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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 **CALIFORNIA'S NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION, WITH MEMORANDUM OF POINTS AND AUTHORITIES** Administrative Procedure Act Case Date: April 18, 2019 Time: 12:30 p.m. Dept: Courtroom 5, 17th Floor Judge: The Honorable Edward M. Chen Trial Date: Not set Action Filed: March 4, 2019

TO THE DEFENDANTS AND THEIR COUNSELS OF RECORD:

PLEASE TAKE NOTICE that on April 18, 2019, at 12:30 p.m., in Courtroom 5 of the above-entitled court, at 450 Golden Gate Avenue, San Francisco, California, Plaintiff State of California will move under Local Rule 7-2 for a preliminary injunction enjoining implementation of the Final Rule, "Compliance with Statutory Program Integrity Requirements," 84 Fed. Reg. 7714 (Mar. 4, 2019) (to be codified at 42 C.F.R. pt. 59).

Because the Final Rule violates the Administrative Procedure Act (APA) and will cause irreparable harm, the States seek a preliminary injunction enjoining enforcement and implementation of the Final Rule or an order of postponement pursuant to 5 U.S.C. § 706(2) of the effective date of the Final Rule pending judicial review against Defendants Alex M. Azar, in his official capacity as Secretary of the U.S. Department of Health & Human Services and the U.S. Department of Health and Human Services (collectively, Defendants).

This motion is based on this notice, the Memorandum of Points and Authorities, the Declarations of Claire Brindis, Ph.D., Mari Cantwell, Carmela Castellano-Garcia, Barbara Ferrer, Ph.D., Elizabeth Forer, Kathryn Kost, Ph.D., Melissa Marshall, M.D., Louise McCarthy, Marie McKinney, Joseph Morris, Ph.D., M.S.N., R..N., Shivaun M. Nestor, Julie Rabinovitz, Anna Rich, Tatiana W. Spirtos, M.D., Jane Thomas, Jenna Tosh, Ph.D., Henry N. Tuttle, Kayla Wilburn, this Court's file, and any matters properly before the Court. Where declarations are offered in support of both California and Essential Access Health's related motions, those declarations are identical.

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INTRODUCTION

Nearly fifty years since its enactment, Title X of the Public Health Service Act (PHSA), the nation's sole federally funded program devoted to family planning, stands as a public health triumph: a strong network of medical providers committed to delivering high quality, evidence-based preventive health services, including needed reproductive care, to low-income women and their families. The new rule issued by the U.S. Department of Health and Human Services (HHS) and Secretary Alex M Azar, II (collectively, Defendants), "Compliance with Statutory Program Integrity Requirements" (hereinafter "Final Rule"), threatens to undo that success by imposing new, onerous requirements on Title X providers, including "gag" rules that prevent them from giving comprehensive, accurate, and nondirective healthcare information to their patients, and mandating unnecessary physical and financial separation between family planning programs and facilities that provide abortion services or referrals to such services.

Defendants' Final Rule flies in the face of the law and the facts. It violates Congress' mandate that all Title X pregnancy counseling be nondirective, and its Affordable Care Act (ACA) prohibition against regulations that interfere with access to healthcare. And Defendants ignored evidence that the Final Rule undermines medically accepted standards of care, interferes with the patient-provider relationship, and contradicts core tenets of the Title X program.

The Final Rule will have a particularly disruptive impact on California, where a well-established network of Title X providers—the nation's largest—plays a central role in ensuring access to comprehensive family planning, education, and related preventive health services. The Final Rule will push out many well-qualified providers who will not compromise their obligations to their patients. It will impede the State's ability to establish ground rules for safe and effective clinical services in the field of reproductive health. And it will impose severe new burdens and costs for California women and their families as well as for the state's Medicaid program, and for public health generally. For these reasons, California asks the court to preliminarily enjoin implementation of the Final Rule.

LEGAL AND FACTUAL BACKGROUND

I. CURRENT TITLE X PROGRAM BRINGS SIGNIFICANT BENEFITS

Nationally, four million Americans rely on affordable family planning services that are funded by Title X, including more than one million patients in California alone. Brindis Decl. ¶ 15. Title X programs provide quality sexual and reproductive healthcare, including contraceptive supplies and information, on a voluntary, non-coercive, and confidential basis, with priority given to low-income individuals. Kost Decl. ¶ 19-20. In addition to offering a broad range of effective. FDA-approved contraceptive methods, Title X-funded clinics provide contraceptive education and counseling; breast and cervical cancer screening; testing, referral, and prevention education for sexually transmitted infections/diseases (STIs/STDs), including HIV; and pregnancy diagnosis and counseling. Tosh Decl. ¶ 14; Rabinovitz Decl. ¶ 11-12.

