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UNITED STATES DISTRICT COURT
DISTRICT OF OREGON
EUGENE DIVISION

STATE OF OREGON, et al.,

Case No.: 6:25-cv-2409-MTK

Plaintiffs,

v.

DEFENDANTS' REPLY IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS
OR, IN THE ALTERNATIVE, FOR
SUMMARY JUDGMENT

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

Defendants.

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INTRODUCTION

Plaintiffs’ opposition confirms that all their claims rest on the same mistaken premise—that the Kennedy Declaration establishes a legally binding standard of health care that predetermines the outcome of OIG¹ exclusion proceedings. *See, e.g.*, Pls.’ Opp’n, ECF No. 77, at 25 (the Declaration “‘supersede[s]’ all contrary standards of care”); *id.* at 26 (the Declaration “render[s] the exclusion of a provider a foregone conclusion”); *id.* at 29, 30, 32, 38 (similar). But, as Defendants explained in their opening brief, the Kennedy Declaration does neither.

Plaintiffs can continue to mischaracterize the Kennedy Declaration only by ignoring its explicit disclaimer and the OIG declaration Defendants submitted with their opening brief. The Kennedy Declaration expressly disclaims that it has any independent legal effect by stating:

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.

Kennedy Decl. § V. And the OIG declaration confirms that the Kennedy Declaration (1) “does not bind OIG’s enforcement discretion”; and (2) “alone is not dispositive of ‘professionally recognized standards of health care’ applicable in OIG exclusion proceedings under 42 C.F.R. § 1001.701(a)(2).” Penezic Decl., ECF No. 75, ¶¶8, 12. Rather, “OIG conducts all exclusion matters in accordance with applicable statutory and regulatory authorities,” and the Kennedy Declaration is only one piece of information OIG may consider in any exclusion proceeding. *Id.* ¶¶3, 10.

¹ Acronyms are used as defined in Defendants’ opening brief. *See* Defs.’ Mot., ECF No. 73.

Plaintiffs’ theory of harm rests on generalized uncertainty and perceived risk tied to the federal government’s overall posture towards certain treatment modalities for children, but they identify no independent legal effect, binding obligation, or exclusion action arising from the Kennedy Declaration itself. Indeed, they concede that “sharing an opinion” like Secretary Kennedy has done in the Declaration “requires no grant of authority.” *See* Pls.’ Opp’n at 17. And they essentially concede that their case fails if Defendants are right about the Declaration’s purpose and effect, devoting less than one page of their opposition to the half-hearted claim that they are entitled to summary judgment if the Kennedy Declaration is not determinative of the standard of care or any exclusion determination. *See* Pls.’ Opp’n at 28. Because Plaintiffs’ claims hinge on an incorrect view of the Kennedy Declaration’s purpose and effect, the Court should dismiss this case in its entirety for lack of jurisdiction or enter summary judgment in favor of Defendants.

ARGUMENT

I. Plaintiffs fail to demonstrate that their claims are ripe for judicial review.

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 ripeness doctrine is designed to prevent courts from adjudicating precisely the type of speculative theory on which Plaintiffs’ claims depend. [*Nat’l Park Hosp. Ass’n v. Dep’t of Interior*, 538 U.S. 803, 807–08 \(2003\)](#) (noting the ripeness doctrine prevents premature adjudication and judicial interference until agency action is final and “its effects felt in a concrete way by the challenging parties”). Plaintiffs’ challenges to the Kennedy Declaration rest on a series of contingencies that have not occurred and may never occur because the Kennedy Declaration does not have any legal effect and whether any practitioners are excluded from federal health care programs depends on independent and speculative future exercises of OIG’s discretionary enforcement authority.

Plaintiffs allege two harms from the Kennedy Declaration: (1) “providers that refuse to comply with the Declaration risk exclusion from Medicaid,” which would allegedly “disrupt[] the Plaintiff States’ Medicaid provider networks”; and (2) injury to “Plaintiff States’ sovereign interest in the regulation in the practice of medicine.” Pls.’ Opp’n at 22. Neither establishes constitutional or prudential ripeness.

Plaintiffs first claim that “[a] number of providers in the Plaintiff States have already sought to insulate themselves from the risk of exclusion” by ceasing certain health care services for minors. *Id.* But Plaintiffs have not shown that these voluntary actions were taken in response to the Kennedy Declaration, as opposed to other government action(s) or the broader policy objectives of the Trump Administration. And even if they were, they would not be sufficient to establish ripeness because the Declaration is not dispositive of the standard of care applicable in OIG exclusion proceedings and, as Plaintiffs concede, *see id.* at 20, it does not determine that any provider should be excluded, *see [Clapper v. Amnesty Int’l USA](#), 568 U.S. 398, 416 (2013)* (“[R]espondents cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending.”); *[Colwell v. Dep’t of Health & Hum. Servs.](#), 558 F.3d 1112, 1128 (9th Cir. 2009)* (noting that “hardship,” for purposes of ripeness, “does not mean just anything that makes life harder; it means hardship of a legal kind . . .” (citation omitted))).

