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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

EUGENE DIVISION

STATE OF OREGON, et al., Plaintiffs, v. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, et al., Defendants.	Case No.: 6:25-cv-2409-MTK DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

LOCAL RULE 7-1 CERTIFICATION

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

DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT*

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 56, Defendants file their motion to dismiss or, in the alternative, for summary judgment. Defendants respectfully request that the Court grant Defendants' motion to dismiss and dismiss this case in its entirety. In the alternative, Defendants request that the Court enter summary judgment in favor of Defendants. Defendants' motions are supported by the following memorandum of law.

* Pursuant to Local Rule 7-1(b), Defendants contemporaneously file their Opposition to Plaintiffs' motion for summary judgment, ECF No. 74. Both the instant motions and Defendants' opposition to Plaintiffs' motion for summary judgment are supported by identical memoranda of law.

MEMORANDUM OF LAW

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I. Introduction

On December 18, 2025, Robert F. Kennedy Jr., the Secretary of the Department of Health and Human Services ("HHS"), issued a declaration (the "Kennedy Declaration" or "Declaration") reflecting the Secretary's non-binding policy position on the safety and efficacy of certain pediatric and adolescent treatment modalities for gender dysphoria, gender incongruence, or other related conditions. *See* ECF No. 1-1 [hereinafter Kennedy Decl.]. Secretary Kennedy, just like anyone else, is entitled to articulate his opinion on the safety and efficacy of emerging and controversial medical practices. The Declaration summarizes Secretary Kennedy's independent evaluation of the cited medical literature and expresses his opinion that certain treatment modalities are not safe and effective and fail to meet professionally recognized standards of health care.

Plaintiffs contend that the Kennedy Declaration violates the notice and comment requirements of the Administrative Procedure Act ("APA") and the Medicare statute, exceeds the Secretary's statutory authority, and conflicts with various provisions of the Medicaid statute. Plaintiffs' claims fail at the threshold and on the merits because they rest on a basic misunderstanding of the Declaration's purpose and effect. All Plaintiffs' claims hinge on their theory that the Kennedy 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 [from federal health care programs]." Pls.' Br. at 9. But that is not what the Declaration does.

Nothing in the APA or Medicare and Medicaid statutes prohibits the Secretary from publicly articulating views formed after reviewing the medical literature about the safety and efficacy of emerging and controversial treatments, where those views do not operate automatically and do not themselves change legal standards or enforcement outcomes. The Declaration makes clear that it "does not constitute a determination that any individual or entity should be excluded

from participation in any Federal health care program" for providing these treatments, and that "[a]ny such determination could only be made after a separate determination [by the HHS's Office of Inspector General ("OIG)"] under 42 C.F.R. § 1001.701, which is subject to further administrative and judicial review under 42 C.F.R. §§ 1001.2007." Kennedy Decl. § V. Under the referenced regulations, OIG considers information from multiple sources, such as state and local professional societies and private insurance companies, as well as any documentary evidence and written argument submitted by a practitioner, before determining whether the practitioner has furnished services that fall below professionally recognized standards of care and whether to exercise OID's discretion to exclude the practitioner from federal health care programs ("FHCPs"). Thus, the Secretary's non-binding opinion expressed in the Declaration is not dispositive of the standard of care applicable in OIG exclusion proceedings and is instead only one piece of information OIG may consider in any exclusion proceedings. Penezic Decl. ¶¶ 8, 10. In this respect, the Declaration is analogous to position statements issued by medical organizations and professional associations that assess the safety and efficacy of emerging treatments: it evaluates the existing medical evidence and expresses a view on treatment efficacy, without independently establishing enforceable legal standards. *See, e.g.*, American Society of Plastic Surgeons, *Position Statement on Gender Surgery for Children and Adolescents* (Feb. 3, 2026), https://www.plasticsurgery.org/documents/health-policy/positions/2026-gender-surgery-children-adolescents.pdf.

A proper understanding of the Kennedy Declaration's purpose and effect demonstrates that all of Plaintiffs' claims fail. The Court should therefore dismiss this case for lack of jurisdiction or, in the alternative, grant summary judgment in favor of Defendants.

II. Background

The Medicare and Medicaid Programs

The Medicare program, established under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, is a nationwide, federally subsidized health insurance program that covers the costs of certain health care services for eligible beneficiaries, primarily individuals aged sixty-five or order and other individuals who qualify based on disability. The Secretary of HHS is responsible for determining what claims are covered by Medicare, 42 U.S.C. § 1395ff(a), and the program is administered by the Centers for Medicare & Medicaid Services ("CMS") on behalf of the Secretary. Medicare is governed by a "complex statutory and regulatory regime." *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993). Any health care provider or supplier that seeks to participate in the Medicare program must submit an application to enroll in Medicare. *See, e.g.*, 42 U.S.C. § 1395cc(j); 42 C.F.R. § 424.510. Through the enrollment process, the provider or supplier agrees to comply with Medicare statutory and regulatory requirements and program instructions. For example, pursuant to statutory authorities, HHS has established Medicare conditions of participation with which facilities must comply to be eligible to receive Medicare funding. *See Biden v. Missouri*, 142 S. Ct. 647, 650 (2022); *see, e.g.*, 42 C.F.R. pt. 482 (hospital conditions of Medicare participation).

The Medicaid program, established under Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.*, is a cooperative program through which the federal government provides financial assistance to states so that they may furnish medical care to persons with limited income and resources. State participation in the Medicaid program is voluntary, and "[t]he Federal Government shares the costs of Medicaid with States that elect to participate in the program."

Atkins v. Rivera, 477 U.S. 154, 156–57 (1986). "In return, participating States are to comply with requirements imposed by the Act and by the Secretary of Health and Human Services." *Id.* at 157.

To be eligible for federal Medicaid funds, a participating state must receive the HHS Secretary's approval of a "State plan for medical assistance" ("state plan"). *See* 42 U.S.C. § 1396a(a)(10)(A), (b). The state plan details the nature and scope of the State's Medicaid program, including the beneficiaries and services covered, among other things, and must demonstrate compliance with the requirements of the Medicaid statute and regulations. *See* 42 U.S.C. § 1396a. If HHS approves the state plan, the federal government reimburses the state for a percentage of qualified Medicaid expenses. *See id.* § 1396d(b). Even after approval, the Secretary can review the administration of state Medicaid plans "to determine whether the State is complying with the Federal requirements and the provisions of its plan." 42 C.F.R. § 430.32(a).

Section 1396a of the Medicaid statute comprehensively lists federal requirements for state Medicaid plans. As relevant here, 42 U.S.C. § 1396a(a)(23)(A) dictates that a state may not limit a Medicaid beneficiary's free choice of provider. Section 42 U.S.C. § 1396a(a)(23)(A) requires a state plan to provide that "any 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." *Id.* This provision gives Medicaid beneficiaries "the right to choose among a range of qualified providers, without government interference." *O'Bannon v. Town Court Nursing Ctr.*, 447 U.S. 773, 785 (1980) (emphasis omitted).