Title X-funded programs are specifically focused on pre-pregnancy care. Under the previous program rules, Title X providers referred all pregnant patients upon request to high-quality, non-Title X programs to handle their pregnancy-related needs, including prenatal care or abortion-related services depending on the woman's choice.

California's sole Title X grantee is Essential Access Health, a non-profit organization that administers sub-grants to a diverse array of qualified family planning and related preventive health service providers. In 2017, HHS's Office of Population Affairs (OPA) awarded Essential Access $20.5 million dollars to support access to high-quality family planning and sexual healthcare. Rabinovitz Decl. ¶ 13. The majority of California Title X sub-grantees are federally qualified health centers, community-based clinics that provide a wide range of primary care services to underserved and uninsured individuals regardless of their ability to pay. Rabinovitz Decl. ¶ 7. Other grantees include family planning and women's health centers, such as Planned Parenthood, faith and community-based education and outreach centers, county health departments, community action partnerships and economic opportunity commissions, Native American health centers, and hospitals. *Id*. Title X subgrants are targeted based on regional needs, including toward rural and underserved areas. *Id*. ¶ 26-27; Tosh Decl. ¶ 18(a).

The services provided by California's existing network of qualified Title X providers have a significant, positive impact on family health and well-being, and by extension public health generally. Title X-provided contraceptive services have resulted in lower unintended pregnancy and abortion rates across the United States, including California. Kost Decl. ¶ 35. Contraception improves health outcomes by allowing women to avoid unintended pregnancies and to time and space wanted pregnancies, and can prevent preexisting health conditions from worsening and new health problems from occurring. In 2015 alone, experts project that the Title X program nationwide helped women avoid an estimated 822,000 unplanned pregnancies, which would have resulted in 387,000 unplanned births and 278,000 abortions; substantially reduced teen unintended pregnancy rates; and reduced the transmission of STIs like gonorrhea and chlamydia. Kost Decl. ¶ 35, 55. Access to contraceptive services benefits women in particular, helping women choose whether to delay childbearing and pursue additional education, and helping narrow the gender wage gap. Kost Decl. ¶¶ 62-65; Brindis Decl. ¶¶ 45-47.

The benefits of Title X extend to society at large. Contraception is one of the most cost-effective investments that governments can make to promote public health. For every dollar invested in publicly funded family planning programs like Title X, federal and state governments saved an estimated $7.09 in 2010 in Medicaid-related costs that would otherwise have been associated with unintended pregnancies as well as higher rates of adverse birth effects, STIs, and cervical cancer. Brindis Decl. ¶ 56; Kost Decl. ¶ 66.

II. TITLE X LAW AND PRIOR REGULATIONS

The Title X statute authorizes the Secretary to "make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of volunteer family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)." 42 U.S.C. § 300(a). Congress's express purposes demonstrate that lawmakers intended to make the program available, effective, coordinated, and research based:

> (l) to assist in making comprehensive voluntary family planning services readily available to all persons desiring services;

> (2) to coordinate domestic population and family planning research with the present and future needs of family planning programs;
> (3) to improve administrative and operational supervision of domestic family planning services and of population research programs related to such services;
> (4) to enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services;
> (5) to develop and make readily available information (including educational materials) on family planning and population growth to all persons desiring such information;
> (6) to evaluate and improve the effectiveness of family planning service programs and of population research; [and]
> (7) to assist in providing trained manpower needed to effectively carry out programs of population research and family planning services[.]

Pub. L. No. 91-572 § 2, 84 Stat. 1504 (1970). The statute lists the factors that the Secretary "shall take into account" in grantmaking: (1) number of patients to be served; (2) the extent of local need for services; (3) applicant's relative need; and (4) its capacity to make rapid and effective use of funds. 42 U.S.C. § 300(b). Title X services "shall be voluntary." 42 U.S.C. § 300a-5.

