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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ESSENTIAL ACCESS HEALTH, INC.; MELISSA MARSHALL, M.D.,

Plaintiffs,

v.

ALEX M. AZAR II, Secretary of U.S. Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and DOES 1-25,

Defendants.

Case No. 3:19-cv-01195-EMC

PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT

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

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APPENDIX OF CITED COMMENTS FROM THE ADMINISTRATIVE RECORD[1]

Abbreviation	Organization Or Individual	Bates Range of Comment
AAMC	Association of American Medical Colleges	264535 - 264540
AAN	American Academy of Nursing	107970 - 107975
AAP	American Academy of Pediatrics; Society for Adolescent Health and Medicine	277786 - 277796
AAPA	American Academy of Physician Assistants	106280 - 106281
ACOG	American College of Obstetricians and Gynecologists	268836 - 268853
AM	Access Matters	256444 - 256455
AMA	American Medical Association	269330 - 269334
APHA	American Public Health Association	239893 - 239899
Brindis	Claire Brindis, DrPH, Professor of Pediatrics and Health Policy	388050 - 388066
Cal AG et al.	Attorneys General of California, Connecticut, Delaware, Hawai'i, Illinois, Iowa, Maine, Maryland, Minnesota, New Jersey, New Mexico, North Carolina, and the District of Columbia	245688 - 245712
CBD	Center for Biological Diversity	54193 - 54197
CRR	Center for Reproductive Rights	315959 - 316004
Drexel	Drexel College of Medicine Women's Care Center	293833 - 293841
EAH	Essential Access Health	245482 - 245496
EM	Empower Missouri	47946 - 47947
FAPP	Federal AIDS Policy Partnership	305096 - 305111
FPCA	Family Planning Councils of America	385031 - 385035
FPCI	Family Planning Council of Iowa	279351 - 279363
Guttmacher	Guttmacher Institute	264415 - 264440

[1] Defendants produced the Administrative Record to Plaintiffs on June 24, 2019 and certified the completeness of the Record on September 20, 2019. An Appendix of cited comments from the produced Administrative Record is attached to this motion for the Court's convenience. Comments are cited in Plaintiffs' Motion for Summary Judgment according to the abbreviations in this chart.

Jacobs	Jacobs Institute of Women's Health	239147 - 239151
Milken	Milken Institute School of Public Health, George Washington University	106795 - 106803
MSAHC	Mount Sinai Adolescent Health Center	106748 - 106755
NACCHO	National Association of County & Health Officials	294042 - 294048
NCJW	National Council of Jewish Women	102346 - 102353
NFPRHA	National Family Planning & Reproductive Health Association	308011 - 308048
NIRH	National Institute for Reproductive Health	106456 - 106467
NLIRH	National Latina Institute for Reproductive Health	307451 - 307457
NWLC	National Women's Law Center	280765 - 280775
PPFA	Planned Parenthood Federation of America	316400 - 316495
VTDOH	Vermont Department of Health	198204 - 198209
Wash	Bob Ferguson, Attorney General of Washington	278551 - 278578

NOTICE OF MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on February 20, 2020 at 1:30 p.m., or as soon as this matter may be heard by the above-captioned Court, at 450 Golden Gate Avenue, Courtroom 5, 17th floor, San Francisco, California, before the Honorable Edward M. Chen, Plaintiffs Essential Access Health, Inc. and Melissa Marshall, M.D. will and hereby do move the Court, pursuant to Rule 56 of the Federal Rules of Civil Procedure, for partial summary judgment against all Defendants: Alex M. Azar II, Secretary of Health and Human Services; the United States Department of Health and Human Services; and their officers, agents, servants, employees, attorneys, and any other persons who are in active concert or participation with them (collectively, "Defendants").

Plaintiffs move that the Court grant summary judgment in their favor, on the grounds that the Final Rule promulgated by Defendants on March 4, 2019, titled "Compliance with Statutory Program Integrity Requirement" and published at 84 Fed. Reg. 7714 is both arbitrary and capricious and contrary to law in violation of the Administrative Procedure Act. Plaintiffs request that the Final Rule be vacated and set aside in its entirety.

This Motion is based on this Notice of Motion; the Memorandum of Points and Authorities and Appendix of Comments filed concurrently herewith; the accompanying Declaration of Julie Rabinovitz M.P.H., President and CEO of Essential Access Health, Inc.; the Proposed Order submitted herewith; further papers and argument as may be submitted to the Court in connection with the Motion; the relevant pleadings and papers on file in this action; and such evidence and argument as may be presented at the hearing before this Court.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

For nearly fifty years, the Title X program has been a critical part of the nation's public health safety net, subsidizing high-quality family planning services for low-income individuals. That safety net has already been eroded by Defendants'[2] promulgation of the Final Rule, which imposes unjustified, unethical, and cost-prohibitive changes to the program. Absent meaningful relief from the Court before March 4, 2020, Plaintiffs will be forced to comply with the Final Rule's physical separation requirement—a costly, draconian measure requiring Title X recipients to conduct their *non*-Title X activities using "mirror" facilities and staff—or leave the program.

Throughout this case, Plaintiffs have been reminded that "elections have consequences." While that is certainly true, our system places important restrictions on any administration's ability to implement its whims. No agency may promulgate rules in violation of the Administrative Procedure Act ("APA") or that contravene the laws of the United States. Thus, "even when reversing a policy after an election, an agency may not simply discard prior factual findings without a reasoned explanation." *Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015). As this Court previously found, "[t]he record evidence indicates that HHS promulgated the Final Rule, which represents a sharp break from prior policy, without engaging in any reasoned decisionmaking." Dkt. 78 ("P.I. Order") at 2. The Final Rule also flouts restrictions on HHS's rulemaking authority passed by Congress in the HHS Appropriations Act and the Affordable Care Act. *Id.* at 26-46. And while Defendants have previously urged this Court to await the Ninth Circuit's decision on Defendants' appeal rather than reach the merits of Plaintiffs' claims, further delay will deny Plaintiffs the opportunity for meaningful relief. In any event, the pending appeal is limited to review of preliminary injunction orders; unlike this Court, the Ninth Circuit does not have the administrative record before it, and its decision will not dispose of this case. Plaintiffs' APA claims are ripe for disposition now.

This is not the first, and unfortunately not likely to be the last, time that the current

[2] "Plaintiffs" refers to Essential Access Health ("Essential Access") and Dr. Melissa Marshall. "Defendants" refers to the Department of Health and Human Services ("HHS") and Secretary Azar.

administration has run roughshod over laws enacted by Congress in its haste to impose ill-conceived policy changes. The Final Rule is unlawful and must be vacated in its entirety.

II. BACKGROUND

The Court is familiar with the background of Title X and the Final Rule. *See* P.I. Order at 3-13. Plaintiffs recount below only the facts relevant to this motion.

A. The Title X Program

Title X of the Public Health Services Act ("PHSA") authorizes the Secretary of Health and Human Services "to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a).

Pursuant to Section 1008 of Title X, "[n]one of the funds appropriated under [Title X] shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. HHS has always interpreted this section to bar the use of Title X funds to perform or subsidize abortions. *See* 36 Fed. Reg. 18447, 18466 (the 1971 Title X regulations, stating that Title X projects "will not provide abortions as a method of family planning."); *see also* 42 C.F.R. §§ 59.5(a)(5), 59.9 (1986) (same). At the same time, HHS distinguished between the use of Title X funds to provide abortions and the use of Title X funds to provide patients with neutral counseling on their pregnancy options. Accordingly, in 1981, HHS issued guidelines that "required nondirective options couns[e]ling on pregnancy termination (abortion), prenatal care, and adoption and foster care when a woman with an unintended pregnancy requests information on her options, followed by referral for these services if she so requests." 53 Fed. Reg. 2922, 2923.[3]

The 1971 regulations and the 1981 guidelines governed the Title X program until 1988, when HHS promulgated new regulations that reversed its longstanding policy in three main ways. First, the 1988 regulations forbid Title X projects from providing "counseling concerning the use

[3] Unless otherwise indicated, all emphases are in the original, and all brackets and internal quotation marks have been omitted.

of abortion as a method of family planning" or providing "referral for abortion as a method of family planning." 42 C.F.R. § 59.8(a)(1) (1989). Second, the regulations prohibited Title X projects from "encourag[ing], promot[ing] or advocat[ing] abortion as a method of family planning." *Id.* § 59.10(a). Third, the regulations required Title X projects to be physically separate from prohibited abortion-related activities. *Id.* § 59.9. Although HHS had already required Title X projects to keep Title X funds separate from non-Title X funds, the 1988 regulations made clear that "[m]ere bookkeeping separation of Title X funds from other monies [was] not sufficient." *Id.*

