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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

NO. 1:19-cv-3040-SAB

STATE OF WASHINGTON'S REPLY IN SUPPORT OF ITS CROSS-MOTION FOR SUMMARY JUDGMENT

NOTED FOR: February 27, 2020
With Oral Argument: 10:00 a.m.
Spokane Courtroom 755

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I. INTRODUCTION

Unable to substantively refute the merits of the actual claims before this Court, Defendants simply pretend nothing of significance happened after *Rust v. Sullivan* was decided in 1991. But three decades of statutory and regulatory evolution—and the reliance that individuals and a national network of providers, including the State of Washington, have placed on the stability of Title X's implementation—cannot be disregarded. More pointedly, HHS is not free to ignore Congress's post-1991 restrictions on its rulemaking authority. The Rule should be set aside as both arbitrary and capricious and contrary to law.

The administrative record overwhelmingly shows that, in reversing decades of program operation and silently jettisoning its own research-backed guidance, HHS failed to rationally address the reliance interests of Title X participants and beneficiaries, the actual exorbitant costs of compliance, the ethical concerns of medical professionals, and the cascading and costly harms the Rule will cause to public health and patients' lives. The Rule is irrational and fails to satisfy the APA's standards for reasoned rulemaking for the numerous and pervasive reasons set out in the NFPRHA Plaintiffs' and Washington's opening briefs. Moreover, HHS's rulemaking process did not comply with the APA because key provisions of the final Rule were undisclosed or changed from the proposed version submitted for public comment, making a charade of the notice-and-comment process. In particular, "medical necessity" was misused to justify the Rule's mandatory prenatal-care referral requirement—but no medical

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authority had a chance to weigh in on that misuse because HHS failed to disclose this justification for a key provision until the final Rule was published. The Rule also contradicts the requirements of three statutes: it prioritizes the interests of potential conscience objectors and other narrow, asserted goals over the agency's compliance with the Nondirective Mandate, Section 1554 of the PPACA, and Title X itself.

Contrary to HHS's protestations, this case does not require the Court to "overrule" *Rust*, which addressed a different regulation promulgated against a different statutory landscape. HHS's 1988 rule may have been one permissible approach when it was adopted, but that does not save the Rule today. To the contrary, HHS itself found the 1988 approach wanting and withdrew the prior rule decades ago, without ever implementing it nationwide. Congress was not required to expressly "repeal" *Rust* or address the old, withdrawn, and completely inoperative 1988 rule when it first enacted the Nondirective Mandate in 1996, or the PPACA in 2010. HHS is unable to reconcile the Rule with those clear statutory limits on its regulatory authority—indeed, it fails to muster any credible argument that the Rule comports with those statutory limits.

Finally, this Court need not reach Plaintiffs' constitutional claims, because the statutory claims are dispositive. Nor should the Court wait for the Ninth Circuit's anticipated opinion before it rules on the merits. The Court of Appeals does not have the benefit of the administrative record and any ruling it issues will be constrained by the procedural posture of the limited appeal it is considering.

II. ARGUMENT

A. The Rule Is Arbitrary and Capricious

The administrative record, which was not before the Court during prior phases of this case, demonstrates unequivocally that HHS's rulemaking (a) contradicted, without explanation, its own clinical standards for family planning care and numerous other prior HHS factual findings; (b) attributed zero costs to the patients Title X serves, even though the country's leading medical and public health authorities explained via their comments the Rule's serious harms to patients; (c) relied on ridiculously low and unsubstantiated estimates of financial costs for provider compliance, while ignoring the detailed submissions in the record that documented the real, orders-of-magnitude higher costs; (d) repeatedly exaggerated non-existent advantages of the Rule and dismissed evidence of its many significant problems; and (e) introduced numerous other unexplained inconsistencies and unjustifiable "compliance" layers within the Rule—all to handicap the functioning and effectiveness of Title X family planning. *See* NFPRHA MSJ[1] at 9–72. Any one of these failures would establish

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[1] The briefs on the instant cross-motions are referenced herein as follows:
Defendants' Motion to Dismiss (ECF No. 112): "HHS MTD"
Washington's Opposition and Cross-Motion (ECF No. 118): "WA MSJ"
NFPRHA's Opposition and Cross-Motion (ECF No. 121): "NFPRHA MSJ"
Defendants' Opposition and Reply (ECF No. 131): "HHS Opp."

an arbitrary rulemaking process; here, the rulemaking was arbitrary and capricious from virtually every vantage point.

In response, HHS does not contest the administrative record evidence highlighted in Plaintiffs' briefs and fails to offer any administrative record evidence to support its own position. Instead, HHS simply invokes its "predictive expertise" to justify adopting a Rule upon conclusory explanations that *directly conflict* with the record before it. HHS Opp. at 2. HHS clearly prioritized its preferred interpretation of one ambiguous section of Title X (Section 1008) above all else, disregarding the negative consequences for patients, providers, and Congress's overall Title X statutory purpose, all of which are well documented in the administrative record. Agencies do not have such unbridled powers.

