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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA,

Plaintiff,

v.

ALEX AZAR, in his OFFICIAL CAPACITY as SECRETARY of the U.S. DEPARTMENT of HEALTH & HUMAN SERVICES; U.S. DEPARTMENT of HEALTH & HUMAN SERVICES,

Defendants.

Case No. 3:19-cv-01184-EMC

CALIFORNIA'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS/ CROSS-MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF CALIFORNIA'S MOTION FOR SUMMARY JUDGMENT

Filed concurrently with:
1. Request for Judicial Notice;
2. Supplemental Appendix of Evidence; and
3. Declaration of Ketakee Kane

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Judge: Hon. Edward M. Chen
Trial Date: TBD
Action Filed: March, 2019

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INTRODUCTION

Defendants' Opposition does little to justify the Rule or the shoddy decisionmaking underpinning it. Instead, it demonstrates that the Rule lacks logic and evidentiary support. Title X. 84 Fed. Reg. 7714 (Mar. 4, 2019) (the Rule). The Defendants' Rule has already caused harm to women and families who rely upon Title X. Since the Rule was implemented, California clinics have been forced to leave the Title X program, impeding their ability to help patients. The Rule's March 4, 2020 physical separation deadline will only escalate that harm.

In their opposition, Defendants double down on their previous positions. In so doing, they fail to meaningfully dispute California's arguments, including that Defendants' rulemaking was speculative, conclusory, riddled with errors, and contrary to the facts before it. The voluminous administrative record demonstrates that the Court should deny Defendants' motion to dismiss for its first, second, third, and fourth cause of action; and grant California's motion for partial summary judgment on its first, second, and third cause of action.

The Rule violates the APA because the Rule is contrary to law, arbitrary and capricious, and in excess of statutory authority.

First, the Rule is contrary to law because Defendants rely upon past precedent from 1988 to argue that the Rule is a valid exercise of the Secretary's authority. But two more recent statutes show that the Rule imposes unlawful conditions on Title X grantees.

Second, the Rule is arbitrary and capricious because the record overwhelmingly catalogues evidence of the catastrophic impacts the Rule would have on Title X patients, communities, and providers. Defendants shrug off this evidence and summarily state—in both the Rule and their opposition—that they "disagree." This does not meet the APA's requirements for agency rulemaking.

Third, the Rule also widely exceeds the scope of authority delegated to the Secretary and violates the purpose of the Title X program.

Separately, Defendants' motion to dismiss California's Equal Protection cause of action should be denied because California has stated a claim for invidious, gender-based

discrimination in the formulation of the Rule, and should have the opportunity to test its allegations through the discovery process.

The Rule has been devastating to California's Title X projects, and will be even more devastating when physical separation goes into effect on March 4, 2020. It is improper and harmful to force providers to comply with a Rule that harms their ability to provide quality reproductive care. The Rule must be vacated in its entirety.

CALIFORNIA IS ENTITLED TO SUMMARY JUDGMENT

I. *RUST V. SULLIVAN* DOES NOT FORECLOSE CALIFORNIA'S CLAIMS

Defendants argue that because *Rust v. Sullivan* upheld a similar regulation, the 2019 Rule is lawful. 500 U.S. 173 (1991); Opp. at 10-14.

This is incorrect. The Rule is contrary to law. *Rust* was decided before Congress issued two specific statutes regarding access to care: the nondirective counseling appropriations rider and Section 1554. Pub. L. No. 104-134, 110 Stat. 1321, 1321-22 (1996); *see, e.g.*, Pub. L. No. 115-245, Div. B., Tit. II, 132 Stat. 2981, 3070-71 (2018) (Nondirective Counseling Mandate); 42 U.S.C. § 18114 (Section 1554). And the Rule violates both of those statutes. As such, *Rust* only established that a similar rule was acceptable in *1991*.

Further, Supreme Court has *never* analyzed whether the Rule—or a similar rule—is compliant with these later-enacted statutes. *See, e.g., United States v. Verdugo-Urquidez*, 494 U.S. 259, 272 (1990) (explaining that Supreme Court decisions should not be interpreted to "encompass" issues beyond the "[t]he question presented for decision"); *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37-38 (1952) (explaining that where a point "was not ... raised in briefs or argument nor discussed in the opinion of the Court ... the case is not a binding precedent on this point"); *Vance v. Hegstrom*, 793 F.2d 1018, 1024 (9th Cir. 1986) (in issuing regulations, "the Secretary may not read [one] subsection …independently of" others).[1]

Further, the instant Rule is not the same 1988 rule evaluated in *Rust*. The following is a brief summary of the relevant differences:

- In 1988, HHS had actual evidence, in the form of reports of the General

[1] PI Ord. at 26 ("Plaintiffs' . . . claim is not automatically foreclosed by *Rust*)

Accounting Office (GAO) and the Office of the Inspector General (OIG), stating that the previous policy failed to properly the distinction between Title X programs and § 1008.[2] 53 Fed. Reg. 2922, 2923-2927 (Feb. 2, 1988); *Rust*, 500 U.S. at 187.

- In 1988, HHS explicitly rejected physical separation of healthcare records systems, separate entrances and exits, workstations, and phone numbers. But the Rule now—without support—requires such separation. *Compare* 42 C.F.R. § 59.15 *with* 53 Fed. Reg. at 2940.
- The Rule has an "infrastructure spending prohibition" which is ambiguous and not in the 1988 rule. 42 C.F.R. § 59.18.
- The 1988 rule sought separation only from material "promoting" abortion, while Rule requires Title X projects to rid themselves of any material that "referenc[es]" abortion. *Compare* 42 C.F.R. § 59.15 *with* 53 Fed. Reg. 2945.
- The 1988 Rule did not place any restrictions on patient referral lists.

The Rule is also arbitrary and capricious. HHS's reliance on *Rust* meant it failed to engage in reasoned analysis of the evidence gathered in the 32 years since the 1988 rule. PI Ord. at 48 ("The justifications supporting the 1988 regulations … cannot insulate the Final Rule from review now, almost three decades later.") Thus, the Rule must be evaluated in light of the current administrative record, the experience under the prior policy, and "the grounds that the agency invoked when it took the action," *i.e.* the reasons for the Rule. *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2710 (2015); *see Sierra Club v. E.P.A.*, 671 F.3d 955, 966 (9th Cir. 2012) ("[An agency] stands on shaky legal ground relying on significantly outdated data" to justify its actions).

II. THE RULE IS CONTRARY TO LAW

A. The Rule Violates the Nondirective Counseling Mandate

Since 1996, Congress has included a mandate requiring that "all pregnancy counseling shall be nondirective." *See, e.g.,* Pub. L. No. 115-245 (2018); Pub. L. No. 104-134 (1996). The requirement is straightforward: Title X providers may not steer or direct clients toward selecting

[2] Unless otherwise indicated, all references to § 1008 or Section 1008 are to 42 U.S.C. § 300a-6.

any option during pregnancy counseling. The Rule itself explains that the purpose of nondirective counseling is "to assist the patient in making a free and informed decision." 84 Fed. Reg. at 7747. Nondirective counseling is "the meaningful presentation of options where the [provider] is not suggesting or advising one option over another" but rather "present[s] the options in a factual, objective, and unbiased manner." *Id*. at 7716, 7747.

However, the Rule violates that requirement by: (1) chilling provider-patient counseling by prohibiting providers from doing anything to "promote. . .or support abortion as a method of family planning," without guidance on what constitutes promotion or support; (2) mandating referrals for prenatal care, even if the patient states she wants an abortion; (3) prohibiting direct referrals for abortion; and (4) providing women seeking an abortion with a list of providers who may *or may not* provide abortions. 42 C.F.R. §§ 59.5; 59.14.

The Court previously—and correctly—held that the Rule violates the statute. PI Ord. at 26-35. The Court held that imposing onerous restrictions on information regarding abortion only—while mandating prenatal care—"does not place abortion on equal basis with all other courses of action," rendering the referral requirements contrary to law. *Id*. at 34. The Court also recognized that the counseling restrictions barring "promotion" or "support" of abortion similarly chill counseling regarding abortion and inhibit unbiased conversation between a provider and a patient. *Id*. at 35. This asymmetry in information renders the counseling restrictions contrary to law. Defendants' arguments to the contrary are unavailing, and have already been dismissed by the Court.

