IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF TEXAS WICHITA FALLS DIVISION

FRANCISCAN ALLIANCE, INC.; SPECIALTY PHYSICIANS OF ILLINOIS, LLC,; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS;

- and -

STATE OF TEXAS; STATE OF WISCONSIN; STATE OF NEBRASKA; COMMONWEALTH OF KENTUCKY, by and through Governor Matthew G. Bevin; STATE OF KANSAS; STATE OF LOUISIANA; STATE OF ARIZONA; and STATE OF MISSISSIPPI, by and through Governor Phil Bryant,

Plaintiffs,

v.

SYLVIA BURWELL, Secretary of the United States Department of Health and Human Services; and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

REPLY BRIEF IN SUPPORT OF STATE PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Civ. Action No. 7:16-cv-00108-O

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INTRODUCTION

In less than a month, an HHS Rule will take full effect and force Plaintiffs to fundamentally alter the way they regulate and provide healthcare under Medicare and Medicaid. This deadline looms because, in yet another case of Executive overreach, Defendants created a Rule, six years after passage of the Affordable Care Act ("ACA"), that redefines the statutory definition of "sex" in Title IX to include "gender identity" and "termination of pregnancy." 45 C.F.R. § 92.4. The Rule eviscerates State laws protecting physicians' independent medical judgment on what Defendants admit is an "evolving" topic, Defs.' Opp. to Mot. Prelim. Inj. 13, ECF No. 50 ("Defs. Br."), by prohibiting them from advising against gender transition procedures and abortion. The Rule also intrudes upon State sovereignty by dictating standards of care and health insurance coverage, and changes the conditions of federal Medicare and Medicaid grants to the States.

Plaintiffs—a multistate coalition joined by private healthcare providers—brought this lawsuit shortly after the Rule began to take effect and moved for injunctive relief immediately after adding several plaintiffs. The State Plaintiffs adopt and incorporate by reference the preliminary injunction briefs filed by the private plaintiffs ("Franciscan"), and herein reply in support of their own motion for preliminary injunction, seeking nationwide relief before December 31, 2016 to prevent enforcement of the Rule.

Rather than responding to the merits of the State Plaintiffs' Spending Clause and Tenth Amendment claims, Defendants attempt to minimize and explain away the unlawful and unconstitutional aspects of their Rule redefining "sex," and assert

¹ Plaintiffs did not delay their pursuit of injunctive relief. Pls.' Suppl. Br. 4, ECF No. 37. Defendants' contention that the U.S. Attorney for the Northern District of Texas was not immediately served with the complaint is belied by the fact that Plaintiffs immediately served Defendants and did not learn of this alleged deficiency until a month later.

the Court should evaluate the Rule under the deferential agency action standard in *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). But *Chevron* is inapplicable here because Congress did not clearly delegate rulemaking power to HHS to redefine "sex" in Title IX, and because that issue involves a major political question reserved to Congress. Moreover, Spending Clause cases do not apply *Chevron* when evaluating cooperative federalism programs.

The State Plaintiffs are suffering irreparable injuries that are ripe for adjudication. Texas is under investigation by HHS, and other states have been in the past. Moreover, to comply with the Rule, States must modify their health insurance plans by January 1, 2017 to remove exclusions for gender transition procedures and abortion, as well as rewriting laws and policies to comply with aspects of the Rule that went into effect in July and October 2016. Because these harms are felt by healthcare providers and states throughout the country, a nationwide injunction is needed to prohibit enforcement of the definition of "on the basis of sex" in the Rule, 45 C.F.R. § 92.4. The Court should grant the Plaintiffs' motions.

ARGUMENT

I. The Rule Is Invalid Under *Chevron* Step Zero Because Congress Did Not Delegate to HHS Rulemaking Power under Title IX.

Defendants are quick to argue that the Rule survives *Chevron* deference. Not so fast. In *King v. Burwell*, 135 S. Ct. 2480, 2488–89 (2015), the Supreme Court held that *Chevron* does not always apply to agency actions and declined to apply it to the health exchange scheme created by the ACA. It did so because there is often good "reason to hesitate before concluding that Congress" intended to delegate rulemaking authority to a federal agency on a particular topic. *Id.* Thus, before applying *Chevron*, the Court must apply *Chevron* Step Zero and assess whether deference even applies. Here, it does not. Instead, this case falls squarely into two of the circumstances when

courts do not defer to agency rulemaking: those involving congressional conditions on state participation in federal funding mechanisms and "major questions."