As it did in its opening papers, Washington adopts and incorporates in their entirety the sections of the NFPRHA Plaintiffs' reply brief that address HHS's arbitrary and capricious rulemaking.[2] Washington respectfully offers the following additional comments on several specific points.

1. Grantee reliance. HHS failed to address the devastating impact of the Rule's physical separation and personnel requirements on grantees' reliance interests. *See* WA MSJ at 15–20 (discussing case law requiring agencies to account for serious reliance interests and the Rule's extensive disruption to the

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[2] Washington also adopts and incorporates the sections of the NPFRHA brief that discuss the proper remedy and the inappropriateness of a stay.

conduct of state business). This impact is particularly acute for state-government grantees, as Washington explained. *Id*. Both in its rulemaking and in its briefing, HHS simply ignores the sudden and impossible burdens its Rule imposes.

As detailed in Washington's brief, the State's Department of Health was Washington's sole Title X grantee for almost half a century, administering a statewide network of providers from its headquarters in a single government building in Olympia. WA MSJ at 16–18. As explained, the Rule's physical separation requirements are uniquely burdensome on states like Washington because they apply not only to direct abortion care, but to all grantee activities—unrelated to Title X—that might "increase the availability or accessibility of abortion for family planning purposes." 42 C.F.R. §§ 59.15, 59.16. In Washington, some of DOH's activities relate to abortion access, care, or policy; accordingly, the Rule would require the State to *physically* separate the administration of its Title X program from all of its other public health work that touches on abortion. *See* 42 C.F.R. §§ 59.15, 59.16. Likewise, because the Secretary of Health and other high-level DOH personnel necessarily oversee multiple programs, compliance with the Rule's "separate personnel" requirement, 42 C.F.R. § 59.15(c), is impossible. WA MSJ at 18–19.

Washington was faced with the Hobson's choice of either curtailing DOH's policy and public health work or undertaking a physical and programmatic reorganization of one of its largest state government agencies in order to comply with the Rule. HHS's bald assertion that it considered reliance

interests, HHS Opp. at 25, does not even acknowledge this wholesale disruption of state governmental functions. It is apparent from the administrative record—and from HHS's failure to address these issues in its brief—that the agency simply failed to consider the serious reliance interests of large health departments such as Washington's DOH, and their ability to administer Title X without having to acquire separate facilities, new senior personnel, and duplicative administrative systems. The Rule's new physical and personnel separation requirements are arbitrary and capricious for this reason, in addition to all the reasons the NFPRHA Plaintiffs discuss.

2. Adverse Impacts to Public Health. HHS's assertion that the providers the Rule forces out of the Title X program will be replaced by others, with no impact on patients, is an unsubstantiated and arbitrary basis for agency decisionmaking. HHS is all over the map: it calls the impact of future grantee turnover "purely speculative," while also claiming that imagined new providers (nowhere evidenced in the record) will appear, and dismissing all the concrete record evidence from then-current Title X providers and others that explained why the Rule would force them from the program. *See, e.g.*, HHS Opp. at 22. The record evidence was clear: the Rule's counseling provisions and separation requirements were poised to push many providers out and would certainly disrupt patients' reproductive health care coordination and continuity. The administrative record is replete with comments highlighting recent real-world examples in which policies like the new Rule led to fewer providers and adverse

health outcomes. *See* WA MSJ at 20–28. In response, HHS is unable to point to *any* administrative record support for its blasé assertions that the Rule will not adversely affect public health, disproportionately impacting already-vulnerable and underserved populations—the very people whom Title X was designed to serve. *See* HHS Opp. at 25 (failing to cite *any* record evidence that the Rule will benefit public health). Simply ignoring those public costs the agency finds inconvenient is, by definition, arbitrary and capricious. *See* WA MSJ at 28 (citing authorities).

3. Patient Reliance Interests. The Rule's counseling distortions and endorsement of limited or non-medically-approved contraceptive options to accommodate provider preferences (rather than patient interests) is a complete betrayal of patients. WA MSJ at 28–33. HHS failed to consider patients' legitimate expectations that medical care providers—regardless of their funding source—will offer complete, medically accurate, ethical, options-based care that puts the patient first. Instead, the Rule removes the requirement that family planning methods be "medically approved" and prioritizes providers who promote fertility awareness-based methods of contraception over more effective methods. *Id.*; *see* HHS Opp. at 22 (describing the Rule as "favoring innovative approaches for underserved populations"). Tellingly, HHS fails to identify *any* evidence in the administrative record that *any* professional medical organization believes that the Rule is consistent with medical ethics. *Cf., e.g.*, HHS Opp. at 20 (declaring HHS's conclusion that the Rule is consistent with medical ethics,

without a single administrative record citation).

HHS's complete failure to meaningfully grapple with the patient harms its Rule promotes was arbitrary and capricious.