1. The Rule is Directive

The totality of the Rule is directive, which Defendants attempt to bypass. Defendants argue that failure to provide referrals for abortion, limitations on counseling, limited patient referral lists, and mandatory prenatal referrals do not constitute a direction, they "merely refers women for necessary care." Opp. at 15-16. This argument does not pass a common sense test: nondirective means a patient is *not* directed to one course of action over another. Here, the Rule mandates that a woman who is pregnant and seeks an abortion leaves a counseling appointment, not with the referral she sought, but with a referral for prenatal care. And the counseling she

receives is one-sided because HHS has failed to explain what it means to not "promote" or "support" abortion in any capacity, leading providers to avoid the subject altogether. Mot. at 32-33. To compound this, even if she insists on obtaining a referral for an abortion, she receives a non-targeted provider list which has such limited information, including whether a provider actually provides abortion, that she has to call multiple providers to obtain the service she actually wants.[3] Nothing about this scenario indicates to the patient that all pregnancy options are being equally considered. Instead, she is in a coercive situation that is endorsing a specific option, carrying a pregnancy to term, over her express wishes. As this Court held, the numerous restrictions on obtaining a referral—especially for time-sensitive medical inquiries—result in the Rule making a woman *worse* off that if she had sought help from a non-Title X clinic. PI Ord. at 43.

Moreover, this situation is contrary to HHS's own federal Quality Family Planning (QFP) recommendations issued by HHS's Office of Population Affairs (OPA) and the Centers for Disease Control and Prevention (CDC), which state that counseling is supposed to be a *patient-led* process, where a "client's primary purpose for visiting the service site must be respected." Appendix Ex. 137 at 2.

Further, Defendants argue that if Congress wanted all pregnancy options to be treated on an equal basis, it would have done so explicitly, rather than using the phrase "nondirective." Opp. at 15. But Congress has used the phrase nondirective to require that programs must "provid[e] adoption information and referrals to pregnant women on an *equal* basis with all other courses of action." 42 U.S.C. § 254c-6 (a)(1) (emphasis added). Canons of statutory construction affirm that Congress is presumed to be consistent with its meaning in a given context: nondirective counseling requires all options to be treated equally. *Erlenbaugh v. United States*,

[3] Notably, some facilities, such as so-called "Crisis Pregnancy Centers" that may be on the patient referral list train their telephone operators not to answer the specific question about whether they provide abortions. Ctr. for Reprod. Rights AR 315964-65; 77 ("Many of these centers also train their staff and volunteers to convince women to make an appointment, regardless of whether the center provides the services they are seeking."); Consumer Health First AR 236029 ("These Crisis Pregnancy Health Centers prey on women at vulnerable moments in their lives by pushing false, incomplete or inaccurate medical information, often from untrained individuals posing as medical professionals.")

409 U.S. 239, 243 (1972) ("[A] legislative body generally uses a particular word with a consistent meaning in a given context.").

HHS has also used previous rulemaking under this definition of nondirective. In 2000, HHS acknowledged that in nondirective counseling "grantees … may not steer or direct clients toward selecting any option, including abortion, in providing options counseling." 65 Fed. Reg. 41270, 41273 (July 3, 2000). And this language stemmed from HHS memorandums from the 1970s which stated that nondirective counseling was neutral counseling on different pregnancy options. *Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 229 (D.C. Cir. 1992) (finding that HHS guidelines have mandated nondirective counseling since 1971).

Further, treating different options equally is the plain-language meaning of nondirective. Merriam-Webster, https://www.merriam-webster.com/dictionary/directive ("directive" means "serving or intended to guide, govern, or influence.") The statute's language is clear that options are meant to be treated equally.

B. The Rule's Prohibition of Anything that Encourages, Promotes, or Supports Abortion is Directive

The Rule's prohibition on anything that "encourage[s]," "promote[s]," or "support[s] abortion" violates the Nondirective Counseling Mandate. 42 C.F.R. §§ 59.5(a)(5), 59.14(a), 59.16(a)(1); Mot. at 32-33. The Rule is unclear as to how a provider can permissibly discuss abortion and simultaneously not "support" or "promote" abortion, leading to providers likely avoiding the subject all together given that the entirety of the program's funding would be at risk. *See* Mot. at 27-28, 32-33; American College of Obstetricians and Gynecologists (ACOG) AR 268839 ("Without additional guidance, grantees may interpret this language as a complete prohibition on any conversation with their patients that references abortion."). As this Court concluded, the "murkiness" of these regulatory provisions "is likely to chill discussions of abortion and thus inhibits neutral and unbiased counseling." PI Ord. at 35. As such, the counseling the Rule requires is not "nondirective" because it steers patients away from abortion and toward childbirth. This unequal treatment violates the Nondirective Counseling Mandate.

1. The Rule's Referral Requirements are Directive

Defendants make several arguments regarding patient referrals, all of which have been previously found unpersuasive by this Court. PI Ord. at 26-35.

First, Defendants argue that referrals are not part of counseling, and as such, referrals do not have to comply with the Nondirective Counseling Mandate.[4] This is contrary to statutes, Defendants' own position in previous ruling making, and industry practice.

Congress considers referrals part of counseling. In the Public Health Service Act (PHSA), 42 U.S.C. § 254c-6(a)(1), Congress mandated that Defendants make grants to train staff "in providing adoption information and *referrals* to pregnant women on an equal basis with *all other courses of action included in nondirective counseling* to pregnant women" (emphases added). Congress clearly considered "referrals" for other services to be part of the "courses of action included in nondirective counseling." *Dir., OWCP v. Newport News Shipbldg. & Dry Dock Co.*, 514 U.S. 122, 130 (1995) (concluding similar statutes are "particularly illuminating" in determining the normal meaning of a statutory phrase"); *Erlenbaugh*, 409 U.S. at 243.[5]

HHS incorporated this definition into the Rule. The Rule incorporates section 254c-6(1), stating that it reflects Congress's "intent that postconception adoption information and referrals be included as part of any nondirective counseling in Title X projects." 84 Fed. Reg. at 7733; *see also id.* at 7730 (same). The Rule also discusses referrals as part of counseling, stating that "nondirective pregnancy counseling can include … referrals to adoption agencies." *Id*. at 7730; *see also id*. at 7733-34 ("Title X providers may provide adoption … referral … as part of nondirective postconception counseling."). There is no reason to believe—and HHS does not

[4] In the Ninth Circuit stay order, the motions panel concluded that "referrals do not constitute 'pregnancy counseling.'" *California by & through Becerra v. Azar*, 927 F.3d 1068, 1077 (9th Cir. 2019), reh'g en banc granted sub nom. *State by & through Becerra v. Azar*, 927 F.3d 1045 (9th Cir. 2019). This Court is not bound by this prediction and should not follow it. *Id*. ("The three-judge panel Order on Motions for Stay Pending Appeal in these cases shall not be cited as precedent by or to any court of the Ninth Circuit.")

[5] *See* 42 U.S.C. § 300ff-33(g)(1)(B)(ii) ("post-test counseling (including referrals for care)" provided to individuals with positive HIV/AIDS test); 38 U.S.C. § 1720D(b)(2)(C) (sexual-trauma counseling includes "referral services"); 42 U.S.C. § 3020e-1(b) (pension counseling encompasses "referral"); 20 U.S.C. § 1161k(c)(4)(A)(iv) (college counseling includes "referrals to … other student services staff").

contend—that somehow referrals for adoption are part of "nondirective counseling" but referrals for abortion are not. Moreover, as early as 1981, HHS defined counseling in its Title X Guidelines to include referrals. *See* HHS, Program Guidelines for Project Grants for Family Planning Servs. § 8.2 (1981) ("Post-examination counseling should be provided to assure that the client … receives appropriate referral for additional services as needed.").[6]

HHS's and the CDC's QFP recommendations also state that referrals are part of counseling. Appendix Ex. 137; PI Ord. at 30; *see La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 372 (1986) ("technical terms of art should be interpreted by reference to the trade or industry to which they apply"); *Ala. Power Co. v. E.P.A.*, 40 F.3d 450, 454 (D.C. 1994)("[W]here Congress has used technical words or terms of art, it is proper to explain them by referring to the art or science to which they [are] appropriate."). The QFPs show that referrals as part of counseling are part of the "accepted usage within the medical field." The "Pregnancy Testing and Counseling" section of the QFP recommendations instructs that "[pregnancy] test results should be presented to the client, followed by a discussion of options and appropriate referrals." QFP at 14; *Id.*[7] The QFP recommendations then advise that "[o]ptions counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG and AAP [American Academy of Pediatrics]." The American Medical Association's (AMA) comment letter to the Proposed Rule likewise states unequivocally that "[t]he inability to counsel patients about all of their options in the event of a pregnancy and to provide any and all appropriate referrals, including for abortion services, [is] contrary to the AMA's Code of Medical Ethics." AMA AR 269332.

The fact that Congress and HHS sometimes refer to counseling and referral separately is not an indication that counseling does not encompass referrals. As the Supreme Court recently

[6] *See also* Mot. at 12, 17, discussing the 2000 regulations.

