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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON
EUGENE DIVISION

STATE OF OREGON, et al,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as the Secretary of the Department of Health and Human Services, et al,

Defendants.

Case No. 6:25-cv-02409-MTK

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

ORAL ARGUMENT REQUESTED

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LR 7-1 CERTIFICATION

Counsel for Plaintiff States conferred in good faith with counsel for Defendants, in accordance with LR 7-1, and the parties were unable to resolve the issues raised in this Motion.

MOTION

Pursuant to Fed. R. Civ. P. 56, Plaintiff States move for summary judgment on Plaintiffs' claims (Counts 1–4) and entry of judgment under Fed. R. Civ. P. 54(b) that:

(a) declares that the Kennedy Declaration is unlawful;

(b) vacates and sets aside the Kennedy Declaration; and

(c) enjoins Defendants and their officers, agents, servants, employees, attorneys, and others acting in concert or participation with Defendants from implementing, instituting, maintaining, or giving effect to the Kennedy Declaration.

Plaintiffs are entitled to relief as a matter of law and no material facts are in dispute. First, the Kennedy Declaration exceeds the statutory authority of the Secretary of the Department of Health and Human Services. Second, the Declaration is procedurally defective in that it fails to comply with the rulemaking requirements of the APA and Medicare law. Third, the Declaration is contrary to law.

This Motion is supported by the following Memorandum of Law, and declarations filed herewith.

MEMORANDUM OF LAW

I. INTRODUCTION

Without prior notice, the Secretary of Health and Human Services issued a declaration entitled "Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents" (Kennedy Declaration). Without citing any statutory authority, the Kennedy Declaration purports to declare that gender-affirming care—labeled "sex-rejecting procedures"—for children and adolescents is "neither safe nor effective as a treatment modality" for gender dysphoria, and therefore claims that such treatments "fail to meet professional [*sic*]

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recognized standards of health care" for providers participating in Medicare and Medicaid programs. The Kennedy Declaration states that practitioners who provide gender-affirming care for minors will be deemed not to meet professionally recognized standards of care, the Kennedy Declaration purports to enable the HHS Office of the Inspector General (OIG) to bar (or "exclude") providers from federal health care programs, including Medicare and Medicaid, based purely on the fact that they provide (or have provided) gender-affirming medical care. Indeed, HHS has already referred at least three children's hospitals to OIG based on this provision.

The Kennedy Declaration seeks to end gender-affirming care for transgender adolescents nationwide. It does so by declaring that provision of this care "fails to meet professionally recognized standards of health care" and thus that providers of such care may be excluded from participating in federal health care programs. 42 U.S.C. § 1320a-7(b)(6). The Secretary has sought to change a substantive legal standard without notice and comment. Further, through his declaration, the Secretary seeks for the first time to substantively regulate the practice of medicine in the Plaintiff States, in plain violation of the statute governing Medicare and Medicaid. And although either of these defects is sufficient to render the Kennedy Declaration illegal, the Kennedy Declaration also separately violates the Medicaid Act by altering the terms of federally approved Medicaid state plans and interfering with recipients' free choice of provider.

The Kennedy Declaration harms the Plaintiff States as administrators of state Medicaid programs. Excluding children's hospitals and providers (including pediatricians and endocrinologists) would devastate States' provider networks, strain the capacity of the remaining providers, and harm the large number of residents in each State that depend on Medicare and Medicaid. Further, Plaintiff States provide coverage for gender-affirming care and many protect that coverage by state law. *See, e.g.*, Or. Rev. Stat. § 414.769. By coercing Medicaid and Medicare providers to cease giving this care, the Kennedy Declaration attempts to unilaterally discard the state Medicaid plans already approved by the Centers for Medicare and Medicaid Services.

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The Kennedy Declaration is transparently designed to end gender-affirming care for adolescents nationwide, even where such care remains legal and protected, by threatening providers with total exclusion from federal health care programs. Secretary Kennedy's Declaration represents an unprecedented attempt to unilaterally alter medical standards by fiat and to regulate the practice of medicine in the Plaintiff States, disregarding bedrock procedural safeguards limiting HHS's authority to change provider requirements, and in excess of HHS's statutory authority.

This Court should grant this motion for summary judgment to prohibit implementation and enforcement of the Kennedy Declaration on grounds that it is beyond the Secretary's statutory authority, procedurally invalid, and contrary to law.

II. FACT SUMMARY

A. State Medicaid Programs

The Medicaid health insurance program is a federally funded program created under Title XIX of the Social Security Act that is administered by the states. Medicaid provides health insurance for individuals, including children, whose household incomes fall below certain eligibility thresholds. Medicaid allows states to create their own Medicaid programs and to specify their own scope of services offered. All participating states, including the Plaintiff States, create their own state Medicaid plan approved by CMS that must cover certain mandatory populations and services, but that also allows states to cover additional services pursuant to waivers authorized by the Social Security Act. *See, e.g.*, Sandoe Decl. ¶¶ 8–10. The Social Security Act mandates that the Secretary of HHS approve state plans so long as they fulfill the statutory requirements, and it further mandates that federal Medicaid funds be paid to states that have an approved plan. 42 U.S.C. §§ 1396a–b. No provision of the Social Security Act permits CMS to refuse federal Medicaid funds for services covered by a state's approved plan.

Each of the Plaintiff States provides coverage for gender-affirming care through their state Medicaid programs, and many prohibit state-regulated health insurance plans from discriminating on the basis of gender identity as to enrollment or coverage. *See, e.g.*, N.Y. Comp. Codes R. &

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Regs. tit. 10, §§ 405.7(b)(2), (c)(2); Cal. Ins. Code § 10140; Colo. Rev. Stat. § 10-16-104(30)(b); D.C. Code § 2-1402.31(a)(1); Del. Code Ann. tit. 6, §§ 4501-4, 4601-5; Haw. Rev. Stat. § 432:1-607.3; N.M. Stat. Ann. § 24-34-3(A); 28 R.I. Gen. Laws § 28-5.1-7. For many Plaintiff States, protections that require coverage for gender-affirming care have been codified into state law. *See, e.g.*, Or. Rev. Stat. §§ 414.769, 743A.325; Wash. Rev. Code § 74.09.700; 775 Ill. Comp. Stat. 5/1-103(O-1), 5/5-102; Me. Rev. Stat. Ann. tit. 22, § 3174-MMM (Supp. 2025); Md. Code Ann., Health § 15-151; Mass. Gen. Laws ch. 12, §§ 11 I ½(a)–(d); Minn. Stat. § 256B.0625, subdiv. 3(a); Nev. Rev. Stat. §§ 422.272362, 689A.0432, 689B.0334, 689C.1652; N.J. Stat. Ann. § 30:4D-9.1; Vt. Stat. Ann. tit. 8, § 4071.

The Plaintiff States have successfully sought reimbursement from the federal government for gender-affirming care, some for decades, and they rely on millions of dollars in federal reimbursement to provide medically necessary gender-affirming care for covered patients. Each of the Plaintiff States provide for gender-affirming care through these federally funded health care programs.[1] Coverage for gender-affirming care is included in Plaintiff States' Medicaid and Children's Health Insurance Program (CHIP) programs through different mechanisms in each state.[2] For example, the State of Oregon's Medicaid program explicitly covers gender-affirming

[1] Emma Sandoe Decl. ¶¶ 10–13 (Oregon); Dr. Judy Zerzan-Thul Decl. ¶¶ 9–13 (Washington); Matthew Faiella Decl. ¶¶ 8–9 (New York); Daniel Southard Decl. ¶¶ 7–8 (California); Adela Flores-Brennan Decl. ¶¶ 8–11 (Colorado); William Halsey Decl. ¶¶ 10–13 (Connecticut); Andrew Wilson Decl. ¶¶ 9–14 (Delaware); Samantha Hall Decl. ¶¶ 6–9 (District of Columbia); Meredith R. Nichols Decl. ¶¶ 9–11 (Hawai'i); Laura Phelan Decl. ¶¶ 16–21 (Illinois); Michelle Probert Decl. ¶¶ 10–13 (Maine); Perrie T. Briskin Decl. ¶¶ 9–12 (Maryland); Joanne Marqusee Decl. ¶¶ 5–6, 8–10 (Massachusetts); Meghan Groen Decl. ¶¶ 7–8 (Michigan); John Connolly Decl. ¶¶ 10–13 (Minnesota); K. Brunetti Ireland Decl. Ex. 1, at 4 (Nevada); Sarah Adelman Decl. ¶¶ 9–12 (New Jersey); Alanna Dancis Decl. ¶¶ 8–11 (New Mexico); Sally A. Kozak Decl. ¶¶ 11–15 (Pennsylvania); Kristin Sousa Decl. ¶¶ 10–12 (Rhode Island); Jill Mazza Olson Decl. ¶¶ 10–12 (Vermont); Debra K. Standridge Decl. ¶¶ 9–11 (Wisconsin).