The Supreme Court upheld the 1988 regulations against challenge in *Rust v. Sullivan*, 500 U.S. 173 (1991), finding that they "reflect[ed] a plausible construction of the plain language of the statute." *Id.* at 184. However, the 1988 regulations never fully went into effect. In 1993, the Secretary restored the program to the 1981 guidelines, based in part on the conclusion that the 1988 regulations "unduly restrict[ed] the information and other services provided to individuals under this program." Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 Fed. Reg. 7462 (Feb. 5, 1993). In 2000, HHS issued new regulations formally revoking the 1988 regulations and largely restoring the pre-1988 policy. Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 65 Fed. Reg. 41270 (July 3, 2000); Provision of Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41281 (July 3, 2000). As part of the 2000 regulations, HHS made detailed factual findings explaining why the 1988 regulations were inappropriate, and even harmful. Specifically, HHS found that a prohibition on abortion counseling and referral (1) "endangers women's lives and health by preventing them from receiving complete and accurate medical information," and (2) "interferes with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients." 65 Fed. Reg. at 41270-75. HHS determined that "requiring a referral for prenatal care . . . where the client rejected those options would seem coercive and inconsistent" with the prevailing medical standards recommended by national medical groups." *Id*. HHS also found that the physical separation requirement was "not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services."

Id. at 41276.

B. Statutory Developments Post-*Rust*

In the years since *Rust* was decided and the 1988 regulations were rescinded, Congress has enacted two statutory provisions which control Title X pregnancy counseling and the Secretary's authority to promulgate regulations under Title X. First, in every year since 1996, the HHS Appropriations Act has set forth that "amounts provided to [Title X] projects under such title shall not be expended for abortions, [and] that all pregnancy counseling shall be nondirective." *E.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, Pub. L. No. 115-245, Div. B, Tit. II, 132 Stat. 2981, 3070-71 (2018).

Second, in 2010, Congress enacted the Affordable Care Act ("ACA"), which provides in Section 1554 that

> [n]otwithstanding any other provision of [the ACA], the Secretary of Health and Human Services 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 providers;
> >
> > (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
> >
> > (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114.

C. The Final Rule

On March 4, 2019, Defendants abandoned regulations that have effectively implemented Title X since 1981 and promulgated new regulations that threaten to reverse decades of public health advancement. *See* Compliance with Statutory Program Integrity Requirements, 84 Fed.

Reg. 7714 (March 4, 2019) (the "Final Rule"). The Final Rule is a sea change from the 2000 regulations—despite no evidence that the 2000 regulations were deficient in any manner.

1. Restriction on Abortion Counseling

The Final Rule eliminates the requirement that Title X projects give pregnant patients neutral, nondirective options counseling and referral for abortion upon request. Instead, the Final Rule prohibits Title X projects from "promot[ing], refer[ring] for, or support[ing] abortion."§ 59.5(a)(5).[4] At the same time, it requires that pregnant Title X clients "***shall*** be referred to a health care provider for medically necessary prenatal health care," regardless of whether the patient wishes to continue the pregnancy. § 59.14(b)(1) (emphasis added). In addition to the mandatory referral, the Title X project "may" provide "[n]ondirective pregnancy counseling," but only if the provider is a "physician[] or advanced practice provider" ("APP"), defined as someone who "receive[d] at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients." §§ 59.2, 59.14(b)(i). However, the Final Rule does not explain how an APP can provide "nondirective pregnancy counseling" that discusses abortion without running afoul of § 59.14(a), which states that "[a] Title X project may not promote, refer for, or support abortion as a method of family planning." § 59.14(a); *see also* § 59.5(a)(5) (similar restriction); § 59.16 (similar restriction). The only discussion of abortion that the Final Rule explicitly allows is telling a pregnant woman who has requested information on abortion that "the project does not consider abortion a method of family planning." § 59.14(e)(5).

2. Ban on Abortion Referral

Under the Final Rule, a provider may provide a pregnant patient who requests an abortion referral only "a list of . . . primary health care providers (including providers of prenatal care)." § 59.14(b)(1)(ii), (c)(2). That list need not include ***any*** abortion providers. § 59.14(c)(2). If abortion providers are included, they must also be "comprehensive primary health care providers," and cannot make up more than half the list. *Id.* "Neither the list nor project staff may

[4] Unless otherwise noted, citations in the form of "§ __" are to the Final Rule published at 84 Fed. Reg. 7717, 7786–91.

identify which providers on the list perform abortion." *Id.* The Final Rule includes no exception to the referral ban for instances in which an abortion is medically necessary. Instead, the Final Rule states that "[i]n cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency." § 59.14(b)(2). The ban on abortion referrals sends patients on a wild goose chase to find the care they need, delaying an extremely time-sensitive procedure.

3. Physical and Financial Separation

The Final Rule also departs from HHS's long-settled policy of mandating financial, but not physical, separation between a Title X project's abortion and non-abortion activities. *See* 65 Fed. Reg. 41276. Under the physical separation requirement, "[a] Title X project must be organized so that it is ***physically*** and financially separate . . . from activities which are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16." § 59.15 (emphasis added). "Prohibited activities" are broadly defined to include the provision of abortions, referrals for abortion, and any activity that "encourage[s], promote[s] or advocate[s] abortion as a method of family planning." §§ 59.14, 59.16(a)(1). Whether the physical separation criterion is met is to be determined through a "review of facts and circumstances," with relevant factors including but not limited to:

> (a) The existence of separate, accurate accounting records; (b) The degree of separation from facilities (e.g., treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities; (c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and (d) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

84 Fed. Reg. at 7789. The Final Rule mandates compliance with the separation requirement by March 4, 2020. 84 Fed. Reg. at 7714.

D. Proceedings in the District Court and Ninth Circuit

Plaintiffs filed their Complaint (Dkt. 1) on March 4, 2019, the day the Final Rule was published in the Federal Register. The same day, the State of California filed a related lawsuit challenging the Final Rule. *See State of California v. Azar et al.*, No. 3:19-cv-1184-EMC (N.D.

Cal.), ECF No. 1. In their Complaint, Plaintiffs allege that the Final Rule is invalid and must be set aside under the Administrative Procedure Act because (1) it is contrary to law, (2) it exceeds the Secretary's statutory authority, and (3) it is arbitrary and capricious. Compl. ¶¶ 173-215. Dr. Marshall further alleges that the Final Rule violates her First Amendment right to freedom of speech, and Plaintiffs both allege that the Final Rule is unconstitutionally vague under the Fifth Amendment. *Id.* ¶¶ 216-26.

Shortly after commencing this action, Plaintiffs and the State of California moved for a preliminary injunction barring enforcement of the Final Rule. Dkt. 25. The Court held a hearing on April 18, 2019, and on April 26, 2019, granted Plaintiffs' motion in part. P.I. Order. The Court concluded that Plaintiffs were likely to succeed on—or at least had raised serious questions concerning—the merits of their APA claims. *Id.* at 25-76. The Court did not reach Plaintiffs' constitutional claims. *Id.* at 76. Although Plaintiffs sought a nationwide injunction, the Court limited the injunction to California. *Id.* at 78.

Defendants appealed, and they moved this Court for a stay of the injunction, which the Court denied. Dkt. 89. Defendants then moved the Ninth Circuit for a stay, which a three-judge motions panel granted in a *per curiam* published order on June 20, 2019. *California v. Azar*, 927 F.3d 1068 (9th Cir. 2019). Plaintiffs, together with the plaintiffs in related cases filed in Washington and Oregon federal courts, moved the Ninth Circuit for reconsideration *en banc* of the motions panel's stay order. The Ninth Circuit granted Plaintiffs' request and ordered that the motions panel's decision not be cited as precedent, but declined to vacate the motions panel's stay order. *California v. Azar*, 927 F.3d 1045 (9th Cir. 2019); *California v. Azar*, 928 F.3d 1153, 1155 (9th Cir. 2019). The *en banc* panel held oral argument on September 23, 2019. It has not issued a decision.