The statute does not define the word "qualified." Longstanding federal regulations, however, recognize States' authority to "set[] reasonable standards relating to the qualifications of providers." 42 C.F.R. § 431.51(c)(2); *see Dep't of Health, Educ., & Welfare Health Care*

Financing Admin., 43 Fed. Reg. 45,176, 45,189 (Sep. 29, 1978); *see also Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 364 (2025). Consistent with Section 1396a(a)(23)'s free-choice-of-provider provision, such standards must relate to a provider's fitness to perform the medical services the patient requires—i.e., "a provider's capability of performing the needed medical services in a professionally competent, safe, legal, and ethical manner." *Planned Parenthood Ariz., Inc. v. Betlach*, 727 F.3d 960, 975 (9th Cir. 2013) (quoting *Planned Parenthood of Ind., Inc. v. Comm'r of the Ind. State Dep't of Health*, 699 F.3d 962, 978 (7th Cir. 2012)) (citation modified).

Exclusion From Federal Health Care Programs

Congress authorized the Secretary of HHS to exclude individuals and entities from participation in FHCPs through section 1128 of the Social Security Act, codified at 42 U.S.C. § 1320a-7. In doing so, Congress made an explicit policy choice to distinguish between grounds mandating exclusion, in which case the Secretary "shall exclude" a practitioner, and grounds permitting exclusion, in which case the Secretary, exercising his discretion, "may exclude" a practitioner. *See id.* § 1320a-7(a), (b). Thus, Congress authorized—but did not require—the Secretary of HHS to impose exclusions in the latter permissive categories, *id.* § 1320a-7(b). Congress did not specify when permissive exclusions must occur, what factors must be considered, or what outcome must follow upon a finding of predicate conduct. Instead, Congress left those determinations to the Secretary's discretion. One ground of permissive exclusion authorizes OIG to exclude an individual or entity from FHCPs that "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." *Id.* § 1320a-7(b)(6)(B).

The Secretary has delegated his exclusion authority to OIG. Delegation of Authority; Centers for Medicare and Medicaid Services, 76 Fed. Reg. 13618, 13619 (Mar. 14, 2011). OIG

implemented this statutory authority through notice-and-comment rulemaking, codified at 42 C.F.R. Part 1001, and mirrored the statutory structure Congress enacted by separating mandatory exclusions in Subpart B, *see* 42 C.F.R. §§ 1001.101–1001.102, from permissive exclusions in Subpart C, *see id.* §§ 1001.201–1001.1701. As relevant here, 42 C.F.R. § 1001.701(a)(2) provides that "OIG may exclude an individual or entity that has . . . [f]urnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services . . . of a quality that fails to meet professionally recognized standards of health care." *See also id.* § 1001.2 ("Professionally recognized standards of health care are 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 . . . .").

The regulations also identify the types of information OIG will consider when determining whether a provider or entity has "[f]urnished or caused to be furnished, to patients, . . . any items or services . . . of a quality which fails to meet professionally recognized standards of health care" under 42 C.F.R. § 1001.701(a)(2). Specifically, subsection (b) provides:

> The OIG's determination under paragraph (a)(2) . . . will be made on the basis of information . . . from the following sources:
>
> (1) The [Quality Improvement Organization] for the area served by the individual or entity;
>
> (2) State or local licensing or certification authorities;
>
> (3) Fiscal agents or contractors, or private insurance companies;
>
> (4) State or local professional societies; or
>
> (5) Any other sources deemed appropriate by the OIG.

Id. § 1001.701(b).

The regulations likewise govern the administrative process for exclusion. *See* 42 C.F.R. §§ 1001.2001–1001.2007. Under 42 C.F.R. § 1001.2001(a), "if the OIG proposes to exclude an individual or entity in accordance with subpart C [permissive exclusions] . . . [OIG] will send written notice of its intent, the basis for the proposed exclusion and the potential effect of an exclusion," (a "notice of intent to exclude"). Within thirty days after OIG sends a notice of intent to exclude, the recipient "may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues." 42 C.F.R. § 1001.2001(a). For recipients of a notice of intent to exclude under a standard-of-care exclusion, *id.* § 1001.701(a)(2), "in conjunction with the submission of documentary evidence and written argument, an individual or entity may request an opportunity to present oral argument to an OIG official." *Id.* § 1001.2001(b).

If OIG determines that exclusion is warranted after considering the types of information listed under *id.* § 1001.701(b) and any evidence and argument submitted by the individual or entity, *id.* §1001.2001(a)–(b), OIG then issues a notice of exclusion under *id.* § 1001.2002. A notice of exclusion identifies "the basis for the exclusion," "the length of the exclusion," its effect on participation in FHCPs, reinstatement procedures, and appeal rights. *Id.* § 1001.2002(c).

Excluded individuals or entities may then request a reconsideration hearing before an Administrative Law Judge ("ALJ"). *Id.* § 1001.2007(a)(1). The ALJ follows the procedures in 42 C.F.R. Part 1005, and issues a written decision, *id.* § 1005.20, which an excluded party may appeal to the Departmental Appeals Board, *id.* § 1005.21. After exhausting administrative remedies, the excluded party may seek judicial review in federal district court. *See* 42 U.S.C. § 405(g).

The Kennedy Declaration

The Kennedy Declaration is a written statement issued by the Secretary of HHS, explaining his non-binding policy position on the safety and efficacy of certain pediatric and adolescent treatment modalities for gender dysphoria, gender incongruence, or other related conditions. The Declaration does not announce enforcement action, impose sanctions, or amend any legal standard or regulatory process. Instead, it explains the Secretary's assessment of existing medical literature and articulates the Secretary's views on health care safety.

The Declaration opens by describing the emerging and rapidly increasing prevalence of gender dysphoria diagnoses among children and adolescents in the United States and Europe, which has raised questions about the safety and effectiveness of current medical interventions. The Declaration identifies HHS's efforts to address these methodological concerns and identify the best practices for the treatment of pediatric gender dysphoria. Specifically, the Declaration discusses HHS's recently published peer-reviewed report, which characterizes the evidence for certain interventions as weak, limited, or lacking rigorous long-term outcome data, and expresses concern about possible irreversible harms and other adverse outcomes. *See* Kennedy Decl. § I–II; *see also* U.S. Dep't of Health & Human Services, *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (November 19, 2025), https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report.pdf. The Declaration also references reviews outside of the United States, noting similar concerns raised in European countries. It points to international reviews and assessments, such as those conducted in the United Kingdom and by other national health authorities, that have questioned the quality of and evidence supporting certain interventions for treating pediatric gender dysphoria. Based on this background, evidence review, and assessments of guidelines, Secretary Kennedy asserts that "standards of care

recommended by certain medical organizations are unsupported by the weight of evidence and threaten the health and safety of children with gender dysphoria." Kennedy Decl. § I.D. He opines that certain treatment modalities for children and adolescents are neither safe nor effective and fail to meet professionally recognized standards of health care. *See* Kennedy Decl. § V.