A. The clear-statement doctrine precludes the application of *Chevron* deference.

Chevron deference does not apply to unclear federal conditions on grants offered to States. As stated in the State Plaintiffs' Brief in Support of Motion for Partial Summary Judgment or, in the alternative, a Preliminary Injunction, ECF No. 23 ("State Pls. Br."), Congress may legitimately exercise cooperative federalism under Article I's spending power only when States "voluntarily and knowingly" accept the "terms of the contract," and not when States are "unaware of the conditions" or "unable to ascertain" their contractual obligations. Pennhurst State Sch. & Hosp. v. Halderman, 451 U.S. 1, 17 (1981). Conditions on federal funds directed to States must be stated "unambiguously," id., so that "a state official would clearly understand" them, Arlington Cent. Sch. Bd. of Educ. v. Murphy, 548 U.S. 291, 296 (2006).

To ensure that Congress actually intended to interfere with areas that are traditionally within the States' sovereign domain, the Spending Clause, Tenth Amendment and concerns of federalism require a "clear statement from Congress." Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Eng'rs, 531 U.S. 159, 174 (2001); Gregory v. Ashcroft, 501 U.S. 452, 460, 463 (1991). "If Congress intends to alter the usual constitutional balance between the States and the Federal Government, it must make its intention to do so unmistakably clear in the language of the statute." Gregory, 501 U.S. at 460 (citation and quotation marks omitted).

In the ACA, and specifically section 1557, Congress did not make a clear statement that it was redefining "sex" in Title IX, or giving Defendants authority to do so. Section 1557 provides, in relevant part, that

an individual shall not, on the ground prohibited under . . . title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), . . . be excluded from participation in, be denied the benefits of, or be subjected

to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance

42 U.S.C. § 18116. Thus, section 1557 states clearly that Title IX's prohibition of "sex" discrimination may be applied in the healthcare context, but not that the definition of "sex" may be fundamentally rewritten by Defendants to achieve new policy goals.

When the States began accepting Medicare and Medicaid funding, "sex" did not mean "gender identity" and "termination of pregnancy." State Pls. Br. 15–16. If Congress intended to give Defendants authority to fundamentally change the definition of "sex" in Title IX, and apply that change to Medicare and Medicaid funding program, it would have done so "unambiguously" through a "clear statement" in the ACA. But rather than creating a new definition of "sex" or authorizing HHS to do so, the plain language of section 1557 shows that Congress relied on the longstanding definition of "sex" contained in Title IX. If anything, Congress's clear statement in the ACA was that the definition of "sex" should not change. Congress did not write a new nondiscrimination statute; it relied on existing law. But Defendants, relying on self-serving letters and memoranda penned by themselves and other federal agencies, 81 Fed. Reg. 31387–88, and not the understanding of "sex" at the time of its enactment, strayed far beyond the congressionally-delegated framework of the ACA and illegally rewrote Title IX through Executive rulemaking, see Bowen v. Am. Hosp. Ass'n, 476 U.S. 610, 646 & n.34 (1986) ("The fact that the agency's interpretation has been neither consistent nor longstanding substantially diminishes the deference to be given to HEW's [now HHS's] present interpretation of the statute.") (quotation marks and citation omitted); cf. Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) ("the agency's interpretation [of a regulation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation") (quotation marks omitted).

The terms of Defendants' Rule were not clearly stated when Title IX was originally enacted, nor were they clearly rewritten in the ACA. "In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 161 (2000) (quoting United States v. An Article of Drug... Bacto-Unidisk, 394 U.S. 784, 800 (1969)). Because Congress gave no clear statement that "sex" now means "gender identity" and "termination of pregnancy," Defendants are powerless to impose those provisions of the Rule and the Rule merits no Chevron deference.

B. The "major question" exception precludes application of *Chevron* deference.

A second circumstance when *Chevron* deference does not apply to agency rulemaking arises from "major questions." *Chevron* presupposes "that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps." *King*, 135 S. Ct. at 2488 (quoting *Brown & Williamson*, 529 U.S. at 159). "In extraordinary cases, however, there may be reason to hesitate before concluding that Congress has intended such an implicit delegation." *Id.* Indeed, if Congress intended to assign "questions of deep 'economic and political significance" to an agency, "it surely would have done so expressly." *Id.* at 2489.