E. Enforcement of the Final Rule

On July 15, 2019, after the *en banc* panel clarified that the preliminary injunction order remained stayed, HHS announced that the Final Rule's restrictions on abortion counseling and

referral were in immediate effect. Rabinovitz MSJ Decl., ¶ 4.[5] Five days later, HHS issued guidance to Title X grantees, requiring them to submit a plan for compliance with the Final Rule and to provide written assurances that the grantee's project does not provide abortion "as a method of family planning." *Id.*, ¶ 5. Essential Access's compliance plan was approved on August 30, 2019. *Id.*

As California's primary Title X grantee, Essential Access assumes the administrative burden of applying for Title X funding, and then distributes the grant to a network of sub-recipient health care organizations. *Id.*, ¶ 3. As a result of the program changes Essential Access made to comply with the Final Rule's abortion counseling and referral restrictions, a significant portion of Essential Access's network has already departed the Title X program. As of June 1, 2019, Essential Access oversaw the largest and most diverse Title X provider network in the country; comprised of more than 350 Title X-funded clinic sites in 38 of 58 California counties, Essential Access's network served nearly one million patients annually, or 25% of all Title X patients nationwide. *Id.*, ¶ 6. Since HHS announced the Final Rule is in effect, however, 15 Essential Access sub-recipient health care organizations, collectively operating 149 clinic sites, have withdrawn from the Title X program. *Id.*, ¶ 7. The number of counties served by a Title X provider has been cut in half. *Id.*, ¶¶ 11-12. In some of the counties that are no longer served by a Title X provider, the former Title X-funded health centers were among the few places—or the only place—to receive comprehensive, quality sexual and reproductive health care and family planning services. *Id.*, ¶ 9.

In August 2019, in light of the departures of health centers from California's Title X program and in order to disburse funds relinquished by former Title X-funded providers, Essential Access issued a new request for proposal ("RFP"). *Id.*, ¶ 8. Essential Access received only three applications in response to the RFP, and Essential Access chose to fund all of them. *Id.* But fewer than 30,000 Title X patients will be served by the funding awarded to the three new

[5] Julie Rabinovitz, MPH, the President and CEO of Essential Access, has submitted multiple declarations in support of pleadings in this case. "Rabinovitz MSJ Decl." refers to Ms. Rabinovitz's declaration filed in support of this motion, while "Rabinovitz PI Decl." refers to her March 21, 2019 declaration in support of Plaintiffs' preliminary injunction motion (Dkt. 27).

applicants, which comes nowhere close to offsetting the loss of 149 Title X-funded clinic sites since the Final Rule went into effect. *Id.* In 2019, Essential Access's sub-recipients provided services to approximately 600,000 patients. *Id.*, ¶ 10. An estimated 375,000 ***fewer*** patients were served by California's Title X providers in 2019 compared to the year prior—a 38% reduction in patients served. *Id.*

The March 4, 2020 compliance deadline for physical separation is fast-approaching. The physical separation requirements impose extraordinary financial burdens on Essential Access and sub-recipient providers. *Id.*, ¶¶ 14, 15. If forced to comply with the Final Rule's physical separation requirements by March 4, 2020, Essential Access must cease many components of its training, advocacy, and education programs which advance its mission to champion and promote quality sexual reproductive health care for all while facing even more health center withdrawals from its network, or else drop out of the Title X program. *Id.*, ¶ 14.

III. LEGAL STANDARD

The APA requires agency actions be set aside where they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or are promulgated "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (D). In an APA case, "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co. v. I.N.S.*, 753 F.2d 766, 769 (9th Cir. 1985).

A party may move for summary judgment on any "claim or defense" or "part of [a] claim or defense," Fed. R. Civ. P. 56(a), and a district court should enter summary judgment where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Id*. Because a district court does not resolve factual questions when reviewing administrative proceedings, summary judgment "is an appropriate mechanism for deciding the legal question" of whether the agency acted in accordance with law and with a reasoned basis grounded in the record. *Boyang, Ltd. v. INS*, 67 F.3d 305 (9th Cir. 1995).

Here, the Final Rule was promulgated with no valid justification for the change in policy and contrary to established reasoning and evidence. The Final Rule also contravenes statutes

governing healthcare. As discussed below, the Final Rule should be vacated in its entirety.

IV. ARGUMENT

A. The Final Rule is arbitrary and capricious

The Court must hold unlawful and set aside agency action that is arbitrary or capricious. 5 U.S.C. § 706(2)(A). The hallmarks of arbitrary and capricious rulemaking include the following:

> if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983). A court deciding this question must assess whether the agency has engaged in "reasoned decisionmaking," *Judulang v. Holder*, 565 U.S. 42, 53 (2011), meaning, has it "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43.

Where an agency has made a change to a previous policy, a court must evaluate the reasons given for the change— "or, as the case may be, the absence of such reasons." *Judulang*, 565 U.S. at 53 (citing *State Farm*, 463 U.S. at 43). An agency whose "new policy rests upon factual findings that contradict those which underlay its prior policy . . . or [whose] prior policy has engendered serious reliance interests," must offer a "more detailed justification for its action" than what would suffice for a new policy created on a blank slate. *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (*Fox)*; *see also Organized Vill. of Kake*, 795 F.3d at 968. "[A] court may uphold agency action only on the grounds that the agency invoked when it took the action," *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2710 (2015), and may not rely *ipse dixit* on outdated justifications. *See Sierra Club v. U.S. 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).[6] Where the justification rests on a purported risk of abuse, the court must determine if there is actually "evidence of a real problem"; if not, the action must be set aside. *Nat'l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 839-41 (D.C. Cir. 2006) (Kavanaugh, J.). Against this legal framework, and as this Court has previously determined, Defendants' justifications for the Final Rule fail. *See* P.I. Order at 47-74.

1. The physical separation requirement is arbitrary and capricious

For the past twenty years, HHS has found financial separation between permitted and prohibited activities sufficient to ensure compliance with Title X's mandate that no funds "shall be used in programs where abortion is a method of family planning." Yet the Final Rule imposes new, onerous physical separation requirements on top of those previously adequate safeguards. *See, e.g.*, §§ 59.13, 59.14, 59.15, 59.16. The Final Rule mandates that a Title X project must be physically separate from "prohibited activities," including abortion, abortion referrals, or any activity that "encourage[s], promote[s] or advocate[s] abortion as a method of family planning." §§ 59.14, 59.16(a)(1).[7] HHS's stated justification for the change is to "protect the statutory integrity of the Title X program, to eliminate the risk of co-mingling or misuse of Title X funds, and to prevent the dilution of Title X resources." 84 Fed. Reg. 7715. Despite abandoning a policy that grantees and subrecipients like Plaintiffs have relied on for years, HHS fails to justify the change at all, much less provide the "more detailed justification" required. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125-26 (2016).

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[6] As the Court ruled in its Preliminary Injunction Order, "[t]he justifications supporting the 1988 regulations upheld in Rust cannot insulate the Final Rule from review now, almost three decades later." P.I. Order at 48. *Rust* held only that, *as of 1991*, the Secretary's interpretation of his authority under Section 1008 was permissible and did not "otherwise conflict with Congress' expressed intent." *Rust*, 500 U.S. at 184-85. The Supreme Court upheld the 1988 regulations because "the Secretary amply justified his change of interpretation with a 'reasoned analysis,'" based on "critical reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG), that prior policy failed to implement properly the statute." *Id.* at 187. HHS did not purport to rely on the 1988 regulations, or the GAO or OIG reports, in promulgating the Final Rule. *See* P.I. Order at 48.

[7] In addition, the Final Rule requires funds to be used only in "direct implementation" of Title X projects with "the majority of grant funds to provide direct services" rather than infrastructure spending. § 59.18. As a result, providers who choose to provide abortion-related services using *non*-Title X funds must physically separate their Title X activities but cannot use Title X funds to do so.

First, Defendants assert that physical separation is necessary because *any* collocation of Title X programs with facilities where abortions or abortion referrals are provided constitutes "subsidization" of abortion through the achievement of "economies of scale." 84 Fed. Reg. at 7766. But "Title X expressly distinguishes between a Title X *grantee* and a Title X *project*," *Rust*, 500 U.S. at 196, and Congress never forbade Title X *grantees* from providing abortion-related services using *non*-Title X funds. *See id.* (a "Title X grantee can continue to . . . provide abortion-related services" so long as it does so "through programs that are separate and independent from the project that receives Title X funds."). Defendants' "subsidization" concern cannot justify their change in policy because Congress never intended to prohibit the activity at which the physical separation requirement takes aim. Moreover, HHS's rationale is "illogical on its own terms," because even grantees that maintain physical separation may still achieve economies of scale. P.I. Order at 52.