[2] Oregon and Maine law expressly requires their Medicaid programs to provide gender-affirming care coverage. *See* Or. Rev. Stat. § 414.769; Me. Rev. Stat. Ann. tit. 22, § 3174-MMM (Supp. 2025); *see also* 2023 Or. Laws 583–609 (enacting House Bill 2002 (2023)). Other states prohibit providers in the state Medicaid program from refusing to provide medically-necessary gender-affirming care, categorically excluding gender-affirming care, or discriminating based on gender identity. *See, e.g.*, Wash. Rev. Code § 74.09.675(2); N.Y. Exec. Law § 296 *et seq.*; Cal. Ins. Code § 10140; Colo. Rev. Stat. § 24-34-601; Colo. Rev. Stat. § 10-16-104(30)(b); Conn. Gen. Stat. § 46a-64; D.C. Code §§ 2-1402.31(a)(1), 31-2231.11(c); 775 Ill. Comp. Stat. 5/1-102(A); 775

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care for patients under the age of nineteen via Oregon's Prioritized List of Health Services, which is authorized by a Medicaid § 1115 demonstration waiver. Sandoe Decl. ¶ 13. This list of health services, which CMS has never rejected or disapproved, explicitly includes gender-affirming care as covered medical care. *Id.*

Critically, gender-affirming care is also delivered through Medicaid Centers of Excellence at major hospitals, including children's hospitals, in the Plaintiff States. Exclusion of such providers would necessarily exclude practitioners that treat a broad variety of patients, and not just those obtaining gender-affirming care. For example, since posting the Kennedy Declaration, HHS has announced referral of three children's hospitals to the OIG for alleged failure to meet professionally recognized standards of care.[3]

B. The Medicare Program

Unlike state Medicaid programs, the Medicare Program is a federally administered program under Title XVIII of the Social Security Act providing medical coverage for tens of millions of Americans over the age of sixty-five and qualifying people with disabilities. Medicare is administered by Medicare Administrative Contractors, which operate on a regional basis. CMS may include or exclude specific services from Medicare coverage (payment) on a national basis through National Coverage Determinations, which are subject to notice-and-comment rulemaking requirements under the Medicare Act. SSA § 1862(1) (42 U.S.C. § 1395y(1)); 2 C.F.R. § 405.1060(a)(1); 42 U.S.C. § 1395y(l)(3). National Coverage Determinations do not restrict providers from providing such services, nor do they constitute a determination that providing such care will trigger sanctions under the program. In 2016, CMS declined to issue a National Coverage

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Ill. Comp. Stat. 5/1-103(O); 775 Ill. Comp. Stat. 5/1-103(O-1); Me. Rev. Stat. Ann. tit. 22, § 3174-MMM(3); Md. Code Ann., Health § 15-151; Mass. Gen. Laws ch. 272, §§ 92A, 98; Minn. Stat. § 256B.0625; Nev. Rev. Stat. §§ 422.272362, 695G.1718; N.J. Stat. Ann. § 30:4D-9.1; N.M. Stat. Ann. § 24-34-3; 23 R.I. Gen. Laws § 23-17-19.1; Vt. Stat. Ann. tit. 8, § 4071; Andrew Wilson Decl. ¶¶ 10–11 (Delaware); Meredith R. Nichols Decl. ¶ 11 (Hawai'i); Meghan Groen Decl. ¶ 8 (Michigan); Sally A. Kozak Decl. ¶¶ 13–14 (Pennsylvania). Wisconsin is prohibited from excluding coverage for gender-affirming care under a permanent federal court injunction. Debra K. Standridge Decl. ¶ 10 (Wisconsin).

[3] *See* notes 6–9, *supra*.

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Determination for gender-affirming care, allowing Medicare Administrative Contractors to make a payment decision for their region by issuing a Local Coverage Determination or continuing to make payment decisions on a case-by-case basis. SSA § 1862(a)(1)(A) (42 U.S.C. § 1395y(a)(1)(A)). The Medicare Administrative Contractors for the Plaintiff States have not issued any Local Coverage Determinations for gender-affirming care.

C. Exclusion of Individuals and Entities from Medicare and Medicaid

HHS has limited authority to "exclude" (i.e., bar) individuals or entities from participation in federal health care programs, including Medicare and Medicaid. Exclusion is an exceedingly serious punishment: if an individual or entity is excluded, Medicare or Medicaid will not pay for any items or services furnished by that individual or entity, or at their direction. Office of the Inspector General, Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs at 6 (May 8, 2013), https://oig.hhs.gov/exclusions/files/sab-05092013.pdf. Exclusion also carries collateral consequences, including, for individuals: termination of employment from participating entities (such as large provider networks); loss of hospital admitting privileges; and, because the list of excluded individuals and entities is published on the HHS website, difficulty obtaining loans for medical practices. For both individuals and entities collateral consequences can also include difficulty with obtaining insurance. And if an individual or entity violates an exclusion, such a violation carries civil penalties and even criminal sanctions. *Id.* at 9–10. For these reasons, exclusion has been referred to as a "financial death sentence" for those in the health care industry. *See* Jennifer A. Staman, Cong. Rsch. Serv., RS22743, Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview 2 n.9 (2016), https://www.congress.gov/crs_external_products/RS/PDF/RS22743/RS22743.14.pdf. Exclusion of hospitals is exceedingly rare. In the history of the Medicare program, OIG has excluded only six hospitals from participation.[4]

[4] Marshall Decl., Ex. 1.

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The conditions and procedures for exclusion are set out in sections 1128 (42 U.S.C. § 1320a-7) and 1156 (42 U.S.C. § 1320c-5) of the Social Security Act, as well as in HHS regulations (42 C.F.R. § 1001.1 *et seq.*). As relevant here, the HHS Office of the Inspector General (OIG) may bring exclusion proceedings against an individual or entity that "has furnished or caused to be furnished items or services to patients"—including to patients not covered by Medicare or Medicaid—that is "of a quality which fails to meet professionally recognized standards of health care." 42 U.S.C. § 1320a-7(b)(6); *see* 42 C.F.R. § 1001.701(a)(2). Exclusion of hospitals under this provision is rarer still: in the Medicare program's history, OIG has excluded only one hospital under this provision.[5]

"Professionally recognized standards of health care" is not defined in the statute, but HHS regulations define the term to mean "Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State." 42 C.F.R. § 1001.2. Critically, the regulatory definition further provides, "When the Department has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care." *Id.* Notwithstanding this reference in the definition section, the Medicare exclusion statute contains no reference to (much less a grant of) authority to the Secretary to make such a unilateral declaration, and Plaintiff States are aware of no prior instance in which the Secretary has made or attempted to make a declaration pursuant to this sentence in the definitional provision. *Compare* 42 U.S.C. §§ 1320a-7(b)(6), 1320c-5(a)(2), *with* 42 C.F.R. § 1001.2.

If OIG seeks to exclude an individual or entity for furnishing services that fail to meet professionally recognized standards of health care, OIG must provide the individual or entity with certain procedures, including a written Notice of Intent to Exclude; an opportunity to respond in writing; a written Notice of Exclusion; an opportunity to appeal to an administrative law judge

[5] *Id.*

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(ALJ); and an opportunity to appeal the ALJ's decision to the HHS Departmental Appeals Board. 42 U.S.C. §§ 1320a-7(c)–(f), 1320c-5(b)(4); 42 C.F.R. §§ 1001.701, 1001.2001(a)–(b), 1001.2002, 1001.2007, 1005.1 *et seq.* This process exists to develop facts and to determine the appropriate length of the sanction. The legality of HHS rules is not at issue in exclusion proceedings because HHS regulations bind all administrative decisionmakers, including OIG, ALJs, and the Departmental Appeals Board. *Id.* § 1001.1(b). HHS regulations further specify that, in an exclusion proceeding, an ALJ "does not have the authority to [f]ind invalid or refuse to follow Federal . . . regulations" or to "[e]njoin any act of the Secretary," *id.* § 1005.4(c)(1)(4).

Once an individual or entity is found to have committed a violation by furnishing services that do not meet professionally recognized standards of health care, HHS regulations *require* that the individual or entity be excluded for a default period of three years. *Id.* § 1001.701(d)(1). OIG may depart downward only if "there were few violations and they occurred over a short period of time," but in all cases OIG must enter an exclusion of at least one year. *Id.* §§ 1001.701(d)(1), (3); *accord* 42 U.S.C. § 1320a-7(c)(3)(F). OIG does not guarantee reinstatement after the exclusion period ends: instead, the individual or entity must apply to OIG for reinstatement and assure OIG that the types of actions that formed the basis for the original exclusion have not recurred and will not recur. 42 C.F.R. §§ 1001.3001–3002. Decisions denying reinstatement are not subject to administrative or judicial review. *Id.* § 1001.3004(c).