Plaintiffs’ own evidence demonstrates that provider changes in practice are motivated by concerns about the broader policy objectives of the Trump Administration, rather than the Kennedy Declaration, citing, for example, the “current regulatory environment” and the general “increase in federal actions.” *See, e.g.*, ECF No. 83-20 at 2 (citing a general “increase in federal actions directed at health systems like ours that provide this care”); ECF No. 83-18 at 2 (noting

that NYU Langone closed its youth medical program “after the Trump administration in December proposed rules that would pull federal dollars from any hospital that provides gender transition treatments for adolescents” and that NYU Langone’s spokesman stated that its decision was based on “the recent departure of [its] medical director, coupled with the current regulatory environment”); ECF No. 83-21 at 3 (discussing Children’s Wisconsin and UW Health who “have stopped providing gender-affirming care treatments to minors, citing recent federal policy changes,” and noting how “[t]he moves come after the Trump administration last month announced plans to block all Medicaid and Medicare funding for any services at hospitals that provide gender-affirming care to minors”); ECF No. 83-23 at 5 (reporting that “a spokesperson for [Washington] state Attorney General Nick Brown’s office” stated that “Brown’s office is less certain about how or when Kennedy’s declaration might be applied,” and “will likely know more about the declaration’s application next week, when the federal government is expected to file its brief”); ECF No. 83-24 at 2–3 (discussing one of President Trump’s executive orders and noting that some hospitals and health systems have stopped providing hormones and puberty blockers to minors “in the wake of federal rules proposed in December that would withhold Medicare and Medicaid funding from clinics that continue pediatric care for transgender people”).

In fact, a number of these voluntary actions predate the Kennedy Declaration. For example, Tacoma Children’s Hospital “ceas[ed] accepting new patients” and “issuing prescriptions” starting September 12, 2025—more than three months before the Kennedy Declaration was announced. *See* ECF No. 83-22 at 2; *see also, e.g.*, ECF No. 83-18 at 3 (“A year ago, following an executive order by President Trump that took aim at gender-related treatment for minors, NYU Langone stopped accepting new patients into its transgender youth medicine program. It also canceled appointments for new patients who were scheduled to receive implants that release puberty-

blocking medication.”); ECF No. 83-19 at 2 (“DenverHealth stopped performing gender-affirming surgeries in early 2025.”).

Tellingly, absent from any of the declarations Plaintiffs submitted in support of their claims is any evidence that these facilities would resume providing this care to minors if the Kennedy Declaration were set aside. *See* ECF Nos. 33–42, 44–59, 62, 78–83 (Plaintiffs’ Declarations). That omission closes the loop on Plaintiffs’ theory of harm and confirms that the Kennedy Declaration is not the source of Plaintiffs’ alleged injuries or hardship.

Plaintiffs’ alleged harm to the Plaintiff States’ “sovereign interest in the regulation of the practice of medicine,” Pls.’ Opp’n at 22, fails for the same reason their prudential ripeness arguments fail. Plaintiffs assert their claims are prudentially ripe because they raise purely legal challenges that “do not depend on any facts that could be developed in any specific exclusion proceeding brought against a particular hospital or doctor,” and that “withholding judgment would subject Plaintiff States to serious hardship” because “Plaintiff States’ Medicaid programs and sovereign interests are being impaired *right now*.” *Id.* at 23 (emphasis in original). But Plaintiffs’ claims do not raise purely legal issues divorced from factual context. Under applicable 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 OIG’s discretion to exclude the practitioner from federal health care programs. *See* 42 C.F.R. § 1001.2001(b). The Secretary’s non-binding opinion expressed in the Declaration is only one piece of information OIG may consider in any exclusion proceedings. Penezic Decl. ¶¶8, 10. Thus, even if OIG did initiate an exclusion proceeding (which it has not), any use of the Kennedy Declaration would occur only

inside a formal exclusion proceeding with a regulatory administrative process and procedural protections, including judicial review. And, at this point, the outcome of any such proceeding is unknown (and unknowable). The mere potential for future exercise of discretionary enforcement authority does not present a ripe controversy. See [*Texas v. United States*, 523 U.S. 296, 300 \(1998\)](#) (“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.” (citation omitted)); [*Trump v. New York*, 592 U.S. 125, 131 \(2020\)](#) (“Any prediction how the Executive Branch might eventually implement this general statement of policy is no more than conjecture at this time.” (citation omitted)).