4. No Evidence of Noncompliance. As detailed, WA MSJ at 33–34, HHS imposed the onerous separation requirements ostensibly to address hypothetical compliance risks with Title X's financial separation requirement. *See* 84 Fed. Reg. 7765. But the administrative record contains *no* evidence that *any* grantee used Title X funds contrary to Section 1008 while the 2000 Regulations were in effect. *See* DOJ Opp. at 23 (failing to identify any record evidence of compliance problems or "confusion"). HHS's failure to identify *any* evidence in the record to support its speculation is dispositive. WA MSJ at 33 (citing cases).

B. The Rule Violates APA Procedural Requirements for Notice-and-Comment Rulemaking

Defendants do not seriously dispute that HHS failed to provide notice of four material provisions of the Final Rule. *See* WA MSJ at 34–39. Their halfhearted argument that the public "should have anticipated" these provisions is insufficient to avoid summary judgment. *See* HHS Opp. at 35–39.

First, Defendants offer no excuse for failing to give commenters an opportunity to explain that prenatal care is not, in fact, "medically necessary" for all pregnant patients, including those who decide to terminate the pregnancy. WA MSJ at 35–36. Defendants now try to distance themselves from this demonstrably false rationale by asserting that "the final rule does not depend on" HHS's false

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pronouncement. HHS Opp. at 36. But that pronouncement is the agency's sole contemporaneous justification for Section 59.14's directive prenatal-care referral requirement. *See, e.g.*, Final Rule, 84 Fed. Reg. 7747 & n.75 ("[T]his rule requires referral for prenatal care . . . because it is a medically necessary care [sic] for all pregnant women."). The Court must review Defendants' actions based on the contemporaneous administrative record, not "some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). In addition, Defendants' current assertion that Title X is a "pre-conceptional" program is both erroneous[3] and irrelevant, and the cited House Report does not speak to prenatal-care referrals at all. *See* HHS Opp. at 36. Contrary to Defendants' portrayal, it does not follow that prenatal-care referrals must be given to *all* patients simply because prenatal care is not part of a Title X program (and may be appropriate for *some* patients). *Id.* The bottom line is that, if the agency had provided adequate notice of its false "medically necessary" premise for the final Rule's mandatory referral requirement, it would have received—and been obligated to address with due consideration—serious medically based criticism of the purported justification for a key provision of the new Rule. WA MSJ at 35–36.

<u>*Second*</u>, Defendants concede that inclusion on the list authorized by the final version of Section 59.14(b) is restricted to *only* primary care providers, whereas the proposed rule referred generally to any "comprehensive health

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[3] *See* WA MSJ at 40–41; *infra* at 20.

service providers." WA MSJ at 37; HHS Opp. at 37. Contrary to Defendants' assertions, no commenter could offer any input on restricting the list to primary care providers, because the proposed rule gave notice of a different, more general concept. *See* HHS Opp. at 37. At best, Defendants' *post hoc* explanation that tries to elide a broader concept with one "include[d]" therein, *id.*, demonstrates the opacity of the proposed rule and the lack of adequate notice.

Third, Defendants' current insistence that Section 59.5(b)(1)'s change from "medically indicated" to "medically necessary" is immaterial and "stylistic," HHS Opp. at 38, conflicts with the rulemaking itself, which describes this change separately from "stylistic" ones and coordinates it substantively with the "medically necessary" addition in Section 59.14(a), already discussed above as another surprise addition. *See* 84 Fed. Reg. 7752. Again, if HHS had provided the proper notice, commenters could have pointed out the insidious effects of the change to Section 59.5(b)(1), particularly when combined with the new standard limiting abortion referrals to "emergency" situations—but the failure to provide notice prevented such submissions. WA MSJ at 37–38.

Under the final Rule, providers can no longer refer patients for medically indicated abortion—contrary to clinical standards. WA MSJ at 38. In addition, the change to Section 59.5(b)(1) alters Title X providers' obligations to help their patients access all kinds of out-of-program care, far beyond abortion, that is "medically indicated," and instead requires referrals only where there is a medical

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necessity, diminishing providers' referral obligations across the board. This diminishment occurred without any opportunity for comment.

Fourth, Defendants offer no support for their assertion that notice is unnecessary where a final provision is "less restrictive" than the proposal. HHS Opp. at 38–39. That is not the standard: rather, the public must receive *notice* of the rulemaking's substance, and the rule's final provisions must be a "logical outgrowth" of the proposed rule. WA MSJ at 35, 38–39. If Defendants' standard were adopted, agencies could effectively promulgate any rule without adequate notice simply by "proposing" outlandishly restrictive rules and then adopting different but arguably more generous provisions without any public input. *See, e.g., Kennecott v. EPA*, 780 F.2d 445, 452 (4th Cir. 1985) ("It is not acceptable for an agency to set unachievable limits, and then when the [regulated entities] object[], to pull a curative [measure] out of its hat. This sort of conduct would frustrate the purpose of the procedural safeguards in the administrative process, and replace participatory rulemaking with rulemaking by ambush.").

Alternatively, even if this Court were to agree with Judge Chen's preliminary ruling that the "APP" limitation does not violate the APA's notice-and-comment requirements, it should still find—as Judge Chen did—that this provision is arbitrary and capricious. *California v. Azar*, 385 F. Supp. 3d 960, 1012–13 (N.D. Cal. 2019). That is especially clear now that Defendants have produced the full administrative record. *See* NFPRHA MSJ at 28–29.