Citing 42 U.S.C. § 1320a-7(b)(6)(B), the Declaration notes the Secretary's permissive authority to exclude providers from participation in FHCPs if OIG determines that they have furnished services to patients of a quality which fails to meet professionally recognized standards of health care. Kennedy Decl. § V. The Declaration is sure to clarify that the Declaration itself "does not constitute a determination that any individual or entity should be excluded from participation in any Federal health care program." Kennedy Decl. § V. It affirmatively confirms that "Any such determination could only be made after a separate determination under 42 C.F.R. § 1001.701, which is subject to further administrative and judicial review under 42 C.F.R. §§ 1001.2007, 1005.21." Kennedy Decl. § V. And that "[b]efore making any such determination, HHS will ensure compliance with applicable laws, regulations, court orders, and any required procedures." Kennedy Decl. § V.

The attached declaration from Robert Penezic, ECF No. 75 ("Penezic Decl."), confirms that OIG does not treat the Kennedy Declaration as either (1) binding on OIG's permissive exclusion authority under 42 C.F.R. § 1001.701(a); or (2) dispositive of "professionally recognized standards of health care applicable in OIG exclusion proceedings under 42 C.F.R. § 1001.701(a)(2)." Penezic Decl. ¶¶ 8, 12. Rather, "OIG conducts all exclusion matters in accordance with applicable statutory and regulatory authorities." Penezic Decl. ¶3. Additionally, "OIG has not issued any notices of intent to exclude, issued any notices of exclusion, or commenced any exclusion proceedings based on the [Declaration]." Penezic Decl. ¶ 4.

This Litigation

On December 23, 2025, eighteen States; the District of Columbia; and Josh Shapiro, in his official capacity as Governor of the Commonwealth of Pennsylvania; filed a five-count Complaint, ECF No. 1, against Robert F. Kennedy, Jr., in his official capacity as the Secretary of HHS; Thomas March Bell, in his official capacity as Inspector General of HHS; OIG; and HHS. On January 6, 2026, Plaintiffs filed an Amended Complaint, ECF No. 28 ("Pls.' Am. Compl."), to add two additional Plaintiff States.

Plaintiffs' Amended Complaint raises five causes of action. Count 1 alleges a violation of the Medicare statute's notice-and-comment rulemaking requirements, 42 U.S.C. § 1395hh. Pls.' Am. Compl. at 28–29. Count 2 alleges a violation of the APA's notice-and-comment rulemaking requirements, 5 U.S.C. § 553. Pls.' Am. Compl. at 29–31. Count 3 alleges the Kennedy Declaration exceeds the Secretary's statutory authority under the APA, 5 U.S.C. § 706(2)(C). *See* Pls.' Am. Compl. at 31–32. Count 4 alleges that the Kennedy Declaration is not in accordance with law under the APA, 5 U.S.C. § 706(2)(A), for violating 42 U.S.C. § 1395 and "multiple, substantive statutory requirements for Medicaid programs." Pls.' Am. Compl. at 32–34. Count 5 alleges that the Kennedy Declaration is arbitrary and capricious under the APA, 5 U.S.C. § 706(2)(A). Pls.' Am. Compl. at 34–35. Plaintiffs ask the Court to declare, hold unlawful, stay, vacate, and set aside the Kennedy Declaration; preliminarily and permanently enjoin Defendants from implementing, instituting, maintaining, enforcing, or giving effect to the Kennedy Declaration in any form; and award Plaintiffs' costs and reasonable attorneys' fees and expenses. Pls.' Am. Compl. at 35–36. On January 6, 2026, Plaintiffs moved for summary judgment, on Counts 1–4. ECF No. 32 ("Pls.' Br."). They did not move for summary judgment on Count 5. *Id.*

III. Legal Standard

Article III of the U.S. Constitution limits a court's subject matter jurisdiction to matters that are "ripe" for adjudication. *Chandler v. State Farm Mut. Auto. Ins. Co.*, 598 F.3d 1115, 1121 (9th Cir. 2010). "The party asserting federal subject matter jurisdiction bears the burden of proving its existence." *Id.* If a case is not ripe, it should be dismissed under Federal Rule of Civil Procedure 12(b)(1). *St. Clair v. City of Chico*, 880 F.2d 199, 201 (9th Cir. 1989).

In challenges to agency action under the APA, "summary judgment is the appropriate mechanism" for deciding, as a matter of law, whether the agency's action is supported by the administrative record and consistent with the APA. *See Occidental Eng'g Co. v. INS.*, 753 F.2d 766, 770 (9th Cir. 1985). Under the APA, a court should only set aside final agency action "found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." *Nw. Motorcycle Ass'n v. U.S. Dep't of Agric.*, 18 F.3d 1468, 1471 (9th Cir. 1994) (quoting 5 U.S.C. § 706(2)(A)).

IV. Argument

A proper understanding of the Declaration's purpose and effect is fatal to all Plaintiffs' claims. As an initial matter, the Court lacks jurisdiction. First, Plaintiffs' challenges to the Kennedy Declaration are not ripe for judicial review because they rest on a series of contingencies that have not occurred and may never occur. The Declaration has no concrete legal consequences. It is not dispositive of the standard of care applicable in OIG exclusion proceedings and it does not determine that any provider should be excluded. Additionally, no Medicaid beneficiaries have been denied the free choice of provider based on the Kennedy Declaration because OIG has not excluded any individual or entity, and any such exclusion would be subject to multiple layers of administrative and judicial review. CMS has also not disapproved of any state plan amendment,

refused payment under any state plan, or terminated funds to the Plaintiff States for noncompliance with the Declaration. Second, the Kennedy Declaration is not final agency action subject to judicial review under the APA. The Declaration reflects only the Secretary's non-binding opinion, which does not establish the standard of care applicable to exclusion proceedings or require OIG to exercise its permissive exclusion authority. Rather, the regulations require OIG to consider information from multiple sources when determining whether a provider has furnished substandard care that warrants exclusion.

Plaintiffs' claims also fail on the merits for similar reasons. First, the Kennedy Declaration is exempt from the APA's notice-and-comment requirements as a "general statement[] of policy," 5 U.S.C. § 553(b)(A). It is not binding. It is not determinative on the issue of whether services fail to meet professionally recognized standards of care or whether an individual should be excluded under OIG's permissive exclusion authority. And it does not make findings about any provider or trigger any enforcement consequences. The Declaration is also not subject to the Medicare statute's notice-and-comment requirements because it does not "establish[] or change[] a substantive legal standard," 42 U.S.C. § 1395hh(a)(2). It has no binding legal effect and, even in the absence of the Declaration, providers would still be subject to OIG's permissive authority to exclude them from FHCPs if they furnished care falling below professionally recognized standards. The Declaration likewise does not exceed the Secretary's statutory authority because, contrary to Plaintiffs' allegations, the Declaration does not unilaterally declare that provision of a particular treatment is legally sufficient grounds for exclusion or otherwise exercise supervision or control over the practice of medicine. Lastly, the Declaration is not contrary to provisions of the Medicaid statute because it does not alter or amend state plans and 42 U.S.C. § 1396a(a)(23)'s

free-choice-of-provider provision does not confer an enforceable right on states against the federal government.