Second, HHS "provided no evidence of a real problem" justifying physical separation. *Nat'l Fuel*, 468 F. 3d at 841; *Ariz. Cattle Growers' Ass'n v. U.S. Fish & Wildlife Serv.*, 273 F.3d 1229, 1244 (9th Cir. 2001). The only sources purportedly justifying Defendants' concerns are an "anecdotal story" from 2007 about abuse of federal funds in *Medicaid* (a different program), and a 2014 Guttmacher Institute report indicating that "abortions are increasingly performed at sites that . . . *could be* recipients of Title X funds." 84 Fed. Reg. at 7774, 7765 (emphasis added). Yet HHS concedes that "demonstrated abuses of Medicaid funds do not necessarily mean Title X grants are being abused." *Id.* at 7725. And the Guttmacher Report provides no support for Defendants' position. P.I. Order at 49-50.

Third, HHS's new concerns run headlong into its prior factual findings. In the 2000 regulations, HHS rejected a physical separation requirement because it was not "likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services." 65 Fed. Reg. at 41276. HHS further found that the 1988 physical separation requirement had caused the "fundamental measure of compliance" to "remain[] ambiguous," which proved the "practical difficulties of line-drawing in this area." *Id.* Rather than make new factual findings in support of the Final Rule, HHS improperly speculates

about a "risk" of co-mingling funds or confusion about Title X's objectives. 84 Fed. Reg. at 7765. But Defendants' judgments must be "based on some logic and evidence, not sheer speculation." *Sorenson Commc'ns Inc. v. F.C.C.*, 755 F. 3d 702, 708 (D.C. Cir. 2014). There is no evidence in the administrative record of any *actual* misuse or confusion—i.e., "evidence of a real problem." *Nat'l Fuel*, 468 F.3d at 841. To the contrary, HHS has long employed robust mechanisms to protect against misuse of Title X funds. "[F]amily 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 Public Health Act* at 14 (Oct. 15, 2018), https://fas.org/sgp/crs/misc/R45181.pdf. OPA ensures grantees' compliance with Title X's requirements through careful application reviews, independent financial audits, periodic site visits, and yearly budget reviews. Rabinovitz PI Decl., ¶ 16 (Dkt. 27). Defendants' reliance on nothing more than a "theoretical threat of abuse" and failure to explain why existing safeguards do not suffice does not pass muster. *Nat'l Fuel*, 468 F.3d at 844; *see also Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 50 (D.D.C. Mar. 7, 2019) (agency rule is arbitrary and capricious where agency failed to explain why existing safeguards would not prevent against risk the rule purported to address).

Fourth, Defendants' prior policy has engendered serious reliance interests for which Defendants fail to account. *See Encino Motorcars*, 136 S. Ct. 2120 ("[I]n explaining its changed position, an agency must be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'") (citing *Fox*, 556 U.S. at 515). For years, Title X providers have structured their affairs in order to provide both abortion-related services using *non*-Title X funds alongside Title X services, developing infrastructure, training, and outreach programs, and hiring staff with the understanding that such activities were permissible so long as Title X projects were separately funded. *See* Rabinovitz PI Decl. at ¶¶ 59-66 [Dkt. 27]; Tosh Decl. at ¶¶ 39-40 [Dkt. 33]; VTDOH Cmt 198208; APHA Cmt 239895-96. Public comments of major providers made clear that the physical separation requirement would make "it financially impractical, if not impossible, to continue" participation in the program. PPFA Cmt 316432; *see*

also AMA Cmt 269333 (these provisions "appear[] designed to make it extremely difficult, if not impossible, for specialized reproductive health providers" to continue in Title X); FAPP Cmt 305102 (these requirements will "force Title X site closures altogether and . . . would cause a decrease or dilution in the provision of quality family planning services"); Drexel Cmt 293840 (physical separation and infrastructure costs "will be more than many Title X projects can bear . . . and will undoubtedly lead to providers leaving Title X for economic reasons alone"). Yet the Final Rule upends those reliance interests without justification, much less the "more detailed justification" necessary. *Encino Motorcars*, 136 S. Ct. at 2125.

Finally, Defendants severely underestimate the cost of compliance with physical separation. HHS asserts that Title X projects will incur "an average of between $20,000 and $40,000" per site to comply, 84 Fed. Reg. at 7781-82, but provides no basis for this figure, no explanation of what it entails, and no assurance that those costs—if accurate—are reasonable. Numerous commenters highlighted this error for HHS. *See, e.g.*, EAH Cmt 245494; FPCI Cmt 279362 ("it typically costs hundreds of thousands, or even millions, of dollars to locate and open any health care facilities . . . staff it, purchase separate workstations, set up record-keeping systems, etc."); CRR Cmt 315994 n. 144 (electronic health record system costs $160,000 for a small practice); FPCI Cmt 279362 (Title X subrecipient's additional physical site cost $85,000 in March 2018). Despite its obligation to consider that evidence, HHS ignored it.

Defendants have promulgated a sweeping rule to remedy an imaginary problem, and it must be set aside.

2. The counseling and referral restrictions are arbitrary and capricious

The Final Rule's counseling and referral restrictions fail arbitrary and capricious review for similar reasons. If the agency's new policy "disregard[s] facts and circumstances that underlay or were engendered by the prior policy," the agency must provide a more detailed justification than that required for a new policy created on a blank slate. *Encino Motorcars*, 136 S. Ct. at 2125-27 (quoting *Fox*, 556 U.S. at 515-16). "An agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore inconvenient facts when it writes on a blank slate." *Fox*, 556 U.S. at 537 (Kennedy, J.,

concurring). But that is precisely what Defendants do here.

First, the Final Rule not only reverses HHS's prior policy on nondirective options counseling, but also fails to address the extensive factual findings underlying it. For example, in 2000, HHS determined that pregnancy counseling is "a necessary component of quality" services and that "nondirective options counseling" is "a necessary and basic health service of Title X projects." 65 Fed. Reg. at 41273. At that time, HHS found that a counselor "removing an option from the client's consideration necessarily steers her toward the options presented" and is impermissible within Title X. *Id.* HHS also determined that "neutral, factual information" about abortion providers, along with prenatal care and adoption providers, should be available upon patient request." 65 Fed. Reg. at 41274. HHS made all of these findings based on record evidence of "medical ethics," "good medical care," and the "prevailing medical standards[.]" 65 Fed. Reg. at 41273-75 (citing comments from medical authorities, then-current ACOG policies and the AMA Code of Medical Ethics).[8]

With the Final Rule, HHS reverses course without acknowledging its prior findings, let alone making countervailing findings that would justify a change. *Fox*, 556 U.S. at 515. The Final Rule's counseling and referral restrictions prohibit providers from "promot[ing], refer[ring] for, or support[ing] abortion as a method of family planning," or taking any other action to assist a patient in securing one—even in response to a patient's direct request. § 59.14(a); *see also* §§ 59.5(a)(5), 59.16(a). The provider must refer a patient for prenatal care even when she does not intend to keep her pregnancy. 84 Fed. Reg. at 7747-78. HHS previously found that these types of restrictions "endanger[ed] women's lives and health by preventing them from receiving complete and accurate medical information"; (2) "interfere[ed] with the doctor-patient relationship by

[8] In addition, in 2014 HHS's Centers for Disease Control and Office of Population Affairs published recommendations for providing Quality Family Planning ("QFP"); the QFP recommendations set forth broadly accepted, evidence-based standards for high-quality clinical practice regarding the provision of family planning services, and they govern national clinical practice today. Centers for Disease Control and Prevention, *Providing Quality Family Planning Services* at 14 (2014), *available at* https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf. The QFP recommendations are "intended for all current or potential providers of family planning services, including those funded by the Title X program." *Id.* at 2. The QFP recommends that pregnancy test results "should be presented to the client, followed by a discussion of options and appropriate referrals." QFP at 14. "Referral to appropriate providers of follow-up care should be made at the request of the client" and "[e]very effort should be made to expedite" referrals. *Id.*

prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients"; and (3) "would seem coercive and inconsistent with the prevailing medical standards recommended by national medical groups" by "requiring a referral for prenatal care . . . where the client rejected those options." 65 Fed. Reg. at 41270-75. Similarly, HHS has long rejected mandatory, prenatal referrals, 65 Fed. Reg. at 41274-75[9], but in the Final Rule it claims—without support—that prenatal referrals are "medically necessary." § 59.14(b).[10]

Yet the administrative record contains no findings whatsoever that call into question the agency's previous conclusions or explain why they no longer apply. "[D]isregarding facts and circumstances that underlay or were engendered by [an agency's] prior policy" is the essence of arbitrary rulemaking. *Fox*, 556 U.S. at 515-516. HHS's failure to even acknowledge the discrepancy between the Final Rule and its prior findings only underscores that point. *See Nat'l Lifeline Assoc. v. F.C.C.*, 921 F.3d 1102, 1111-12 (D.C. Circ. 2019) (agency acted arbitrarily in failing to acknowledge contradictions with previous findings).