Plaintiffs cite [*Erickson v. U.S. ex rel. Dep’t of Health & Hum. Servs.*, 67 F.3d 858 \(9th Cir. 1995\)](#), in an attempt to discount the relevance of OIG’s regulatory process. Pls.’ Opp’n at 23–24. But *Erickson* involved a mandatory exclusion under 42 U.S.C. § 1320a–7(a)(1), where HHS had a “statutory duty” imposed by Congress to exclude a provider that was “convicted of program fraud.” [67 F.3d at 860](#). As a result, the provider’s double jeopardy argument was “not collateral to the [provider’s] claim that they cannot be excluded” to warrant the district court’s judicial waiver of the exhaustion of administrative remedies requirement. [Id. at 864](#). But see [*Winter v. California Med. Rev., Inc.*, 900 F.2d 1322, 1326 \(9th Cir. 1989\)](#) (providing a mechanism for waiver of the exhaustion of administrative remedies requirement before district court judicial review under 42 U.S.C. § 405(g)). Any suggestion that an individual or entity subject to a standard-of-care exclusion proceeding would not have the opportunity for proper administrative or judicial review is simply wrong.

II. Plaintiffs fail to establish that the Kennedy Declaration constitutes final agency action.

The Kennedy Declaration is not final agency action. It does not “mark the consummation of the agency’s decisionmaking process,” nor does it “determine[] rights or obligations” or have

“legal consequences,” either with respect to the applicable standard of care or to exclusion more generally. See Bennett v. Spear, 520 U.S. 154, 178 (1996). On its face, the Declaration explains how it is “tentative” and not HHS’s “last word on the matter.” See Or. Nat. Desert Ass’n v. U.S. Forest Serv., 465 F.3d 977, 984 (9th Cir. 2006). Plaintiffs’ arguments to the contrary ignore the portion of the Declaration that states:

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.

Kennedy Decl. § V (emphasis added).

Plaintiffs conflate the firmness of the Secretary’s views on the safety and efficacy of these treatment modalities with the finality of agency action. The relevant decisionmaking process here is not the Secretary’s formulation of an opinion after reviewing the cited medical literature, *contra* Pls.’ Opp’n at 25–26, but rather OIG’s decision to exclude an individual or entity under 42 C.F.R. Part 1001. Only the latter decision determines rights and carries legal consequences, and as Defendants explained in their opening brief and supporting OIG declaration (the latter of which Plaintiffs largely ignore), the Kennedy Declaration is not dispositive of the standard of care applicable in OIG exclusion proceedings or exclusion more generally. Penezic Decl. ¶¶8, 12.

If OIG decides to initiate a standard-of-care exclusion proceeding against an individual or entity based on the type of care described in the Kennedy Declaration, that proceeding would require OIG to decide—by itself, for the first time—whether the provider has furnished services that fail to meet “professionally recognized standards of care.” OIG makes that determination through the required adjudicatory process using the factors listed in 42 C.F.R. § 1001.701(b).

The Kennedy Declaration does not “predetermine the result of an exclusion proceeding,” “‘supersede’ all contrary standards of care,” or “render the exclusion of a provider a foregone conclusion.” *Contra* Pls.’ Opp’n at 25–26. By its terms, the regulatory exclusion process requires OIG to consider information from multiple sources, as well as evidence submitted by a practitioner, and any other sources deemed appropriate by OIG, such as statewide standards, before determining whether the practitioner has furnished services that fall below “professionally recognized standards of health care” and whether to exercise OIG’s discretion to exclude that practitioner. *See* 42 C.F.R. § 1001.701(b); *id.* §§ 1001.2001(a), (b); *id.* § 1001.2; *see also* Penezic Decl. ¶10 (explaining that the Kennedy Declaration “is only one factor that OIG may consider in any exclusion proceeding”). Such a decision is then subject to review by an Administrative Law Judge, 42 C.F.R. § 1001.2007(a)(1), and the Departmental Appeals Board, *id.* § 1005.21, and to judicial review in federal district court. *See e.g., id.*; 42 U.S.C. § 405(g). Plaintiffs seek a shortcut around these regulatory-prescribed agency decision points, but that’s not how the APA works. The governing regulations confirm that the Kennedy Declaration is not HHS’s “last word on the matter” so as to constitute final agency action. *See [Harrison v. PPG Indus., Inc.](#), 446 U.S. 578, 586 (1980).*