The Court should dismiss this case in its entirety for lack of jurisdiction or, in the alternative, grant summary judgment in favor of Defendants.

1. The Court lacks jurisdiction over Plaintiffs' claims.

A. Plaintiffs' challenges to the Kennedy Declaration are not ripe for judicial review because they rest on a series of contingencies that have not occurred and may never occur.

"The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003) (citation omitted). The doctrine "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies" and "protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Id.* at 807–08 (citation omitted); *see also Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990).

To determine whether a challenge to an agency action is ripe for constitutional purposes (and satisfies the injury-in-fact requirement of Article III standing), courts ask "whether the issues presented are definite and concrete, not hypothetical or abstract." *Stavrianoudakis v. United States Fish & Wildlife Serv.*, 108 F.4th 1128, 1139 (9th Cir. 2024) (quotation marks omitted). And to determine whether a challenge is ripe prudentially, courts evaluate two factors: (1) "the fitness of the issues for judicial decision"; and (2) "the hardship to the parties of withholding court consideration." *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 149 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977). "Hardship in this context 'does not mean just

anything that makes life harder; it means hardship of a legal kind, or something that imposes a significant practical harm upon the plaintiff.'" *Colwell v. Dep't of Health & Hum. Servs.*, 558 F.3d 1112, 1128 (9th Cir. 2009) (quoting *Nat. Res. Def. Council v. Abraham*, 388 F.3d 701, 706 (9th Cir. 2004)). "A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (citation omitted).

Plaintiffs challenge a declaration setting forth the Secretary's non-binding policy view on the safety and efficacy of certain pediatric and adolescent treatment modalities for gender dysphoria, gender incongruence, or other related conditions. The Declaration has no concrete legal consequences because it is not dispositive of the standard of care applicable in OIG exclusion proceedings and is instead only one piece of information OIG may consider in any exclusion proceedings. *See* Penezic Decl. ¶ 10. Moreover, its alleged effects depend on a speculative chain of future events that may never occur and, even if they do, any proposed exclusion would be subject to multiple layers of administrative and judicial review. Simply put, Plaintiffs are not "subject to a genuine threat of imminent prosecution," *Wolfson v. Brammer*, 616 F.3d 1045, 1058 (9th Cir. 2010) (quotation marks omitted), and "[a]ny prediction how the Executive Branch might eventually implement this general statement of policy is no more than conjecture at this time," *Trump v. New York*, 592 U.S. 125, 131 (2020) (quotation marks omitted). Accordingly, Plaintiffs' claims are not sufficiently definite and concrete, not fit for judicial review, and there is no hardship by withholding judicial consideration.

Plaintiffs' claims are not fit for judicial review because the Kennedy Declaration is not "a definitive statement of an agency's position"; it has no "direct and immediate effect on the complaining parties"; it does not have "the status of law"; and it does not "require[] immediate

compliance with its terms." Flaxman v. Ferguson, 151 F.4th 1178, 1188 (9th Cir. 2025) (quoting *Skyline Wesleyan Church v. Cal. Dep't of Managed Health Care*, 968 F.3d 738, 752 (9th Cir. 2020)). The Declaration merely reflects the Secretary's non-binding opinion about the safety and efficacy of certain pediatric and adolescent treatment modalities. It is not dispositive of the applicable "professionally recognized standards of care" for exclusions.

The Kennedy Declaration also does not bind OIG's enforcement discretion. Plaintiffs' claims depend on the unfounded premise that the Declaration binds OIG decision-making, even though neither the Declaration nor the governing regulations impose such a constraint. Nothing in the Declaration purports to bind OIG. To the contrary, the Declaration confirms that it does not predetermine the outcome of any hypothetical exclusion proceedings by expressly stating that it "does not constitute a determination that any individual or entity should be excluded from participation in any Federal health care program." Kennedy Decl. § V. The Declaration further recognizes that exclusion determinations are governed by a regulatory process, stating that "Any such determination could only be made after a separate determination under 42 C.F.R. § 1001.701, which is subject to further administrative and judicial review under 42 C.F.R. §§ 1001.2007, 1005.21." Kennedy Decl. § V.

The referenced regulatory framework likewise confirms that the Declaration does not establish the standard of care and is not binding on OIG's permissive authority to exclude providers for substandard care. The applicable regulations require OIG to consider multiple sources of information when determining whether care falls below "professionally recognized standards of health care," including, for example, information from state and local professional societies and private insurance companies. *See* 42 C.F.R. § 1001.701(b). The regulations also require OIG to consider any documentary evidence and written argument submitted by a practitioner in assessing

whether the practitioner has furnished services that fall below professionally recognized standards of care and whether to exercise its discretion to exclude the practitioner from FHCPs. *See* *id.* § 1001.2001(a). Finally, statute and applicable regulations grant OIG permissive—not mandatory—authority to exclude providers for substandard care, leaving room for OIG to exercise additional discretion before excluding any practitioner. *See* 42 U.S.C. § 1320a-7(b)(6)(B); 42 C.F.R. § 1001.701(a).

Although ALJs lack authority to "[f]ind invalid or refuse to follow" federal regulations or "enjoin any act of the Secretary," *see* 42 C.F.R. § 1005.4(c)(1)(4); Pls.' Br. at 22–23, those features reflect Congressional limits on administrative adjudication—not the absence of meaningful administrative review. The limitations are jurisdictional, not substantive; they restrict what adjudicators may remedy. They do not convert the Declaration into a binding, dispositive rule with the force of law. ALJs are similarly not bound by the Kennedy Declaration.

The referrals Plaintiffs reference in their brief, *see* Pls.' Br. at 18 nn.6–7, 9, also do not establish that the Declaration is binding or dispositive of the standard of care. Similar to the Declaration, referrals alone do not trigger OIG exclusion or establish the relevant standard of care. Under 42 C.F.R. § 1001.701, OIG's permissive exclusion authority preserves its discretion to accept, reject, or prioritize referrals as it sees fit.

Plaintiffs' challenges based on Medicaid state plans and 42 U.S.C. § 1396a(a)(23)(A)'s free-choice-of-provider provision are also not ripe for judicial review because they rest on speculative effects of the Kennedy Declaration that have not occurred. Plaintiffs do not allege—because they cannot—that CMS has disapproved any state plan amendment, refused payment under any state plan, or terminated funds to the Plaintiff States for noncompliance with the

Kennedy Declaration. Nor has any beneficiary been denied the free choice of provider based on the Kennedy Declaration because OIG has not excluded any providers. *See* Penezic Decl. ¶ 4.

Even if OIG were to begin exclusion proceedings against an individual or entity in one of the Plaintiff states, or CMS were to disapprove of a state plan amendment or refuse payment under an approved state plan—neither of which have happened—OIG and CMS have a statutory and regulatory administrative process that must be exhausted. *See* 42 U.S.C. § 405(g); *see also* 42 U.S.C. § 1396c; 42 C.F.R. §§ 430.15–18; *Glob. Rescue Jets, LLC v. Kaiser Found. Health Plan, Inc.*, 30 F.4th 905, 913 (9th Cir. 2022) ("Exhaustion is generally required as a matter of preventing premature interference with agency processes, so that the agency may function . . . .") (quoting *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975)). As explained above, the Kennedy Declaration does not disrupt OIG's or CMS's regulatory processes, nor is it binding in those proceedings or dispositive of any issues in those proceedings.