C. The Rule Violates Three Controlling Statutes

Congress unequivocally mandated that all Title X pregnancy counseling "shall be nondirective"; that HHS "shall not promulgate" regulations restricting health care providers' communications with patients, violating providers' ethical standards, or creating "unreasonable barriers" to care; and that all Title X services "shall be voluntary." Defendants make little effort to engage with Plaintiffs' actual statutory claims, largely repeating the talking points from their initial motion.[4] Their efforts to sidestep statutory requirements—or alternatively, twist those requirements to comport with the new Rule—are all unavailing.

1. The Nondirective Mandate renders the Rule unlawful

a. The "implied repeal" doctrine is inapplicable and irrelevant

Defendants continue to insist that this Court must "overrule" *Rust* in order to apply directly applicable, later-enacted statutes, citing the "presumption against implied repeals." That doctrine has no application here: rather, it aids courts in resolving *statutory* conflicts under circumstances not presented by this case. *See* WA MSJ at 43–46.

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[4] As one glaring example, Defendants begin by repeating their tired assertion that the New Rule is "materially indistinguishable" from the 1988 regulations at issue in *Rust*, studiously ignoring the significant differences Plaintiffs have repeatedly and exhaustively identified. HHS Opp. at 3; *see, e.g.*, NFPRHA MSJ at 6–7 and sources cited therein.

Defendants implicitly concede, as they must, that the doctrine applies only where two statutes irreconcilably conflict or where a later statute is clearly intended as a substitute. *See* WA MSJ at 43. There is no such irreconcilable conflict here. Rather, Section 1008's prohibition on the use of Title X funds in "programs where abortion is a method of family planning"[5] and the Nondirective Mandate's requirement that "all pregnancy counseling shall be nondirective" are perfectly consistent, and this Court has a "duty" to "regard each as effective." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1018 (1984); WA MSJ at 43–44. It is HHS's new Rule—not the Nondirective Mandate—that creates a conflict where none existed before.

Further, even if the Nondirective Mandate *could* be read as an "amendment" of Congress's "implicit" delegation of authority to HHS to interpret the "ambiguity" in Section 1008—which it cannot—Supreme Court case law explains that the implied-repeal doctrine does not apply in such circumstances. WA MSJ at 45–46. The later-enacted Nondirective Mandate (1) expressly addresses the issue of pregnancy counseling within Title X and (2) is

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[5] Defendants criticize Washington for describing Section 1008 at one point in a historical summary as a prohibition on "funding abortion." HHS Opp. at 4. This one shorthand reference, however, occurs in a brief that repeatedly spells out exactly what Section 1008 prohibits, WA MSJ at 4, 43, and cannot be used to manufacture a purported argument Plaintiffs have not made.

more narrow, precise, and specific on that score than Section 1008 (and by extension, any "implied" agency authority to interpret Section 1008). *See id.* Section 1008, entitled "Prohibition of Abortion," consists of a single sentence and does not mention pregnancy counseling at all.[6] 42 U.S.C. § 300a-6. Because the Nondirective Mandate expressly and specifically addresses pregnancy counseling whereas Section 1008 does not, the Mandate cannot be considered an "implied repeal" of the more general implicit delegation of authority to interpret Section 1008. WA MSJ at 45–46. Defendants offer no response to this argument whatsoever.

Unsurprisingly, Defendants also still fail to cite any precedent[7] supporting their statutory "conflict" argument, which is based on the notion that an implicit

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[6] Defendants erroneously assert that Section 1008 "plainly authorizes the Rule's restrictions on referrals and counseling." HHS Opp. at 4. Actually, Section 1008 is "ambiguous" in that respect because it "does not speak directly to" those matters. *Rust v. Sullivan*, 500 U.S. 173, 184 (1991). It contains no affirmative expression of authority on those topics. Moreover, any agency regulations adopted today must be consistent with all current statutory boundaries, not just Section 1008.

[7] *Reading Law* does not support Defendants' theory. *See* Opp. at 8. First, the Supreme Court did not "authoritatively construe" Section 1008, but rather was "unable to say" the agency's 1988 interpretation was "impermissible" at the

delegation of interpretive authority by way of an ambiguity presumptively trumps a specific, explicit, and later-enacted Congressional limitation. *See* WA MSJ at 44–45. Defendants place far too much weight on the general proposition "that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps." *Smith v. Berryhill*, 139 S. Ct. 1765, 1778 (2019). An agency's interpretive authority is necessarily cabined by any other applicable statutory limitations: an ambiguity implicitly grants the agency authority to adopt an interpretation *that is not foreclosed by then-existing law*. WA MSJ at 40, 43–45. Here, Congress did not implicitly give HHS irrevocable authority decades ago to adopt a *Rust*-style interpretation of Section 1008's ambiguity regardless of Congress's later statutory directions to the agency. *See* HHS Opp. at 8. The Nondirective Mandate does not "amend" or "repeal" an ambiguous, implicit delegation of interpretive authority to the agency; it simply informs the scope of that interpretive authority after the date of its adoption by Congress.