Second, Defendants' contention that the new counseling and referral restrictions are necessary for consistence with federal conscience laws is without merit. 84 Fed. Reg. at 7746. As this Court found, those laws—which include the Church, Coats-Snowe, and Weldon Amendments—do not provide a reasoned explanation because the 2000 regulations already contained protections for conscience objections. P.I. Order at 62. HHS did not explain why those existing safeguards were inadequate. *See DeVos*, 365 F. Supp. 3d. at 50 (rule invalid where agency "failed to explain why the [existing] safeguards as a whole would not prevent against the risk" the rule purported to address). Moreover, "the conscience laws do not provide a basis for HHS to bar *all* Title X grantees from providing abortion referrals," P.I. Order at 63 (emphasis in original)—particularly since "the abortion referral and counseling requirements in the 2000 regulations cannot be enforced against *objecting* grantees." 84 Fed. Reg. at 7746 (emphasis added).

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[9] The 2000 regulations state "requiring a referral for prenatal care and delivery or adoption where the client rejected those options would seem coercive and inconsistent with the concerns underlying the 'nondirective' counseling requirement."

[10] The QFP recommendations provide for abortion referrals at the request of the client, QFP at 5, whereas the Final Rule requires practitioners to provide referral lists that do not identify abortion providers and need not include any abortion providers at all. § 59.14(c)(2).

Defendants' justification for the restrictions rings hollow, confirming they have no real justification at all.

3. The removal of the "medically approved" requirement is arbitrary and capricious

The 2000 regulations required Title X projects to "[p]rovide a broad range of acceptable and effective *medically approved* family planning methods . . . and services." 42 C.F.R. § 59.5(a)(1) (emphasis added). The Final Rule removes the "medically approved" requirement, allowing Title X-funded providers to peddle family planning methods that have no verification of quality or efficacy. Again, HHS has not provided a reasoned explanation for this change.

Instead, HHS's only justification stems from pure speculation. It contends that "[t]he 'medically approved' language risked creating confusion about what kind of approval is required for a method to be deemed 'medically approved.'" 84 Fed. Reg. at 7741. But HHS has not identified a single instance in which a Title X recipient has expressed confusion about the meaning of "medically approved." Rather, the comments indicate that medical providers understand "medically approved" to mean "FDA approved," consistent with HHS's own usage.[11] Guttmacher Cmt 264416; ACOG Cmt 268843; AMA Cmt at 269332; APHA Cmt at 239897. Though HHS noted that commenters believed removing the "medically appropriate" language "could reduce access to the safest, effective, and medically approved contraceptive methods, increase risks associated with promoting medically unreliable methods, place political ideology over science, and undermine recommendations jointly issued by OPA and the CDC on Quality Family Planning," it failed address those concerns. 84 Fed. Reg. at 7740. Because HHS's justification for the change "runs counter to the evidence before the agency," it is arbitrary and capricious. *State Farm*, 463 U.S. at 43.

4. The "physician or advanced practice provider" and "comprehensive primary health care provider" requirements are arbitrary and capricious

The Final Rule further requires that nondirective pregnancy counseling be provided only by "physicians or advanced practice providers." § 54.14(b)(1)(i). But Defendants fail to articulate

[11] In the QFP recommendations HHS encourages providers of family planning services to offer "a full range of *FDA-approved* contraceptive methods." QFP at 7 (emphasis added).

any explanation at all for the requirement, much less "a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (internal citation omitted). To the contrary, the facts highlight the arbitrariness of the requirement.

First, HHS ignored public comments explaining that family planning services are often effectively delivered by registered nurses, health educators, and social workers. *See* NFPRHA Cmt 308017 ("Physicians make up less than a quarter by type of clinical service providers within Title X, and in some regions, only 8% are physicians."); AAN Cmt 107972; ACOG Cmt 268840 ("arbitrarily limiting the providers" permitted to provide non-directive pregnancy counseling "erects an unnecessary and unsupported barrier to care").

Second, HHS itself concedes that non-APPs "were involved with 1.7 million Title X family planning encounters in 2016," approximately one-quarter of the total number of Title X family planning encounters that year. 84 Fed. Reg. at 7778. It is difficult to identify any rational reason for HHS to restrict nondirective pregnancy counseling to only a subset of medical professionals while, at the same time, allowing Title X projects (and non-APPs) to provide family planning methods that are not even medically approved. Concern with the quality or medical necessity of the services provided cannot be it. Defendants fail to provide any "satisfactory explanation" for the requirement, rendering it arbitrary and capricious. *State Farm*, 463 U.S. at 43.

In a similar fashion, the Final Rule arbitrarily requires that all the providers on the "referral list" permitted under Section 59.14(b)(ii) must also be "comprehensive primary health care providers." Defendants' only justification for this new requirement is that it "prevents distribution of [the referral] list from violating section 1008." 84 Fed. Reg. at 7761. That conclusion does not follow. Moreover, Defendants fail to consider the requirement's impact on the availability of local referral options for patients in rural areas, where providers of requested prenatal or abortion services may not also be "comprehensive primary care" providers. *See* PPFA Cmt 316468-69. Defendants thus "failed to consider an important aspect of the problems," *State Farm*, 43 U.S. at 43, rendering Section 59.14(b)(ii) arbitrary and capricious.

5. The reporting requirements are arbitrary and capricious

The Final Rule's seemingly mundane ministerial provisions are infected with irrational decision-making, as well. For example, Section 59.5(a)(13) imposes a host of duplicative and burdensome reporting requirements that serve only to dissuade large referral networks from participating in the Title X program. In particular, Section 59.5(a)(13) requires grantees to provide in "all required reports"—which must be submitted at least quarterly—a description of their subrecipients' and referral providers' "expertise and services provided"; "[d]etailed descriptions of the extent of collaboration with subrecipients, referral agencies, and any individuals providing referral services"; and a "[c]lear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients." § 59.5(a)(13).

In promulgating these new requirements, Defendants fail to acknowledge that grantees were *already* required to disclose their subrecipients and service sites to HHS, and have always been responsible for ensuring that subrecipients provide quality care in accordance with Title X and its implementing regulations. As commentators (including Essential Access) warned, by adding even more reporting requirements and increasing their frequency, the Final Rule imposes higher costs on subrecipients and referral providers (which do not receive Title X funding), thereby discouraging broad referral networks. EAH Cmt 245493-94; AM Cmt 256452. HHS fails to meaningfully address these concerns, and instead relies on conclusory assertions that the reporting requirements are necessary and do not impose any "inappropriate administrative burden." 84 Fed. Reg. at 7750. These responses are belied by the record before the agency, rendering Section 59.5(a)(13)'s reporting requirements arbitrary and capricious.

6. Defendants' cost-benefit analysis is arbitrary and capricious

Defendants' flawed cost-benefit analysis also fails APA review because it "entirely fail[s] to consider an important aspect of the problem[,]" and improperly prioritizes claimed benefits which "run[] counter to the evidence before the agency." *State Farm,* 463 U.S. at 43. Costs are "centrally relevant" to an evaluation of whether an agency should regulate, and "reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency

decisions." *Michigan v. EPA*, 135 S. Ct. at 2707. Defendants engaged in arbitrary and capricious rulemaking when they focused only on the Final Rule's purported benefits and ignored the exorbitant costs that scores of commenters warned the Final Rule would impose on patients, providers, and the public health.