D. The Kennedy Declaration

On December 18, 2025, without prior notice, HHS posted on its website a "Declaration of the Secretary of the Department of Health and Human Services," subtitled, "RE: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents." The Kennedy Declaration purports to declare, pursuant to the Secretary's "authority and responsibilities under federal law, and pursuant to 42 C.F.R. § 1001.2," that "[s]ex-rejecting procedures for children and adolescents are neither safe nor effective as a treatment modality for gender dysphoria, gender incongruence, or other related disorders in minors, and therefore, fail to

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meet professional [*sic*] recognized standards of health care." The Kennedy Declaration defines "sex-rejecting procedures" to include pharmaceutical interventions like puberty blockers and hormone therapy, as well as surgeries like mastectomies. The Kennedy Declaration purports to base its determination of safety and effectiveness on a report issued by HHS in May 2025, which was initially published without peer review, and which the President had directed HHS to publish as support for the administration's agenda of ending gender-affirming care for youth.

The Kennedy Declaration reiterates that HHS OIG may "exclude individuals or entities from participation in any Federal health care program if the Secretary determines the individual or entity has furnished or caused to be furnished items or services to patients of a quality which fails to meet professionally recognized standards of health care." While the Kennedy Declaration frames this exclusion as permissive in referencing that providers "may" be excluded, and even that a separate determination would have to be made under 42 C.F.R. § 1001.701, the Declaration purports to establish a rule whereby any provision of gender-affirming medical treatment is *per se* sufficient to render a provider subject to exclusion.

Defendants moved swiftly to implement the Kennedy Declaration against three major children's hospitals. On December 26, 2025, the General Counsel of HHS posted on social media that he had referred Seattle Children's Hospital to HHS OIG for exclusion from the Medicare and Medicaid programs, pursuant to the Kennedy Declaration.[6] On December 30, 2025, the General Counsel of HHS posted on social media that he had referred Colorado Children's Hospital to HHS OIG for exclusion, also based on the Kennedy Declaration.[7] The post warned that this "may not

[6] Marshall Decl., Ex. 2, HHS (@hhsgov), X (Dec. 26, 2025, at 11:47 a.m. ET), https://x.com/HHSGov/status/2004640322580578440 (".@HHSGCMikeStuart today referred Seattle Children's Hospital to @OIGatHHS for failure to meet professional recognized standards of health care as according to Secretary Kennedy's declaration that sex-rejecting procedures for children and adolescents are neither safe nor effective as a treatment modality for gender dysphoria, gender incongruence, or other related disorders in minors.").

[7] Marshall Decl., Ex. 3, HHS General Counsel Mike Stuart (@HHSGCMikeStuart), X (Dec. 30, 2025, at 4:08 p.m. ET), https://x.com/HHSGCMikeStuart/status/2006110061114851333 ("Today I again referred for investigation to @OIGatHHS another hospital for failure to meet recognized standards of health care per the @HHSGov @SecKennedy declaration that sex-

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be the last referral."[8] True to his word, on January 5, 2026, the General Counsel of HHS posted on social media that he had referred Children's Minnesota to HHS OIG for exclusion, again based on the Kennedy Declaration.[9] The impact of exclusion of these hospitals would be extraordinary. For one example, Seattle Children's Hospital is a premier children's hospital that serves a region including Washington, Alaska, Idaho, and Montana, and provides complex medical care that includes specialties and technology not available anywhere else in the Pacific Northwest. Trinity Wilson Decl. ¶ 6.

III. LEGAL STANDARD

Summary judgment is appropriate when there exists no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

IV. ARGUMENT

A. The Kennedy Declaration is a final agency action subject to APA review.

The Kennedy Declaration definitively declares that gender-affirming care "for children and adolescents is neither safe nor effective as a treatment modality" and "fail[s] to meet professional [*sic*] recognized standards of care." Kennedy Declaration § II.E (emphasis added). Because the Kennedy Declaration supplies a new substantive, binding rule of decision that personnel within HHS must apply in administrative exclusion proceedings, *id.* § V, and because exclusion carries

rejecting procedures for children and adolescents are neither safe nor effective - Children's Hospital Colorado. Sadly, it may not be the last referral.").

[8] *Id.*

[9] Marshall Decl., Ex. 4, HHS General Counsel Mike Stuart (@HHSGCMikeStuart), X (Jan. 5, 2025, at 3:35 p.m. ET), https://x.com/HHSGCMikeStuart/status/2008321502765093348?s=20 ("Another day, another sad referral. When I say we will protect children, well, that's exactly what I mean. Today, I referred for investigation to @OIGatHHS another hospital- Children's Minnesota including its Gender Health program- for failure to meet recognized standards of health care. According to claims data, the hospital has billed extensively for hormone therapy. The HHS @SecKennedy declaration made clear that sex-rejecting procedures for children and adolescents are neither safe nor effective. @HHSOGC and @HHSGov will continue to take all necessary action to protect children all across the nation.").

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significant legal and financial consequences for providers, the Kennedy Declaration is a final agency action subject to judicial review.

The Administrative Procedure Act (APA) "creates a basic presumption of judicial review for one suffering legal wrong because of agency action." *Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv.*, 586 U.S. 9, 22 (2018) (quotation marks omitted). The statute authorizes judicial review of "final agency action," 5 U.S.C. § 704; *Bennett v. Spear*, 520 U.S. 154, 178 (1997), which "is meant to cover comprehensively every manner in which an agency may exercise its power" that is "final." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 478 (2001). To be considered "final," the action must (1) "mark the 'consummation' of the agency's decisionmaking process[,]" and (2) the action "must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow . . . .'" *Id.* (quoting *Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)). Finality is a "pragmatic" inquiry, *U.S. Army Corps of Eng'rs v. Hawkes Co., Inc.*, 578 U.S. 590, 599 (2016), that asks whether an action is a "definitive statement of the agency's position" with "a 'direct and immediate . . . effect on the day-to-day business' of the complaining parties." *Sig Sauer, Inc. v. Brandon*, 826 F.3d 598, 600 n.1 (1st Cir. 2016).

The Kennedy Declaration meets both requirements for final agency action. *See Texas v. Becerra*, 89 F.4th 529, 541 (5th Cir. 2024), *cert. denied*, 145 S. Ct. 139 (2024) (holding CMS Quality, Safety and Oversight Guidance regarding EMTALA and conditions of participation after *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), was final agency action). As to the first prong, the Secretary declares definitively and categorically that medical gender-affirming care "for children and adolescents [is] *neither safe nor effective as a treatment modality* for gender dysphoria, gender incongruence, or other related disorders . . . and therefore, *fail[s] to meet professional recognized standards of care*." Kennedy Declaration § V (emphasis added). Nothing indicates that the Secretary's Declaration is "tentative or interlocutory." *Bennett*, 520 U.S. at 178; *cf. Tennessee v. Dep't of Educ.*, 104 F.4th 577, 599 (6th Cir. 2024) (agency guidance

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interpreting Title IX's nondiscrimination provision in light of *Bostock v. Clayton Cnty.*, 590 U.S. 644 (2020), was final agency action); *Akebia Therapeutics, Inc. v. Becerra*, 548 F. Supp. 3d 274, 288 (D. Mass. 2021) (CMS pharmaceutical coverage exclusion announced via email was final agency action because there was no indication agency would change its position and as a result patients would be unable to access the drug). Indeed, HHS has already relied on the Kennedy Declaration to trigger exclusion proceedings against three major children's hospitals and announced that others may be coming—confirming that the Secretary has "rendered [his] last word on the matter."[10] *Omnipoint Holdings, Inc. v. City of Cranston*, 586 F.3d 38, 46 (1st Cir. 2009); *cf. Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021 (D.C. Cir. 2000) (action issued at headquarters was final where agency treated it as "controlling in the field").

Second, the Declaration is an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett*, 520 U.S. at 177–78 (quotations omitted). The Declaration both determines rights and creates legal consequences because it "leaves . . . no room" for HHS personnel to depart from a binding rule of decision in administrative exclusion proceedings: if the individual or entity that is the subject of the exclusion proceedings has provided gender-affirming medical care to children or adolescents, HHS personnel are *required* to find that the individual or entity has furnished services that fail to meet professionally recognized standards of health care—a violation that carries a minimum penalty of one year of exclusion, with no guarantee that the individual or entity will *ever* be reinstated. *See Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA (NEDACAP)*, 752 F.3d 999, 1007 (D.C. Cir. 2014); 42 C.F.R. §§ 1001.2, 1001.701(d)(1). In other words, because the HHS staff are "bound to implement" the Declaration in exclusion proceedings against providers of gender-affirming medical care to adolescents, even in States where that care is legal, it is final. *See Immigrant Defs. L. Ctr. v. Noem*, 145 F.4th 972, 991 (9th Cir. 2025); *NEDACAP*, 752 F.3d at 1007 (guidance was final where it bound enforcement officials); *Hawkes*, 578 U.S. at 598–99 (jurisdictional declaration by Army Corps of Engineers

[10] *See* notes 6–9, *infra*.

