IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

STATE OF TENNESSEE, STATE OF MISSISSIPPI, STATE OF ALABAMA, STATE OF GEORGIA, STATE OF INDIANA, STATE OF KANSAS, COMMONWEALTH OF KENTUCKY, STATE OF LOUISIANA, STATE OF NEBRASKA, STATE OF OHIO, STATE OF OKLAHOMA, STATE OF SOUTH CAROLINA, STATE OF SOUTH DAKOTA, COMMONWEALTH OF VIRGINIA, AND STATE OF WEST VIRGINIA, *Plaintiffs*, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; MELANIE FONTES RAINER, in her official capacity as the Director of the Office for Civil Rights; CENTERS FOR MEDICARE AND MEDICAID SERVICES; and CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services, *Defendants.*	Civil Action No. 1:24-cv-161-LG-BWR

REPLY IN SUPPORT OF PLAINTIFFS'
MOTION FOR § 705 RELIEF AND A PRELIMINARY INJUNCTION

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INTRODUCTION

HHS touted the 2024 Rule as a "giant step forward" in fighting gender-identity discrimination.[1] Now that the States have challenged HHS's "bold action" as patently unlawful, *id.*, HHS dramatically downplays the 2024 Rule's gender-identity mandates. But the text of the rule, not HHS counsel's after-the-fact rationalization, controls. And the 2024 Rule expressly requires the steps—like dividing medical spaces by gender identity rather than sex, providing controversial gender-transition interventions, and subsidizing the same with state funds—the States now challenge. (If the 2024 Rule is not in fact that broad, HHS must clearly say so on remand with reasoning that satisfies the APA.) HHS's effort to sidestep the 2024 Rule's plain terms—or to avoid merits review altogether—speaks volumes about the rule's lack of legal basis. This Court should grant preliminary relief.

ARGUMENT

I. Plaintiffs Are Likely to Succeed on the Merits.

A. Plaintiffs can challenge the 2024 Rule now.

Standing. Standing is "easy to establish" in this case. *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 367 (2024). That is because the "text of the [2024 Rule]" directly regulates the States in their capacity as providers of medical care, facilities, and insurance plans. *Tennessee v. Dep't of Educ.*, No. 22-5807, 2024 WL 2984295, at *5 (6th Cir. 2024). The 2024 Rule "proscribes their conduct" with new gender-identity mandates, which impose compliance costs and derogate state sovereignty. *W. Va. Ex rel. Morrisey v. U.S. Dep't of the Treasury*, 59 F.4th 1124, 1136-38 (11th Cir. 2023). If nothing else, since HHS agrees (at 23) that Tennessee has standing, this Court can review the 2024 Rule. *Gen. Land Off. v. Biden*, 71 F.4th 264, 271 (5th Cir. 2023).

Implied Preclusion. Plaintiffs' challenge is not reserved for agency proceedings. *See Tennessee*,

[1] HHS, *HHS Issues New Rule to Strengthen Nondiscrimination Protections and Advance Civil Rights in Health Care* (Apr. 26, 2024), https://perma.cc/GRZ6-LAN7.

2024 WL 2984295, *17-21; *cf.* Opp'n 21 n.14. None of the "enforcement mechanisms" Section 1557 incorporates, 42 U.S.C. § 18116, contains "a special statutory scheme" that forecloses this Court's review of HHS rules under the APA, *e.g.*, *Louisiana v. EPA*, No. 2:23-CV-00692, 2024 WL 250798, at *19 (W.D. La. 2024) (Title VI); *Tennessee*, 2024 WL 2984295, at *18 (Title IX). To the contrary, the incorporated statutes specify that "agency action"—including rules—"shall be subject to such judicial review as may otherwise be provided by law for similar action taken by such department or agency on other grounds." 20 U.S.C. § 1683. Directing that courts "shall" review rules as "provided by" the APA is the opposite of a preclusive "special statutory review scheme." *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 185 (2023).