[7] *See also* Providers Oppose Rule (2018) AR 254414-254416 (press release stating that the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), the American College of Nurse-Midwives (ACNM), the American College of Physicians (ACP), the Association for Physician Assistants in Obstetrics and Gynecology (APAOG), the National Association of Nurse Practitioners in Women's Health (NPWH), Nurses for Sexual and Reproductive Health (NSRH), and the Society for Adolescent Health and Medicine (SAHM) oppose the Title X rule.)

observed, Congress sometimes "list[s]" items separately even though they "have substantial overlap." *Azar v. Allina Health Servs*., 139 S. Ct. 1804, 1814 n.1 (2019) (reasoning that "many manual instructions surely qualify as guidelines of general applicability" even though the statute listed "manual instructions" and "guidelines of general applicability" separately). That insight aligns with common usage. For example, one might refer to "roads and bridges," but that does not mean that a road ceases to be a road when it crosses a bridge. As such, referrals are part of nondirective counseling.

Second, Defendants make a convoluted argument that suggests that the referral list restrictions are lawful because if HHS can directly ban abortion-referrals under *Rust*, it also has implicit authority to require misleading abortion-referral lists to ban "indirect referrals." Opp. at 16. But Defendants do not have the authority to directly ban abortion referrals, let alone indirectly.

Rust held that the then-Secretary's interpretation of Section 1008—as prohibiting all counseling (and referrals) regarding abortion—was a "permissible construction of the statute," not that it was the only reasonable interpretation. 500 U.S. at 184 (stating that Section 1008 "does not speak directly to the issues of counseling, referral, advocacy, or program integrity"). This was true in 1991, before Congress spoke to enact the Nondirective Counseling Mandate. Now that Congress has enacted the mandate, all counseling—and the referrals which are part of that counseling—must be nondirective.

As such, while that interpretation of § 1008 was permissible in 1991, HHS no longer has the authority to forbid abortion counseling and referrals under the Nondirective Counseling Mandate. Therefore, even if the incomplete referral list was not inherently directive—which it is—HHS does not have the authority—implicitly or explicitly—to forbid abortion referrals.

2. There is No Implied Repeal of Section 1008

Defendants reiterate their unpersuasive argument that California is seeking an implied repeal of § 1008 by arguing that the Nondirective Counseling Mandate limits HHS's authority to promulgate restrictions on counseling and referrals. But California does not argue that the Nondirective Counseling Mandate repeals § 1008. Rather, California argues that the Court

should harmonize the two statutes.

If two statutes appear to conflict, the court seeks to harmonize the two statutes rather than finding an implied repeal of one of the statutes. *Carcieri v. Salazar*, 555 U.S. 379, 395 (2009); *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666 (2007). California and this Court have offered an interpretation that harmonizes the two statutes: while Section 1008 prohibits Title X funds from being used to pay for abortions, the Nondirective Counseling Mandate requires providers who engage in counseling to deliver neutral, factual information regarding any option in which a patient expresses interest, including abortion, and provide a referral.

In harmonizing the two statutes, a later-enacted statute, like the Nondirective Counseling Mandate, "give[s] meaning to a previously enacted ambiguity," and does not implicate the canon against implied repeals. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 146 (2001) (Scalia, J., concurring); *see also Am. Bank & Trust Co. v. Dallas County*, 463 U.S. 855, 872 (1983) (presumption against implied repeals "does not justify the use of an unnecessary construction of the language of an ambiguous [earlier-enacted] statute"). "At the time a statute is enacted, it may have a range of plausible meanings," but "subsequent acts can shape or focus those meanings" without impliedly repealing the earlier statute. *F.D.A. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000); *see also United States v. Fausto*, 484 U.S. 439, 453 (1988) ("the implications of a statute may be altered by the implications of a later statute" without violating the presumption against implied repeals).

Here, the Nondirective Counseling Mandate clarified an ambiguity that the *Rust* Court identified in § 1008. 500 U.S. at 184 (noting that Section 1008 "does not speak directly to the issues of counseling, referral, advocacy, or program integrity"). Congress has made clear that providers in Title X programs may not direct pregnant patients toward or away from any option, but instead must provide complete, neutral, factual information in response to patient requests. This is not a "repeal" of § 1008; its prohibition on using Title X dollars to perform abortions remains in place. Rather, Defendants no longer have the authority or discretion to interpret § 1008 to prohibit Title X providers from counseling patients regarding abortion.

Further, the Nondirective Counseling Mandate controls the interpretation of § 1008 because it is more specific. The Nondirective Counseling Mandate explicitly addresses what type of counseling may occur in Title X programs—it expressly mandates that all counseling be "nondirective." *Republic of Iraq v. Beaty*, 556 U.S. 848, 861 (2009) (holding that the presumption against implied repeal does not apply when, as here, the later-enacted statute "expressly" addresses the question at issue and "the only question is its scope."). In contrast, the presumption against implied repeals generally applies only when the earlier-enacted statute addresses "a narrow, precise, and specific subject," and the "later enacted statute cover[s] a more generalized spectrum." *Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 153 (1976). Here, the later-enacted statute (the Nondirective Counseling Mandate) is more specific: it expressly mandates that Title X programs provide a particular type of counseling, whereas Section 1008 "does not speak directly" to that issue. *Rust*, 500 U.S. at 184.

C. The Rule Violates Section 1554 of the Affordable Care Act

Section 1554 expressly provides that the Secretary HHS "shall not promulgate any regulation that"

> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
>
> (5) violates the principles of informed consent and the ethical standards of health care professionals; or

42 U.S.C. § 18114.

The Rule violates Section 1554 of the ACA. PI Ord. at 43-46.

1. Several Provisions of the Rule Directly Violate Section 1554

The Rule's requirements that Title X clinicians may not provide abortion referrals, that clinicians must refer all patients for prenatal care, and the counseling restrictions violate several of Section 1554's subsections. 42 C.F.R. § 59.14(b)(1). They place a "barrier" between patients

and the care they seek, and they impede patients from timely accessing healthcare services. 42 U.S.C. § 18114 (1)-(2). And the restrictions directly "interfere[] with" communications about one particular "treatment option" and restrict the ability of a provider to provider "full disclosure of all relevant information." *Id*. § 18114 (3). There can be no question that a referral for an abortion provider is "relevant information" to a pregnant woman who seeks to terminate her pregnancy.

Further, the Rule's limitations on the referral lists create another unreasonable barrier to the ability of individuals to receive the care they seek and impede "timely access" to abortion for Title X patients. *Id*. § 18114 (1), (2). The restrictions on patient referral lists appear specifically designed to keep women in the dark regarding where they can obtain an abortion, even if they have already elected to do so. Even if a patient specifically requests a referral to an abortion provider, a Title X provider may (at most) offer a list of "comprehensive primary health care providers … some, but not the majority of which, also provide abortion," yet "[n]either the list nor project staff may identify which providers on the list perform abortion." 42 C.F.R. § 59.14(c)(2). Providers who specialize in reproductive care but do not provide comprehensive care may not be included, even if they are the highest quality, most convenient, or most affordable providers. *Id*. And the list "may be limited to those that do not provide abortion." *Id*. That approach forces patients to investigate which of the listed providers (if any) perform abortions, creating an "unreasonable barrier" and "imped[ing] timely access" to abortion.

> As a Fourth Circuit Judge explained:
> I cannot fathom a more direct violation of [Section 1554] than a regulation prohibiting Title X health care providers from referring a woman for an abortion when she requests it. What is worse, the Final Rule actually requires health care providers to hide the ball from their patients by giving them a list of providers without telling them which ones actually perform abortions. How can this possibly be "full disclosure of all relevant information"?

Mayor & City Council of Baltimore v. Azar, 778 F. App'x 212, 213 (4th Cir. 2019) (Thacker, J., dissenting).

Further, as discussed in Section III.B, the Rule violates the "ethical standards of health care professionals" 42 U.S.C. § 18114 (5); Mot. at 5-6, 12-17, 27. The rule is contrary to the

ethical standards of leading professional organizations like the AMA, ACOG, AAP, as well as, HHS's and CDC's own QFPs. In fact, counsel for Defendants conceded that *not a single professional organization* finds the Rule compliant with prevailing standards of medical ethics. RJN iso Opp., Ex. A at 24:5-26:4.

The Rule's physical separation requirement also violates several sections of Section 1554. The Rule will result in clinic closures, creating a direct and significant barrier to access. Mot. at 21-29; 42 U.S.C. § 18114 (1), (2). Thus, a patient who learns that she is pregnant at a Title X clinic will have to spend valuable time—which she may not have—searching for, traveling to, or waiting for an appointment at a separate facility just to receive full disclosure of the healthcare options available to her. This is yet another unreasonable barrier to time-sensitive care.

Finally, the Rule's removal of the medically necessary requirement, the physical proximity to primary care requirements, and the limits on who can provide nondirective counseling will increase strain on facilities, reduce access to care, and create impermissible barriers to care. Mot. at 16, 29-31.