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was final where it bound agencies "authorized to bring civil enforcement proceedings" under the Clean Water Act).

Further, the Declaration undisputedly creates legal consequences because it eliminates well-established "norm[s] or safe harbor[s]." *Texas v. EEOC*, 933 F.3d 433, 442 (5th Cir. 2019). The Declaration disrupts numerous safe harbors—including in state laws and State Medicaid plans that protect (and, where medically necessary, require) the provision of gender-affirming medical care—as well as norms relating to the practice of medicine, including that providers may rely on state law and evidence-based practice guidelines endorsed by relevant professional associations. And the Kennedy Declaration likewise creates legal consequences because it dictates that providers of gender-affirming medical care continue providing such treatments at the risk of incurring severe penalties—including civil fines and criminal prosecution. *See* *Hawkes*, 578 U.S. at 600; *Frozen Food Express v. United States*, 351 U.S. 40, 44 (1956). *See* § II.E, *supra* (discussing consequences of exclusion). The consequences of exclusion are numerous, including being placed on a national database maintained by OIG, which impacts the provider's ability obtain malpractice insurance, admission to hospitals, and practice of medicine. Beyer Decl. ¶ 34

Finally, it is of no consequence that the Kennedy Declaration disclaims making a "determination that any individual or entity should be excluded from participation in any Federal health care program." Kennedy Declaration § V. That disclaimer simply recognizes that the exclusion of specific providers cannot take legal effect without certain statutorily mandated processes, such as notice and an opportunity to be heard. The disclaimer does not change the fact that, once OIG chooses to initiate exclusion proceedings against a provider of gender-affirming care, exclusion—and the myriad negative consequences—is a foregone conclusion. *See, e.g.*, *Tennessee v. Dep't of Educ.*, 615 F. Supp. 3d 807, 831 (E.D. Tenn. 2022), *aff'd*, 104 F.4th 577 (6th Cir. 2024) ("The Court must consider whether the practical effects of an agency's decision make it final agency action, regardless of how it is labeled." (internal quotation and citation omitted)); *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 487–88 (D. Md. 2019). Indeed,

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the existence of additional proceedings changes nothing because neither OIG nor an ALJ possesses authority to "[f]ind invalid or refuse to follow Federal . . . regulations" or to "[e]njoin any act of the Secretary[.]" *See* 42 C.F.R. § 1005.4(c)(1)(4). And it is well settled that "parties need not await enforcement proceedings before challenging final agency action where such proceedings carry the risk"—or, here, the certainty—of serious civil penalties. *Hawkes*, 578 U.S. at 600 (quotations omitted). Rather, "[o]nce the agency publicly articulates an unequivocal position . . . and expects regulated entities to alter their primary conduct to conform to that position, the agency has voluntarily relinquished the benefit of postponed judicial review." *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986).

B. The Kennedy Declaration exceeds the Secretary's statutory authority.

As explained below, the Declaration should be declared unlawful and set aside because it exceeds the Secretary's statutory authority. *See* 5 U.S.C. § 706(2)(C) (requiring a court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right"). No statute grants the Secretary of HHS authority to unilaterally declare that a treatment modality is not safe and effective or that providing that treatment is legally sufficient grounds for exclusion from the program. On the contrary, under the Medicare statute, Federal officers or employees are expressly prohibited from "exercis[ing] any supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395. This provision explicitly states the intent "to minimize federal intrusion" into state health care regulation. *Mass. Med. Soc. v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987) (opinion of Breyer, J.).

1. The Kennedy Declaration exceeds HHS authority under 42 U.S.C. § 1395

Secretary Kennedy's declaration exceeds his statutory authority. The Kennedy Declaration is based on no express authority, does not cite any such authority, and it clearly usurps the authority of the Plaintiff States.

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Federal agencies "are creatures of statute." *Nat'l Fed'n of Indep. Bus. v. Dep't of Labor (NFIB)*, 595 U.S. 109, 117 (2022). An agency's "power to act and how they are to act is authoritatively prescribed by Congress." *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013). "An agency literally has no power to act . . . unless and until Congress confers powers upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 357 (1986); *see also Civ. Aeronautics Bd. v. Delta AirLines, Inc.*, 367 U.S. 316, 322 (1961) (where an agency is "entirely a creature of Congress," the "determinative question is not what the [agency] thinks it should do but what Congress has said it can do"). "Any action that an agency takes outside the bounds of its statutory authority is ultra vires." *City of Arlington*, 569 U.S. at 297. Additionally, if a federal agency seeks to upset "the usual constitutional balance of federal and state powers," the agency must have a "clear statement" from a federal statute demonstrating that Congress "in fact . . . intended to" empower the agency to do so. *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991).

Tellingly, the Kennedy Declaration does not identify any statutory authority for its purported action at all, only referencing a definitional regulation, 42 C.F.R. § 1001.2, that confers no authority. *See generally* ECF 1-1. That's because there is none. The statutes that grant the Secretary the power to exclude individuals and entities from the federal health care programs say nothing about allowing the Secretary to exclude based on top-down declarations about the appropriate standards of care, much less contain the requisite clear statements to that effect. *See* 42 U.S.C. §§ 1320a-7, 1320c-5. And the Declaration cites no other statutes for its purported authority.

The regulation the Declaration cites is a definitional provision that does not provide any substantive grant of authority. That provision merely refers to instances HHS or a component agency has exercised specific statutory authority to pronounce a treatment safe and effective—for example, the FDA's authority to determine whether drugs and medical devices are safe and effective—and does not confer any such authority to do so. *See* 62 Fed. Reg. 47,182, 47,185 (Sep. 8, 1997) (agency's explanation of the language). In any event, an agency cannot grant itself

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authority to create substantive law by promulgating a regulation. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress.").

Further, the federal health care statutes should not be read to give the Secretary the authority that he claims. Congress has never authorized the Secretary to make unilateral medical determinations or otherwise dictate a national standard of health care. It is "state lawmakers, not the federal government" that are "the primary regulators of professional [medical] conduct." *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004), *aff'd sub nom.*, *Gonzales v. Oregon*, 546 U.S. 243 (2006); *see also United States v. Skrmetti*, 605 U.S. 495, 524 (2025) ("We afford States wide discretion to pass legislation in areas where there is medical and scientific uncertainty," and questions regarding gender-affirming care should be left to "the people, their elected representatives, and the democratic process") (internal quotations and citation omitted). "Obviously, direct control of medical practice in the states is beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18 (1925); *see also Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power."). In other words, "the doctor-patient relationship is an area that falls squarely within the states' traditional police powers. The federal government may not force the states to regulate that relationship to advance federal policy." *Conant v. Walters*, 309 F.3d 629, 647 (9th Cir. 2002) (Kozinski, J., concurring).

Last, the Kennedy Declaration directly interferes with Plaintiff States' regulation of health care by "supersed[ing] 'Statewide . . . standards of care . . . ." Plaintiff States each license and regulate physicians in their states, *see* ECF 28 ¶¶ 63–64, as well as administer state Medicaid and CHIP programs that provide coverage for medically necessary gender-affirming care services, *see* ECF 28 ¶ 56. Plaintiff States have enacted laws to ensure their health care network includes providers who offer gender-affirming care. *See* ECF 28 ¶¶ 12–33; *see also, e.g.*, N.Y. Exec. Law

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§ 296 *et. seq*.; 225 Ill. Comp. Stat. 60/22(C)(3); 735 Ill. Comp. Stat. 40/28-10. Some Plaintiff States guarantee the coverage of gender-affirming care. *See, e.g.*, Or. Rev. Stat. §§ 414.769, 743A.325; Wash. Rev. Code § 74.09.700; Mass. Gen. Laws ch. 12, §§ 11 I ½(a)–(d); Minn. Stat. § 256B.0625, subdiv. 3(a); Nev. Rev. Stat. §§ 422.272362, 689A.0432, 689B.0334, 689C.1652; N.J. Stat. Ann. § 30:4D-9.1; Vt. Stat. Ann. tit. 8, § 4071. Other Plaintiff States have civil rights laws that prohibit discrimination in the provision of health care based on gender identity or expression. *See, e.g.*, N.Y. Comp. Civ. R. & Regs. tit. 10, § 405.7; Cal. Ins. Code § 10140; Conn. Gen. Stat. § 46a-64; D.C. Code §§ 2-1402.31(a)(1); Del. Code Ann. tit. 6, §§ 4501-4, 4601-5; Haw. Rev. Stat. § 432:1-607.3; N.M. Stat. Ann. § 24-34-3(A); 23 R.I. Gen. Laws § 23-17-19.1; 28 R.I. Gen. Laws § 28-5.1-12; 220 R.I. Code R. 80-05-1. Still other Plaintiff States protect health care providers from discipline based solely on their provision of gender-affirming care. *See, e.g.*, Or. Rev. Stat. § 676.313; Colo. Rev. Stat. § 12-30-121(2)(a); Me. Rev. Stat. Ann. tit. 14 § 9001; Md. Code Ann., Ins., § 19-117; Wash. Rev. Code § 18.130.450.