Plaintiffs’ reliance on referrals to suggest there is final agency action is unavailing. Referrals may be one way that OIG decides to initiate an exclusion investigation, but they do not determine rights or impose obligations. OIG could receive referrals from any source, and HHS personnel represent only one of many potential referral pathways. Setting aside the Kennedy Declaration would not (and could not) rescind any referral or otherwise limit OIG’s ability to receive new exclusion referrals. Moreover, an exclusion referral reflects only the referrer’s view. OIG retains discretion whether to act on any referral, and OIG must still conduct an independent,

case-specific analysis under the applicable exclusion regulations before taking any action. Penezic Decl. ¶11. Because referrals neither bind OIG nor produce legal consequences, they provide no basis for treating the Kennedy Declaration as final agency action. Indeed, if anything, the referrals confirm that the Kennedy Declaration does not dictate enforcement outcomes, as they indicate that certain providers were referred “for investigation.” *See, e.g.*, ECF No. 83-2 at 2. An “investigation” would serve no purpose if the agency’s decisionmaking process had already been completed or if the outcome were predetermined, as Plaintiffs suggest.

The fact that the Declaration “includes HHS’s seal” and states that it “is issued pursuant to the authority vested in the HHS Secretary” also does not render it final agency action. *Contra* Pls.’ Opp’n at 17. “It is the effect of the action and not its label that must be considered,” [*Abramowitz v. U.S. E.P.A.*, 832 F.2d 1071, 1075 \(9th Cir. 1987\)](#) (superseded by statute on other grounds), and “finality is to be interpreted ‘in a pragmatic way,’” [*Oregon v. Ashcroft*, 368 F.3d 1118, 1147 \(9th Cir. 2004\)](#) (quoting [*Abbott Labs. v. Gardner*, 387 U.S. 136, 149–50 \(1967\)](#)). The Kennedy Declaration has no legal effect. And pragmatically, it only expresses the Secretary’s non-binding opinion on the safety and efficacy of certain pediatric and adolescent treatment modalities, based on his review of the cited medical literature.

Similarly, Secretary Kennedy’s statements at a press conference do not cause the Kennedy Declaration to have a legally binding effect. Like anyone else, Secretary Kennedy “can share [his] views freely and criticize particular beliefs, and []he can do so forcefully in the hopes of persuading others to follow [his] lead.” [*Nat’l Rifle Ass’n of Am. v. Vullo*, 602 U.S. 175, 187 \(2024\)](#); *see also*, *e.g.*, [*Snyder v. Phelps*, 562 U.S. 443, 451–52 \(2011\)](#) (“Speech on matters of public concern is at the heart of the First Amendment’s protection.” (citation modified)). Accordingly, Secretary Kennedy coupled his Declaration with a plea to medical providers to “follow the science and the

overwhelming body of evidence that these procedures hurt—not help—children.” ECF No. 83-27. His words were not a mandate to follow the Declaration, nor did they give any legally binding effect to the Declaration. They were a plea to providers to follow the science and the evidence. Because the Kennedy Declaration has no legal effect, all its invalidation would do is interfere with Secretary Kennedy’s right to express his views.

III. Plaintiffs fail to show that the Kennedy Declaration required notice-and-comment rulemaking.

A. The Kennedy Declaration is a general statement of policy.

The Kennedy Declaration does not “establish a binding norm” and is not “finally determinative of issues or rights.” [*Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1014 \(9th Cir. 1987\)](#) (citation modified). It neither binds OIG to predetermined outcomes nor displaces the applicable regulations. Not only is OIG “free to consider the individual facts in the various cases that arise,” [*id.*](#) (citation modified), but the applicable regulations require OIG to do so. The Kennedy Declaration thus is exempt from the APA’s notice-and-comment requirements as a general statement of policy.

Plaintiffs contend that the Kennedy Declaration is a legislative rule because it “purports” to “create a substantive legal standard.” *See* Pls.’ Opp’n at 32. This argument mistakenly equates the firmness of the Secretary’s opinion expressed in the Declaration with legal force. A statement does not become legislative merely because it asserts a policy position; it becomes legislative only if it alters governing law or binds agency decisionmaking. *See, e.g., Gill v. U. S. Dep’t of Just.*, [913 F.3d 1179, 1184 \(9th Cir. 2019\)](#) (“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.” (citation

modified)). The Kennedy Declaration does not alter the governing law, which remains the standard set forth in 42 U.S.C. § 1320a-7(b)(6)(B) (services “which fail[] to meet professionally recognized standards of health care”), or the regulatory process that controls OIG’s exclusion determinations in 42 C.F.R. § 1001.701(b). Nor does the Declaration bind agency decisionmakers in that regulatory process. Penezic Decl. ¶10 (stating the Kennedy Declaration “is only *one factor* that OIG *may* consider” (emphasis added)). The Kennedy Declaration also does not bind OIG to predetermined outcomes, either when determining whether services fail to meet “professionally recognized standards of health care” or when exercising OIG’s permissive exclusion authority. *Id.* at ¶¶8, 12. Not only is OIG “free to consider the individual facts in the various cases that arise,” [*Mada-Luna*, 813 F.2d at 1014](#) (citation modified), but as discussed, the applicable regulations require it.