2. Defendants' Arguments to the Contrary are Unpersuasive

First, Defendants argue that California has waived their Section 1554 argument by failing to object on this ground in the administrative level. Opp. at 17. But Defendants do not dispute that many commenters brought the substance of these issues to their attention. That is sufficient. "Plaintiffs need not state their claims in precise legal terms, and need only raise an issue 'with sufficient clarity to allow the decision maker to understand and rule on the issues raised.'" *Nat'l Parks & Conserv. Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010); *see also, e.g.*, *Idaho Sporting Congress, Inc. v. Rittenhouse*, 305 F.3d 957, 966 (9th Cir. 2002) (plaintiffs need not "incant … magic words" or cite specific legal authority).[8]

As this Court observed, although no commenters referenced Section 1554 specifically,

[8] The motions panel stated that it "seems likely" that a challenge to the Rule under Section 1554 had been waived, but the panel ignored these Ninth Circuit cases, and relied instead on a D.C. Circuit case that is not on point. *See California*, 927 F.3d at 1078.

"numerous comments use[d] identical or substantially identical language to Section 1554 to describe how the Final Rule would impede access to care." PI Ord. at 37; *see also* ECF 97 (California Suppl. Sub. re: PI). Commenters objected to the Rule on the ground that it would "ban Title X providers from giving women full information about their health care options" (*id*.); would "prevent Title X providers from sharing complete and accurate medical information necessary to ensure that their patients are able to … obtain timely care" (*id*.); and would "limit[] how Title X providers can discuss and/or counsel on the full range of sexual and reproductive health care options with their patients" (*id*.). Commenters also noted that the Rule would "require[] physicians to disregard their Code of Medical Ethics" and would violate "ethical and professional standards around informed consent." *Id*. at 38.

Finally, Defendants do not dispute that the Affordable Care Act, including Section 1554 was before the agency during their rulemaking.[9] Defendants produced the entire Affordable Care Act—including Section 1554—as part of the administrative record. AR 397742-43.

Second, relying upon *Rust,* Defendants argue that the Rule merely imposes a condition on what the government chooses to fund, arguing to there is a distinction between "impeding something and choosing not to subsidize it." 500 U.S. at 202. But *Rust* uses this language to discuss burdens on a constitutional right. *Id*. As this Court held, California is arguing that the Rule is contrary to a specific statutory provision, which is far more specific that the constitutional requirement asserted in *Rust*. *Id*.; PI Ord. at 42-43.

Third, Defendants argue that imposing a condition on what the "government chooses to fund" does not "create" any barriers or "impede" access. Opp. at 17. This is inaccurate. "Create" does not require an "affirmative act" instead, "create" means "to produce or bring about by a course of action or behavior" or "to cause, occasion." Webster's New International Dictionary (3d ed. 1986). Similarly, "impede" does not have an affirmative act requirement. *See id.* ("impede" means "to interfere with or slow the progress of") Here, as discussed above, Defendants' course of action creates barriers to access to care and impedes timely access to care.

[9] ECF 98 Declaration of Melanie Fontes Rainer ¶ 2 (During the meeting [with the Office of Management and Budget], I briefly discussed the impact of the Final Rule on the Title X program and how that impact undermined the Affordable Care Act ("ACA").")

Fourth, Defendants argue that it is implausible that Congress would impose such a significant limitation on HHS authority in an "ancillary" provision of the ACA. Opp. at 17-18. But, as this Court held, when Section 1554 was enacted, it was entirely consistent with the prevailing Title X scheme. PI Ord. at 40-41. Moreover, Defendants' arguments that Section 1554 implicitly repeals § 1008 fail for the same reasons its arguments regarding implicit repeat regarding the Nondirective Counseling Mandate fail. *See* Section II.A.4. The two statutes can—and *were*—harmonized in the previous 2000 regulatory Title X scheme, as permissible construction of § 1008.

III. THE RULE IS ARBITRARY AND CAPRICIOUS

The Rule is a product of arbitrary and capricious decision making.

Defendants' opposition fails to explain how the Rule can pass muster under the Administrative Procedure Act (APA) in the face of the considerable evidence regarding the problems in the Rule's counseling and referral restrictions and physical separation requirement, as well as the Rule's failure to meaningfully consider its devastating impacts on the Title X program, providers, and patients. Mot. at 10-31; ECF 160-61.

Further, Defendants fail to persuasively respond to the legal arguments explaining why the Rule should be found arbitrary and capricious. Specifically, the Rule is: (1) an unreasoned departure from previous ruling making; (2) contrary to the evidence before HHS; and (3) relies upon speculative and conclusory rulemaking.

A. The Rule Ignores HHS's Previous Factual Findings

The Rule fails to explain why HHS has rejected its own past fact findings, hiding behind a catchall concept that a similar rule was once deemed to be an acceptable exercise of the Secretary's authority. But a more "detailed justification" is necessary where, as here, an agency departs from a prior policy, like here, and there are "serious reliance interests" at stake or the new policy "rests upon factual findings that contradict those which underlay its prior policy." *F.C.C. v. Fox Television Stations*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.* ("*State Farm*"), 463 U.S. 29, 47-51 (1983) (holding that a new administration's rule change was arbitrary and capricious where agency

failed to address prior factual findings); *Organized Vill. of Kake v. U.S. Dep't of Agriculture*, 795 F.3d 956, 966 (9th Cir. 2015) ("The absence of reasoned explanation for disregarding previous factual findings violates the APA.").

Further, in several instances, HHS does not acknowledge that it has changed position from previous rulemaking. *Fox*, 556 U.S. at 515 ("The requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position.") (emphasis in original).

First, HHS fails to acknowledge instances where it rejected its past findings. In 2000, HHS interpreted the Nondirective Counseling Mandate to require that "pregnancy counseling and referral must be provided to patients facing an unwanted pregnancy upon request." 65 Fed. Reg. 73. But in the Rule, HHS does not acknowledge that it is changing its interpretation of the Nondirective Counseling Mandate by stripping out the referral requirement. *Fox*, 556 U.S. at 515. This violates *Encino Motorcars, LLC. v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (holding that an agency acts arbitrarily and capriciously where it fails to "display awareness that it is changing position" and "show that there are good reasons" for the change.)

Second, HHS's rulemaking fails to discuss the QFPs, its own clinical standards, in any capacity. And both the 2000 regulations and the QFPs specified that: (1) counseling must be client centered, not focused on provider's conscience concerns; (2) pregnancy counseling includes a referral; and (3) automatic prenatal referrals are inappropriate. QFP at 2-14; Mot. at 13-14. These specifics were based upon recommendations from professional medical associations such as ACOG and AAP. It also states that the counseling and referral restrictions "endanger[] women's health," "interfere[] with the doctor-patient relationship." 65 Fed. Reg. 41270-75. In the Rule, HHS abandons all of these factual findings, based upon leading professional organizations, and fails to explain, or provide a more detailed explanation, why it is rejecting them.

Third, the 2000 regulations and QFPs were specifically predicated on ethical codes that were created by leading healthcare organizations *after* 1988. 65 Fed. Reg. at 41273-75; *see* ACOG AR 268838-41 (referencing ACOG policies and opinions); AAP AR 277788-89

(counseling changes "conflict [] with medical practice guidelines, including those of the American Academy of Pediatrics"); Fam. Planning Councils of Am. AR 385053 (the Rule "undermine[s] the evidence-based standard of care" in the QFP recommendations). HHS instead attempts to rewind the clock to 1988, states it does not agree that the Rule is noncompliant with ethical standards, without any reasoned explanation. It does not discuss these ethical codes or the fact that multiple professional organizations believes that nondirective counseling and referrals, open communication between providers and patients, and respecting client decisions. 84 Fed. Reg. 7746-48.

Fourth, in 2000, HHS found that physical separation was "unnecessary, costly, and medically unwise" and "since Title X grantees are subject to rigorous financial audits, it can be determined whether program funds have been spent on permissible family planning services, without additional requirements being necessary." 65 Fed. Reg. at 41275. In the Rule, HHS ignored these factual determinations and focused solely on perceived *risk* of misuse (without any evidence). 84 Fed. Reg. at 7729, 7764. Compare this to the 1988 rule where HHS had evidence from the GAO and OIG that stated the previous policy failed to implement properly the distinction between Title X programs and abortion as a method of family planning. 53 Fed. Reg. at 2923-2927; *Rust*, 500 U.S. at 187. Now, in contrast, there is no evidence or discussion of any confusion or comingling of funds.

Fifth, HHS even ignores its own findings from the 1988 rule it relies so heavily upon. In 1988, HHS found that separate entrances, exits, and medical records were not necessary for physical separation, based upon an evaluation of provider comments regarding the cost and strain of compliance. 53 Fed. Reg. at 2940. In 2019, HHS has changed its mind regarding entrances, exits, and records, but did not acknowledge the change, let alone provide any facts supporting the change.