In an influential 1986 article, then-Judge Breyer said that courts look to the "practical features of the particular circumstance to determine whether it 'makes sense" to presume a congressional intent for agency deference. Stephen P. Breyer, *Judicial Review of Questions of Law and Policy*, 38 ADMIN. L. REV. 363, 370 (1986). The nature of the question at issue is a relevant inquiry. Judge Breyer explained:

Is the particular question one that the agency or the court is more likely to answer correctly? Does the question, for example, concern common law or constitutional law, or does it concern matters of agency administration? A court may also ask whether the legal question is an important one. Congress is more likely to have focused upon, and

answered major questions, while leaving interstitial matters to answer themselves in the course of the statute's daily administration.

Id.

The Supreme Court recognizes the "major question" exception articulated by Justice Breyer. In *King*, the Court declined to apply *Chevron* to the ACA's tax credit scheme because the legal question at issue was one of "deep economic and political significance that is central to this statutory scheme; had Congress wished to assign that question to an agency, it surely would have done so expressly." 135 S. Ct. at 2489 (internal quotations omitted); *see also Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2444 (2014) ("We expect Congress to speak clearly if it wishes to assign to an agency decisions of vast economic and political significance.") (internal citations and quotations omitted).

During our nation's history, we have addressed major political questions by enacting statutes, not agency rules like the one at issue here. Congress does not "delegate [] decision[s] of such economic and political significance to an agency in so cryptic a fashion." *Brown & Williamson*, 529 U.S. at 160. "[N]o matter how 'important, conspicuous, and controversial' the issue, . . . an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *Id.* at 161.

Reading Defendants' brief, one might think that the ACA granted HHS broad power to address any topic remotely implicating "sex" in ways never considered until this year. But section 1557 merely reaffirms that men and women (the immutable, biological categories of "sex") should be treated equally. Section 1557 does not create new statutory protections, but merely incorporates by reference Title IX. The text of Title IX prohibits invidious discrimination "on the basis of sex." And because Title IX does not define "sex," the ordinary meaning prevails. See Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 187 (1995) ("When terms used in a statute are undefined,

we give them their ordinary meaning."). When Title IX was enacted, virtually every dictionary definition of "sex" referred to physiological distinctions between females and males, particularly with respect to their reproductive functions. *See* State Pls. Br. 14–15. Clearly, a biologically-grounded meaning of "sex" is what Congress had in mind when it enacted Title IX.

Defendants brief also leads one to believe that "on the basis of sex" in Title IX has long been interpreted to refer to "gender identity" and "termination of pregnancy." But "[w]hen an agency claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy,' we typically greet its announcement with a measure of skepticism." *Util. Air Regulatory Grp.*, 134 S. Ct. at 2444 (quoting *Brown & Williamson*, 529 U.S. at 159). "Thus, an agency interpretation that is 'inconsisten[t] with the design and structure of the statute as a whole,' does not merit deference." *Id.* at 2442 (quoting *Univ. of Tex. S. Med. Ctr. v. Nassar*, 133 S. Ct. 2517, 2529 (2013)).

Both "gender identity" and abortion are major questions that remove the presumption of delegation under *Chevron* Step Zero. Only recently have Defendants asserted that "gender identity" is encompassed within Congress's 1972 enactment of "sex." But when Congress enacted Title IX, "gender" was wholly distinct from "sex." State Pls. Br. 15–16. Lawmakers have attempted to add "gender identity" to other laws, but not as a subpart to "sex." *Id.* at 16. And courts are only now beginning to wrestle with the issue in the Title IX context. *See*, *e.g.*, *G.G. ex rel. Grimm v. Gloucester Cty. Sch. Bd.*, 822 F.3d 709 (4th Cir.), recalling mandate & issuing stay, 136 S. Ct. 2442, cert. granted, 2016 WL 4565643 (U.S. Oct. 28, 2016) (No. 16-273); Texas v. United States, No. 7:16-cv-00054-O, 2016 WL 4426495, at *1 (N.D. Tex. Aug. 21, 2016). Given the importance of this issue, one can hardly say that Congress delegated rulemaking power to HHS.

The same can be said of Defendants adding "termination of pregnancy" to "on the basis of sex" under Title IX. As Defendants acknowledge, several federal and state laws prohibit the government from dictating that medical professionals and States participate in abortions. Defs. Br. 8–9. After all, to say that abortion is a major political question in our nation is a gross understatement of the feelings by both sides.