Nor does the Social Security Act ("SSA") implicitly strip this Court of jurisdiction to review the Rule's new requirements for Medicaid contracts with managed-care organizations. Opp'n 17-18 (invoking 42 U.S.C. § 1316(a), (e)). The SSA provisions HHS relies on have nothing to do with reviewing managed-care-plan contracts. HHS's contrary reading, moreover, "could foreclose all meaningful judicial review," *Axon*, 598 U.S. at 190, since a private managed-care entity would need to agree to a non-compliant contract with the States to provoke HHS retaliation. And HHS's authority to issue the challenged gender-identity mandates is "wholly collateral" to the agency process and has "nothing to do with the … matters" at issue in CMS's reimbursement adjudications. *Id.* at 193.

Ripeness. HHS argues (at 7) that "judicial review" should wait until HHS determines that a particular law or policy violates Section 1557 "and completion of … administrative procedures." But that would "immunize nearly all agency rulemaking activities from the coverage" of the APA. *Abbott Labs. v. Gardner*, 387 U.S. 136, 147 (1967). That is not the law, and Plaintiffs' challenge is ripe. The issues are "fit for judicial resolution," *id.* at 153, and hinge on a core question of law: Whether Section 1557 incorporates *Bostock*'s reasoning to cover gender-identity discrimination. The 2024 Rule further threatens Plaintiffs with the loss of billions of dollars in federal funds. *See Tennessee*, 2024 WL 2984295,

at *17 (holding States could pursue pre-enforcement challenge to agency action that risked loss of funding). Plaintiffs "need not assume such risks while waiting for [HHS] to drop the hammer." *Id.*

Neese v. Becerra. The decision in *Neese*, 640 F. Supp. 3d 668 (N.D. Tex. 2022), does not cut off review here. First, *Neese* did not issue *injunctive* relief, *id.* at 684, so nothing in that case blocks HHS from enforcing the 2024 Rule against the States. If HHS disagrees, then the 2024 Rule should be set aside as arbitrarily ignoring a binding directive that it is unlawful. Second, *Neese* addressed only HHS's 2021 guidance—not the 2024 Rule. Third, there is little reason to believe that *Neese*'s certified class of physicians extends to the States. It certainly does not include the States' Medicaid, CHIP, or other state-sponsored health plans. Fourth, HHS's promise to not apply "the challenged interpretation" of Section 1557 (the 2021 guidance) against *Neese* class members "pending appeal," 89 Fed. Reg. at 37,574 n.118, is empty since its delayed *enforcement* does not necessarily permit delayed *compliance*. HHS's "voluntary cessation" of enforcement must be disregarded. *Tennessee*, 2024 WL 2984295, at *5 n.8.

B. The 2024 Rule is contrary to law and exceeds HHS's statutory authority.

Contrary to Law. Section 1557's prohibition on sex discrimination does not encompass "gender identity." PI Br. 11-12. HHS makes no serious attempt to reconcile the male/female language in Title IX and the ACA with "gender identity" in the 2024 Rule. Opp'n 7-10. Instead, HHS relies on *Bostock* for the proposition that sex discrimination equals gender-identity discrimination. *See id.* But *Bostock* neither says nor means that any statutory reference to "sex" likewise prohibits gender-identity discrimination, *see* PI Br. 12-14, as a raft of courts have recently concluded.[2]

HHS's reading makes a hash of Title IX, which throughout allows for different treatment of males and females because of biological differences between the sexes, *see* Compl. ¶¶ 52-53, which are relevant in education and medicine, but not employment, *see Adams v. Sch. Bd. of St. Johns Cnty.*, 57

[2] *See, e.g.*, *Tennessee v. Cardona*, No. 2:24-cv-0072-DCR, 2024 WL 3019146, at *9-13 (E.D. Ky. 2024); *Texas v. Cardona*, No. 4:23-cv-00604-O, 2024 WL 2947022, at *28 (N.D. Tex. 2024); *Louisiana v. U.S. Dep't of Educ.*, No. 3:24-CV-00563-TAD, 2024 WL 2978786, at *11 (W.D. La. 2024); *see also Meriwether v. Hartop*, 992 F.3d 492, 510 n.4 (6th Cir. 2021).