Moreover, an agency's "reasonable statutory interpretation must account for both the specific context in which language is used and the broader context of the statute as a whole." *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 321

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time. WA MSJ at 40. Second, the Nondirective Mandate and Section 1554 *do* establish an "unavoidably implied contradiction" with HHS's current interpretation of Section 1008. *See* WA MSJ at 40–41.

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(2014) (cleaned up). "A statutory provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law." *Id.* (cleaned up). The law HHS must account for when interpreting Section 1008 encompasses statutes within the present *corpus juris*, including the Nondirective Mandate. WA MSJ at 45. By its plain language, the Nondirective Mandate forecloses HHS from adopting any interpretation of Section 1008 that permits directive pregnancy counseling within a Title X program. That is precisely what the Rule does, so it must be invalidated as contrary to law.

b. The Rule violates the Nondirective Mandate

Defendants repeatedly invite the Court to find that the Nondirective Mandate doesn't mean what it says.[8] But the Nondirective Mandate is unambiguous and Defendants' litigation-driven interpretation of it warrants no deference whatsoever. *See* WA MSJ at 47.

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[8] Defendants now concede the Nondirective Mandate is binding law, HHS Opp. at 7 n.2, although they continue to disparage it as a "single clause" in a "rider," *id.* at 2, claim it is an impermissible "implied repeal," *id.* at 3, 7, and urge that it has no discernable "impact on the Title X program," *id.* at 40. The implied-repeal doctrine is irrelevant here regardless of the purpose for which it is invoked.

Bizarrely, Defendants now seem to be claiming that, while the Nondirective Mandate prohibits directive counseling "*toward* abortion" (which is true), it somehow *permits* directive counseling *away from* abortion and toward carrying the pregnancy to term (which is false). HHS Opp. at 4, 6–7; *see also* HHS MTD at 25. Such a reading flatly contradicts the Nondirective Mandate's plain language, which is neutral on its face. WA MSJ at 46–47. Even without going that far, HHS misapprehends the plain meaning of the term "nondirective" when it argues in the rulemaking that a Title X provider may restrict counseling to discussing options that involve carrying the pregnancy to term, including for patients asking only about abortion.

Defendants' arguments about counseling try to muddy the waters by conflating the adjective "directive" with the verb "direct," *see* HHS Opp. at 4–6, and by confusing referral at patient request with "promoting" an option. Defendants' own preferred dictionary, however, defines "directive" to mean "serving or intended to guide, govern, or influence." *Merriam-Webster*, https://www.merriam-webster.com/dictionary/directive. Under this definition, the Nondirective Mandate prohibits pregnancy counseling that influences patients toward *either* carrying to term or terminating the pregnancy. Making information about all options available and discussing only the one or more in which *the patient* is interested fully complies with this mandate. Additionally, the Supreme Court instructs that terminology should be read consistently across related statutes. *See* WA MSJ at 48. Violating this principle, Defendants'

purported reading undisputedly contradicts the definition of "nondirective counseling" in the related IAAA, which makes clear that information and referral about all pregnancy options must be made available on an "equal basis." *See id.* at 47.

Further, Defendants' current reading contradicts *HHS's own concession* that nondirective pregnancy counseling means "the provision of information on all available options *without promoting, advocating, or encouraging one option over another*." 83 Fed. Reg. 25,512 n.41 (Jun. 1, 2018, proposed rule) (emphasis added); *contra* HHS Opp. at 7 (arguing that "nothing in the [Nondirective Mandate] prohibits the promotion of childbirth or adoption"). The Court should ignore Defendants' contrary, *post hoc* assertions. *See* WA MSJ at 42–43, 47. Moreover, while a nondirective approach forbids Title X clinicians from promoting one option over others, clinicians' responses to patient requests or questions is not "promotion," and thus referral upon request to abortion (like referral upon request to prenatal care) is compliant with both the Nondirective Mandate and Section 1008. Finally, Defendants' argument that the prenatal-care mandatory referral requirement is "severable" from the prohibition on abortion referral is wholly misplaced, as it relies on only Section 59.16 of the Rule (involving promotion), ignoring Section 59.14 (which includes both the mandatory prenatal requirement and the "prohibition on referral for abortion"). *See* WA MSJ at 52–53. It is also beside the point, because both aspects of the Rule are directive, alone or together, and must be invalidated. *See id.*

Defendants continue to insist that referrals are not part of counseling (even as they concede that referrals "may occur *at the same time* as counseling"). HHS Opp. at 5–6. Again, the Court should ignore this litigation-driven position; HHS undisputedly acknowledged in the Rule's preamble that referrals are "part of" nondirective pregnancy counseling. WA MSJ at 49. Further, Defendants do not dispute that the IAAA is *in pari materia* with the Nondirective Mandate. *See id.* at 48–49. Any way you look at it, the IAAA makes clear that "nondirective counseling to pregnant women" consists of "information and referrals" concerning all available courses of action. *Id.* at 48. Defendants offer no possible reading of the IAAA that would allow counseling to include "referrals" for adoption, but that would not include referrals "on an equal basis" for the "other courses of action" referenced in the statute. *See* 42 U.S.C. § 254c-6(a)(1).