Since the issues of sex discrimination and abortion are major political issues, Congress did not delegate rulemaking authority so that HHS may to fundamentally rewrite federal law and thereby undercut the very political debate these issues deserve. Based on the clear statement by Congress that it was not rewriting Title IX to include "gender identity" and "termination of pregnancy," and based on the major political questions raised by these issues, the Rule deserves no *Chevron* deference. Thus, the Court should evaluate the Rule under the State Plaintiffs' Spending Clause and Tenth Amendment claims, not *Chevron*.

II. Violations of the Spending Clause Are Not Analyzed Under Chevron.

Defendants also wrongly assert that Spending Clause claims are analyzed under *Chevron* because both inquiries assess ambiguity. Defs. Br. 33 & 43–44. Whether Congress spoke clearly in placing conditions on a federal funding program is a different question from whether a court should defer to agency rulemaking when a statute is ambiguous. *Appalachian States Low-Level Radioactive Waste Comm'n v. O'Leary*, 93 F.3d 103, 109 n.6 (3d Cir. 1996) ("we are not at all convinced that statutory ambiguity in the sense of *Chevron* is the same thing as statutory ambiguity in the sense of *Pennhurst*").

Spending Clause case law does not "reprise[]" Chevron deference. Defs. Br. 43. The predominant Spending Clause cases that post-date Chevron make no mention of it. See, e.g., Arlington Cent., 548 U.S. 291; Sossamon v. Texas, 563 U.S. 277 (2011); Canutillo Indep. Sch. Dist. v. Leija, 101 F.3d 393 (5th Cir. 1996); see also David Engstrom, Drawing Lines Between Chevron and Pennhurst: A Functional Analysis of

the Spending Power, Federalism, and the Administrative State, 82 Tex. L. Rev. 1197, 1203–04 (2004) (discussing the differences between the doctrines).

The Spending Clause asks whether a statute clearly states the "unambiguous" conditions states must accept to receive federal funding. *Chevron* asks whether a court should defer to an agency interpretation of statutory ambiguity. And *Chevron* applies only if Congress clearly delegates rulemaking authority. If it does not apply, then the Supreme Court indicates that the statute is interpreted in its normal fashion under the Spending Clause, not *Chevron*. *Cf. King*, 135 S. Ct. at 2489 (declining to apply *Chevron* deference and instead reading the statute in context). Based on the reasons the State Plaintiffs articulate in their prior briefs, the Court should preliminarily enjoin the Rule under the Spending Clause.

III. Plaintiffs Are Suffering Injuries Ripe for Review.

In challenging Plaintiffs' standing to bring this suit, Defendants assert that Plaintiffs' injuries are conjectural and hypothetical. They claim the Rule allows for "application of medical judgment," protects religious and conscience-based objections, retains protections from abortion procedures, and does not require the performance or coverage of any particular medical service. Defs. Br. 25–26. Defendants also assert that the State Plaintiffs' claims are not ripe. They are wrong in all respects.

"Standing and ripeness are jurisdictional questions which must be resolved as a preliminary matter." Am. S. Ins. Co. v. Buckley, 748 F. Supp. 2d 610, 618 (E.D. Tex. 2010). Standing is concerned with whether a proper party is bringing suit while ripeness is concerned with whether the suit is being brought at the proper time. Texas v. United States, 497 F.3d 491, 496 (5th Cir. 2007) (citing Elend v. Basham, 471 F.3d 1199, 1205 (11th Cir. 2006)). Although standing and ripeness are two distinct doctrines, "the doctrines often overlap in practice, particularly in an examination of whether a plaintiff has suffered a concrete injury." Id.

To establish federal jurisdiction, a plaintiff must show an injury-in-fact: "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992) (citations and quotation marks omitted). "A challenge to administrative regulations is fit for review if (1) the questions presented are 'purely legal one[s],' (2) the challenged regulations constitute 'final agency action,' and (3) further factual development would not 'significantly advance [the court's] ability to deal with the legal issues presented." Texas, 497 F.3d at 498 (quoting Nat'l Park Hosp. Ass'n v. U.S. Dep't of Interior, 538 U.S. 803, 812 (2003)). This is not a preenforcement challenges as Defendants' assert. Defs. Br. 30. The State Plaintiffs are suffering ripe injuries because HHS is currently investigating Texas for compliance with the Rule. The State Plaintiffs exclude gender transition procedures/services, as well as abortion services, from both their Medicaid and health insurance programs. Moreover, all State Plaintiffs are already beginning to comply with aspects of the Rule that took effect in July 2016. And looming is a January 1, 2017 deadline, under the Rule, for the State Plaintiffs' Medicaid and health insurance programs to begin covering gender transition procedures/services, as well as abortion services.