Plaintiffs, moreover, have not shown "that postponing review imposes a hardship on them 'that is immediate, direct, and significant.'" *Colwell*, 558 F.3d at 1128 (quoting *Mun. of Anchorage v. United States*, 980 F.2d 1320, 1324–25 (9th Cir. 1992)). Instead, Plaintiffs challenge the non-binding Kennedy Declaration in the abstract, detached from any scenario in which OIG has relied on it to exclude a practitioner from FHCPs. Simply put, Plaintiffs seek an improper advisory opinion from the Court about whether OIG or CMS might, in a hypothetical future exclusion proceeding, misapply or improperly rely on the Kennedy Declaration. *Sierra Club v. Morton*, 405 U.S. 727, 732, n.3 (1972) ("Congress may not confer jurisdiction on Art. III federal courts to render advisory opinions."); *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 809-12 (2003) (holding hardship prong was not satisfied where plaintiffs challenged general statement of policy that was not yet applied to them).

Because Plaintiffs' claims rest on speculation about "contingent future events that may not occur as anticipated, or indeed may not occur at all," their claims are unripe. *See* *Texas*, 523 U.S. at 300. The Court thus lacks jurisdiction.

B. The Kennedy Declaration is not final agency action subject to judicial review under the APA.

"The APA sets forth the procedures by which federal agencies are accountable to the public and their actions are subject to review by the courts." *Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992). The APA provides for judicial review of only "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704; *see also* *Gill v. U. S. Dep't of Just.*, 913 F.3d 1179, 1184 (9th Cir. 2019). Final agency action must (1) "mark the consummation of the agency's decisionmaking process," and (2) "be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (citation omitted); *see also* *Franklin*, 505 U.S. at 797 ("The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties.").

"The bite in the phrase 'final action' . . . is not in the word 'action,' which is meant to cover comprehensively every manner in which an agency may exercise its power." *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 478 (2001) (citations omitted). "It is rather in the word 'final,' which requires that the action under review 'mark the consummation of the agency's decisionmaking process.'" *Id.* (quoting *Bennett*, 520 U.S. at 177–178). Only if the agency "has rendered its last word on the matter" is the action reviewable under the APA as final. *Harrison v. PPG Indus., Inc.*, 446 U.S. 578, 586 (1980).

Plaintiffs' challenge to the Kennedy Declaration fails both prongs of the test for final agency action. First, the Kennedy Declaration does not "mark the consummation of the agency's decisionmaking process," either with respect to the applicable standard of care or to exclusion more generally. *See* *Bennett*, 520 U.S. at 178. As discussed, the Kennedy Declaration reflects only the Secretary's non-binding opinion on the safety and efficacy of the identified pediatric and adolescent treatment modalities. The Declaration does not establish the standard of care, and it "does not constitute a determination that any individual or entity should be excluded from participation in any Federal health care program" for providing these treatments. Kennedy Decl. § V. Rather, as explained in the applicable regulations referenced in the Declaration, OIG must consider information from a variety of sources when determining whether a practitioner has furnished services that fall below professionally recognized standards of care and whether to exercise its discretion to exclude the practitioner from FHCPs. Those sources include Quality Improvement Organizations for the area served by the practitioner, state or local licensing or certification authorities, state and local professional societies, private insurance companies, and any other sources deemed appropriate by the OIG, such as the Kennedy Declaration and the "state law[s]" and "practice guidelines [of] relevant professional associations," referenced by Plaintiffs, Pls.' Br. at 13. *See* 42 C.F.R. § 1001.701(b). OIG also must consider any documentary evidence and written argument submitted by the practitioner. 42 C.F.R. § 1001.2001(a). Indeed, Plaintiffs admit that "[t]his process exists to develop facts," Pls.' Br. at 8, including whether a service meets professionally recognized standards of care. Because OIG independently decides through its required regulatory and administrative process whether services fall below "professionally recognized standards of health care," and whether a practitioner providing substandard care should

be excluded, the Declaration did not render HHS's "last word on the matter." *Harrison*, 446 U.S. at 586.

Second, the Declaration does not determine rights or obligations, and no legal consequences flow from it. As discussed, the Secretary's non-binding policy view expressed in the Declaration is not a "definitive statement" on the standard of care applicable in OIG exclusion proceedings; it merely "represents a threshold determination that further inquiry is warranted." *See FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 241 (1980). The Declaration does not impose any binding legal obligations on practitioners or OIG. Rather, OIG must make "a separate determination under 42 C.F.R. § 1001.701," that a practitioner has furnished services that fall below professionally recognized standards of care, and that separate and independent determination "is subject to further administrative and judicial review under 42 C.F.R. §§ 1001.2007." Kennedy Decl. § V. Only after the conclusion of that process would a practitioner be subject to any legal consequences, and those consequences would not stem from the Declaration but rather the separate administrative process itself.

The Kennedy Declaration neither "mark[s] the "consummation of the agency's decisionmaking process" nor is it agency action "by which rights or obligations have been determined, or from which legal consequences will flow." *See Bennett*, 520 U.S. at 178. It is thus not reviewable under the APA as final agency action. *See* 5 U.S.C. § 704.

2. Plaintiffs' claims fail on the merits.

The Court need not, and should not, reach the merits of this case given the dispositive threshold defects discussed above. However, even if the Court concludes that this case is ripe and the Kennedy Declaration is final agency action, Plaintiffs' claims fail on the merits. The Kennedy Declaration is exempt from the APA's notice-and-comment requirements as a general statement

of policy, 5 U.S.C. § 553(b)(A), and is not subject to the Medicare statute's notice-and-comment requirements because it does not "establish[] or change[] a substantive legal standard," *see* 42 U.S.C. § 1395hh(a)(2). Additionally, the Kennedy Declaration does not exceed the Secretary's statutory authority because the Secretary does not exercise the authority Plaintiffs allege. It also does not alter or change Medicaid state plans and Plaintiffs cannot enforce 42 U.S.C. § 1396a(a)(23)'s free-choice-of-provider provision, which is a requirement on states, against the federal government.

A. The Kennedy Declaration is exempt from the APA's notice-and-comment requirements as a general statement of policy.

The APA's notice-and-comment procedures do not apply to every agency pronouncement. *See Rank v. Nimmo*, 677 F.2d 692, 698 (9th Cir. 1982) ("[N]ot all agency policy pronouncements which find their way to the public can be considered regulations enforceable in a federal court." (quoting *Chasse v. Chasen*, 595 F.2d 59, 62 (1st Cir. 1979))). In particular, the APA explicitly exempts "general statements of policy" from its notice-and-comment requirements. *See* 5 U.S.C. § 553(b)(4)(A). Unlike legislative rules, general statements of policy "do not have the force and effect of law." *Gill*, 913 F.3d at 1186 (quoting *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995)).