Moreover, Defendants implicitly concede that a referral inconsistent with the course of action selected by the patient during counseling is necessarily directive. *See* WA MSJ at 49–51. While it may be true that providers could also give a confusing "disclaimer" as Defendants suggest, HHS Opp. at 5, the Rule nonetheless mandates directive prenatal-care referrals and permits further directive counseling away from abortion without any such disclaimer. Again, Defendants ignore the fact that the Nondirective Mandate protects *patients* from undue manipulation, not providers with "conscience" objections. *See* WA MSJ at 46–48, 50–51. And although Defendants now try to justify the referral requirement for prenatal (literally "pre-birth") care based on the deeply flawed

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assertion that patients need such care "while they are pregnant" (even when the pregnancy will be terminated), HHS Opp. at 5, elsewhere Defendants back away from this unjustifiable rationale. *See id.* at 35–36; *supra* at 8–9.

As for the Rule's optional further counseling distortions, which permit three alternatives to so-called "nondirective" counseling,[9] Defendants misunderstand Plaintiffs' argument. Plaintiffs do not argue that the Nondirective Mandate requires Title X projects to offer pregnancy counseling, *see* HHS Opp. at 6–7, but rather that *all* pregnancy counseling—if offered—"shall be nondirective." WA MSJ at 51–52. Section 59.14(b)(1)(iv), for example, is another avenue for directive Title X pregnancy counseling, contrary to this requirement. Defendants' related insistence that counseling is not a Title X service because the program is "preconceptional," HHS Opp. at 6, is erroneous; the Nondirective Mandate makes clear that pregnancy counseling *is* a Title X service. WA MSJ at 40–41. Obviously, pregnancy counseling occurs "postconception" by definition, as HHS acknowledges in the Rule's preamble. 84 Fed. Reg. 7730, 7760 (discussing "nondirective postconception counseling").

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[9] Again, Defendants' claim that the Rule requires all pregnancy counseling to be nondirective, HHS Opp. at 7 n.2, is a mischaracterization. The Rule makes "nondirective" counseling just one of four options for providing information to pregnant patients, and even for that one option, "nondirective" is a misnomer. Final Rule § 59.14(b)(i)–(iv); *see* WA MSJ at 52.

2. The Rule plainly violates Section 1554's limits on HHS rulemaking

As exhaustively detailed, the Rule violates the specific statutory limits on HHS's regulatory authority that Congress enshrined in the PPACA. WA MSJ at 53–64. Since Section 1554's enactment in 2010, HHS has been prohibited from promulgating "any regulation" that, among other things, creates "unreasonable barriers" to a patient's receipt of appropriate health care or interferes with a provider's ability to communicate about the "full range of treatment options" or "to provide full disclosure of all relevant information to patients making health care decisions[.]" 42 U.S.C. § 18114. The Rule plainly violates all five relevant subsections of Section 1554. WA MSJ at 57–64. Defendants do not seriously contend otherwise.

HHS cannot harmonize its Rule with the governing provisions of Section 1554; they are hopelessly in conflict. Instead, Defendants reiterate the odd protest that Congress did not intend Section 1554 to "erase the Secretary's pre-existing [general] authority to adopt regulations [for Title X]" in Section 1006. HHS MTD at 28–29; HHS Opp. at 12. But this argument has the same fundamental flaw as the claim that Congress was required to "overturn" *Rust* in order to later limit HHS's regulatory authority to interpret Section 1008. *Supra* at 12–16. In 2010, when Section 1554 was enacted, HHS's long-abandoned 1988 rule formed no part of the statutory or regulatory landscape, and Congress added the restrictions in Section 1554 to limit "any" HHS rulemaking. Because the Rule, as adopted, violates Section 1554, it must be set aside.

Defendants rely on the contorted argument that Plaintiffs waived this claim by failing to specifically cite Section 1554 in comments on the proposed rule. But HHS has an independent obligation to stay within Congressional limitations on its rulemaking authority, and this is not a "waivable" obligation. *Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050, 1061 (N.D. Cal. 2018); *accord Nat. Res. Def. Council v. EPA*, 755 F.3d 1010, 1023 (D.C. Cir. 2014).[10] The Ninth Circuit has made clear, moreover, that it "will not invoke the waiver rule . . . if the issue was considered sua sponte by the agency . . . ." *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1024 (9th Cir. 2007). Here, the record confirms that HHS in fact considered Section 1554 and its limits during the rulemaking. AR397742-43 (copy of Section 1554); HHS Opp. at 9 n.3 (Defendants concede that HHS "relied upon" the entire PPACA in promulgating the Rule); ECF No. 119-6 (Verbatim Rpt.) at 67:24–68:8 (Defendants concede that HHS was aware of Section 1554's substantive provisions at time of rulemaking). The obvious and palpable conflicts between the Rule and Section 1554's prohibitions were "adequately before the agency for consideration." *Pruitt*, 293 F. Supp. 3d at 1061. HHS's purported complete failure to examine the limits of its own regulatory

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[10] The 1994 case with the same caption (HHS Opp. at 9) is inapposite because it concerned an agency's "statutory construction" of its "governing statute"—not unambiguous statutory limitations on the agency's rulemaking authority.

authority—despite its conceded knowledge of Section 1554's provisions—does not provide it with a defense here.