The Kennedy Declaration deliberately undermines Plaintiff States' numerous protections for medically necessary gender-affirming care and it does so without any "clear statement" from Congress. *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004), and *Gonzales v. Oregon*, 546 U.S. 243 (2006) are instructive. In both, the Ninth Circuit and the Supreme Court considered a U.S. Attorney General's directive that physicians who assist terminally ill patients pursuant to Oregon's Death with Dignity Act would violate the federal Controlled Substances Act and be subject to discipline. The Ninth Circuit struck down the Ashcroft Directive because the Attorney General "may not exercise control over an area of law traditionally reserved for state authority, such as regulation of medical care" "[u]nless Congress' authorization is 'unmistakably clear,'" *Ashcroft*, 368 F.3d at 1125, and the Attorney General's "unilateral attempt to regulate general medical practices historically entrusted to state lawmakers interfere[d] with the democratic debate about physician assisted suicide," *id.* at 1131. On appeal, the Supreme Court affirmed. However, the Supreme Court found it "unnecessary" even to consider the application of clear statement

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requirements. Although the Attorney General had the authority to suspend a doctor's registration to prescribe controlled substances if it was "inconsistent with the public interest," the Supreme Court rejected the suggestion that federal law supported the Attorney General's claimed authority over physician assisted suicide, observing that "the background principles of our federal system . . . belie the notion that Congress would use such an obscure grant of authority to regulate areas traditionally supervised by the States' police power." *Gonzales*, 546 U.S. at 251.

The same is true here. All that the Kennedy Declaration offers in support is that it is "informed by" a regulation, 42 C.F.R. § 1001.2. But the cited regulation is a definitional provision that does not provide any substantive grant of authority. Section 1001.2 references 42 U.S.C. § 1320a-7 and 42 U.S.C. § 1320c-5, but neither statute suggests (let alone clearly states) a "radical shift" of authority from the States to the Federal Government to define general standards of medical practice in every locality. *See Gonzales*, 546 U.S. at 274; *see also infra* § IV.D.2. Indeed, one of the permissive reasons Congress identified for excluding a health care provider "rel[ies] upon a functioning medical profession regulated under the States' police powers." *Gonzales*, 546 U.S. at 740; *see* 42 U.S.C. § 1320a-7(b)(4) (authorizing exclusion if state license is revoked or suspended).

Put another way, Congress has nowhere authorized the Secretary to define what are "*professionally recognized* standards of health care[,]" as the Kennedy Declaration purports to do—let alone to do so by fiat. If anything, Congress has said just the opposite. *See* 42 U.S.C. § 1395 ("Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine"); *see also Mass. Medical Soc.*, 815 F.2d 790 (recognizing Section 1395's intent to "minimize federal intrusions" and upholding state law forbidding Medicare providers from "balance billing"). Congress does not speak in "muffled hints," *see Gonzales*, 546 U.S. at 274, or "hide elephants in mouseholes," *Whitman*, 531 U.S. at 468. A definitional regulation, coupled with explicit statutory restrictions on HHS's discretion in excluding health care providers, cannot vest the Secretary with the sweeping

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power to dictate national standards of care and usurp power that the Constitution reserves for the States themselves.

Yet, the effect of the Kennedy Declaration is precisely that: By precluding doctors, on pain of exclusion from Medicaid, the federal policy makes it impossible for Plaintiff States to ensure access to non-discriminatory gender-affirming care, as guaranteed by state law. When faced with Medicaid exclusion, and all its collateral consequences, health care providers will stop providing gender-affirming care. Zerzan Decl. ¶¶ 17–18; Beyer Decl. ¶ 34. If doctors are taken out of the picture—as the Kennedy Declaration clearly aims to do—Plaintiff States' efforts to regulate the health profession and ensure access to medically necessary gender-affirming care will inevitably be frustrated. *See* *Conant*, 309 F.3d 646 (Kozinski, J. concurring) (invalidating a federal policy that prohibited doctors from recommending medicinal marijuana to patients because "[t]he federal government's attempt to target doctors . . . [was] a backdoor attempt to 'control or influence the manner in which States regulate private parties.'") (quoting *Reno v. Condon*, 528 U.S. 141, 150 (2000)).

The Supreme Court has struck down agencies' attempts to extrapolate broad authority from narrow delegations of power. *See* *NFIB*, 595 U.S. at 117 (upholding injunction where the act at issue "empower[ed] the Secretary to set workplace safety standards, not broad public health measures"); *see also* *Biden v. Nebraska*, 600 U.S. 477, 494–99 (2023) (holding that delegated authority to modify loan requirements did not include authority for loan forgiveness). This Court should do the same. In creating Medicaid under Title XIX of the Social Security Act, Congress left room for States as program administrators to determine what makes a provider "qualified" to perform services pursuant to 42 U.S.C. § 1396a(a)(23). *See* *Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 364 (2025); *see also infra* § IV.D.2 (discussing states' rights to determine whether a provider is "qualified" or not). The Kennedy Declaration is a unilateral medical determination that falls far outside the bounds of the Secretary's statutory authority. In banning an entire category of health care, the Secretary acted *ultra vires* and violated the Administrative Procedure Act. *See*

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City of Providence v. Barr, 954 F.3d 23, 31 (1st Cir. 2020); *see also* *PFLAG, Inc. v. Trump*, 766 F. Supp. 3d 535, 570 (D. Md. 2025) (enjoining the Department from conditioning federal funding on denial of gender-affirming medical care); *Washington v. Trump*, 768 F. Supp. 3d 1239 (2025) (similar).

2. The Kennedy Declaration exceeds HHS authority under 42 U.S.C. §§ 1320a-7 and 1320c-5

The Kennedy Declaration is unsupported by 42 U.S.C. § 1320a-7, which permits exclusion from federal health care programs for the provision of services "which fail[] to meet professionally recognized standards of health care[.]" 42 U.S.C. § 1320a-7(b)(6)(B) and § 1320c-5, which requires providers to attest that the Medicare services they provide are "of a quality which meets professionally recognized standards of health care." *Id.* § 1320c-5(a)(2).

These statutes do not give the Secretary authority to determine "professionally recognized standards," and the plain language of the statutes are inconsistent with such authority. The statutes do not permit exclusion for services that fall below *governmentally declared* standards, but "professionally recognized standards," meaning that the standards to be applied are those that professionals in the health care industry adhere to. *See* *Doyle v. Sec'y of Health & Hum. Servs.*, 848 F.2d 296, 301 (1st Cir. 1988) (holding that 42 U.S.C. § 1320c-5(a)(2) is not unconstitutionally vague because "[t]o the medical profession, which will administer this standard, it has reasonably clear meaning."); *Varandani v. Bowen*, 824 F.2d 307, 312 (4th Cir. 1987) (holding that 42 U.S.C. § 1320c-5 is "grounded in what, from time to time, other health professionals consider to be acceptable standards of health care.").[11]

[11] This conclusion is buttressed by the statutorily mandated "quality improvement organizations", which are contracted by the Department to review Medicare services, including whether "the quality of such services meets professionally recognized standards of health care[.]" *See* 42 U.S.C. § 1320c-3(a)(1)(B); *see also id.* § 1320c-1 (defining "quality improvement organization" and requiring they have at least one health care provider representative and one consumer representative on their governing body). Quality improvement organizations review only the services in the particular area for which they have been established, permitting the professionally recognized standards they apply to be tailored to the local standard of care. *See* 42 U.S.C. § 1320c-2(a) (requiring the Secretary to establish geographic areas for quality improvement organizations). And the Department's own rules governing quality improvement organizations

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Even if 42 U.S.C. §§ 1320a-7 and 1320c-5 implied a power on the part of the Secretary to declare the content of "professionally recognized standards," and they do not, that power still would not permit the Secretary to declare that *all* provision of gender-affirming care for children and adolescents falls below it. This is because the statutory phrase "professionally recognized standards" has to do with the *quality of delivery* of a health care service, not its medical necessity for a given patient. The "statutory design supports the conclusion that the medical necessity for a procedure and its quality are distinct considerations." *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) *abrogated on other grounds by Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 186 (2016). This tracks the statutory language. 42 U.S.C. § 1320a-7(b)(6)(B) permits exclusion when health care "items or services" are provided "substantially in excess of the needs of such patients *or of a quality* which fails to meet professionally recognized standards of health care[.]" (emphasis added). Similarly, § 1320c-5(a)(1) requires providers to attest that the services they provide are "medically necessary" and subparagraph (a)(2) requires certification that they "will be of a *quality* which meets professionally recognized standards of health care" (emphasis added).