General statements of policy are "statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Lincoln v. Vigil*, 508 U.S. 182, 197 (1993) (citation omitted); *see also Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979) (citing Attorney General's Manual on the Administrative Procedure Act 30 n.3 (1947)). To qualify under the "general statement of policy exception," the agency action must (1) "operate only prospectively," and (2) "must not establish a binding norm or be finally

determinative of the issues or rights to which they are addressed, but must instead leave [agency] officials free to consider the individual facts in the various cases that arise." *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1014 (9th Cir. 1987) (citation modified). "The critical factor to determine whether a directive announcing a new policy constitutes a legislative rule or a general statement of policy is the extent to which the challenged directive leaves the agency, or its implementing official, free to exercise discretion to follow, or not to follow, the announced policy in an individual case." *Gill*, 913 F.3d at 1186 (citation modified).

When determining whether an agency statement qualifies for a § 553 exemption, the Ninth Circuit "focuse[s] upon the effect of the regulation or directive upon agency decisionmaking, not the public at large." *Mada-Luna*, 813 F.2d at 1016 (collecting cases). "Simply because agency action has substantial impact does not mean it is subject to notice and comment if it is otherwise expressly exempt under the APA." *Alcaraz v. Block*, 746 F.2d 593, 613 (9th Cir. 1984) (citations omitted); *Mada-Luna*, 813 F.2d at 1016 n.11 (acknowledging that broad application of a substantial impact test "could well obliterate much of the 'general statement of policy' exception" and concluding "that Congress could not have intended such a result"); *see also Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council*, 435 U.S. 519, 524 (1978) (admonishing that courts should not impose procedural requirements upon agencies beyond those expressly provided in the APA). "In such cases, Congress has determined that notice-and-comment rulemaking would be of limited utility, . . . and parties can challenge the policy determinations made by the agency only if and when the directive has been applied specifically to them." *Mada-Luna*, 813 F.2d at 1013 (internal citations omitted).

The Kennedy Declaration is exempt from the APA's notice-and-comment requirements as a general statement of policy. It "operate[s] only prospectively," *see id.*, because it does not

evaluate past conduct, make findings about any specific entity or provider, apply facts to a regulatory standard, or trigger any enforcement consequences. Instead, it expresses the Secretary's non-binding policy view on specific treatment modalities.

The Kennedy Declaration does not "establish a binding norm" and is not "finally determinative of the issues or rights" it addresses. *Id.* at 1014 (citation modified). Instead, OIG is "free to exercise discretion to follow, or not to follow, the announced policy in an individual case." *See Gill*, 913 F.3d at 1186. As discussed, the Kennedy Declaration does not bind OIG to predetermined outcomes either when determining whether services fail to meet professionally recognized standards of care or when exercising its permissive exclusion authority. In other words, OIG is "free to consider the individual facts in the various cases that arise," *Mada-Luna*, 813 F.2d at 1014 (citation modified), including all the sources of information identified in the applicable regulations and any information submitted by a practitioner. Similarly, as explained above, ALJs are not in any way bound by the policy views expressed in the Declaration. The Kennedy Declaration thus is a general statement of policy. *See id.* at 1013 ("To the extent that the directive merely provides guidance to agency officials in exercising their discretionary powers while preserving their flexibility and their opportunity to make individualized determinations, it constitutes a general statement of policy." (citation modified)). It is exempt from the APA's notice-and-comment requirements.

Plaintiffs contend that the Kennedy Declaration functions like a legislative rule because it identifies certain treatment modalities as failing to meet professionally recognized standards of care and, in their (incorrect) view, thereby triggers automatic exclusion from FHCPs or a violation of provider participation agreements. Pls.' Br. at 36–38. Plaintiffs rely on *Hemp Indus. Ass'n v. Drug Enft Admin.*, 333 F.3d 1082, 1084, 1088 (9th Cir. 2003), which held that a DEA rule banning

the sale of certain hemp products constituted a legislative rule because it imposed legal obligations directly on third parties, creating new rights and obligations. Plaintiffs' reliance is misplaced.

Unlike the rule in *Hemp Indus.*, the Kennedy Declaration does not create or establish the legal authority to exclude providers; an independent statutory basis already exists. Before the Declaration was issued, Congress had already empowered OIG to exclude providers for furnishing services that fail to meet professionally recognized standards of care. 42 U.S.C. § 1320a-7(b)(6). The Declaration does not trigger exclusion because it is not dispositive of the standard of care applicable in OIG exclusion proceedings and is instead only one piece of information OIG may consider. *See* Penezic Decl. ¶¶ 8, 10. Nor does it eliminate any procedural safeguards, as any attempt by OIG to exclude a practitioner would be subject to multiple layers of administrative (and judicial) review during which a practitioner can present evidence and argument. Because any consequences are contingent, discretionary, and procedurally filtered, the Declaration does not operate of its own force. *Contra* *Hemp Indus.*, 333 F.3d at 1084, 1088.

Plaintiffs also assert that the Declaration constitutes a legislative rule because it unilaterally reverses HHS's past practice of reimbursing the types of care identified in the Kennedy Declaration. *See* Pls.' Br. at 37–38. Their argument misunderstands both the law and the purpose and effect of the Declaration. The Kennedy Declaration does not change obligations of individuals or entities—they have always risked exclusion from FHCPs if they provide services that fail to meet professionally recognized standards of care. 42 U.S.C. § 1320a-7. And prior reimbursement of specific services does not transform the nonbinding opinion expressed in the Kennedy Declaration into a legislative rule. Prior reimbursement reflects only that OIG and CMS have not made a determination that these services warrant exclusion or that they fail to meet the requirements for reimbursement. It does not create a legal right to continue performing services

without risk of review under the relevant statutory criteria. The fact that OIG has not historically excluded practitioners who furnish these services also does not transform the Declaration's policy statement into a legislative rule—but it does further support the lack of ripeness here. *See* Gill, 913 F.3d at 1186 ("That a policy provides direction—where once there was none—does not automatically transform it into a legislative rule.") (citation modified).[1]

Because the Kennedy Declaration "operate[s] only prospectively," does not "establish a binding norm," and is not "finally determinative of the issues or rights" it addresses, *Mada-Luna*, 813 F.2d at 1013, it is exempt from the APA's notice-and-comment requirements as a general statement of policy.

B. The Kennedy Declaration is not subject to the Medicare statute's notice and comment requirements because it does not establish or change a substantive legal standard.

The Medicare statute's notice and comment requirements are not coextensive with the APA's. *See, e.g.*, *Azar v. Allina Health Servs.*, 587 U.S. 566, 579 (2019) *(Allina II)* (holding that the Medicare statute does not "borrow[] the APA's interpretive-rule exception"). The Medicare statute requires notice and comment rulemaking when the agency promulgates a (1) "rule, requirement, or other statement of policy"; (2) "that establishes or changes a substantive legal standard"; (3) "governing . . . the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services." 42 U.S.C. § 1395hh(a)(2).