First, in September, HHS's Office for Civil Rights contacted Texas's Health and Human Services Commission to investigate a complaint concerning the Texas Medicaid Program. HHS is investigating whether Texas covers "sex change therapy," who determines the "medical necessity" for such therapy, and "whether there is a different process for determining medical necessity criteria for hormonal fertility treatment and cosmetic surgery." Decl. of Dana Williamson Ex. 1, Dec. 2, 2016; accord Decl. of Doneshia Ates Ex. 2, Dec. 2, 2016, attached hereto. Texas does not cover these procedures, but the Rule prohibits categoricals exclusion. 45 C.F.R. § 92.207(b)(4). So HHS's investigation is an actual injury. After all, in another enforcement action HHS already determined that denying coverage for a gender transition procedure was

unlawful. Defs. Br. 40 n.20. And, even before promulgating the Rule, HHS enforced section 1557 against providers in other States.² The investigation and HHS's previous activities show that Defendants are enforcing the Rule against the States and that the State Plaintiffs are suffering concrete injuries as a result.

Second, the Rule mandates that States "as a condition of any application for Federal financial assistance, submit an assurance" that their "health programs and activities will be operated in compliance with Section 1557 and this part." 45 C.F.R. § 92.5. "[H]ealth program or activity" includes "health-related services, health-related insurance coverage, or other health-related coverage," and "all . . . operations" of an entity engaged in providing health services or insurance. *Id.* § 92.4. The Rule requires the States to provide insurance coverage for gender transition procedures and abortions. *Id.* § 92.207(b). But, as Defendants acknowledge, the State Plaintiffs prohibit coverage for abortions. Defs. Br. 20 n.10. In addition, the State Plaintiffs categorically exclude coverage for gender transition procedures and/or sex change operations. Thus, States who exclude transition procedures and abortions from Medicaid coverage, must now modify their health plans to provide for these procedures.

² U.S. Dep't of Health & Human Servs., *OCR Enforcement under Section 1557 of the Affordable Care Act Sex Discrimination Cases*, available at http://www.hhs.gov/civilrights/for-individuals/section-1557/ocr-enforcement-section-1557-aca-sex-discrimination/.

³ See Tex. Medicaid Provider Procedures Manual § 1.11, available at http://www.tmhp.com/HTMLmanuals/TMPPM/Current/Vol1_01_Provider_Enrollment.02.90.html ("sex change operations" under Medicaid); ARIZ. ADMIN. CODE R9-22-205(B)(4) ("gender reassignment surgeries"); Kan. Medicaid State Plan 407 & 419, available at http://www.kdheks.gov/hcf/Medicaid/download/StatePlan/Kansas_SPA_Volume1.pdf (no coverage for elective or experimental surgery); Ky. Medicaid Member Handbook 18, available at http://chfs.ky.gov/nr/rdonlyres/f6b5f330-ee69-4cc8-83a8-1a1c0dc4bf46/0/finalhandbook62014.pdf (same); 23-200 MISS. CODE R. § 2.2(A)(7) ("Any operative procedure . . . performed primarily to . . . treat a mental condition through change in bodily form"); 210 NEB. ADMIN. CODE § 44-006 ("gender transformation or changes"); 471 NEB. ADMIN. CODE § 10-004.01(31) ("sex change procedures"); WIS. ADMIN. CODE DHS §§ 107.03(23–24), § 107.10(4)(p) ("transsexual surgery" and "hormone therapy").

Finally, some aspects of the Rule, including the replacement of physicians' medical judgment for federal judgment, took effect in July. The Rule purports to accommodate medical judgment, but when a physician advises against gender transition, the patient can accuse him of "gender identity" discrimination under the Rule. And when HHS investigates, the physician's reasoned medical judgment is not the end of the query, as it should be. Rather, the physician's medical judgment is only one of several factors HHS uses to evaluate compliance with the Rule. Defs. Br. 21. Thus, the Rule invades the sovereignty of the State Plaintiffs by supplanting their laws deferring to the "independent medical judgment" of physicians, see, e.g., Murk v. Scheele, 120 S.W.3d 865, 867 (Tex. 2003) (per curiam); Tex. Occ. Code §§ 162.0021–0022, with a federal standard that reduces medical judgment to a mere factor.