But the Kennedy Declaration has nothing to do with the standards of quality for the provision of gender-affirming care to children and adolescents. Instead, it declares that in *no case* is the provision of gender-affirming care for this population ever consistent with professionally recognized standards. It's simply not the kind of thing that "professionally recognized standards" as used in the applicable statutes speak to. Neither § 1320a-7 nor § 1320c-5 provide any statutory authority for the Kennedy Declaration.

Since the Secretary's declaration lacks *any* statutory basis for his authority, it is unnecessary to reach the major questions doctrine here. Nevertheless, the HHS's assertion of "'extravagant statutory power over the national economy'" would run afoul of the doctrine for at

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further support the notion that "professional recognized standards" are not national standards set by the Department, but are instead the local prevailing standards of care as established by the professionals within it. For example, under 42 C.F.R. § 475.102(a)(3) quality improvement organizations must "take into consideration urban versus rural, local, and regional characteristics in the health care setting where the care under review was provided[.]"

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least two independent reasons. *See* *West Virginia v. EPA*, 597 U.S. 697, 724 (2022) (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)). First, as detailed in § IV.B.1, *supra* (discussing 42 U.S.C. § 1395), the declaration seeks to regulate the practice of medicine. Something that up until now is typically left to the state. *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 761–64 (2021) (per curiam) (holding that a rule which intruded into landlord-tenant relationships, an area typically within state-law domain, supported the conclusion that the case involved exercise of powers of "vast 'economic and political significance.'") (cleaned up); *West Virginia*, 597 U.S. at 744 (Gorsuch, J., concurring) (noting that "unsurprisingly" agency action may trigger the major questions doctrine when it "seeks to intrude into an area that is the particular domain of state law") (cleaned up).

Second, the historical practice of HHS's exclusion authority buttresses the conclusion that the declaration runs afoul of the major questions doctrine. HHS Agency data shows that only six hospitals have ever been excluded from participation in federal health care programs. *See* Marshall Decl., Ex. 1. The only time *any* hospital has been excluded for failure to meet professionally recognized standards under 42 U.S.C. § 1320a-7(b)(6) was in 1979, for a twenty-eight bed facility that local health authorities described as having "an insufficient number of nurses," "medications . . . not being administered in the frequency or even the dosages prescribed by physicians," and "infection control procedures . . . not being implemented." *See id.*, Ex. 5 at 4. Because HHS has "claim[ed] to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy,'" its statutory interpretation should be "greet[ed] . . . with a measure of skepticism." *Util. Air Regul. Grp.*, 573 U.S. at 324. The major questions doctrine—whether treated as a canon of statutory construction or just a commonsense inference about what Congress intended—counsels against reading these statutes to delegate the sweeping regulatory authority the Secretary seeks to exert. If Congress had wanted to grant the Secretary such authority, it would have said so. *See* *Ala. Ass'n of Realtors*, 594 U.S. at 764 ("[o]ur precedents require Congress to enact exceedingly clear language" in major questions cases).

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C. The Kennedy Declaration violates notice and comment requirements.

As explained further below, the Kennedy Declaration must be vacated and set aside because it seeks to establish a new rule dramatically changing the agency's policy regarding gender-affirming care that was promulgated in violation of the notice-and-comment procedures set by statute for the Medicare program. It also violates the general notice-and-comment requirements applicable to the Medicaid program. On that basis alone, the Plaintiff States are entitled to summary judgment.

1. The Kennedy Declaration fails to adhere to Medicare rulemaking requirements.

HHS was required to subject the Kennedy Declaration to notice and comment. Under the Medicare Act, an agency is required to conduct notice-and-comment rulemaking when promulgating any "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services" or "the eligibility of individuals, entities, or organizations to furnish . . . services." 42 U.S.C. § 1395hh(a)(2); *see also* *Azar v. Allina Health Servs.*, 587 U.S. 566, 568–69 (2019) (holding that Congress imposed a "statutory duty" of notice and comment when establishing or changing a substantive legal standard affecting Medicare benefits). Subject to exceptions not applicable here, "before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment." 42 U.S.C. § 1395hh(b)(1). The notice and comment requirement under the Medicare statute is far broader than the Administrative Procedure Act's requirement of notice and comment for substantive rules. *Allina Health Servs.*, 587 U.S. at 573–79 (recognizing the Medicare Act requires notice and comment for interpretive rules and statements of policy that would not require that under the APA). As the Supreme Court observed, Congress created this stringent rule because Medicare "touches the lives of nearly all Americans," making the need for careful consideration of agency decisions all the more critical. *See* *id.*, 587 U.S. at 568–70.

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In other words, as relevant here, the Medicare Act requires notice-and-comment rulemaking for any (1) "rule, requirement, or other statement of policy" that (2) "establishes or changes a substantive legal standard" that (3) governs "payment of services or "eligibility of individuals, entities, or organizations to furnish or receive services or benefits." 42 U.S.C. § 1395hh(a)(2). All three requirements are readily met here.

First, the Kennedy Declaration is a rule or requirement. The Declaration constitutes a "rule or requirement" because, as noted *supra* § IV.F (discussing finality), it purports to establish a binding national standard that a particular treatment is unsafe and ineffective. The Declaration then mandates that the provision of such treatment does not meet professionally recognized standards of heath care, and therefore serves as a basis for exclusion of participation in the Medicare program. Consequently, Secretary Kennedy cannot evade notice-and-comment requirements by simply calling the action a "Declaration" as opposed to a rule or regulation. *Allina Health Servs.*, 587 U.S. at 574–75 (explaining that reviewing courts have "long looked to the contents of the agency's action, not the agency's self-serving label, when deciding whether statutory notice-and-comment demands apply"); *see also Guardian Fed. Sav. & Loan Ass'n v. Fed Sav. Loan Ins. Corp.*, 589 F.2d 658, 666–67 (D.C. Cir. 1978) (if "a so-called policy statement is in purpose or likely effect . . . a binding rule of substantive law," it "will be taken for what it is").

Although the Kennedy Declaration is plainly a rule or requirement under the Medicare Act, in the event that the court disagrees, the Kennedy Declaration is at minimum a "statement of policy" that is also subject to notice and comment under the Medicare act because it "lets the public know [HHS's] current" enforcement or "adjudicatory approach." *Allina Health Servs.*, 587 U.S. at 572–73. The Kennedy Declaration does that by threatening providers and institutions with the loss of Medicare participation if they provide gender-affirming care to minors and adolescents. And although the Kennedy Declaration frames that exclusion in permissive terms by referencing the requirement for a separate determination under 42 C.F.R. § 1001.701, the outcome of such a proceeding is a foregone conclusion given that the Declaration establishes an HHS determination

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that the provision of gender-affirming care to children and adolescents is per se failure to meet professionally recognized standards of care.

Second, the Kennedy Declaration amounts to a substantive change in a legal standard under the Medicare Act. Before December 18, 2025, HHS used federal dollars to reimburse for this care and had no substantive policy prohibiting gender-affirming care for transgender children and adolescents. The Kennedy Declaration purports to unilaterally change that: moving forward, such care has been deemed to be "neither safe nor effective" as a treatment modality for transgender minors and adolescents and is thus prohibited. In addition, at least after December 18, 2025, practitioners who provide such care "will be deemed not to meet professionally recognized standards of health care" and HHS may therefore bar practitioners and institutions providing such treatment from Medicare and other Federal health care programs. That action both changes and establishes a "substantive legal standard." *See e.g.*, *Allina Health Servs.*, 587 U.S. at 573 (holding HHS action changed "a substantive legal standard" applying to Medicare providers because it "affect[ed] a hospital's right to payment"); *Allina Health Servs. v. Price*, 863 F.3d 937, 943 (D.C. Cir. 2017) (Kavanaugh, J.) (explaining that "a 'substantive legal standard' at a minimum includes a standard that 'creates, defines, and regulates the rights, duties, and powers of parties'"); *Agendia, Inc. v. Becerra*, 4 F.4th 896, 900 (9th Cir. 2021), *cert denied*, 142 S. Ct. 898 (2022) (concluding that local coverage determinations were not subject to notice and comment because agency adjudicators were not bound by the decision)*;* *Texas v. Becerra*, 89 F.4th 529, 541 (5th Cir. 2024)*i*, *cert. denied,* 145 S. Ct. 139 (2024) (holding CMS Quality, Safety and Oversight Guidance regarding EMTALA's application to patients experiencing pregnancy loss, along with conditions of participation, after *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), required notice-and-comment rulemaking because it altered EMTALA's generally applicable mandate to provide stabilizing treatment for emergency conditions).