Plaintiffs’ arguments to the contrary ignore the Declaration’s explicit disclaimer, *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.”), as well as the declaration OIG submitted in this case, *see* Penezic Decl. ¶¶8, 12 (explaining the Kennedy Declaration (1) “does not bind OIG’s enforcement discretion”; and (2) “alone is not dispositive of ‘professionally recognized standards of health care’ applicable in OIG exclusion proceedings under 42 C.F.R. § 1001.701(a)(2)”). The fact that some state Medicaid directors misunderstood the Kennedy Declaration, *see* Pls.’ Opp’n at 18 n.12, does not provide a basis to discount the declaration provided by OIG’s Branch Chief, who is “responsible for supervising/overseeing OIG’s affirmative enforcement activities, including exclusion matters.”

Penezic Decl. ¶1. A state court order cited by Plaintiffs is also not persuasive. *See* ECF No. 83-30. That state court expressly declined to speculate on the merits of the issues before this Court, *id.* at 22, and its decision was issued in a preliminary injunction posture without the benefit of briefing from the federal government, which was not a party. *See id.*

To accept Plaintiffs’ theory, the Court would have to conclude that the Declaration both rewrites the regulatory standard for “professionally recognized standards of health care” in 42 C.F.R. § 1001.2 and displaces the structured determination process prescribed by the exclusion regulations in 42 C.F.R. § 1001.701, despite the absence of any final agency action. Because the Kennedy Declaration 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](#) (citation modified), it is exempt from the APA’s notice-and-comment requirements as a general statement of policy.

B. The Medicare statute does not independently require notice-and-comment rulemaking.

The Kennedy Declaration “do[es] not create or amend a substantive legal standard” “for the same reason” that it does not “constitute[s] a policy statement—[it] has[] no binding legal effect.” *See* [*Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 357 \(D.C. Cir. 2017\)](#).

The Kennedy Declaration does not “establish” or “change” the relevant “substantive legal standard,” 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. The Kennedy Declaration does not amend the definition of “professionally recognized standards of health care” in 42 C.F.R. § 1001.2, change the substantive grounds for exclusion in 42 C.F.R. § 1001.701(a), or alter the evidentiary considerations in 42 C.F.R. § 1001.701(b). *See* discussion *supra* § II. In this regard, if the Kennedy Declaration did not exist, OIG would still have the statutory authority—the legality of which Plaintiffs do not challenge—

to exclude practitioners for furnishing services that fail to meet “professionally recognized standards of health care.” *See* 42 U.S.C. § 1320a-7(b)(6)(B); *see also* [*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 . . .”). And OIG would conduct that process in the exact same way using the applicable regulations. *See* 42 C.F.R. § 1001.701.

Plaintiffs fail to show how “even accepting Defendants’ characterization of the Kennedy Declaration as a mere statement of policy,” Pls.’ Opp’n at 30, it would still be subject to the Medicare statute’s notice-and-comment rulemaking requirements. Their only argument is that the Medicare statute’s rulemaking requirements would still apply because “the Declaration clearly establishes eligibility criteria to ‘furnish . . . services.’” *Id.* (omission in original). But Plaintiffs overlook the Medicare statute’s separate limitation that notice-and-comment is only required when agency action “establishes or changes a substantive legal standard.” 42 U.S.C. § 1395hh(a)(2). The Court need not even reach the question of whether the Kennedy Declaration “govern[s] . . . the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services,” 42 U.S.C. § 1395hh(a)(2), because it does not establish or change any “substantive legal standard.”

IV. Plaintiffs fail to show that the Kennedy Declaration exceeds statutory authority.

Plaintiffs’ statutory authority theory depends on the same false premise as their other claims—that the Kennedy Declaration dispositively declares a binding standard of care applicable to exclusion proceedings, Pls.’ Opp’n at 27, that “override[s] the standards of care applicable in the Plaintiff States,” and creates “a general prohibition on the practice of medically necessary transgender health care for adolescents,” *id.* at 38. But as explained, and as attested to by OIG, *see* Penezic Decl., the Declaration does none of those things.