Courts evaluating whether agency action "establishes" or "changes" a "substantive legal standard" under the Medicare statute apply the ordinary meaning of those terms. *See, e.g.*, *Agendia,*

[1] The Court need not (and should not) address Plaintiffs' arguments regarding rescission of the Richardson Waiver. *See* Pls.' Br. at 38–39. The Richardson Waiver relates to the notice and comment exemption for rules "relating to agency management or personnel or to public property, loans, grants, benefits, or contracts," 5 U.S.C. § 553(a)(2), and Defendants do not rely on that exemption here.

Inc. v. Becerra, 4 F.4th 896, 899 (9th Cir. 2021); *Allina Health Servs. v. Price*, 863 F.3d 937, 943 (D.C. Cir. 2017) *(Allina I)*, *aff'd sub nom. Allina II*, 587 U.S. 566 (citing Black's Law Dictionary to define a "substantive legal standard" under the Medicare statute to include "at a minimum . . . a standard that creates, defines, and regulates the rights, duties, and powers of parties"). In this context, the Ninth Circuit adopted a definition for "establish," which means "[t]o make or form; to bring about into existence." *Agendia*, 4 F.4th at 900 (quoting Black's Law Dictionary (11th ed. 2019)). And a definition for "change," which means "[t]o substitute one thing for (another); to replace (something) with something else." *Id.* (quoting Oxford English Dictionary Online). Ultimately, this inquiry asks whether the agency has created new binding criteria or altered existing ones—not whether the agency's evaluative judgment or enforcement priorities have shifted.

The Kennedy Declaration does not "establish" or "change" the "substantive legal standard" at issue in this case; nor could it, as that legal standard is provided by the statute, *i.e.*, services "which fail[] to meet professionally recognized standards of health care." 42 U.S.C. § 1320a-7(b)(6)(B); *see* 42 C.F.R. § 1001.701. Before the Kennedy Declaration was published, individuals and entities were already subject to OIG's permissive authority to exclude them from FHCPs if they furnished care falling below "professionally recognized standards." 42 U.S.C. § 1320a-7(b)(6)(B); 42 C.F.R. § 1001.701. And in the absence of the Declaration, individuals and entities would still be subject to OIG's permissive authority to exclude them from FHCPs if they furnish care falling below "professionally recognized standards." Thus, even if Plaintiffs were right (and they are not) that the Kennedy Declaration dispositively resolved the question of whether the identified pediatric and adolescent treatment modalities meet professionally recognized standards of care, that determination would not (and could not) establish or change the substantive legal standard found in the statute. Therefore, the Declaration does not establish or change a substantive

legal standard. *See* *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 357 (D.C. Cir. 2017) ("[I]t is clear that the Manual instructions constitute a policy statement for the same reason that they do not create or amend a substantive legal standard—they have no binding legal effect.").

The Ninth Circuit in *Agendia*, recently held that local coverage determinations did not establish or change a substantive legal standard because the governing statutory requirement—that Medicare cover only services that are "reasonable and necessary"—remained unchanged. 4 F.4th at 904–06. The local coverage determinations reflected the Medicare administrative contractor's "view of what qualifies as reasonable and necessary" and directly controlled that contractor's claim determinations at the initial level of claim reimbursement decisionmaking. *Id.* at 900. Although the local coverage determinations were not binding on the ALJ or administrative counsel "at the higher levels of administrative review," *id.* at 898, they "help[ed] adjudicators apply the reasonable and necessary standard to the facts of a claim." *Id.* at 902. In concluding that local coverage determinations did not establish or change a substantive legal standard so as to require notice and comment procedures, the court reasoned that, if the local coverage determinations "did not exist, Medicare contractors would still have an overarching duty to deny claims for items and services that are not 'reasonable and necessary,'" as required by the statute. *Id.* (quoting *Erringer v. Thompson*, 371 F.3d 625, 631 (9th Cir. 2004)).

The Kennedy Declaration does far less. Unlike local coverage determinations, the Kennedy Declaration does not control at the initial point of decisionmaking—or at any point in the administrative process for exclusion. If a determination that directly controls at the initial decisionmaking stage does not establish or change a substantive legal standard, *see* *Agendia*, 4 F.4th at 900, then a non-binding statement that merely articulates the Secretary's policy view cannot establish or change a substantive legal standard. Just like with local coverage

determinations, if the Kennedy Declaration did not exist, OIG would still have the permissive authority to exclude practitioners for providing services that fail to meet professionally recognized standards of health care. *See* 42 U.S.C. § 1320a-7(b)(6)(B); 42 C.F.R. § 1001.701.

Plaintiffs assert that the Kennedy Declaration amounts to a change in the substantive legal standard because, prior to its issuance, HHS reimbursed practitioners for providing the treatment modalities discussed in the Declaration. Pls.' Br. at 34. But this argument confuses the substantive legal standard "governing . . . the payment for services," with the substantive legal standard governing "eligibility of individuals, entities, or organizations to furnish . . . services," which the Medicare notice and comment provision itself signifies are two different substantive legal standards. 42 U.S.C. § 1395hh(a)(2).

Plaintiffs' reliance on *Allina II*, 587 U.S. 566, is misplaced. The *Allina II* Court expressly declined to determine whether the rule at issue "establishe[d] or change[d] a substantive legal standard" and explicitly limited its holding to "whether the Medicare Act borrows the APA's interpretive-rule exception," answering only that question in the negative. *Allina II*, 587 U.S. at 579; *see also Agendia*, 4 F.4th at 902 (recognizing that the *Allina II* Court "decid[ed] only that the § 1395hh notice-and-comment process does not contain the same exemption for interpretive rules as does the [APA], 5 U.S.C. § 553(b)"). *Allina II's* narrow holding is inapplicable here.

Ultimately, the "substantive legal standard" for exclusion is derived from the statute, which has always permitted OIG to exclude practitioners for providing services that fail to meet professionally recognized standards of care, 42 U.S.C. § 1320a-7. Because the Kennedy Declaration does not establish or change that substantive legal standard, section 1395hh(a)(2)'s rulemaking requirements do not apply.

C. The Kennedy Declaration does not exceed the Secretary's statutory authority.

Like their other claims, Plaintiffs' claim that the Kennedy Declaration exceeds statutory authority is premised on a misunderstanding of the purpose and effect of the Declaration. Plaintiffs contend that the Declaration exceeds statutory authority because "[n]o statute grants the Secretary of HHS authority to unilaterally declare . . . that providing [a treatment modality] is legally sufficient grounds for exclusion from" federal health care programs and the Medicare statute prohibits the federal government from exercising "supervision or control over the practice of medicine." Pls.' Br. at 14. But as explained above, the Declaration does not do either of those things.

The Secretary, just like anyone else, has the right to share his non-binding opinion on the safety and efficacy of certain pediatric and adolescent treatment modalities, based on an evaluation of the cited medical literature. Just as statements issued by private organizations and professional bodies, the Declaration communicates an evaluative judgment about the medical evidence; it does not, standing alone, prescribe conduct or determine legal consequences. *See, e.g.*, Am. Soc'y of Plastic Surgeons, *Position Statement on Gender Surgery for Children and Adolescents* (Feb. 3, 2026), https://www.plasticsurgery.org/documents/health-policy/positions/2026-gender-surgery-children-adolescents.pdf.

