent invalidity. *See* 42 C.F.R. § 412.106(b)(4)(iii); *see also Forrest*, 926 F.3d 221. Because the Fifth Circuit prefers vacatur to remedy unlawful agency actions, *see Data Mktg. P'ship*, 45 F.4th at 859, and because the Exclusion Rule warrants a lesser equitable remedy than an injunction, the Court must **GRANT** the Hospitals' request for vacatur under 5 U.S.C. § 706. *See* ECF No. 1 at 26.

CONCLUSION

For the above reasons, the Court concludes Plaintiffs' appeals are jurisdictionally proper, the Board erred in dismissing Plaintiffs' appeals, and the Exclusion Rule is unlawful. Accordingly, the Court **GRANTS** summary judgment in the Hospitals' favor on Counts 1–3 and **DECLARES** 42 C.F.R. § 412.106(b)(4)(iii) to be unlawful. The agency action being unlawful, the Court hereby **VACATES** 42 C.F.R. § 412.106(b)(4)(iii).

The Court further notes the Hospitals' request for fees and costs. *See* ECF No. 1 at 26. Should the Hospitals intend to pursue an award of fees

and/or costs, the Court **ORDERS** them to submit a properly supported motion for same within **five days** of the date of this Order.

SO ORDERED on this 15th day of August 2024.

Mark T. Pittman

UNITED STATES DISTRICT JUDGE