Third, and finally, there can be no reasonable dispute that the Kennedy Declaration "govern[s] . . . the eligibility of individuals, entities, or organizations to furnish . . . services . . . ."

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42 U.S.C. § 1395hh(a)(2). Indeed, it purports to set a binding national standard deeming an entire modality of treatment unsafe and ineffective, and if providers and institutions do not comply with the Declaration's commands, HHS has authority to exclude them from participation in Medicare (and every other Federal health care program).

In sum, the Kennedy Declaration is procedurally invalid because it violates Medicare's notice-and-comment requirements. And "[b]ecause affected members of the public received no advance warning and no chance to comment first, and because the government has not identified a lawful excuse for neglecting its statutory notice-and-comment obligations, . . . the new policy cannot stand." *Allina Health Servs.*, 587 U.S. at 568; *see also* 42 U.S.C. § 1395hh(a)(2).

2. The Kennedy Declaration fails to adhere to APA rulemaking requirements.

Even aside from the failure to meet the Medicare Act's rulemaking requirements, the Kennedy Declaration should be set aside on the independent ground that the Secretary failed to adhere to the notice-and-comment requirements of the Administrative Procedure Act that apply to Medicaid and other federal health programs.

The APA requires agencies to follow notice-and-comment procedures when engaging in rulemaking unless an exemption applies. 5 U.S.C. § 553. Specifically, the APA requires that "general notice of proposed rule making shall be published in the Federal Register," 5 U.S.C. § 553(b); that "[a]fter notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission[s]; 5 U.S.C. § 553(c); that "[a]fter consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose," *id.*; and that a "substantive rule shall be published not less than 30 days before its effective date. 5 U.S.C. § 553(d). "Rule," in turn, is defined broadly, to include "statement[s] of general or particular applicability and future effect" that are designed to "implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4).

The procedural rulemaking requirements outlined above apply to "legislative rules" (*i.e.*, those that have the "force" and effect "of law"), *Cal. Cities v. FCC*, 118 F.4th 995, 1012 (9th Cir.

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2024) (cleaned up), and not to "interpretive rules" or "statements of policy"[12] (*i.e.*, rules that merely "advise the public of the agency's construction of the statutes and rules which it administers"). *Allina Health Servs.*, 587 U.S. at 573; *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015); and 5 U.S.C. § 553(b).

HHS was required to subject the Kennedy Declaration to notice and comment because the Declaration amounts to a legislative rule under the APA for at least two reasons, either of which is sufficient to require notice and comment.

First, the purpose and effect of the Kennedy Declaration establishes that it is a legislative rule. As detailed above, the Declaration purports to set a new binding national standard deeming an entire modality of treatment "unsafe and ineffective" and definitively declares that providers and institutions that do not comply with the Declaration "fail to meet professionally recognized standards of care." The mandatory language used in the Kennedy Declaration has been recognized as "a 'powerful' indication" that the agency action is legislative. *See Alaska v. Dep't of Transp.*, 868 F.2d 441, 446, (D.C. Cir. 1989) (quoting *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1987)). And the conclusion that the mandatory rules that the Declaration purports to establish are legislative is cemented when considering the Declaration's effect: a violation of the terms of the Declaration provides a basis for exclusion of providers and institutions from participation in "any Federal health care program." In other words, the violation of the Declaration's mandates, without more, establishes a violation of the terms and conditions of participation in any Federal health care program.

Courts have repeatedly found that such a result renders a rule legislative, and thus subject to notice-and-comment procedural requirements. *See e.g.*, *Hemp Indus. Ass'n v. Drug Enf't*

[12] As discussed in the section (§ IV.C.1.), *supra*, even if this court determines that the Kennedy Declaration is a "statement of policy," it was nevertheless required to go through notice-and-comment under the Medicare Act. The "substantive legal standard" of Medicare's notice-and-comment requirement has "a more expansive scope than that borne by the term 'substantive rule' under the APA." *Allina Health Servs.*, 587 U.S. at 578; *see also Texas v. Becerra*, 89 F.4th 529, 545 (2019) (explaining that policy statements establishing or changing a substantive legal standard are subject to notice and comment under the Medicare Act, even if similar policy statements subject only to the APA would not be required to undergo that process).

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Admin., 333 F.3d 1082, 1084, 1088 (9th Cir. 2003) (DEA rule banning the sale of consumable products containing particular hemp product constituted a legislative rule because "the rule would force plaintiffs either to risk sanction or to forego the theretofore legal activity"; further noting "if there is no legislative basis for enforcement action on third parties without the rule, then the rule necessarily creates new rights and imposes new obligations", which makes it legislative); *Am. Mining Cong. v. Mine Safety & Health Admin*, 995 F.2d 1106, 1112 (D.C. Cir. 1993) (a rule is legislative when "in the absence of the rule there would not be an adequate legislative basis for enforcement action . . ."); *Alaska*, 868 F.2d at 445–47 (concluding that purported agency policy statement was a legislative rule, in part, because of binding nature of rule—which purported to "set forth bright-line tests to shape and channel agency enforcement"—and its impact on downstream agency discretion). The claimed purpose and effect of the Declaration establishes that it is a legislative rule. Consequently, it was required to undergo notice and comment.

Second, and in addition, notice-and-comment procedures were required because the Declaration adopted a new position in policy, effecting a substantive change in the regulation of gender-affirming care. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 100 (1995) (explaining that if an agency adopts "a new position *inconsistent with*" an existing regulation, or effects "*a substantive change in* the regulations[,]" notice and comment are required); *Hemp Indus.*, 333 F.3d at 1109–12 (observing that agency action has the "force of the law" and is thus legislative when the "rule effectively amends a prior legislative rule"). As detailed in the Medicare notice-and-comment section, before December 18, 2025, HHS used federal dollars to reimburse for this care, approved State Medicaid plans that expressly provided for this treatment, and had no substantive policy prohibiting gender-affirming care for transgender children and adolescents. The Declaration purports to unilaterally change that moving forward, mandating that such treatment fails "to meet professionally recognized standards of health care." The Secretary's unilateral attempt to declare what amounts to a national standard of health care through those provisions undeniably constitutes a legislative act. *See e.g.*, *Hemp Indus.*, 333 F.3d at 1087 (explaining that in "general terms,

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interpretive rules merely explain, but do not add to, the substantive law that already exists in the form of a statute or legislative rule") (citing *Yesler Terrace Cmty. Council v. Cisneros*, 37 F.3d 442, 449 (9th Cir. 1994); *Am. Mining*, 995 F.2d at 1110 (explaining that a rule that is based on an agency's power to exercise its judgment about how best to implement a general statutory mandate is legislative). For those additional reasons, notice-and-comment was required.

Because HHS failed to provide notice and opportunity to comment before issuing the Declaration, the Declaration amounts to a procedurally invalid legislative rule and should be set aside and declared invalid. *Hemp Indus.*, 333 F.3d at 1091 (imposing that remedy when agency failed to follow notice-and-comment requirements); *see also Cal. Cities v. F.C.C.*, 118 F.4th 995, 1012 (9th Cir. 2024) (agency action is "not in accordance with law" under the APA if it "is a legislative rule masquerading as an interpretive rule" and agency failed to comply with notice-and-comment rulemaking).

HHS will presumably rely on its recent attempt to eliminate notice-and-comment for changes to the Medicaid program. *See* Policy on Adhering to the Text of the Administrative Procedure Act, 90 Fed. Reg. 11029 (Mar. 3, 2025). But any such reliance is misplaced.

APA rulemaking procedures generally require notice and comment for promulgation of rules, subject to certain exemptions for rulemaking "relating to … public property, loans, grants, benefits, or contracts." 5 U.S.C. § 553(a)(2). In 1971, HHS issued the Richardson Waiver by notice in the Federal Register, 36 Fed. Reg. 2532 (Feb. 5, 1971). In that notice, HHS formally waived the APA rulemaking procedure exemption, obligating HHS to follow the APA's notice and comment procedures for changes to Medicaid regardless of whether it fell within § 553(a)(2) exemptions. *Id.* Since issuing the Richardson Waiver, HHS has been bound to follow the APA procedures for Medicaid rulemaking. *See Humana of S.C., Inc. v. Califano*, 590 F.2d 1070, 1084 (D.C. Cir. 1978). In March 2025, Secretary Kennedy purported to rescind the Richardson Waiver, asserting that the policy had "impose[d] costs on the Department and the public" and that it "impede[s] the Department's flexibility to adapt quickly to legal and policy mandates." 90 Fed. Reg. 11029.