The Declaration expresses the Secretary's view that certain treatment modalities are not safe and effective and fail to meet professionally recognized standards of health care, but the Secretary's opinion is not binding on anyone. As the Declaration itself explains, it "does not constitute a determination that any individual or entity should be excluded from participation in any Federal health care program" for providing these treatments, and "[a]ny such determination

could only be made after a separate determination [by the HHS's Office of Inspector General (OIG)] under 42 C.F.R. § 1001.701." Kennedy Decl. § V. Although OIG may consider the views expressed in the Kennedy Declaration when determining whether a practitioner has furnished services of a qualify that fail to meet professionally recognized standards of care under 42 U.S.C. § 1320a-7(b)(6)(B), the Declaration is not dispositive and OIG is required by its regulations to consider information from numerous other sources as well, such as such as state and local professional societies, private insurance companies, and documentary evidence and written argument submitted by a practitioner. *See* Penezic Decl. ¶ 9. Thus, the Court need not decide whether the Secretary possesses the authority to unilaterally declare that provision of a particular treatment is legally sufficient grounds for exclusion or otherwise exercise supervision or control over the practice of medicine, because the agency action Plaintiffs challenge here does not claim any authority to do so and does not in fact do so. *See* *Sierra Club*, 405 U.S. at 732 n.3 ("Congress may not confer jurisdiction on Art. III federal courts to render advisory opinions.").

Plaintiffs note that the Declaration references and is "informed by" a definitional provision from OIG's regulations, Pls.' Br. at 18, which states that "[w]hen 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." 42 C.F.R. § 1001.2. But, as Plaintiffs acknowledge, that regulatory "provision merely refers to instances HHS or a component agency has exercised specific statutory authority to pronounce a treatment safe and effective." Pls.' Br. at 24; *see also* Penezic Decl. ¶ 6. And the Secretary does not purport to be exercising such specific statutory authority here. Nor does the non-binding Declaration supersede any statewide or national standards of care, Pls.' Br. 25. It merely explains the Secretary's opinion that "standards of care recommended by certain medical organizations are

unsupported by the weight of evidence and threaten the health and safety of children with gender dysphoria." Kennedy Decl. § I.D. The Declaration leaves it to OIG to determine, in accordance with applicable legal standards and regulatory processes, including consideration of multiple factors and evidence from multiple sources, whether the identified pediatric and adolescent treatment modalities meet professionally recognized standards of care and whether to exclude a practitioner who provides such treatments from federal health care programs. *See* Kennedy Decl. § V ("This declaration does not constitute a determination that any individual or entity should be excluded from participation in any Federal health care program. Any such determination could only be made after a separate determination under 42 C.F.R. § 1001.701, which is subject to further administrative and judicial review under 42 C.F.R. §§ 1001.2007, 1005.21. Before making any such determination, HHS will ensure compliance with applicable laws, regulations, court orders, and any required procedures.").

D. The Kennedy Declaration is not contrary to the Medicaid statute.

i. The Kennedy Declaration does not amend Medicaid state plans.

Plaintiffs' first Medicaid claim fails for the simple reason that the Kennedy Declaration does not "alter[] the terms of federally approved Medicaid state plans." *See* Pls.' Br. at 31. The Kennedy Declaration merely expresses the Secretary's non-binding opinion on the safety and efficacy of certain pediatric and adolescent treatment modalities. It is not dispositive of the applicable standard of care in any OIG exclusion proceedings, so it does not automatically "subject[] providers to exclusion from [FHCPs], including Medicaid, for providing" these treatments. *See* Pls.' Br. at 32. Nor does it displace CMS's statutory and regulatory process governing state plans or the procedures for amending state plans. *See* 42 U.S.C. § 1396c; 42 C.F.R.

§§ 430.15–430.18. Because Plaintiffs' claim rests on a misunderstanding of the purpose and effect of the Kennedy Declaration, it fails.

ii. Plaintiffs cannot enforce 42 U.S.C. § 1396a(a)(23)'s free-choice-of-provider provision against the federal government.

The Medicaid statute's free-choice-of-provider provision does not impose any duties on the federal government or confer upon Plaintiff States an enforceable right. Rather, 42 U.S.C. § 1396a(a)(23)(A) "speaks only to a State's duties to the federal government." *Medina*, 606 U.S. at 379. And just as that section does not clearly and unambiguously confer an individually enforceable right on beneficiaries against the states under 42 U.S.C. § 1983, *Medina*, 606 U.S. at 379, it does not clearly and unambiguously confer an enforceable right on states against the federal government. Plaintiffs therefore cannot enforce 42 U.S.C. § 1396a(a)(23)(A) against HHS.

In any event, Plaintiffs' claim fails. The Kennedy Declaration does not restrict beneficiaries' ability to obtain services from state-licensed and qualified providers under 42 U.S.C. § 1396a(a)(23) because the Declaration does not "constitute a determination that any individual or entity should be excluded from participation in [Medicaid]." Kennedy Decl. § V. Plaintiffs claim that the federal government cannot "override the Plaintiff States' decisions about what makes a provider qualified to provide medical services." Pls.' Br. at 34. Even if the Kennedy Declaration played some dispositive role in exclusion under 42 U.S.C. § 1320a-7—which it does not—states' primary role in determining provider qualifications would not constrain federal program-integrity enforcement. Instead, states' flexibility in designing their Medicaid programs and the Secretary's exclusion authority operate in parallel within the Medicaid framework. Within the parameters set by the Medicaid statute, states can determine which services they will cover and how those services are administered, *see, e.g.*, *Beal v. Doe*, 432 U.S. 438, 444 (1977); 42 U.S.C. § 1396a(a)(17), and

state law governs provider qualifications such as licensure and scope of practice, *Medina*, 606 U.S. at 364. At the same time, however, Congress clearly granted the Secretary the authority to exclude health care providers from participation in FHCPs for a wide range of misconduct, including, but not limited to, substandard care. 42 U.S.C. § 1320a-7(a), (b). There is no conflict between state plan coverage and exclusion, and principles of statutory interpretation require courts to construe statutory provisions "in harmony, not set them at cross-purposes." *Jones v. Hendrix*, 599 U.S. 465, 478, 143 (2023); *see also California v. Trump*, 963 F.3d 926, 944 (9th Cir. 2020) (collecting cases and acknowledging that statutory language is read in context). Thus, if a provider is excluded consistent with 42 U.S.C. § 1320a-7, that exclusion cannot violate the free choice of provider provision. Plaintiffs' claim is without merit.

V. Conclusion

For the foregoing reasons, Defendants respectfully request that the Court grant Defendants' motion to dismiss and dismiss this case in its entirety. In the alternative, the Court should deny Plaintiffs' motion for summary judgment and enter summary judgment in favor of Defendants.

Dated: February 10, 2026.

Respectfully submitted,

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