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Plaintiffs essentially concede that if the Kennedy Declaration is not dispositive in an exclusion proceeding, then their claims fail. *See* Pls.’ Opp’n at 36. Plaintiffs admit that “sharing an opinion requires no grant of authority,” and that the Secretary could “open press conferences” or “publish op-eds” without a grant of authority. *Id.* at 17. The Kennedy Declaration, at bottom, is no different. Just like anyone else, Secretary Kennedy is entitled to articulate his opinion on the safety and efficacy of pediatric and adolescent treatment modalities for gender dysphoria, gender incongruence, or other related conditions without referencing statutory authority. Plaintiffs provide no explanation for why “a non-dispositive Declaration” expressing the Secretary’s opinion, which does not alter legal rights or obligations, would require a grant of statutory authority. *See id.* at 36; *supra* discussion § III.B.

Setting aside the Kennedy Declaration would interfere with Secretary Kennedy’s right to express his views on the safety and efficacy of emerging and controversial medical practices. There is a significant “public interest in having free and unhindered debate on matters of public importance.” [*Rosaura Bldg. Corp. v. Municipality of Mayaguez*, 778 F.3d 55, 66 \(1st Cir. 2015\)](#) (quoting [*Pickering v. Bd. of Educ.*, 391 U.S. 563, 573 \(1968\)](#)). And “the public expression of ideas may not be prohibited merely because the ideas are themselves offensive to some of their hearers.” [*Bachellar v. Maryland*, 397 U.S. 564, 567 \(1970\)](#) (citation omitted). Secretary Kennedy’s ideas about the safety and efficacy of certain pediatric and adolescent treatment modalities for gender dysphoria, gender incongruence, or other related conditions, are no exception, regardless of how strenuously Plaintiffs, or others, disagree with some of them.

V. Plaintiffs fail to establish that the Kennedy Declaration is contrary to the Medicaid statute.

Contrary to Plaintiffs’ argument, Pls.’ Opp’n at 34, the Plaintiff States have nothing to “reconcile” between their state’s Medicaid plans and the Kennedy Declaration because the Defendants’ Reply in Support of Motion to Dismiss or for Summary Judgment

Kennedy Declaration does not change any state plan or require the exclusion of any provider. 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 does not constrain federal program-integrity enforcement. If a provider were to be excluded for any reason consistent with 42 U.S.C. § 1320a-7, that exclusion would not violate the free choice of provider provision because the statutory provisions must be read harmoniously. *See Jones v. Hendrix*, 599 U.S. 465, 478 (2023) (“Basic principles of statutory interpretation require that we construe [provisions] in harmony, not set them at cross-purposes.”); *see also California v. Trump*, 963 F.3d 926, 944 (9th Cir. 2020) (collecting cases and acknowledging that statutory language is read in context). Plaintiffs’ Medicaid statute claims are without merit.

VI. The prohibition on “post hoc rationalizations” is irrelevant here.

Plaintiffs contend Defendants’ assertion that the Kennedy Declaration is a nonbinding opinion is merely a “litigation position” and constitutes an impermissible post hoc rationalization. Pls.’ Opp’n at 36; *see also id.* at 9, 17, 20. That argument is incorrect, as it ignores the Declaration’s explicit disclaimer. Kennedy Decl. § V. In any event, Plaintiffs misunderstand the doctrine.

The prohibition on “post hoc” rationalizations in the APA context arises when a court is called to decide “whether agency action was adequately explained.” *See Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020). It applies when an agency has taken final agency action and later attempts to defend the substance of the action on grounds that the agency did not itself articulate “contemporaneous” with the action taken. *Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2573 (2019). The doctrine ensures that courts review agency decisions based on the agency’s contemporaneous reasoning contained in the administrative record.

But here, even assuming the Declaration was final agency action, Plaintiffs do not challenge the adequacy of the Secretary’s explanation for his views on the safety and efficacy of Defendants’ Reply in Support of Motion to Dismiss or for Summary Judgment

the treatment modalities he discusses. Despite Plaintiffs’ assertion that Defendants “make no attempt to defend the terms of the Kennedy Declaration,” Pls.’ Opp’n at 20–21, Plaintiffs did not challenge the Secretary’s opinions expressed therein. Instead, they chose to forfeit the arbitrary and capricious claims raised in their complaint. *See* Pls.’ Am. Compl., ECF No. 28, at 34–35; Pls.’ Mot., ECF No. 32 (failing to raise arbitrary and capricious claim in motion for summary judgment). The prohibition on post hoc rationalizations prevents agencies from inventing new reasons to justify an agency decision; it does not prevent the government from explaining or clarifying the nature of an action. The doctrine thus has no application here.