Further, commenters did in fact raise Section 1554 concerns "with sufficient clarity to allow the decision maker to understand and rule on the issue raised[.]" *Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010). As detailed, commenters explained that the Rule would create unreasonable barriers to care, impede timely access to services, interfere with patient–provider communications, and violate principles of informed consent and medical ethics. *See, e.g.*, WA MSJ at 56–57 (describing comments).[11]

Finally, even after commencement of this case and Plaintiffs' pleading and briefing of the violation of Section 1554 claims, HHS had another chance to back away from the regulations' provisions that conflict with Section 1554's explicit limits on its rulemaking authority. But HHS, in the midst of this litigation, instead

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[11] Defendants erroneously claim that "Plaintiffs interpretation of § 1554" would mean that HHS could not regulate Medicaid coverage or make "minor changes to programs." HHS Opp. at 12 n.5. That claim ignores that Section 1554 focuses only on "unreasonable barriers" and other specific, harmful regulatory obstacles that are *not* run-of-the-mill regulation, but are regulations like the Rule that, *inter alia*, violate ethical rules and interfere with health care providers' communication of relevant information to patients.

took additional action in the face of the Section 1554 claims. HHS began in August 2019 to enforce the Rule against all Title X grantees, including Washington. With that application of the Rule, and on all the other grounds discussed above, Washington is not blocked by any waiver. *Cf.* HHS MTD at 29 ("[a] plaintiff can raise such 'statutory arguments if and when the Secretary applies the rule' to them") (quoting *Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) (per curiam)). Contrary to Defendants' assertions, moreover, it is plain that Washington's departure from Title X was not "voluntary," HHS Opp. at 10 & n.4; HHS solicited and then rejected Washington's proposal for continuing its program under the Rule, forcing the State to end its participation because it was unable to comply with the Rule's unlawful and harmful counseling restrictions and other currently-effective provisions that violate Section 1554. There is no other avenue for Washington to bring the contrary-to-Section 1554 claims, and Defendants' arguments that they should simply escape any obligation to comply with that statute fall flat.

3. The Rule violates Title X

Defendants imply that *Rust* considered and rejected the arguments raised here based on Title X's central purpose and Section 1007's voluntariness requirement. HHS Opp. at 13. In fact, Plaintiffs' conflict-with-Title X claims in this case are entirely different than issues raised or alluded to in *Rust*. *Rust*, for example, considered whether the 1988 rule's separation requirements violated Congress's intent "that Title X programs be an integral part of a broader,

comprehensive, health-care system," 500 U.S. at 187–88, and whether the 1988 rule violated the "Fifth Amendment right to medical self-determination," *id.* at 202. *See* HHS Opp. at 13. Here, by contrast, Plaintiffs have shown that the 2019 Rule violates Title X's central purpose of improving access to "comprehensive" and "effective" family planning services, WA MSJ at 65, because its provisions decimate Title X's functioning, and that providing unwanted information to unwilling patients violates Title X's statutory requirement that the receipt of all services and information be "voluntary," *id.* at 66–68. *Rust* does not speak to these claims. At best, Defendants try to frame questions that "merely lurk in the record" of *Rust*, and thus "are not to be considered as having been so decided as to constitute precedents." *Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 170 (2004).

Defendants argue that their Rule incorporates the statute's "voluntary" language, HHS Opp. at 13, but they fail to explain how providers are supposed to reconcile this with the Rule's requirement that they force unwanted information on patients. As Defendants' own arguments make clear, Title X providers must comply with the mandatory prenatal-care referral requirement, and are empowered by the Rule to determine the scope of counseling, even contrary to patients' wishes. The pre-existing "voluntary" language in Section 59.5(a)(2) cannot save the Rule from being invalidated because the Rule imposes involuntary information and services on patients, in violation of Section 1007.

Furthermore, Defendants offer no response to Plaintiffs' textual arguments, tacitly conceding these points. *See* WA MSJ at 67–68.

Section 59.18 of the Rule also violates Title X by drawing a distinction between "infrastructure" building and "direct implementation" of the statute, and providing that federal funds may only be used for the latter and "as expressly permitted by this regulation." Section 59.18(a); WA MSJ at 68. The Rule does not define "direct implementation," but it does describe "infrastructure building" to include "bulk purchasing of contraceptives," as well as training and education. 84 Fed. Reg. 7774; WA MSJ at 68. Defendants now suggest that Section 59.18 is more limited, HHS Opp. at 13-14, but that suggestion fails to give meaning to all of the express provisions in Section 59.18(a) and fails to reconcile them with the rulemaking's lengthy discussion of its objective to rein in "infrastructure" spending. 84 Fed. Reg. 7774 ("The Department is concerned about this infrastructure building on both statutory and policy grounds."). Newly requiring Title X projects to avoid critical spending for the "establishment and operation of voluntary family planning projects," 42 U.S.C. § 300(a), even if that spending relates to infrastructure and not "direct implementation" or "direct services," conflicts with the Title X statute. *Id.* Notably, Title X funds have always been reserved for Title X expenses only and their use restricted by Section 1008. NFPRHA MSJ at 51–52.