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The recission of the Richardson Waiver does not exempt the Kennedy Declaration from notice-and-comment requirements because the § 553(a)(2) exemption is inapplicable to the Declaration's attempt to determine a nationwide standard of care, and HHS's recission was improper. First, the Declaration is not a mere rulemaking related merely to "grants, [or] benefits," but an attempt to regulate medical practice more broadly. Second, the Secretary's reasoning for the purported recission was arbitrary and capricious, ignoring the reliance engendered by HHS's 50-year policy, and providing no explanation for why immediate rescission was appropriate despite that reliance. "When an agency changes course, … it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Dep't of Homeland Sec. v. Regents of Univ. of Cal.*, 591 U.S. 1, 30 (2020). In doing so, agencies must determine whether reliance interests were "significant," and "weigh any such interests against competing policy concerns," and must provide its reasoning at the time of its decision. *Id.* at 23–24, 33. An agency's failure to assess and consider those reliance interests makes its decision arbitrary and capricious. *Id.* at 30.

Examples of reliance interests that HHS failed to assess and consider are numerous. Every state participates in Medicaid. *Nat'l Fed'n of Indep. Bus. (NFIB) v. Sebelius*, 567 U.S. 519, 542 (2012) (noting that by 1982 every state had chosen to participate in Medicaid). That level of reliance on federal funds is premised on the expectation that major changes to those programs—such as announcing new rules to exclude providers from participation—would occur only after notice of proposed changes and an opportunity to provide public comment to ensure that CMS is fully informed before finalizing the changes. *See* *Biden v. Missouri*, 595 U.S. 87, 105 (2022) (Alito, J., dissenting) (noting that notice-and-comment procedures are necessary to "give individuals and entities who may be seriously impacted by agency rules at least some opportunity to make their views heard and to have them given serious consideration"). Eligible patients also rely on the existence of meaningful public participation in CMS's decision making. Because HHS and CMS did not provide any opportunity for public comment, patients were unable to inform

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HHS how the decision will diminish their ability to afford care—including care entirely unrelated to gender-affirming care—from their chosen providers. HHS entirely failed to assess and consider these reliance interests when it attempted to rescind the Richardson Waiver. HHS's attempted rescission of the Richardson waiver was thus arbitrary and capricious and legally ineffective. For that reason, even if the Declaration could be considered to fall within the § 553(a)(2) exemption, notice and comment was required.

Thus, in addition to failing to meet the rulemaking requirements under the Medicare Act, the Kennedy Declaration fails to meet the rulemaking requirements under the APA. Accordingly, the rule is unlawful and should be set aside.

D. The Kennedy Declaration is contrary to numerous provisions of the Medicaid Act.

Although either the absence of statutory authority for the Declaration or the Secretary's violation of mandatory procedural requirements would be sufficient to render the Kennedy Declaration illegal on its own, the Kennedy Declaration is also independently unlawful because it contravenes numerous provisions of the Medicaid Act. Under the APA, courts must set aside agency actions that are "not in accordance with law[.]" 5 U.S.C. § 706(2)(A). The Kennedy Declaration contravenes the terms of approved Medicaid state plans, and violates provisions guaranteeing Medicaid clients a free choice of any qualified provider.

1. The Kennedy Declaration violates the terms of federally approved Medicaid state plans.

The Kennedy Declaration unilaterally and impermissibly alters the terms of federally approved Medicaid state plans. Spending Clause legislation like Medicaid "is much in the nature of a contract." *Pennhurst State School & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). Each Plaintiff State maintains such a contract, referred to as a Medicaid Plan, which "contains all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program." 42 C.F.R. § 430.10; *see also* 42 U.S.C. § 1396a(a) (setting out the requirements of state plans). Pursuant to 42 U.S.C. § 1396b(a), "the

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Secretary . . . shall pay to each State which has a plan approved" amounts specified by statute. Medicaid affords each participating state "substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage." *Alexander v. Choate*, 469 U.S. 287, 303 (1985). State Medicaid plans follow a "standardized template, issued and updated by CMS, that includes both basic requirements and individualized content that reflects the characteristics of the State's program." 42 C.F.R. § 430.12(a).

Changes to a State's Plan must follow the amendment process delineated by the Social Security Act and its implementing regulations. States propose plans and amendments to plans, which HHS must approve or disapprove. *See*, *e.g.*, 42 U.S.C. § 1396a(b) (requiring the Secretary to approve any state plan that meets the requirements of the Medicaid Act); 42 C.F.R. § 430.15 (setting out approval and disapproval authority). If HHS determines a state plan, or a state proposed amendment to a state plan, should be disapproved then HHS must give the state notice and provide an opportunity for the state to request an administrative hearing to contest the decision. 42 C.F.R. §§ 430.16, 430.18. And while HHS may disallow payments if a state is no longer operating its Medicaid program consistently with its approved plan, HHS cannot make unilateral changes to state plans. 42 U.S.C. § 1396c (permitting disallowance of funds after "reasonable notice . . . and opportunity for hearing").

Here, each of the Plaintiff States provide for gender-affirming care through their state Medicaid programs. *See supra* note 1. But the Kennedy Declaration effectively amends these plans by declaring that such care falls below professionally recognized standards, subjecting providers to exclusion from federal health care programs, including Medicaid, for providing it. It is an oxymoron for gender-affirming care to both be a covered service under a state plan and for its provision to subject a provider to exclusion from Medicaid. HHS gave no notice to the Plaintiff States that any part of their plans was being disapproved. They were not given the opportunity to contest that decision in an administrative hearing. Instead, the Kennedy Declaration was simply

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posted to HHS's website and announced on social media on December 18, 2025. This violates 42 U.S.C. § 1396a(b), and 42 C.F.R. §§ 430.14 through .18 dealing with state plan disapprovals.

2. The Kennedy Declaration violates the statutory requirement of a free choice of provider.

"Under the free choice of providers provision, a state plan must provide that 'a beneficiary may obtain Medicaid services from any institution, agency, pharmacy, person, or organization that is (i) Qualified to furnish the services; and (ii) Willing to furnish them to that particular beneficiary.'" *Wash. State Health Care Auth. v. Ctrs. for Medicare & Medicaid Servs.*, 57 F.4th 703, 706 (9th Cir. 2023) (quoting 42 C.F.R. § 431.51(b)(1)); *see also* 42 U.S.C. § 1396a(a)(23) ("[A]ny individual eligible for medical assistance . . . may obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required . . . who undertakes to provide him such services."). "[T]he free-choice-of-provider provision unambiguously requires that states participating in the Medicaid program allow covered patients to choose among the . . . practitioners they could use were they paying out of their own pockets." *Planned Parenthood Ariz. Inc. v. Betlach*, 727 F.3d 960, 971 (9th Cir. 2013), *abrogated on other grounds by Medina v. Planned Parenthood of South Atlantic*, 606 U.S. 357 (2025).

Under the free-choice-of-provider provision it is the relevant state law that governs whether a provider is "qualified" or not. *See Medina*, 606 U.S. at 364 ("The provision does not define the term 'qualified,' perhaps because States have traditionally exercised primary responsibility over 'matters of health and safety,' including the regulation of the practice of medicine." (quoting *De Buono v. NYSA-ILA Medical & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997))); *see also Planned Parenthood Ariz. Inc.*, 727 F.3d at 969 ("the pertinent professions which providers must be 'qualified' to practice are the various medical professions"). "Under the Medicaid Act, states have the 'authority to regulate the practice of medicine within [their] borders,' which includes setting out state licensing standards and scope of practice requirements." *Wash. State Health Care Auth.*, 57 F.4th at 708 (quoting *Planned Parenthood Ariz. Inc.*, 727 F.3d at 975).

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The Kennedy Declaration amounts to an end-run around the free choice of provider statute because it effectively bars Medicaid beneficiaries from choosing providers that are otherwise qualified, simply because they furnish gender-affirming care to children or adolescents. Providers who provide gender-affirming care are qualified providers in the Plaintiff States—beneficiaries would straightforwardly have the ability to request services from such providers in the Plaintiff States were they paying out of their own pockets. Moreover, "the free-choice-of-provider provision appears in a list of *mandatory* requirements that apply to all state Medicaid plans" as part of Congress's design. *See* *Planned Parenthood Ariz. Inc.*, 727 F.3d at 971. Secretary Kennedy is not free to override the Plaintiff States' decisions about what makes a provider qualified to provide medical services, and therefore whether they can provide Medicaid services. The Declaration is contrary to law and should be vacated.

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V. CONCLUSION

The Court should grant summary judgment to the Plaintiff States.

DATED: January 6, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on January 6, 2026, I served the foregoing PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT upon the parties hereto by the method indicated below, and addressed to the following:

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