VII. Any relief should be limited to the Kennedy Declaration.

Plaintiffs’ omnibus opposition/reply improperly seeks declaratory and injunctive relief beyond what Plaintiffs requested in their motion for summary judgment or complaint. In their motion for summary judgment, Plaintiffs requested an order enjoining Defendants “from implementing, instituting, maintaining, or giving effect to the Kennedy Declaration.” *See* Pls.’ Mot. at 10. But in their opposition/reply, Plaintiffs added a request that the Court enjoin HHS from enforcing, implementing, giving effect to, or relying on any “materially similar policy which supersedes or purports to supersede the professionally recognized standards of care that exist in the Plaintiff States.” *See* Pls.’ Opp’n at 43. Similarly, with respect to declaratory relief, Plaintiffs’ motion for summary judgment requested entry of a judgment that “declares that the Kennedy Declaration is unlawful.” Pls.’ Mot. at 10. But now, Plaintiffs have expanded that request in their opposition/reply to seek a “declaratory judgment to clarify that Defendants lack the authority to establish superseding standards of care to exclude providers from federal health care programs.” Pls.’ Opp’n at 39. Plaintiffs’ amended complaint likewise included only the narrower requests for relief. *See* Pls.’ Am. Compl. at 35–36.

Even if the Court rules for Plaintiffs on the merits (and it should not), the Court should reject Plaintiffs' broadened requests for injunctive and declaratory relief. As an initial matter, the expanded relief requested for the first time in Plaintiffs' opposition/reply is improper and/or waived. A party responding to a motion "may not seek affirmative relief through its Opposition." [*Smith v. Premiere Valet Servs., Inc.*, No. 2:19-cv-9888-CJC-MAA, 2020 WL 7034346, at *14 \(C.D. Cal. Aug. 4, 2020\)](#). Several district courts in this Circuit and others "have concluded that a request for affirmative relief is not proper when raised for the first time in an opposition." *See, e.g., id.* (collecting cases); *see also* Fed. R. Civ. P. 7(b)(1) ("A request for a court order must be made by motion."). Moreover, even though Plaintiffs filed an omnibus opposition/reply, "[t]he district court need not consider arguments raised for the first time in a reply brief" either. [*Zamani v. Carnes*, 491 F.3d 990, 997 \(9th Cir. 2007\)](#) (citing [*Koerner v. Grigas*, 328 F.3d 1039, 1048 \(9th Cir. 2003\)](#)); [*United States v. Bohn*, 956 F.2d 208, 209 \(9th Cir.1992\)](#) (per curiam) (noting courts generally decline to consider arguments raised for the first time in a reply brief). Although a court may address an argument "raised by [the movant] for the first time in the reply brief if [the respondent] raised the issue in the responding brief," [*United States v. Dupard*, 43 F.3d 1480 \(9th Cir. 1994\)](#) (citing [*Bohn*, 956 F.2d at 209](#)), that is not the case here. Defendants did not object to the scope of relief sought in Plaintiffs' motion for summary judgment (if the Court rules for Plaintiffs on the merits), ECF No. 32, in either Defendants' cross-motion, ECF No. 73, or in Defendants' opposition to Plaintiffs' motion for summary judgment, ECF No. 74. Because Plaintiffs' newly expanded request for relief is improper, the Court should not consider it.

Furthermore, even if the Court considers Plaintiffs' broadened requests for relief, it should reject them because they are overbroad and impermissibly vague. First, Plaintiffs' expanded requests are overbroad because they extend beyond the challenged Kennedy Declaration. By

asking the Court to bar reliance on any “materially similar policy which supersedes or purports to supersede the professionally recognized standards of care that exist in the Plaintiff States,” and to declare that “Defendants lack the authority to establish superseding standards of care to exclude providers from federal health care programs,” Plaintiffs seek relief that is untethered to any specific agency action or specific exercise of agency authority. Pls.’ Opp’n at 39. Even if Plaintiffs were entitled to relief from the Kennedy Declaration (and they are not), that does not entitle them to sweeping relief that “reaches beyond the scope of the complaint and enjoins government regulations [or actions] that were explicitly never challenged or litigated,” and have not even occurred. [*Church of the Holy Light of the Queen v. Holder*, 443 F. App’x 302, 303 \(9th Cir. 2011\)](#) (vacating injunction against enforcement of generally-applicable controlled substances regulations that swept beyond the particular “outright prohibition” the plaintiff had challenged as burden on religious observance).