Finally, HHS does not acknowledge that it is making a change to limit only APPs to provide nondirective counseling that may include a discussion of abortion. 42 C.F.R. § 59.14(b); 59.2. Previous rulemaking did not have this requirement.

B. The Administrative Record Contradicts HHS's Evidentiary Conclusions

The Rule is arbitrary and capricious because it "runs counter to the evidence before the agency," and it "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43; *Am. Fed'n of Gov't Emps., Local 2924 v. Fed. Labor Relations Auth*., 470 F.3d 375, 380 (D.C. Cir. 2006). The Court should find that HHS failed to examine the "relevant data" and failed to articulate a "satisfactory explanation for [its decision] including a rational connection between the facts found and the choice made." *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019)(quoting *State Farm*, 463 U.S. at 43.).

First, the administrative record shows that HHS was informed the counseling restrictions, referral restrictions, and physical separation would cause individuals to have diminished access to quality care.[10] Further there was evidence that Rule would lead to increased maternal and child mortality, an increase of abortions, and worse health outcomes.[11] There was also evidence on how similar past regulations had led to an increase in unintended pregnancies (often paid for by Medicaid), and worldwide negative health impacts.[12]

The Rule instead claims that the Rule will have a positive impact on public health and it

[10] Mot. at 20-21; Health Res. & Servs. Admin. AR 406633-40; Alliance of Penn. AR 243108-10; AltaMed AR 280185; ABA AR 249527; Ctr. For Am. Prog. AR 309214; Comm. Catalyst AR 271297; Santa Clara AR 308564 Drexel AR 293836; Empower Missouri AR 47946; Family Planning Coalition AR 256580-81; Wordby AR 254763-64; Legal Voice AR 310406; Prine AR 5457; Nat'l Coalition of STD Directors AR 106826; NHeLP AR 306193-95; New York AR 269293; Patient-Centered Primary Care Collab. AR 271224; Provide Inc. AR 246152; Sexual Info. & Educ. Council AR 263515; Texas Pol. AR 269930; Univ. Healthcare Found. AR 293617; U.S Congress AR 197721; Women's Health Specialists AR 252372-73; Scheppers, et al. p. 344-46.

[11] Mot. at 23-26; Medicines360 AR 247736-64; APIAHF AR 96231; Bixby Ctr. AR 246647; Ctr. For Am. Prog. AR 30917; CHANGE AR 293931; AR 239554; Federal AIDS Policy Partnership AR 305097, 08; Jane's Due Process AR 307168; Leadership Conf. on Civil & Human Rights AR 306348; Legal Voice AR 310409; Maine Women's Lobby AR 102270; Nat'l Center for Lesbian Rights AR 264994-10; Nat'l Ctr. For Transgender Equality AR 238681; Nat'l Women's Health AR 372638; Northeast Valley Health Corp. AR 313430; Appendix Ex. 115 AR 271277-76.

[12] Mot. at 26-27; Markus et. Al AR 239152; Piepert, et al. AR 305523 (Washington University study showing contraceptive access resulted in a significant reduction in abortion rates); Impact of global gag rule AR 308093-26; Cal. Pan Ethnic Network AR 269398; Ctr. For Public Policy Priorities AR 315477; Chapa-Da Indian Health AR 280725; Nat'l Asian Pacific-Am. Women's AR 278303; Pub. Counsel AR 280471; Guttmacher: Moving Forward Report p. 19-23.

will "contribute to more clients being served, gaps in services being closed, and improved client care." 84 Fed. Reg. at 7723.[13] It does not cite to any evidence, studies, or experts for this claim. Such a conclusion is implausible, given the evidence before the agency. *See* Assoc. of Reprod. Health Prof. AR 238659 ("We have seen no evidence that HHS has analyzed the economic, educational, health care and social consequences these proposed rule changes will mean for our nation.")

Second, governing medical experts explained in their comments that the Rule was contrary to prevailing ethical standards. The AMA, which wrote and interprets the Code of Medical Ethics, emphasized that the Rule "would force physicians to violate their ethical obligations," by prohibiting referrals upon patient request and unbalancing the doctor-patient relationship. AMA AR 269332.[14]

HHS again concluded the exact opposite, claiming that the Rule would not impinge on prevailing ethical standards. The Rule does not reference a single organization which believes these rules are ethical. And, as discussed in Section II.B.2, HHS has conceded that there is not a single organization supporting the ethical ramifications of the Rule.

Third, the administrative record states that various providers discussed the extensive investment they made with respect to its physical infrastructure, programming, and records systems over the years in reliance on the 2000 regulations. PI Ord. at 55-56; Mot. at 22; VTDOH

[13] *Compare with* Foster AR 239174-80 (finding "[w]omen denied an abortion were more likely than were women who received an abortion to experience economic hardship and insecurity lasting years. Laws that restrict access to abortion may result in worsened economic outcomes for women."); Goldwaite, et al. AR 239167-73; Roberts et al. AR 239160-239166 ("Policies restricting abortion provision may result in more women being unable to terminate unwanted pregnancies, potentially keeping them in contact with violent partners, and putting women and their children at risk."); Nat'l Educ. Assoc. AR 285208; Tenn. Dep't of Health AR 102528; Texas Latina Adov. Network AR 311112; Guttmacher Inst. Perspectives on Sexual and Reprod. Health p. 11-12.

[14] Mot. at 27-29; *see also* Am. Acad. of Phys. Asst. AR 106281; NASW AR 107236-37 (NASW Code of Ethics); Bixby Ctr. AR 246647; Dehlendorf AR 251842; Columbia AR 293864 (finding the Rule violates international human rights law); Fam. Planning of Iowa AR 279352; HIV Med. Assoc. AR 26913; Maine Women's Lobby AR 102267; Nat'l Abortion Fed. AR 305593; Nat'l Immigration Law Ctr. AR 252972; New York State Dep't of Health AR 239328; Texas Women's Healthcare Coalition AR 306446; Ryan AR 280324; Women's Law Proj. AR 306426; Chipidza, et al. "Impact of Doctor Patient Relationship" p. 3-4 (finding that trust was essential to a doctor-patient relationship).

AR 198208; Guttmacher AR 264117. The Rule ignores these reliance interests.

Fourth, the Rule claims that the separation requirement was necessary to assure that taxpayer dollars were not being used to fund projects where abortion is a method of family planning. 84 Fed. Reg. 7724. But the administrative record is devoid of evidence that any Title X grantee has misused Title X funds, and HHS's own reports state that "family planning projects that receive Title X funds are closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities, such as abortion." Angela Napili, Congressional Research Service Report for Congress: Family Planning Program Under Title X of the Public Health Service Act, at 14 (Oct. 15, 2018), https://fas.org/sgp/crs/misc/R45181.pdf., *see also* 2017 Report Ex. 139.[15]

C. The Rule is Speculative and Conclusory

HHS's rulemaking shows that HHS had a thumb on the scale to undervalue any compliance costs with its alleged interest in statutory compliance. This renders the Rule invalid. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008) (holding that an agency "cannot put a thumb on the scale by undervaluing the benefits and overvaluing the costs of more stringent standards," and doing so is arbitrary and capricious.) *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017) (holding that an agency may not brush aside critical facts.)

In furtherance of some perceived "benefit," HHS makes wildly conclusory assertions with no support. *See McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182,

[15] Commenters have affirmed that they follow strict financial separation and there is no comingling of funds. Mot. at 18-20; Health Quarters AR 104025 ("Health Quarters provides abortion services currently. The revenue and expenses for these services are completely separate from our Title X funded family planning program. All staff time, direct, and shared expenses are allocated to each program appropriately. The annual A133 audit verifies the financial separation."); Missouri Family Health Council AR 268686 ("Title X grantees and subrecipients take existing program requirements seriously and fully comply with them; there is no confusion among Title X providers as to what the Title X statute and current rules require."); Mt. Sinai AR ("Title X projects already face regular and extensive audits to ensure compliance with Section 1008's requirement that Title X funds do not fund abortion; in fact, the AHC undergoes a comprehensive audit at a minimum of every three years. These audits are carried out by experienced auditors from IPRO who conduct exhaustive multi-day on-site reviews of the program. There has never been any allegation that these audits are superficial, inadequate, or biased. And, there have been no concerns raised through these audits that the Title X funds have been used improperly beyond what is allowed pursuant to Section 1008.")

1186–87 (D.C. Cir. 2004) (holding that courts "do not defer to the agency's conclusory or unsupported suppositions."); *See Ctr. For Biological Diversity*, 538 F.3d at 1200 (agency acted arbitrarily by assigning zero value to a relevant factor reflected in the record); *Make the Road New York v. McAleenan*, 405 F. Supp. 3d 1, 55 (D.D.C. 2019) ("An agency cannot possibly conduct reasoned, non-arbitrary decision making concerning policies that might impact real people and not take *real life circumstances* into account.") (emphasis in original).