First, the administrative record contains ample evidence that the Final Rule would impose substantial costs on patients by diminishing access to quality care, requiring patients to spend valuable time searching for fulsome counseling, and disrupting the provider-patient relationship. *See e.g.* EAH Cmt 245489 ("allowing Title X funded entities to offer only a single method [of contraception], places additional burdens on low-income patients, including transportation costs and extra time needed to access the method that is right for them."); ACOG Cmt 268838 ("The patient-physician relationship is essential to the provision of safe and quality medical care, and political efforts to regulate elements of patient care and counseling can drive a wedge between a patient and her medical provider."); MSAHC Cmt 106753 (the Rule's "restriction on providing complete information will inevitably lead to frustration and perceived unresponsiveness on the part of our patients, making them less likely to return for future care.").[12] Numerous commenters warn that patients will bear the "brunt of [the Rule's] impact." AM Cmt 256454; *see also* Jacobs Cmt 239147–50 (Texas's exclusion of abortion providers from its family planning program resulted in a 24% decline in enrollment and a 41% drop in the number of women accessing contraception); NFPRHA Cmt 308042–45 (rule will "radically change the makeup of the Title X network, leaving patients without access to critical care in many instances and requiring subpar, ineffective care in others"); PPFA Cmt 316419 (describing the "negative effects on the quality of patient care at Title X-funded sites that attempt to adhere" to the rule).[13]

Rather than grapple with the evidence, HHS simply asserts that it "does not believe" the Final Rule will impact patients' access to care. 84 Fed. Reg. at 7725; *see also id.* at 7769, 7781.

[12] *See also* AMA Cmt 269330-32; AAP Cmt 277788-89; AAMC Cmt 264536; NLIRH Cmt 307455-56; FAPP Cmt 305098-100; EM Cmt 47947; NFPRHA Cmt 308018-20.

[13] *See also* EAH Cmt 245483; CBD Cmt 54193–95; NCJW Cmt 102349; NIRH Cmt 106457; Miliken Cmt 106800–01; AAN Cmt 107973; Cal AG et al. Cmt 245693; NWLC Cmt 280767–68; NACCHO Cmt 294047.

This "generalized conclusion" does not satisfy the agency's obligation to consider "important aspect[s] of the problem." *AEP Texas N. Co. v. Surface Transp. Bd.*, 609 F.3d 432, 441 (D.C. Cir. 2010); *State Farm*, 463 U.S. at 43. HHS also asserts that instead of imposing additional costs on patients, the Final Rule "is likely to decrease unintended pregnancies" because patients "are more likely to visit clinics that respect their views and beliefs." 84 Fed. Reg. at 7743. But HHS fails to provide any basis for its assertion that patients do not avail themselves of Title X care because their "views and beliefs" are disrespected, or that the Final Rule will result in an increase Title X clinic visits. P.I. Order at 69-70. The assertion is also illogical. Whereas under the prior regulations, providers could tailor their care to a *patient's* wishes, the Final Rule requires providers to impose HHS's views and beliefs on patients regardless of their expressed desires. For example, under the Final Rule's blanket prohibition on abortion referrals, a provider may not identify an abortion provider to a patient who specifically seeks one; instead the patient may only receive a referral list at least half-comprised (and perhaps entirely comprised) of *non*-abortion providers, without so indicating. §§ 59.5(a)(5), 59.14(b)(1)(ii), (c)(2). The patient is forced to discern the information herself. Moreover, HHS fails to provide any basis for its assertion that patients do not avail themselves of Title X care because their "views and beliefs" are disrespected, or that the Final Rule will increase in Title X clinic visits. P.I. Order at 69-70. Relying entirely on baseless, self-serving assertions, HHS disregards the costs to patients, creating a "serious flaw" in its analysis. *Nat'l Ass'n of Home Builders v. E.P.A.*, 682 F.3d 1032, 1039-40 (D.C. Cir. 2012).

Second, Defendants similarly disregarded substantial evidence (now confirmed) that the Final Rule will decimate the Title X network, further harming providers and the patients they serve. These costs were exhaustively documented in the public comments. *See, e.g.*, PPFA Cmt 316477 ("Fifty-six percent of Planned Parenthood health centers are in health provider deserts, where residents live in areas that are medically underserved and they may have nowhere else to go to access essential health services without Planned Parenthood."); FPCA Cmt 385034 (the counseling requirements "would greatly reduce the number of high quality providers willing and able to deliver" Title X services); NFPRHA Cmt 308014-21 ("[I]f adopted, [the counseling

restrictions] will drive a number of Title X providers from the program" and "shrink and diminish the effectiveness of the Title X network.").

Contrary to these concerns, HHS states that it "does not anticipate that there will be a decrease in the overall number of facilities offering [Title X] services, since it anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule." 84 Fed. Reg.at 7782. It speculates that "under the 2000 regulations, some individuals and entities *may have* chosen not to apply to provide Title X services because they anticipated they would be pressured to counsel or refer for abortions." 84 Fed. Reg. at 7780 (emphasis added). Yet Defendants cannot identify a single comment in the administrative record in which an organization announced that it would apply for Title X funding only if the Final Rule were implemented. HHS further predicted, without support, that the Final Rule may "lead to an increase in the number of healthcare providers who apply and receive funding under the Title X program, thus decreasing current gaps in family planning services in certain areas of the country." *Id.* at 7780. That prediction flies in the face of numerous comments warning that rural patients would be left without family planning services due to the Final Rule, with no alternative providers stepping in to fill the void. *See* Wash Cmt 278575; EAH Cmt 245484. Defendants "put a thumb on the scale by [over]valuing the benefits and [under]valuing the costs." *Ctr. For Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008). Defendants' failure to consider both sides of the equation in their cost-benefit analysis is arbitrary and capricious. *See California v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017).

Third, Defendants downplayed the effect of the Final Rule on public health and the purpose of the Title X program. Commenters warned that decreased access to reproductive health services will lead to an increase in the number of unintended pregnancies and births, APHA Cmt 239895-97 ("The gag rule has been associated with an increase in abortions, an increase in maternal deaths and encouraging unsafe abortions."), and give rise to attendant health costs, because "for many low-income women, visits to a family planning provider are their only interaction with the health care system at all." Brindis Cmt 388055,388063-067; APHA Cmt

239895. Each unintended pregnancy in California costs an estimated $6,557 in medical, welfare, and other social service costs. Tosh Decl. paragraph 26, 44 [Dkt. 33]. HHS entirely discounts commenters' warnings that the Final Rule will increase unintended pregnancies and decrease access to contraception. 84 Fed. Reg. 7775, 7785. HHS simply states that "it is not aware" of any source connecting the requirements in the Final Rule to an increase in unintended pregnancy or the costs associated. *Id.* at 7775. "The mere fact that the . . . effect of a rule is *uncertain* is no justification for *disregarding* the effect entirely." *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004); *see also Nat'l Lifeline Assoc. v. F.C.C.*, 921 F. 3d at 1112-13 (failing to consider providers' unwillingness to offer services to aid low-income individuals and the impact on those vulnerable considers when there were gaps in service was an arbitrary agency action).

Finally, Defendants downplay what compliance with the Final Rule will cost Title X providers. As discussed in section IV.A.1, *supra*, the costs of complying with the physical separation requirement are significantly higher than HHS estimates. Essential Access estimates that the cost of implementing the Final Rule's requirements "would total over $479,000 . . . including additional time for current project staff, recruiting and hiring new staff and consultants, and engaging legal support for developing new contracts and agreements to meet the overly burdensome requirements." EAH Cmt 245494. As this Court has ruled, Defendants' estimate of $30,000 per site is not grounded in any evidence. P.I. Order at 59.

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For all of these reasons discussed above, the Final Rule is arbitrary and capricious, and must be set aside.

B. The Final Rule is contrary to law

The APA requires this Court to "hold unlawful and set aside agency action" that is "not in accordance with law." 5 U.S.C. § 706(2)(A). Agency action is "not in accordance with law" if it is contrary to "***any*** law, and not merely those laws that the agency itself is charged with administering." *F.C.C. v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003). The Court has already concluded that the Final Rule likely violates the HHS Appropriations Act and the

ACA. *See* P.I. Order at 33-35, 43-46. The Court should confirm that conclusion here.

1. The Final Rule violates the HHS Appropriations Act

The HHS Appropriations Act provides that "all pregnancy counseling" in the Title X program "shall be nondirective." Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, Div. A, Tit. II, 133 Stat. 2534, 2558 (2019). The requirement that all Title X pregnancy counseling be nondirective (the "Nondirective Counseling Provision") has been included in every HHS appropriation since 1996. *See, e.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, Pub. L. No. 115-245, Div. B, Tit. II, 132 Stat. 2981, 3070-71 (2018); Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. No. 104-134, 110 Stat. 1321, 1321-22. Although the HHS Appropriations Act does not define the term "nondirective," the Nondirective Counseling Provision is unambiguous—it means that pregnancy counseling must not direct the patient toward one course of action over another.