F.4th 791, 814 n.7 (11th Cir. 2022) (en banc). Yet HHS (at 10) asks this Court to ignore the surrounding provisions and implementing regulations of Title IX and just pluck out the term "sex." But what constitutes "discrimination" for purposes of Title IX (and thus Section 1557) is informed by the Act in its entirety. Section 1557 thus uses "et seq." when incorporating Title IX, which imports that Section 1557 incorporates all of Title IX. PI Br. 14. HHS offers no response.

HHS's remaining attempts to square *Bostock* with Title IX and Section 1557 fail too. HHS insists (at 3, 10, 15) that covered entities may "operat[e] sex separated programs and facilities." At the same time, the Final Rule makes clear that refusing to place a transgender person "in facilities consistent with their gender identity" is actionable discrimination *per se*. 89 Fed. Reg. at 37,593. This view renders any allowance for sex-separation "meaningless." *Adams*, 57 F.4th at 813. A "sex-separation" policy that must give way to patients' gender-identity preferences does not "allow" sex-separation—just gender-identity-based separation. Nor can HHS's new *de minimis* harm standard change what discrimination entails: treatment of a person that is "worse than others *who are similarly situated*." *Bostock v. Clayton Cnty.*, 590 U.S. 644, 657 (2020) (emphasis added). A woman and a man who identifies as a woman are not "similarly situated" for purposes of seeking certain medical treatments, like a vaginoplasty. PI Br. 14-16. The 2024 Rule's failure to abide this blackletter tenet renders it unlawful.

Exceeds Authority. The 2024 Rule exceeds HHS's authority by requiring doctors to provide and insurers to cover gender-transition treatments. PI Br. 17-19. HHS counters (at 4) that "no § 1557 violation occurs where the denial of a service [or coverage] is based on 'a legitimate, nondiscriminatory reason,' and not 'unlawful animus or bias' or 'pretext for discrimination.'" So, HHS says (at 14), the States are wrong to "presuppose" that the rule directs gender-identity related treatments or coverage.

HHS cannot so easily misdirect from what the 2024 Rule plainly requires. The rule's text makes clear that a *categorical* refusal to provide or cover gender-transition treatments—as required by the laws and health plans maintained by many of the Plaintiff States—*is prohibited discrimination*. *See,*

e.g., 89 Fed. Reg. at 37,701 (to be codified at 45 C.F.R. §§ 92.206(b)(4), 92.207(b)(4)-(5)) (illegal to "[d]eny or limit" services for gender transition "that the covered entity would provide for other purposes" or to maintain "categorial coverage exclusion" that "results in discrimination based on sex"). HHS's brief (at 12, 14) confirms this no-categorial-exclusion reading by stressing the need for "particular patient" determinations. HHS's touted revisions (at 12-13) thus accomplish the same result—outlawing providers and States from categorically denying treatment—through subtext. Such a reading not only aligns with the 2024 Rule's continued directive that it will "preempt" contrary state law, *see* 89 Fed. Reg. at 37,535; it also reflects the recent litigation position of the Department of Justice, which has argued that "categorical exclusion[s] of gender-affirming care" violate Medicaid and Section 1557. Brief for United States as *Amicus Curiae* 19-25 & 21 n.8, *Dekker v. Sec'y, Fla. Agency for Health Care Admin.*, No. 23-12155 (11th Cir. Dec. 4, 2023). Nor can health plans deny such procedures for certain non-discriminatory reasons—like their being "experimental or cosmetic." NPRM, 87 Fed. Reg. at 47,874. HHS has already opined that such designations "would be considered evidence of pretext" and "result in prohibited discrimination." *Id.* HHS's brief cannot walk back the 2024 Rule's requirements now. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947).