Several courts, including the Ninth Circuit, have vacated injunctions that purport to invalidate agency decisions that were never challenged in litigation, or that prohibit an agency from taking action that might produce a result similar to the action in which the court has identified some defect. *E.g.*, [*Meinhold v. U.S. Dep’t of Def.*, 34 F.3d 1469, 1480 \(9th Cir. 1994\)](#) (vacating injunction to the extent it went beyond ordering that the Navy reinstate unlawfully discharged sailor and not discharge him on same ground in the future); *see also* [*Flathead-Lolo-Bitterroot Citizen Task Force v. Montana*, 98 F.4th 1180, 1197 \(9th Cir. 2024\)](#) (vacating injunction to the extent it went beyond recreational wolf trapping to prohibit other types of wolf trapping that the plaintiffs had not challenged); [*Gulf Oil Corp. v. Brock*, 778 F.2d 834, 842–43 \(D.C. Cir. 1985\)](#) (vacating injunction that “enjoin[ed] disclosure not only of the [specific document at issue], but also of all ‘substantially similar’ documents”).

Plaintiffs only challenge the Kennedy Declaration. They do not challenge the legality of any statutory or regulatory provision, or any other action. Even if this Court were to accept Plaintiffs' arguments and find fault with the Kennedy Declaration, it would remain for HHS to determine in the first instance whether any specific statutory or regulatory provision authorizes HHS to "supersede the professionally recognized standards of care that exist in the Plaintiff States." The Court cannot restrain the agency from taking an action under unspecified authority before it even acts. See [*E. Bay Sanctuary Covenant v. Barr*, 934 F.3d 1026, 1029 \(9th Cir. 2019\)](#) ("An injunction must be 'narrowly tailored to remedy the specific harm shown.'" (quoting [*City & Cnty. of San Francisco v. Trump*, 897 F.3d 1225, 1243–45 \(9th Cir. 2018\)](#))).

Second, Plaintiffs' expanded requests for relief fail to satisfy Federal Rule of Civil Procedure 65(d)'s specificity requirements. That rule requires that "[e]very order granting an injunction" must "state its terms specifically" and "describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." "[T]he specificity provisions of Rule 65(d) are no mere technical requirements." [*Schmidt v. Lessard*, 414 U.S. 473, 476 \(1974\)](#). Rule 65(d) "was designed to prevent uncertainty and confusion on the part of those faced with injunctive orders, and to avoid the possible founding of a contempt citation on a decree too vague to be understood." [*Id.*](#) "Since an injunctive order prohibits conduct under threat of judicial punishment, basic fairness requires that those enjoined receive explicit notice of precisely what conduct is outlawed." [*Id.*](#) Simply put, Rule 65(d) "requires the language of injunctions to be reasonably clear so that ordinary persons will know precisely what action is proscribed." [*Premier Commc'ns Network, Inc. v. Fuentes*, 880 F.2d 1096, 1100 \(9th Cir. 1989\)](#) (quoting [*United States v. Holtzman*, 762 F.2d 720, 726 \(9th Cir.1985\)](#))).

The language of Plaintiffs' requested injunction is not "reasonably clear." See [*id.*](#) One is

left to guess what is meant by “a materially similar policy which supersedes or purports to supersede the professionally recognized standards of care that exist in the Plaintiff States” Pls.’ Opp’n at 39–40. Plaintiffs do not explain what they mean by “professionally recognized standards of care that exist in the Plaintiff States.” *See id.* Nor do they identify the “material[]” aspects of the Kennedy Declaration that the injunction would prohibit in any future policy. *See id.* Thus, the requested injunction does not inform Defendants, or “ordinary persons,” “precisely what action” is prohibited. [*Premier*, 880 F.2d at 1100](#) (quoting [*Holtzman*, 762 F.2d at 726](#)).

The vagueness of Plaintiffs’ expanded injunction request is exemplified by the fact that, although Plaintiffs do not challenge the legality of OIG’s exclusion regulations, their newly requested injunctive relief appears to functionally rewrite them. The exclusion regulations do not treat “professionally recognized standards of health care” as fixed by any single source but instead require a case-specific determination informed by multiple professional and regulatory inputs. *See* 42 C.F.R. §§ 1001.2, 1001.701. By seeking to prohibit Defendants from relying on anything that allegedly supersedes “statewide standards,” Plaintiffs effectively ask the Court to elevate one category of evidence (“statewide standards,” whatever Plaintiffs mean by that) above all others and conclusively restrict how OIG conducts the individual case-by-case factual determinations the regulations require. Such relief would not align with OIG’s unchallenged regulations. Instead, it would displace OIG’s regulatory process for determining what “professionally recognized standards of health care” are and when they have been violated to warrant exclusion.

For these reasons, if the Court rules for Plaintiffs on the merits, any relief should be limited to setting aside the Kennedy Declaration. In all events, relief should be no broader than that requested in Plaintiffs’ motion for summary judgment.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss this case in its entirety for lack of jurisdiction or enter summary judgment in favor of Defendants.

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Respectfully submitted,

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