The term's usage elsewhere in the Title X statutory context confirms that it requires the neutral presentation of all options available to a patient, along with referrals to appropriate care upon request.[14] The Public Health Service Act (which includes Title X) indicates that counseling is "nondirective" when options are presented to a patient "on an equal basis." *See* 42 U.S.C. § 254c-6(a)(1) (directing the Secretary to make grants to train health center 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). Prior to this lawsuit, HHS shared the same interpretation, acknowledging in the Final Rule's preamble that "[n]ondirective pregnancy counseling is the meaningful presentation of options where the [medical provider] is not suggesting or advising one option over another." 84 Fed. Reg. at 7716 (citing 138 Cong. Rec. H2822, H2826, 1992 WL 86830); *see also* 83 Fed. Reg. 25512 n.41 (Proposed Rule) ("[N]ondirective counseling is the provision of information on *all available options* without promoting, advocating, or encouraging one option over another.") (emphasis

[14] When interpreting an undefined statutory phrase, it is appropriate to consider how the phrase is used in another statutory provision in the same context. *See Dir., OWCP v. Newport News Shipbldg. & Dry Dock Co.*, 514 U.S. 122, 130 (1995); *Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972).

added). For counseling to be nondirective, the medical provider must "present[] the options in a factual, objective, and unbiased manner . . . rather than present[] the options in a subjective or coercive manner." 84 Fed. Reg. at 7747. In nondirective counseling, "clients take an active role in processing their experiences and identifying the direction of the interaction." 84 Fed. Reg. at 7716. These interpretations comport with the common-sense understanding of "nondirective," which is that a patient must not be directed toward one course over others.

As explained below, the Final Rule violates the Nondirective Counseling Provision in at least two ways. First, the Final Rule's provisions forbidding referrals for abortion and mandating referrals for prenatal care amount to directive counseling. Second, the Final Rule's restrictions on discussing abortion with pregnant patients pushes patients toward one course of action—carrying the pregnancy to term—in violation of the HHS Appropriations Act.

a. The Final Rule's counseling and referral restrictions violate the Nondirective Counseling Provision

Sections 59.5(a)(5) and 59.14(a) of the Final Rule prohibit medical professionals from providing referrals for abortion, even when the patient specifically requests such a referral. At the same time, § 59.14(b)(1) mandates that every pregnant patient be referred for prenatal health care, even if she does not wish to continue her pregnancy, and even if she has requested a referral for an abortion. By taking abortion referrals off the table while simultaneously requiring referrals for prenatal care, the Final Rule sets up a scheme where options available to a pregnant patient are not presented "on an equal basis." 42 U.S.C. § 254c-6(a)(1); 83 Fed. Reg. at 25512 n.41 ("[N]ondirective counseling is the provision of information on *all available options* without *promoting, advocating, or encouraging* one option over another.") (emphasis added). Further, by directing patients to prenatal care regardless of their wishes, the Final Rule limits patients' "role in processing their experiences and identifying the direction of the interaction." 84 Fed. Reg. at 7716. This unequal treatment renders pregnancy counseling directive in violation of the Appropriations Act. *See* P.I. Order at 33-34. Indeed, at oral argument on Plaintiffs' preliminary-injunction motion, Defendants conceded that if referrals are part of counseling—which they are, as explained below—then the Final Rule's mandatory referrals for prenatal care likely violate the

Appropriations Act. *See* Apr. 18, 2019 Hr'g Tr. at 52:3-6; *see also* P.I. Order at 34-35.

The Final Rule's restrictions on the so-called "referral list" that may be provided to pregnant patients also run afoul of the Appropriations Act. Sections 59.14(b)(1)(ii) and 59.14(c)(2) allow Title X projects to provide pregnant patients with a list of "licensed, qualified comprehensive primary health care providers (including providers of prenatal care)," but unbeknownst to the patient—and even if the patient requests a referral for an abortion—this list need not actually include a single abortion provider. 84 Fed. Reg. at 7789. If the list does include abortion providers, they may not constitute more than half the list, and the Title X project may not identify them to patients. *Id.* Rather than give patients seeking abortion care the information they need, providers must send them on a wild goose chase, delaying access to time-sensitive care, and refer them for prenatal care in disregard of their wishes. By contrast, the Final Rule places no similar restrictions on the provision of referrals for prenatal or adoption services. The Final Rule thus requires the biased presentation of options to pregnant patients, which cannot be reconciled with the Nondirective Counseling Provision. *See* P.I. Order at 34.

b. The Final Rule's restrictions on discussions about abortion violate the Nondirective Counseling Provision

The Final Rule's broad prohibition on anything that "encourage[s]," "promote[s]," or "support[s] abortion" also violates the Nondirective Counseling Provision. *See* 84 Fed. Reg. at 7788, 7789 (§§ 59.5(a)(5), 59.14(a), and 59.16(a)(1)). While the Final Rule allows a Title X provider to "discuss abortion" with a patient (§ 59.14(e)(5)), it is silent on what the content of that discussion may be. The Final Rule does not explain how a provider may present abortion as a viable option without violating the prohibition against encouraging, promoting, or supporting abortion, requiring medical providers to "walk on eggshells to avoid a potential transgression of the Final Rule, whereas those describing the option of continuing the pregnancy face no comparable risk." P.I. Order at 35. This unequal treatment of abortion compared to other options renders pregnancy counseling under the Final Rule directive in violation of the Appropriations Act.

In addition to circumscribing what Title X providers may say about abortion as part of "pregnancy counseling," the Final Rule unlawfully permits providers to withhold relevant information about abortion altogether—even if the patient requests it—while presenting childbirth as the only available option. *See* § 59.14(b)(1). The so-called "pregnancy counseling" described in the Rule is entirely optional; in its place, a Title X provider may simply give the patient a list of primary care providers, a referral to adoption or social services, or information about maintaining the health of the "mother and unborn child," omitting any mention of the options for terminating the pregnancy. *Id.* But the Final Rule's facile distinction between "pregnancy counseling" in subsection 59.14(b)(1)(i) and the presentment of other options in subsections 59.14(b)(1)(ii)-(iv) should fool no one. *Any* presentation of options to a pregnant patient is pregnancy counseling, so if options like childbirth, adoption, and social services are presented, then the Nondirective Counseling Provision requires that *all* options—including abortion—be presented "on an equal basis" with each other, unless the patient expresses that she does not wish to hear about a particular option. 42 U.S.C. § 254c-6(a)(1); *see* 84 Fed. Reg. at 7716 (explaining that in nondirective pregnancy counseling, "clients take an active role in processing their experiences and identifying the direction of the interaction."). By allowing Title X providers to pick and choose which options to present to their patients during counseling, the Final Rule allows for directive counseling in violation of the Nondirective Counseling Provision.

2. The Final Rule violates the Affordable Care Act

The Final Rule also violates the Affordable Care Act. Section 1554 of the ACA expressly prohibits the Secretary from promulgating regulations that, among other things, create "unreasonable barriers" to medical care, "impede[] timely access to health care services," "interfere[] with communications" between providers and patients "regarding a full range of treatment options," "restrict[] the ability of health care providers to provide full disclosure of all relevant information to patients," and "violate[] the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114.

As the Court concluded in its Preliminary Injunction Order, the Final Rule "directly compromise[s] providers' ability to deliver effective care and force[s] them to obstruct and delay

patients with pressing medical needs. Abortion is a time-sensitive procedure; the medical risks and costs associated with it 'increase with any delay.'" P.I. Order at 15 (citing Dkt. No. 29 (Kost Decl.) ¶ 93). Multiple provisions in the Final Rule interfere with patient-provider communications and erect barriers between patients and time-sensitive abortion care.

First, the Final Rule forbids Title X clinicians from providing referrals for abortion and *requires* clinicians to refer all pregnant patients for prenatal care, even if a patient voices her decision to terminate the pregnancy. § 59.14(b)(1). This alone erects a barrier between the patient and abortion care and steers her toward medical care she does not want, in violation of § 1554. *See* 42 U.S.C. § 18114(1)-(2). The prohibition on referrals for abortion and the restrictions on discussions that support, encourage, or promote abortion also unquestionably "interfere[] with communications regarding a full range of treatment options between the patient and the providers" and "restrict[] the ability of health care providers to provide full disclosure of all relevant information to patients," contrary to § 1554. *Id.* § 18114(3)-(4).