HHS claims (at 17) that because it has rulemaking authority to implement the SSA, its Medicaid and CHIP rules must be lawful. That is not how agency authority works. HHS's rulemaking power is instead constrained by limits Congress placed within the SSA. *See Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 328 (2014). For example, HHS must ensure that participants' "methods of administration" are "necessary for the proper and efficient operation of the plan," 42 U.S.C. § 1396a(a)(4), and that States "initiate and expand the provision of child health assistance … in an effective and efficient manner," *id.* § 1397aa(a). But the 2024 Rule's gender-identity mandates are not "methods of administration," nor are they means of ensuring "effective and efficient" provision of child health assistance. PI Br. 19-20. They are substantive mandates. Congress would not have hidden the "elephant[]" of

across-the-board gender-identity mandates on States in the "mousehole[]" of Medicaid-program minutiae. *Chamber of Com. v. Dep't of Labor*, 885 F.3d 360, 376 (5th Cir. 2018). And parties' prior failure to challenge distinct HHS actions does not short circuit the States' right to obtain review of HHS's novel gender-identity mandates through this timely challenge. *Cf.* Opp'n 17.

C. The 2024 Rule is contrary to the Spending Clause.

The 2024 Rule violates the Spending Clause by unveiling new, extra-statutory gender-identity conditions and unlawfully coercing States with billions of dollars in Medicaid funding. PI Br. 20-22.

HHS's proposed private-suit limit (at 18) on the clear-statement rule defies law and logic—and the case HHS cites observed that a spending-program grantee needs to know "what rules it must follow," not just "what sort of penalties might be on the table." *Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 220 (2022). Nor did Section 1557's limit on "sex" discrimination generally put States on notice of HHS's "gender-identity" rule specifically. *Cf.* Opp'n 18-19. HHS admits as much by repeating that "[t]he Rule … *clarifies* § 1557's scope in light of *Bostock*." *Id.* at 19. A provision that "unambiguously condition[s] a federal grant" needs no clarifying. *Tex. Educ. Dep't v. U.S. Dep't of Educ.*, 992 F.3d 350, 360 (5th Cir. 2021). Contra HHS (at 19), there is no nondiscrimination exception to the clear-statement rule. *The basis* for discrimination must be "clear and actionable"—even if what actions qualify as discriminatory conduct on that basis requires case-by-case analysis. *See Benning v. Georgia*, 391 F.3d 1299, 1306 (11th Cir. 2004). Last, HHS casts off *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012), as "one-of-a-kind." Opp'n 20. Maybe it was—but only until the 2024 Rule again threatened billions in States' Medicaid funding. PI Br. 21-22. Here, as in *NFIB*, "[t]he threatened loss" of the States' Medicaid funding is unlawful "economic dragooning that leaves the States with no real option." 567 U.S. at 581 (plurality opinion). These Spending Clause concerns underscore the implausibility of HHS's interpretation of Title IX and Section 1557. *See Inhance Techs., L.L.C. v. EPA*, 96 F.4th 888, 893 (5th Cir. 2024) (discussing avoidance).

D. The 2024 Rule is arbitrary and capricious.

HHS (at 20) continues to insist the Rule imposes no "standard of care" or "attempt to supplant the medical judgment of healthcare professionals." The Rule's plain text disagrees. *Supra* at 4-5.

HHS's insistence (at 20) that the Rule's gender-identity mandates do not implicate WPATH's so-called "standards of care" likewise rings hollow, given the agency's reliance on those standards to define "gender transition or gender affirming care," *see* NPRM, 87 Fed. Reg. at 47,867 & n.416, and its citation to the same in explaining that "[g]ender-affirming care … should follow clinical practice guidelines and professional standards of care," *id.* at 47,868 & n.423.