These injuries are ripe for review because they are organized under a purely legal question: whether Defendants exceeded their authority under the Spending Clause and APA in rewriting the definition of "sex" in Title IX. Defendants do not dispute that the challenged Rule is final agency action. And further factual development will not advance the Court's ability to deal with the legal issues presented. Texas, 497 F.3d at 498. Indeed, "Texas [will] suffer hardship if we [] withhold consideration of its claims," id. at 499, including the "harmful creation of legal rights or obligations; practical harms on the interests advanced by the party seeking relief; and the harm of being 'force[d] . . . to modify [one's] behavior in order to avoid future adverse consequences," id. (quoting Ohio Forestry Ass'n v. Sierra Club, 523 U.S. 726, 734 (1998)). The Rule forces the State Plaintiffs to modify their laws, policies, and procedures, and has subjected at least one plaintiff state to investigation. These injuries are ripe for review.

IV. Plaintiffs' Injuries Are Irreparable.

As articulated above and in the Plaintiffs' prior briefing, the State Plaintiffs are suffering irreparable injuries because the Rule forces them to modify their own

laws, policies, practices, and health insurance plans. For example, the State Plaintiffs currently exclude from their health insurance coverage both gender transition procedures and abortion. They have hundreds of thousands of employees who are covered by health insurance plans, and those employees have myriad dependents enrolled on their coverage. The sheer number of covered beneficiaries undoubtedly means that someone covered by state health insurance will request that the Rule be honored and coverage extended for gender transition procedures and/or abortion. Even putative intervenors acknowledge this point. See, e.g., Decl. of Cheryl Newcomb ¶¶ 4–5, Sept. 15, 2016, attached as Ex. 2 to Putative Intervenors' Mot. to Intervene, ECF No. 8. But for a preliminary injunction by year's end, the Rule will force the State Plaintiffs to modify their health insurance coverage and Medicaid plans to include the currently prohibited transition procedures and abortions. This injury is more than financial; it forces the Plaintiff States to expend resources and energy undoing their sovereign choice in lieu of that imposed upon them by Defendants.

Moreover, Defendants assert that the Rule does not displace "scientific or medical reasons" for making distinctions based on sex. Defs. Br. 19. But as stated above, in Texas and other states, the independent medical judgment of physicians is paramount. The Rule lowers this standard of care by making medical judgment just one of many factors HHS may consider when deciding whether a covered entity has violated the Rule. Curtailing the laws of the State Plaintiffs that extol the judgment of their medical professionals is irreparable injury.

The Rule also threatens the State-sovereigns with private lawsuits and enforcement actions by HHS for not providing gender transition services, or abortions, to state employees or patients at State hospitals. Defendants plead that the threat of enforcement is not an irreparable injury because none have materialized in the six years since section 1557 was enacted. But the Rule was not made final until this year. Moreover, HHS is currently investigating Texas and reports multiple

enforcement actions in other States, including some States who are party to this lawsuit, for noncompliance with the Rule, despite the fact that it has only been on the books for six months. See OCR Enforcement under Section 1557, supra note 2. Thus, the State Plaintiffs are suffering irreparable harm from the mandate that they reform their laws, policies, procedures, and health plans, and from the threat of lawsuits and investigations from private parties and HHS.

V. The Court Should Issue a Nationwide Injunction Against the Rule.

"[D]istrict courts enjoy broad discretion in awarding injunctive relief." Nat'l Min. Ass'n v. U.S. Army Corps of Eng'rs, 145 F.3d 1399, 1408 (D.C. Cir. 1998). This includes the issuance of nationwide injunctions, because the judicial power "is not limited to the district wherein the court sits but extends across the country. It is not beyond the power of a court, in appropriate circumstances, to issue a nationwide injunction." Texas v. United States, 809 F.3d 134, 188 (5th Cir. 2015), aff'd by an equally divided court, 136 S. Ct. 2271 (2016). Indeed, "courts should not be loathe to issue injunctions of general applicability," Hodgson v. First Fed. Sav. & Loan Ass'n of Broward Cty., 455 F.2d 818, 826 (5th Cir. 1972), as "[t]he injunctive processes are a means of effecting general compliance with national policy as expressed by Congress, a public policy judges too must carry out—actuated by the spirit of the law and not begrudgingly as if it were a newly imposed fiat of a presidium," Mitchell v. Pidcock, 299 F.2d 281, 287 (5th Cir. 1962).