First, for all the examples listed in Section III.B, HHS clearly disregarded contrary evidence by arbitrarily assigning them zero value. HHS concluded that it "does not believe" the Rule will impact patients' access to care. 84 Fed. Reg. 7725, 7769, 7781. In doing so, the Rule dismisses the multitude of very real consequences from loss of care.

Second, the administrative record shows HHS was warned that the Rule would result in providers leaving the Title X program as soon as it became effective. Mot. 20-21.[16] HHS ignored this evidence and concluded that "new providers" would join the program due to HHS's emphasis on provider-driver care. 84 Fed. Reg. at 7782. This is "wholly conclusory and unsupported." PI Ord. at 68. Nothing in the record supports their argument that new providers seek to join the program at levels sufficient to replace all the providers who warned HHS that they would have to leave the program.[17]

Third, HHS's compliance cost estimate, stating that it would take $20,000 to $40,000 to come into compliance, is conclusory and unsubstantiated. As this Court found, this estimate is seemingly "pulled from thin air" and does not address ongoing compliance costs. PI Ord. at 59.

Fourth, HHS's removal of the "medically approved" requirement is conclusory. HHS stated that the requirement "risked creating confusion about what kind of approval is required," 84 Fed. Reg. at 7774, but as this Court noted, there is no evidence that any provider had expressed any confusion. PI Ord. at 65; QFP at 7.

[16] YWCA AR 268933; PPFA AR 316476-77; 316414; NFPRHA AR 308014-21; Balt. AR 245624; S. Ctr. Fam AR 308742; Vermont Med. Society AR 107267.

[17] California acknowledges that the arbitrary and capricious review is intended to be based solely on the "record before the agency at the time the agency acted," but notes that this prediction has been borne out and California has experienced a catastrophic decimation of its Title X network due to provider loss. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 419 (1971); Decl. of Julie Rabinovitz in support of California's Motion for Partial Summary Judgment.

D. Defendants' Arguments that the Rule is the Product of Reasoned Decisionmaking are Unpersuasive

Defendants' arguments to support many of the Rule's provisions can be boiled down to: we passed a similar rule in 1988 so we can implement a similar Rule again. This does not meet the APA's test for reasoned rulemaking. *See Michigan*, 135 S. Ct. at 2710 (It is a "foundational principle of administrative law that a court may uphold agency action only on the grounds that the agency invoked when it took the action.") Nor can HHS rely on the factual bases justifying the 1988 regulations. *See Sierra Club*, 671 F.3d 955, 966 (9th Cir. 2012) ("[An agency] stands on shaky legal ground relying on significantly outdated data" to justify its actions.); *Ctr. for Biological Diversity*, 538 F.3d at 1198 ("What was a reasonable balancing of competing statutory priorities twenty years ago may not be a reasonable balancing of those priorities today."). As discussed in Section III.A, HHS has made multiple findings of fact since 1988, and it cannot abandon those findings without reasoned explanation.

Further, *Rust* was based upon different facts, specifically a GAO and OIG report, as well as "client experiences." *Rust*, 500 U.S. at 187 ("He also determined that the new regulations. . . are justified by client experiences under the prior policy.")

Defendants cite no authority for the proposition that they may adopt a policy with substantial costs and no apparent benefit where the underlying statute is ambiguous and does not mandate that approach.[18] A "reasoned analysis" is still required. *Id*. at 187. Finally, as discussed above in Section I, the 1988 rule upheld in *Rust* is also distinguishable from the Rule, and HHS does not explain why it has made those distinctions.

Defendants also generally argue that they are under no obligation to respond to each commenter who has different "policy preferences" than Defendants. This argument obscures that Defendants did not just fail to respond to some commenters, and that those comments were not just expressing differences in policy, but rather, Defendants uniformly failed to respond to countless commenters and record evidence that demonstrated that the Rule was unworkable and

[18] U.S. Senators Margaret Wood Hassan & Kamala D. Harris Comment Letter AR 388396 ("Given that the Department acknowledges that there is no statutory or other legal requirement to issue the rule, along with the fact that the rule conveys to quantifiable benefit we are alarmed and confused by this expedited time frame.")

would decimate the Title X network. This included the actual Title X grantees charged with administering the program. HHS's dismissal of this evidence as a "policy difference" is an abrogation of its duty to engage in reasoned rulemaking when enacting a sea-change in an established government program. Defendants' other arguments similarly do not refute California's arguments that the Rule is riddled with arbitrary and capricious decisionmaking.

1. The counseling and referral restrictions are arbitrary and capricious

Defendants argue that the counseling and referral restrictions are not arbitrary and capricious because they were allowed by *Rust*. Opp. at 19. As discussed above, this is inadequate. Further, *Rust* held that that § 1008 "does not speak directly to the issues of counseling [and] referral." 500 U.S. at 184. As such, HHS must still conduct its own fact-finding.

Defendants then argue that they "merely" relied upon conscience statutes to conclude that the Rule does not require Title X projects to provide nondirective counseling. Opp. at 20. But this is contrary to plain language of the Rule which states that "the 2000 regulations are not consistent with federal conscience laws." 84 Fed. Reg. at 7746. And, as the Court held in the PI Order, HHS must demonstrate why more sweeping regulations are necessary in light of Title X's existing federal conscience law safeguards. PI Ord. at 62; *Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 50 (D.D.C. 2019) (holding that a rule is arbitrary and capricious with the "government failed to explain why the [existing] safeguards as a whole would not prevent against the risk" the rule purports to address.)[19]

Defendants also argue that there is no reversal from the 2000 regulations because HHS never concluded that the Nondirective Counseling Mandate required suspension of the 1988 regulations. Opp. at 20. This argument relies on believing that HHS must use "magic words" to say it was suspending the 1988 regulations. First, there was no need to explicitly suspend the 1988 regulations in 2000 because they were suspended by 1993. 58 Fed. Reg. 7462, 7462 (1993). Second, HHS made numerous factual findings that the 1988 regulations were contrary to

[19] Ctr. for Health Policy and Law, Northeastern Univ. School AR 316815.

ethics, best practices for patient care, and unnecessary. Mot. at 12, 17. As such, there is a clear reversal in Defendants' position on what constitutes nondirective counseling, and there is clear reversal in Defendants' position that referrals are no longer part of counseling.

Defendants further argue that they are not required to address every statement or rationale underpinning the prior policy because they discussed the changes at length in the Rule. Opp. at 20-21. But all the Rule says is: (1) Defendants believe that the Rule is more compliant with § 1008; and (2) *Rust* found this interpretation acceptable. 84 Fed. Reg. 7758-59. This does not address any of the evidence in the record. Nothing about this explanation is reasoned. It is conclusory and does not respond to any of the arguments made by commenters. *See State Farm*, 463 U.S. at 43; *Delta Air Lines, Inc. v. Exp.-Imp. Bank of the U.S.*, 718 F.3d 974, 978 (D.C. Cir. 2013) (*per curiam*) (concluding an agency's unexplained categorical conclusion violated the APA.)

Regarding the QFPs, Defendants claim that they expect people to comply with the QFPs to the extent they are compliant with the Rule. Opp. at 21. Defendants do not dispute that HHS failed to review the QFPs in its decisionmaking. The Rule also does not acknowledge or explain why it was departing from reasoned, long-held, and specific conclusions regarding best-practices for providing care.

Defendants argue that there is no tension between medical ethics and the Rule. Opp. at 21. But as California has demonstrated, there is no evidence that a single medical organization believes this Rule is compliant with the standards of medical ethics. Mot. at 21-27. The Rule sidesteps these arguments to rely upon *Rust* and states that it "disagrees." 84 Fed. Reg. 7748. A bald disagreement is not reasoned decision making.

Regarding the Advanced Practice Provider (APP) requirement, Defendants argue that the APP requirement is "sensible" but does not actually discuss any reasons for imposing the requirement. Opp. at 22. Nothing in the Rule to explains the reason for imposing the requirement or refutes any of the evidence establishing why this section is unnecessary.[20] And the Rule is

[20] Christian Healthcare Professional AR 101746 ("Nurse practitioners (the by and large health care providers in most Title X networks) may not provide this information under the current

internally inconsistent. It allows directive counseling about carrying a pregnancy to term from *any* provider, but only *nondirective* counseling (which includes abortion counseling) from a narrow set of providers. 42 C.F.R. § 59.14(b)(1)(i); (b)(iv).

Finally, Defendants argue that HHS adequately weighed policy considerations versus the potential costs on patients, and "merely reached a different conclusion." Opp. at 22. But, as discussed in California's motion and Sections III.A-C, any weighing is arbitrary when HHS claims benefits and costs in starkly different than the record evidence supports.