Section 1008 of the PHSA prohibits Title X funds from being "used in programs where abortion is a method of family planning."[1] 42 U.S.C. § 300a-6 (hereinafter referred to as "Section 1008"). In 1988, in order to "preserve the distinction between Title X programs and abortion as a method of family planning," HHS issued regulations banning abortion options counseling and referral and mandating strict physical and financial separation between a recipient's Title X programs and any abortion-related services. 53 Fed Reg. 1923-2924. The Supreme Court held that Section 1008 of the PHSA was ambiguous, and that HHS's regulation banning abortion referral and counseling, and imposing physical and financial separation requirements, was a permissible interpretation of that provision. *Rust v. Sullivan*, 500 U.S. 173, 186, 191 (1991). Despite the *Rust* decision, the 1988 rule was never fully implemented, and was ultimately short-lived. HHS completely rescinded the rules in 1993, concluding that they "inappropriately restrict[ed] grantees." 58 Fed. Reg. 7462, 7462 (Feb. 5, 1993).

Since then, Congress has passed laws resolving the ambiguity that led the *Rust* Court to uphold gag and separation rules. Starting in 1996, Congress has attached so-called "policy

[1] Title X "expressly distinguishes between a Title X *grantee* and a Title X *project*." *Rust*, 500 U.S. at 196 (emphasis in original). As the Court explained, a "Title X grantee can continue to […] provide abortion-related services […] it simply is required to conduct those activities through programs that are separate and independent from the project that receives Title X funds."

riders" in HHS appropriations bills clarifying that "all pregnancy counseling" using Title X family planning funds "shall be nondirective." *See, e.g.,* Pub. L. 115-245, 132 Stat. at 3070-71 (2018). In 2000, consistent with Section 1008's prohibition and the nondirective mandate, HHS issued regulations protecting women's access to comprehensive and accurate information about their reproductive choices. 65 Fed. Reg. 41282 (July 3, 2000). Each Title X project was required to "[p]rovide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents)." 42 C.F.R. § 59.5 (July 3, 2000); 42 U.S.C. § 300(a). Title X family planning grantees were required to "[o]ffer pregnant women the opportunity to be provided with information and counseling regarding . . . [p]regnancy termination," and "provide neutral, factual information and nondirective counseling" if requested. *Id*. at § 59.5(a)(5)(i-ii). HHS permitted shared facilities that host Title X programs and provide abortions "so long as it is possible to distinguish between the Title X supported activities and non-Title X abortion-related activities," and costs of waiting rooms, staff, and filing systems were properly pro-rated. 65 Fed. Reg. at 41282. More recently, in Section 1554 of the ACA, Congress forbade HHS from promulgating "any regulation" that creates barriers or impedes access to healthcare services, or that interfered with providers' ability to disclose relevant information or violated ethical principles like informed consent. 42 U.S.C. § 18114 (hereinafter referred to as "Section 1554").

OPA provides strict oversight of Title X-programs to ensure that federal funds are used appropriately. Rabinovitz Decl. ¶ 16. Existing safeguards include: (1) careful review of grant applications to ensure that the applicant understands and has the capacity to comply with all requirements; (2) independent financial audits to examine whether there is a system to account for program-funded activities and non-allowable program activities; (3) yearly comprehensive reviews of the grantees' financial status and budget report; and (4) periodic and comprehensive program reviews and site visits by OPA. *Id*. ¶¶ 16-18. Essential Access Health itself closely monitors compliance by its sub-grantees. Rabinovitz Decl. ¶¶ 19-20. HHS did not identify a single confirmed instance of inappropriate use of Title X funds for abortion services in its rule.

OPA also routinely sets forth specific clinical standards for Title X services. Prior to the Final Rule, OPA required grantees to adhere to federal Quality Family Planning (QFP) recommendations issued by OPA and the Centers for Disease Control and Prevention (CDC) which set forth broadly accepted, evidence-based standards for high-quality clinical practice for the provision of family planning services.[2] *See* Brindis Decl. Ex. C, HHS, "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. [OPA]." The CDC developed these nationally recognized protocols in collaboration with professional medical associations like the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics. *Id*. at 13. The QFP recommendations were incorporated by OPA into their standards for Title X care. *See* Rich Decl. Ex. A, OPA, "Program Requirements for Title X Funded Family Planning Projects" (April 2014), p. 5. According to the recommendations, quality family planning services should take a "client-centered approach" in which "the client's primary purpose for visiting the service site [is] respected." Brindis Decl. Ex. C at 2. Pregnancy testing and counseling services are considered a "core" part of "family planning services," and after administration of a pregnancy test, providers are instructed that the "test results should be presented to the client, followed by a discussion of options *and appropriate referrals*," which "should be made *at the request of the client, as needed*." *Id*. at 13-14 (emphasis added); *see also* 42 C.F.R. 59.5(a)(5)(ii) (2000) (patient who does not wish to receive information, counseling, or referral about a particular option for her pregnancy cannot be forced).