A nationwide injunction is appropriate when a party challenges an agency regulation on its face under the APA. The Supreme Court has indirectly affirmed this principle. In *Lujan v. National Wildlife Federation*, Justice Blackmun noted this in dissent, but apparently consistently with the views of the other eight justices:

The Administrative Procedure Act permits suit to be brought by any person "adversely affected or aggrieved by agency action." In some cases the "agency action" will consist of a rule of broad applicability; and if the plaintiff prevails, the result is that the rule is invalidated, not simply

that the court forbids its application to a particular individual. Under these circumstances a single plaintiff, so long as he is injured by the rule, may obtain "programmatic" relief that affects the rights of parties not before the court.

497 U.S. 871, 913 (1990) (Blackmun, J., dissenting) (citation omitted); *cf. id.* at 890 n.2 (majority opinion) (noting under the APA, a successful challenge by an aggrieved individual can affect the entire agency program); *see also Nat'l Min. Ass'n*, 145 F.3d at 1410 ("APA's command that rules 'found to be . . . in excess of statutory jurisdiction' shall be not only 'h[e]ld unlawful' but 'set aside.") (quoting 5 U.S.C. § 706(2)(C)).

A nationwide injunction is appropriate here. The Rule is applicable to all fifty states and Plaintiffs represent a coalition of private parties and State-sovereigns affected by the Rule. The scope of the injury extends to medical practitioners, providers, and regulators in all corners of the country. Thus, the Rule should be enjoined nationwide as other courts have done in similar contexts. See, e.g., Nevada, Texas, et al. v. U.S. Dep't of Labor, No. 4:16-cv-00731, 2016 WL 6879615, at *9 (E.D. Tex. Nov. 22, 2016) (Mazzant, J.); Associated Builders & Contractors of S.E. Texas v. Rung, No. 1:16-cv-425, slip op. at 32, ECF No. 22 (E.D. Tex. Oct. 24, 2016) (Crone, J.); Texas, 2016 WL 4426495, at *17 (O'Connor, J.); Nat'l Fed. of Indep. Bus. v. Perez, No. 5:16-cv-00066-C, 2016 WL 3766121, *46 (N.D. Tex. June 27, 2016) (Cummings, J.); Texas v. United States, 86 F. Supp. 3d 591, 677–78 (S.D. Tex.) (Hanen, J.), aff'd, 809 F.3d 134, 188 (5th Cir. 2015), aff'd by an equally divided court, 136 S. Ct. 2271 (2016).

CONCLUSION

For the foregoing reasons and those stated in Plaintiffs prior briefs, the Court should issue a preliminary injunction against the definition of "on the basis of sex" in the Rule, 45 C.F.R. § 92.4.

Respectfully submitted this the 2nd day of December, 2016.

KEN PAXTON

Attorney General of Texas

JEFFREY C. MATEER

First Assistant Attorney General

BRANTLEY D. STARR

Deputy First Assistant Attorney General

PRERAK SHAH

Senior Counsel to the Attorney General

ANDREW D. LEONIE

Associate Deputy Attorney General

/s/ Austin R. Nimocks

AUSTIN R. NIMOCKS

Associate Deputy Attorney General

Texas Bar No. 24002695

austin.nimocks@oag.texas.gov

MICHAEL C. TOTH

Senior Counsel

JOEL STONEDALE

Counsel

Office of Special Litigation ATTORNEY GENERAL OF TEXAS P.O. Box 12548, Mail Code 009 Austin, Texas 78711-2548

(512) 936-1414

ATTORNEYS FOR PLAINTIFFS
STATE OF TEXAS; STATE OF
WISCONSIN; STATE OF
NEBRASKA; COMMONWEALTH
OF KENTUCKY, by and through
Governor Matthew G. Bevin;
STATE OF KANSAS; STATE OF
LOUISIANA, STATE OF ARIZONA, and
STATE OF MISSISSIPPI, by and through
Governor Phil Bryant

CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2016, I electronically filed the foregoing document through the Court's ECF system, which automatically serves notification of the filing on counsel for all parties.

/s/ Austin R. Nimocks
AUSTIN R. NIMOCKS