The Rule also violates Title X by imposing the extra-statutory requirement that Title X clinics be onsite with or in "close physical proximity" to

"comprehensive primary health services." WA MSJ at 68–69. To be clear, Title X clinics have always referred patients for care outside the scope of the program, in accordance with medical ethics and clinical standards, which is consistent with the statute. *Contra* HHS Opp. at 14–15. The problem with the new requirement is it will disqualify clinics (particularly in rural areas) that are not in "close physical proximity" to a primary care referral site—a requirement not imposed or authorized by the statute—even if they are highly qualified to provide family planning services and would serve a great need for such Title X services in that location. *Cf.* 42 U.S.C. § 300(b) (establishing statutory criteria for awarding Title X grants).

D. The Constitutional Claims Have Merit, but Need Not Be Reached

As previously discussed, Plaintiffs have established several constitutional violations, but the Court need not (and in fact, should not) reach those claims because the numerous statutory violations are more than sufficient to vacate and set aside the Rule in its entirety. WA MSJ at 70–73. Should the Court nevertheless consider these claims, it should reject Defendants' arguments—which, once again, rest on the erroneous assumption that Plaintiffs are seeking to overturn *Rust*, and ignore the key differences that distinguish this case from *Rust*. *See id.*; HHS Opp. at 39–42.

Rust upheld under the First Amendment certain speech restrictions that the Court viewed as consistent with patients' reasonable expectations in the context of a "preconceptional" program, where services abruptly ended with a positive

pregnancy test. But that reasoning does not apply to the current program, which does *not* artificially segregate pregnancy testing from pregnancy information, discussion, and referral—as clarified by the Nondirective Mandate and as reinforced by decades of regulations and guidance, including the QFP, that incorporate pregnancy counseling in Title X care. *See* WA MSJ at 21–22, 40–41.

Defendants also misleadingly describe the *AOSI* case. While their statement reflects one "general matter," HHS Opp. at 40, it leaves out discussion of *AOSI*'s important unconstitutional-conditions doctrine, under which a government funding program may not require its participants to endorse as their own a government view, or otherwise accede to restrictions that improperly interfere with "activities on [their] own time and dime." *Agency for Int'l Devel. v. AOSI*, 570 U.S. 205, 218 (2013). Here, both the 2019 requirement that Title X clinicians must deem a prenatal-care referral "medically necessary" for all pregnant patients (contrary to medical fact) and the untenable 2019 physical separation scheme—which requires *inter alia* no shared infrastructure, including staff (and thus clinicians cannot participate both in Title X and abortion care, even when the latter is far outside the federal program)—impose excessive restrictions on providers' "own time and dime." *See* WA MSJ at 15–19. Moreover, the *NIFLA* case teaches that regardless of the source of funding for medical care, the First Amendment is extraordinarily protective of medical professionals' speech. *NIFLA v. Becerra*, 138 S. Ct. 2361, 2374 (2018) (explaining that "in the fields of medicine and public health, . . . information can

save lives" and that "[d]octors help patients make deeply personal decisions, and their candor is crucial"). The 2019 rulemaking crosses the line to violate the First Amendment in ways that were not litigated—and certainly not approved—in *Rust*.

In addition, Defendants fail to address the cited case law holding that federal funding restrictions can be—as here—unconstitutionally vague. *See* WA MSJ at 72–73. They fail to address any of Plaintiffs' many specific examples of the unclear, subjective, and extraordinarily vague terms built into the Rule, which leave grantees, subrecipients, clinicians, and grant applicants without clarity and subject them to HHS's unpredictable and opaque *ad hoc* decisions. *See, e.g.*, NFPRHA MSJ at 61; WA MSJ at 72. Bald assertions that the Rule "provides extensive guidance" and "is not unconstitutionally vague," without any explanation of what the vague provisions Plaintiffs have identified actually mean, are not persuasive. HHS Opp. at 42. The Court can see for itself the unfettered and unreviewable discretion the Rule grants the Secretary in determining applicant eligibility and the many other impenetrable standards included in the Rule. *See* NFPRHA MSJ at 60–65.

III. CONCLUSION

For the reasons above and those in NFPRHA's reply brief, and in Plaintiffs' respective cross-motions, the Court should grant summary judgment in Washington's favor as to Counts I–IV of its Complaint.

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DATED this 3rd day of February 2020.

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DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court's CM/ECF System which will serve a copy of this document upon all counsel of record.

DATED this 3rd day of February 2020, at Seattle, Washington.

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