Like the Final Rule, HHS's brief stays mum on the harmful and lifelong effects of gender-transition treatments. This silence is telling, but not surprising. After all, discovery in a case involving Alabama's restrictions on transitioning interventions for minors has revealed that *HHS itself* rushed WPATH to publish the latest version of its "standards" in 2022 in order to show "policy progress" for the Biden Administration; HHS further urged WPATH to remove all recommended age minimums for transitioning treatments. *See Boe v. Marshall*, 2:22-cv-184-LCB-CWB (M.D. Ala.), Doc. 619 at 19-20. The APA required HHS to grapple with this contrary evidence, not ignore it. PI Br. 22.

II. Plaintiffs Will Be Irreparably Harmed Absent Injunctive Relief.

Starting July 5, the 2024 Rule requires the States—as directly regulated parties—to come into compliance with its gender-identity mandates. To do so, States will need to expend unrecoverable compliance costs altering policies, PI Br. 22, abandon enforcement of their own contrary laws and regulations that fall within HHS's new definition of sex-based "discrimination," 89 Fed. Reg. at 37,699 (to be codified at 45 C.F.R. § 92.101), and provide "assurances" of their compliance, *id.* at 37,696 (to be codified at § 92.5). Failure to do so risks the loss of *billions* of dollars in federal funding designed to help some of the States' neediest citizens. All of this is textbook irreparable harm. PI Br. 23-25.

HHS (at 22, 25) argues that any harm to the States is "speculative and not imminent" because

the States might be able "to demonstrate a legitimate, nondiscriminatory reason" for any law or policy that conflicts with the 2024 Rule during a future investigation or enforcement action. Of course, the "upshot of winning this claim is that the States shouldn't be subjected to administrative investigations or proceedings at all." *Tennessee*, 2024 WL 2984295, at *20. Regardless, the 2024 Rule makes the result of any future enforcement a foregone conclusion: It sets a binding HHS mandate that Plaintiff States' laws prohibiting and categorical coverage exclusions for gender-transition services are unlawful. *See supra* at 4-5. As discussed, the States "need not await enforcement proceedings before challenging final agency action where such proceedings carry the risk of 'serious … civil penalties.'" *Tennessee*, 2024 WL 2984295, at *17 (citation omitted). Because the Final Rule means States "will continue to face pressure to change their laws to avoid legal consequences," it inflicts irreparable injury. *Id.* at *25.

Reality obliterates HHS's assertion (at 27) that States would not incur any compliance costs until they are in the throes of an enforcement action. Compliance with the 2024 Rule's gender-identity mandates will require the States to expend significant, unrecoverable sums *now*. *See* PI Br. 22-23. The 2024 Rule concedes the point. 89 Fed. Reg. at 37,679-82. The Rule's "immediate effects on the States' ordering of their own affairs" is a "here-and-now injury." *Tennessee*, 2024 WL 2984295, at *17 (quoting *Axon*, 598 U.S. at 191. HHS's counter (at 27 n. 20) that other provisions may impose *additional* costs in the form of updating policies or providing training does not erase the harm from the gender-identity mandates. HHS's view would shield any manner of unlawful regulations from challenge so long as packaged alongside a few benign provisions. But "complying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016) (emphasis in original).

HHS (at 27) denies that States' health plans would incur increased coverage costs because the Rule purportedly does not endorse or impose any "standard of care" for gender transition. But again, that contradicts the Rule's plain text, which prohibits the very "categorical coverage exclusions" for

gender-transition services featured in many of the Plaintiffs' health plans. *Supra* at 4-5. Saying that States cannot maintain exclusions for gender-transition procedures and that States must cover them is the flip side of the same coin. Indeed, that is a key holding of Section 1557 cases on which HHS relies. *E.g.*, *Kadel v. Folwell*, 100 F.4th 122, 135-39, 164 (4th Cir. 2024) (en banc) (cited at Opp'n 9, 12).