Second, the referral list providers may give patients in response to a request for an abortion referral erects yet another hurdle between the patient and care. *See id.* 59.14(b)(1)(ii). At least half of the referral list must be providers who *do not* provide abortion services—and are thus not responsive to the patient's request—and the Title X clinician is prohibited from identifying which providers on the list are the ones the patient requested. *Id.* § 59.14(c)(2). Even worse, the Final Rule allows clinicians to furnish the patient with a list that contains *no* abortion providers—even if the patient requested abortion services—without notifying her that the list does not contain the information she requested. *See id.* (the list "may be limited to those that do not provide abortion"). The Final Rule thus needlessly imposes the burden on a pregnant patient to spend time and resources seeking the care she needs, and allows providers to intentionally misdirect patients to unwanted services, in violation of § 1554's prohibition against regulations that create "unreasonable barriers," "impede[] timely access to health care services," and interfere with full disclosure of relevant information to patients. 42 U.S.C. § 18114(1)-(4); *see* P.I. Order at 15, 35.

Third, the Final Rule's restrictions on abortion counseling and referral run headlong into § 1554 by forcing Title X providers to violate principles of informed consent and ethical standards governing the practice of medicine. *Id.* § 18114(5). For example, the American Medical Association ("AMA"), which writes and interprets the Code of Medical Ethics, explained that the Final Rule "would force physicians to violate their ethical obligations" because, among other things, it prohibits abortion referrals upon request. AMA Cmt 269332. Similarly, the American Academy of Physician Assistants wrote that physician assistants "must . . . be able to provide referrals" for care that is desired by their patients and "have an ethical obligation to provide . . . unbiased clinical information." AAPA Cmt 106281. The American Academy of Nursing cited the Code of Ethics for Nurses in pointing out that the Rule would force registered nurses, nurse midwives, and nurse practitioners to "violate their professional ethics in order to participate in Title X." AAN Cmt 107973. And the American College of Obstetricians and Gynecologists ("ACOG") stated that the Rule would force its member to violate its Code of Professional Ethics. ACOG Cmt 268838; *see also* P.I. Order at 44-45 (listing additional governing bodies' comments).[15]

The Final Rule also contravenes HHS's *own* guidelines. HHS's QFP recommendations provide that once a patient receives a positive pregnancy test:

> Referral to appropriate providers of follow-up care should be made at the request of the client as needed. Every effort should be made to expedite and follow through on all referrals. For example, providers might provide a resource listing or directory of providers to help the client identify options for care.

QFP at 14. The QFP recommendations further incorporate the recommendations of "major professional medical organizations, such as the American College of Obstetricians and Gynecologists." *Id.* at 13. And as ACOG explained to HHS during the rulemaking, physicians have an ethical obligation to "provide a pregnant woman who may be ambivalent about her pregnancy full information about all options in a balanced manner, including raising the child herself, placing the child for adoption, and abortion." ACOG Cmt 268841. The Final Rule's

[15] Despite this overwhelming and united wave of protest from the nation's leading medical authorities, HHS responded only with a conclusory assertion that it "disagrees," without actually discussing any of the ethical principles or professional standards cited in the many comments submitted. 84 Fed. Reg. at 7724, 7745, 7748.

referral and counseling restrictions are squarely at odds with the QFP guidelines.

Fourth, the Final Rule's "family participation" requirement forces providers to violate their ethical duties. The Title X statute requires grantees to "encourage family participation" in Title X projects, but only "to the extent practical." 42 U.S.C. § 300(a). Section 59.5(a)(14) of the Final Rule goes far beyond that directive, requiring providers to

> [e]ncourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).

42 C.F.R. § 59.5(a)(14). The only exception to this requirement is where a provider "suspects the minor to be the victim of child abuse or incest." *Id.* § 59.2(1)(i). As the American Academy of Pediatrics ("AAP") noted in comments to HHS, "clinicians sometimes learn of circumstances (short of abuse) in a minor's family that make it not 'practicable,' or unrealistic or even harmful to encourage the minor to involve their parents or guardians." AAP Cmt. 277791. Requiring clinicians to nevertheless bring the minor's parents or guardians into family planning decisions would breach clinicians' ethical obligations and "drive some minors away from returning for critical health services." *Id.*; *see also* ACOG Cmt. 268848-49; P.I. Order at 46.

Finally, the Final Rule's physical separation requirement creates additional barriers to timely care. *See* § 59.15. Those requirements mandate that Title X-funded activities occur in physically separate facilities from "prohibited" activities, which include not only abortion services, but also abortion referrals and meaningful discussion of abortion options. *See id.* Thus, a patient who learns that she is pregnant at a Title X site 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 options available to her. This is yet another unreasonable barrier to time-sensitive care. *See* 42 U.S.C. § 18114.

* * *

Because the Final Rule violates the HHS Appropriations Act and the ACA by mandating conduct those laws were designed to thwart, it should be set aside. 5 U.S.C. § 706(2).

C. This motion is ripe for disposition, and the Final Rule should be vacated

The Court previously noted that the Ninth Circuit may address the merits of this case in its ruling on Defendants' appeal of the preliminary injunctions (and related stays pending appeal) issued in this and related cases. *See* Dkt. 128, 151. The Court should nevertheless decide this motion for at least the following reasons.

First, Defendants' appeal challenges only preliminary injunction orders. The Ninth Circuit's review will evaluate district court decisions made under a different standard, on an incomplete record. *See, e.g., California v. U.S. Dep't of Health & Human Servs.*, 941 F.3d 410, 431 (9th Cir. 2019) ("Because of the limited scope of our review and 'because the fully developed factual record may be materially different from that initially before the district court,' our disposition is only preliminary.") (citations omitted).

Second, and relatedly, this motion is based upon a complete record—including the administrative record, which is not before the Ninth Circuit. *See Portland Audubon Soc. v. Endangered Species Comm.*, 984 F.2d 1534, 1548 (9th Cir. 1993) ("Section 706 of the APA provides that judicial review of agency action shall be based on 'the whole record.'"); *see also* Audio recording of Sept. 23, 2019 *En Banc* Hearing, Ninth Circuit Court of Appeal, No. 19-15974, at 59:31-59:52, *available at* https://www.ca9.uscourts.gov/media/view.php?pk_id=0000034441 ("The Court: '. . . Do we have the entire administrative record in front of us?' Defendants' counsel: '[T]he PIs were granted before the administrative record had been put in, so technically I think the record on the PI is without the administrative record.'"). The record is of paramount importance here because it establishes as a matter of law that the Final Rule is, among other things, arbitrary and capricious.

Third, as this Court has recognized, the Ninth Circuit has instructed that district court cases should proceed pending appeal of a preliminary injunction order. *See, e.g., California v. Azar*, 911 F.3d 558, 583–84 (9th Cir. 2018) (citations omitted) ("We have repeatedly admonished district courts not to delay trial preparation to await an interim ruling on a preliminary injunction."); Dkt. 104 at 2 (citing same). That directive is especially applicable here given the urgency of Plaintiffs' claims. Plaintiffs filed suit to challenge the Final Rule nearly a year ago.

Though the Final Rule takes aim at abortion, it inhibits access to *non*-abortion services funded by Title X, including access to contraceptives, sexually transmitted infection screenings, breast exams, Pap tests, public education, and community outreach. If it stands, the Final Rule will continue to decimate California's Title X network, disproportionately harming underserved and vulnerable communities that rely on Title X-funded services for critical care. Continued inaction will amount to a pocket veto of Plaintiffs' claims, rendering the Final Rule effectively unreviewable. Plaintiffs' motion is ripe for disposition now.

Finally, where, as here, an agency rule is invalid, "the result is that the rule is vacated, 'not that [its] application to the individual petitioners is proscribed.'" *City & Cty. of San Francisco v. Azar*, — F. Supp. 3d —, 2019 WL 6139750, at *17 (N.D. Cal. 2019) (quoting *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998)). Because the Final Rule violates multiple laws and is thoroughly infected with arbitrary and capricious decision making, it should be vacated in its entirety.

V. CONCLUSION

For all of the foregoing reasons, the Court should grant summary judgment to Plaintiffs on their APA claims and vacate and set aside the Final Rule in its entirety.

Respectfully submitted,

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