2. The physical separation requirement is arbitrary and capricious.

Defendants' arguments in favor of the physical separation requirement fare no better. Their reliance on *Rust* is inadequate, as discussed above, and *Rust* expressly held that § 1008 "does not speak directly" to "program integrity," so the physical separation requirement is not required for compliance. 500 U.S. at 184.

Similarly, Defendants argue that physical separation was reasonable to address the "risk" that funds would be misused. Opp. at 23. But again, there is no evidence of misuse nor can Defendants point to any. Mot. at 17-21. *See Sorensen Commc'ns, Inc. v. F.C.C.*, 755 F.3d 702, 708 (D.C. Cir. 2014) (holding that a rule is arbitrary and capricious when the agency relies on its predicative judgment to ignore questions and its claimed fears are speculative).

Defendants further argue that they considered reliance interests in drafting the Rule, as well as the effects on public health and patients, and "reasonably" explained why they were departing from past practice. Opp. at 23. But they cannot point to any part of the Rule where HHS weighs any of the evidence provided or cites to any evidence that is contrary to the studies and evidence in the administrative record. HHS simply dismisses all evidence contrary to HHS's desired outcome. A more detailed examination is required when serious reliance interests are at stake. *See Encino Motorcars,* 136 S. Ct. at 2126-27. HHS fails to meet this standard.

Further, Defendants argue that they weighed the cost of coming into compliance with the physical separation requirement. 84 Fed. Reg. 7781-82; Opp. at 24. But, as this Court held, their

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language. This will have significant effects both in urban and rural areas where MDs are in short supply."); Comm. Health. Network AR 294154.

cost of compliance estimates are pulled from thin air. PI Ord. at 59. Moreover, HHS's general evaluation of compliance costs is conclusory and speculative, with HHS summarily deciding that compliance would be affordable.[21] There is no reasoned analysis in the Rule and Defendants' opposition again rests on HHS simply having different priorities, an inadequate explanation.

Finally, Defendants fail to respond to California's argument that the "infrastructure" prohibitions are arbitrary and capricious, in light of evidence that wrap-around services are an essential and important part of the Title X program. Mot. at 18-21.

3. Removal of the medically approved requirement is arbitrary and capricious.

Defendants further argue that they addressed concerns that removal of the medically approved requirement was a reversal of previous positions and that it would degrade care. Opp. at 25. But Defendants' argument obfuscates the actual purpose of the removal of the requirement: to increase availability of non-FDA approved, inaccurate, and less effective methods of family planning based upon tracking fertility levels (which are best suited for women *trying* to get pregnant). Mot. at 29-30. Multiple commenters warned that promotion of fertility based methods would "actively undermine the program's mandate." *Id*.; Guttmacher AR 264110; Montclair Univ. AR 107091 ("data shows that fertility awareness methods are among the least effective family planning methods. . . the FDA has warned that these methods are not reliable forms of contraception."); Raising Women's Voices AR 23827-28; Health Quarters AR 104023; Cal. PP Educ. Fund AR 248998. The Rule fails to respond to commenters who expressed this concern.

Further, Defendants argue that the agency explained that medically approved had been difficult to enforce in the past. But again, as discussed in California's motion, all Title X recipients were aware that medically approved meant FDA-approved. Mot. at 29. Defendants do

[21] Cook Cty AR 305263 ("To maintain a separate medical records system for abortion-related activities would present challenges in our ability to maintain continuity of quality care for our patients and likely be very expensive and not an efficient use of our limited resources."); Brown AR 245854-55 (""Depending upon where in the country a facility is located as property rental and construction costs vary widely, these additional expenses could easily cost at least 20 or 25 times the estimates that HHS is providing for the first year."); Mass. Dep't of Pub. Health AR 91194.

not respond this argument.

4. The primary care requirement is arbitrary and capricious

Defendants misstate California's argument that the primary care linkage provision is arbitrary and capricious. California argued that multiple commenters informed HHS that requiring "close physical proximity" to a Title X site would result in fewer Title X sites in rural areas. Mot. at 30. Emphasis on primary care to the detriment of Title X would be contrary to Title X.

Defendants' motion makes several non-sequitur arguments regarding the value of primary care but does not actually address the evidence cited by California, that the proximity requirement would block existing or future Title X sites in areas where Title X sites offer the *only* care. Guttmacher AR 264118-19; ACP AR 281210-11; Cal. AR 245699; ASTHO AR 199037.[22]

Defendants further argue that geographic proximity is a factor in evaluating grant decisions and that the Rule does not impose an absolute requirement that primary case must be in close proximity. Opp. at 27. But nothing in the text of the regulation affirms that the proximity requirement is a "suggestion," not a requirement.

5. The differential treatment for minors requirement is arbitrary and capricious.

Defendants again misstate California's argument regarding minors seeking free/ reduced-cost services. HHS argues that it is reasonable to address the circumstances in which a minor is seeking free or reduced services. But HHS does not meaningfully address why there is now a discrepancy in how minors are treated if they are seeking free or reduced services versus if they are seeking standard-cost services. Mot. at 30-31. Defendants instead default to referring to the requirement as reasonable. This is insufficient.

IV. THE RULE IS IN EXCESS OF STATUTORY AUTHORITY

Defendants' again rely upon *Rust* to argue that the Rule is a valid exercise of statutory

[22] Title X Family Planning Annual Reports: 2017 National Summary (Aug. 2018) and 2016 National Summary (Aug. 2017) AR 406177-12 (finding that the Title X network is the often the only source of health care and education for many clients)

authority. Opp. at 14-15. But as discussed above in Sections II.A-B and as this Court held, Section 1554 and the Nondirective Counseling Mandate are limitations on the Secretary's authority to promulgate regulations. And this Rule overreaches.

Further, the Rule in totality conflicts with the purpose of Title X, making it contrary to the intent of Congress in creating a program to provide low-cost healthcare for women. HHS has laser-focused on § 1008, creating an endless series of compliance layers that make it difficult to actually implement the program. HHS cannot add more compliance steps without any showing of need, especially since the record is clear that HHS's actions will result in harm to the Title X program. *See* Sections III.A-C.

Finally, to the extent the Rule has focused on ensuring that providers are protected under the conscience statutes—despite the existing safeguards protecting conscience—courts have held that HHS has limited to no authority to implement regulations to effectuate the conscience statutes. *New York v. United States Dep't of Health & Human Servs*., 2019 WL 5781789, at *32 (S.D.N.Y. Nov. 6, 2019); *City & Cty. of San Francisco v. Azar*, 2019 WL 6139750, at *16-17 (N.D. Cal. Nov. 19, 2019).

THE RULE VIOLATES THE EQUAL PROTECTION CLAUSE

The Court should deny Defendants' motion to dismiss California's equal protection claim. California has stated a claim for invidious, gender-based discrimination in the formulation of the Rule, and should have the opportunity to test its allegations through the discovery process. Fed. R. Civ. P. 56 (d); Kane Decl., ¶¶ 2-4.

The Equal Protection component of the Fifth Amendment prohibits the federal government from denying equal protection of the laws. The Rule violates the Clause by singling out and harming women's access to healthcare, creating a constitutionally impermissible gender-based classification. *See Caban v. Mohammed*, 441 U.S. 380 (1979) (sex-based law that permit unwed mother, but not unwed father to block adoption of a child was unconstitutional); *Int'l Union v. Johnson Controls*, 499 U.S. 187 (1991) (employer's sex-based policy that barred women from certain jobs was facially discriminatory); *Arce v. Douglas*, 793 F.3d 968, 977 (9th Cir. 2015) (challenged statute and/or its enforcement "unconstitutional if its enactment or the

manner in which it was enforced were motivated by a discriminatory purpose").

Defendants argue that the Rule does not discriminate of the basis of sex because it imposes requirements on the receipt of federal funds—regardless of gender. But many of the Rule's specific requirements result in adverse healthcare treatment for *only* women. For example, only women are impacted by the ethical violations of the Rules, the limitations on counseling, the interference in the doctor-patient relationship, the emphasis on non-evidence based contraception, the prenatal referral requirement, the restrictions on obtaining a referral for abortion, the limitation on who can provide them with counseling, and the requirement to visit multiple clinics to receive healthcare because of physical separation.