HHS's assertion (at 23) that only Tennessee has standing to challenge the 2024 Rule's mandates on "healthcare providers" gets it nowhere, since "only one [State] needs standing for the action to proceed." *Gen. Land Off.*, 71 F.4th at 271. In any event, HHS ignores the sovereign harm to *all* Plaintiff States from the 2024 Rule's stripping them of their traditional authority to establish and enforce their own laws regulating the practice of medicine within their borders. *See Texas*, 2024 WL 2947022 at *49. Section 92.206 would require doctors to provide gender-transition services in violation of laws adopted by most all the Plaintiff States. Compl. ¶¶ 107-36. The 2024 Rule's overriding of "statutes enacted by representatives of [the States'] people" inflicts a quintessential "irreparable injury" on States' sovereignty. *Vote.org v. Callanen*, 39 F.4th 297, 308 (5th Cir. 2022) (citation omitted).

HHS's last assertion (at 28) that the States "cannot invoke the health and welfare of their citizens" overlooks the States' "quasi-sovereign interest in the 'health and well-being … of [their] residents in general.'" *Kentucky v. Biden*, 23 F.4th 585, 599 (6th Cir. 2022) (citation omitted). That interest encompasses safeguarding children from treatments for which there is "uncertainty regarding benefits, recent surges in use, and irreversible effects," *Eknes-Tucker v. Alabama*, 80 F.4th 1205, 1225 (11th Cir. 2023), and "protecting the integrity and ethics of the medical profession," *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997); *see also Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015).

II. The Balance of the Equities and Public Interest Both Favor Preliminary Relief.

The public interest overwhelmingly favors temporarily staying the status quo pending judicial review. PI Br. 25. HHS (at 28) insists there is "significant public interest in permitting enforcement of the Rule to combat discrimination" by covered entities. But "the public's *true* interest lies in the

correct application of the law." *Tennessee*, 2024 WL 2984295 at *26. And the States have shown that the 2024 Rule's conception of discrimination is unlawful. The public interest likewise favors addressing difficult gender-identity issues through "[e]lected representatives" and state-and-local policy, *L.W. v. Skrmetti*, 83 F.4th 460, 491 (6th Cir. 2023), not through an agency-made mandate. That is particularly so when what is at stake are unproven gender interventions with life-long effects. Compl. ¶¶ 87-104.

III. The APA and Equity Support Entry of the Preliminary Relief Sought.

Section 705 of the APA authorizes a reviewing court to "issue all necessary and appropriate process to postpone the effective date of an agency action" that is pending review. 5 U.S.C. § 705. And HHS's relief argument (at 30) supports enjoining all of the 2024 Rule's gender-identity mandates, which the Plaintiff States "actually challenge." PI Br. 2. HHS is wrong to suggest Plaintiffs' argument implicates only § 92.101(a)(2)(iv)—*i.e.*, the provision defining sex discrimination to include gender-identity discrimination. Rather, gender-identity mandates appear throughout the 2024 Rule. For example, proposed § 92.206 never references § 92.101, yet prohibits doctors from refusing to provide gender-transition services if they provide similar treatments "for other purposes." Likewise, § 92.207 itself prohibits a "categorical coverage exclusion" for gender-transition services in covered health plans. HHS's gender-identity mandates are embedded in other provisions, too—including the 2024 Rule's requirements regarding assurances of compliance, remedial actions, coordinator investigations, the revision of policies and procedures, and training. Principles of equity counsel in favor of issuing temporary relief from the Rule's challenged provisions to avoid States and providers' needing to parse through piecemeal provisions and engage in multiple rounds of costly compliance activities. That relief should have the breadth appropriate to avoid any harm the Rule may improperly inflict. *Cf. Career Colls. & Sch. of Tex. v. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024).

CONCLUSION

The Court should grant Plaintiff States' motion for a § 705 stay and a preliminary injunction.

Date: July 1, 2024.

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**Pro Hac Vice Application Pending

CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2024, a true and correct copy of the foregoing document was filed using the Court's electronic court-filing system, which sent notice of filing to all counsel of record.

/s/ Steven J. Griffin
STEVEN J. GRIFFIN