Defendants fail to demonstrate an "exceedingly persuasive justification" for the Rule because the Rule creates a gender-based classification by singling out women's healthcare for adverse treatment in the Title X program. *United States v. Virginia*, 518 U.S. 515, 531 (1996); *Miss. Univ. for Women v. Hogan*, 458 U.S. 718, 724 (1982). The Supreme Court has "repeatedly recognized that neither federal nor state government acts compatibly with the equal protection principle when a law . . . denies to women, simply because they are women, full citizenship stature—equal opportunity to aspire, achieve, participate in and contribute to society based on individual talents and capacities." *Virginia*, 518 U.S. at 532 (court must "carefully inspect[] official act that closes a door or denies opportunity to women"). In such instances, the government must meet a "demanding" standard of review. *Id*. at 533. The government must show "at least that the [challenged] classification serves important government objectives and that the discriminatory means employed are substantially related to the achievement of those objectives.'" *Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1690 (2017). Like in *Nevada Dep't of Human Res. v. Hibbs*, 538 U.S. 721, 728-29 (2003), where the Supreme Court applied "heightened scrutiny" analysis to a governmental justification that relied on overbroad generalizations about women, here Defendants seem to have relied upon a generalized view that medical ethics and evidence should be disregarded when the subject of regulation is women's reproductive healthcare, as Defendants' abandonment of their own, evidence-based standards for quality care demonstrate. Defendants cannot meet this rigorous standard, particularly given the

arbitrary and capricious nature of their rulemaking, as discussed in Section III.A-C.

Defendants rely on *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263 (1993) to argue that rational basis standard applies. Opp. at 27-28. *Bray* is distinguishable. *Bray* was statutory interpretation issue: whether 42 U.S.C. § 1985(3) provided a federal cause of action against private persons obstructing access to abortion clinics. 506 U.S. at 266. The Court held that plaintiffs had not demonstrated that "class-based, invidiously discriminatory animus lay behind" the individual protestors' action and had failed to show that the protestors interfered with rights that are protected against private and official encroachment. *Id*. at 268. In contrast, this Court is faced with a constitutional cause of action for a Rule that is the product of invidious discrimination—as opposed to a statutory claim—and plaintiff is challenging the conduct of governmental actors, not private protestors.

Defendants' reply in support of their motion to dismiss cited to *Harris v. McRae*, 448 U.S. 297, 322-23 (1980) (challenging the Hyde amendment's limitations on use for federal funds to reimburse the cost of abortions under Medicaid) and *Maher v. Roe*, 432 U.S. 464, 470-71 (1977) (challenging a Connecticut regulation prohibiting the funding of abortions that were not medically necessary) in further support of their claim that rational scrutiny was the applicable standard of review. ECF 145 at 13. Both cases are also distinguishable. Again, like in *Bray*, both cases deal with questions of statutory interpretation, not a constitutional causes of action. Further, unlike here, neither case determined that invidious discrimination was a factor in creation of the statute. Finally, the cases held that the government may not place obstacles in the path of a women's exercise of her right to choose an abortion, and women have the same range of choices they would have had if Congress had chosen to subsidize no health care costs. 432 U.S. at 317; 432 U.S. at 475-76. In contrast, here, the restrictions place active obstacles in front of women seeking specific care, for example by making women engage in a wild goose chase to find an abortion provider, and the restrictions make women worse off than had they gone to a non-Title X provider. *See* PI Ord. at 43.

Moreover, contrary to Defendants' suggestions, this Rule goes well beyond merely disfavoring abortion. Defendants have promulgated a Rule that "directly compromise[s]

providers' ability to deliver effective care [to women] and coerce[s] [providers] to obstruct and delay [female] patients with pressing medical needs." PI Ord. at 15. As a direct result of the Rule, there will be "'contraceptive deserts' where women in need of Title X-funded contraceptive services will be unable to find an affordable, well-qualified provider within their county." *Id*. at 17. Thus, the Rule has implications beyond abortion and funding; by singling out women's healthcare, it will directly harm women because of their unique reproductive healthcare needs

Further, there is no rational relationship between seeking to disfavor abortion by reducing women's access to Title X services. As this Court previously held, Title X will lead to a lack of access (and, ultimately, more unintended pregnancies and higher rates of abortion). PI Ord. at 37. Such diminished access is more likely to increase unwanted and unplanned pregnancies. Moreover, as California has alleged, Defendants' faulty rulemaking is not accidental, but a deliberate and invidious disregard for facts and medical evidence relating to women's healthcare. *Arce v. Douglas*, 793 F.3d 968, 977-80 (9th Cir. 2015); *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp*., 429 U.S. 252, 265 (1977).

As discussed in Section III, the decisionmaking process upon which this Rule rests demonstrates Defendants' animus toward women and women's healthcare needs. The Rule fits within the overall context of Defendants' deliberate effort to limit women's access to the full range of reproductive healthcare, including abortion care. Compl. ¶ 8. In formulating the Rule, Defendants deliberately failed to solicit input from leading healthcare experts, while soliciting the input of proponents of the Rule who lacked in-depth expertise on reproductive healthcare issues. *Id*. ¶ 79.

THE COURT SHOULD RULE NOW

The Court should not wait for the Ninth Circuit to issue an order before it rules on the Motion for Summary Judgment.

First, the administrative record was not available at the time the plaintiffs moved for preliminary injunction, and it is not now before the Ninth Circuit. The Ninth Circuit cannot render a meaningful and final evaluation of California's arbitrary and capricious claims because

it cannot evaluate the evidence before HHS when it promulgated the Rule.

Second, in light of the physical-separation provision that takes effect on March 4, 2020, a timely order is critical. If physical-separation was to take place, California's Title X network would face an even greater loss of providers, to the detriment of Californian women and families. *See* Rabinovitz Decl. ¶¶ 13-15.

Third, there are no grounds for a stay if the Court issues an order in California's favor. Vacatur of the Rule would simply reinstate a 19-year-old regulation that HHS and grantees are familiar with and can easily comply with. Defendants do not explain their reasons for needing emergency appellate relief.

Fourth, the entire Rule should be vacated, not severed. California has demonstrated that the entire Rule, not just specific sections, is contrary to the APA and should be vacated. Any attempt to "leave standing isolated shards of the Rule that have not been found specifically infirm would ignore the big picture: that the rulemaking exercise here was sufficiently shot through with glaring legal defects as to not justify a search for survivors." *New York,* 2019 WL 5781789 at *69; *see also Humane Soc'y of United States v. Zinke*, 865 F.3d 585, 614-15 (D.C. Cir. 2017) (when there are "major shortcomings that go to the heart of the" agency's actions and those deficiencies played a "serious and pervading role… in the agency's decisionmaking," vacatur of the entire rule is appropriate).

CONCLUSION

For the reasons set forth here and in California's motion for partial summary judgment, the Court should grant summary judgment to California, and deny Defendants' Motion to Dismiss/ Cross-Motion for Summary Judgment, and vacate the Rule in its entirety.

Dated: February 10, 2020

Respectfully Submitted,

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA,

Plaintiff,

v.

ALEX AZAR, in his OFFICIAL CAPACITY as SECRETARY of the U.S. DEPARTMENT of HEALTH & HUMAN SERVICES; U.S. DEPARTMENT of HEALTH & HUMAN SERVICES,

Defendants.

3:19-cv-01184-EMC

DECLARATION OF KETAKEE KANE IN SUPPORT OF CALIFORNIA'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS/CROSS-MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF CALIFORNIA'S MOTION FOR SUMMARY JUDGMENT

Filed concurrently with:
1. California's Opposition to Defendants' Motion to Dismiss/Cross-Motion for Summary Judgment and Reply in Support of California's Motion for Summary Judgment;
2. Supplemental Appendix of Evidence; and
3. Request for Judicial Notice

Date:	February 20, 2020
Time:	1:30 p.m.
Dept:	Courtroom 5, 17th floor
Judge:	Hon. Edward M. Chen
Date Filed:	March 4, 2019
Trial Date:	None Set

I, Ketakee Kane, declare as follows:

1. I am an attorney licensed to practice before the courts of the State of California. I am employed by the Office of the California Attorney General as a Deputy Attorney General, counsel to Plaintiff California, by and through Attorney General Xavier Becerra (California), in this case. I have personal knowledge of the facts set forth in this declaration. If called as a witness in this action, I could and would testify competently to these facts.

2. On January 15, 2020, California filed a motion requesting that the Court bifurcate California's APA claims from its Constitutional Equal Protection claim (Dkt. No. 157), which the Court granted (Dkt. No. 158).

3. Out of an abundance of caution, this declaration is submitted under Fed. R. Civ. Pro. 56(d) in support of California's request that the Court's decision on California's Equal Protection Claim be deferred.

4. Deferring any decision on California's Equal Protection Claim will be appropriate because doing so would promote judicial economy. The Court can decide California's APA claims based the administrative record; there is no need for additional discovery on those claims. In contrast, California's Constitutional claim will require discovery, which could be deferred by this Court's adjudication of the APA claims. Through discovery, California will be seeking HHS meeting records and HHS communications with third parties. California anticipates that such documents will demonstrate HHS's intent in promulgating the Rule.

5. Attached as **Exhibits 137** through **148** to the Supplemental Appendix of Evidence are true and correct excerpts from Defendants' production of the Administrative Record.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct, and that I signed this declaration on February 10, 2020 in Oakland, California.

/s/ Ketakee Kane
Ketakee Kane

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