These standards were developed to provide quality family planning services in a safe, effective, and client-centered manner, Brindis Decl. Ex. C at 2, consistent with Congressional intent. They help instill trust between patients and their Title X providers and ensure the delivery of unbiased information regarding patients' reproductive and sexual health. Kost Decl. ¶ 20-28. This high standard of care helps patients make the best decisions for themselves and their loved

[2] HHS continues to refer Title X providers to the Quality Family Planning Guidelines. *See* HHS Office of Population Affairs, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html (last visited March 21, 2019).

ones when facing an unintended pregnancy, or needing to make other time-sensitive decisions about their reproductive health. Brindis Decl. ¶ 17.

III. California's Current Title X Provider Network

The 2000 regulations and subsequent OPA guidance have resulted in a robust Title X network of diverse providers who provide a high quality of care to their patients. California's current network of Title X providers is more likely than other publicly funded providers to offer patients on-site, specialized services that have a higher up-front cost, but are more effective and cost-efficient in the long run, such as vasectomies or long-acting reversible contraception (LARC); they have greater adherence to evidence-based protocols like chlamydia screening guidelines; they are more likely to incorporate advanced technologies in their clinics; and they are more likely to participate in clinical training opportunities. Brindis Decl. ¶¶ 20-33.

California's existing Title X providers are particularly effective at outreach and serving vulnerable or marginalized patient populations. They have greater proportions of bilingual staff, and are more likely to provide services targeting adolescents; male and transgender individuals; lesbian and gay individuals; persons experiencing homelessness those with limited English proficiency; migrant workers; individuals coping with alcohol and substance abuse; refugees and immigrants; and persons with disabilities. Brindis Decl. ¶ 70-72. Title X-funded providers are more likely, compared to other publicly funded family planning providers, to offer extended clinic hours and to provide sexual and reproductive health education. Brindis Decl. ¶ 29.

IV. The Final Rule Reverses Longstanding Agency Rules and Policies

In light of these successes, one might reasonably expect any regulatory overhaul to occur only after thoughtful, evidence-based consideration. This regulatory overhaul decidedly—and unlawfully—did not. The Final Rule is a throw-back to 1988 that ignores the weight of the available evidence, with convoluted additions to offer a veneer of compliance with Congress's nondirective counseling requirement while failing to comply with the core nondirective requirement. Key unlawful features of the Final Rule are summarized below.

A new level of "physical and financial separation" is required between a Title X program and a facility that engages in so-called "prohibited activities." 42 C.F.R. § 59.15 (Mar. 4, 2019).[3] Factors that HHS considers relevant to this determination include having separate waiting, consultation, examination, and treatment rooms, office entrances and exits, phone numbers, email addresses, educational services, websites, personnel, electronic or paper-based healthcare records, and workstations. *Id*. The separation requirements apply not only to the minority of Title X providers that actually offer abortion, but also to all Title X projects that give only referrals for abortions and to all Title X projects, including Essential Access Health, that engage in separately funded advocacy or public education activities that Defendants may determine "promote" or "support" abortion. *Id*. § 59.14(a). To continue to receive Title X funding, providers would in the future effectively be required to open a second clinic site to continue to provide even a *referral* to patients requesting a list of abortion providers—an option that is entirely impracticable.

A new gag rule places restrictions on services for and communications with pregnant patients, and limits who may provide those services. Title X providers may not "promote, refer for, or support abortion as a method of family planning." *Id*. §§ 59.5(a)(5), 59.14(a). The Final Rule requires that when a woman is "medically verified as pregnant, she *shall* be referred" for "prenatal health care," regardless of the woman's choices, and it permits Title X providers to provide "information about maintaining the health of the mother and unborn child during pregnancy" even if the woman does not wish to continue the pregnancy. *Id*. § 59.14(b)(1)(iii, iv) (emphasis added). Even where a pregnant Title X patient wishes to exercise her lawful choice to access an abortion, the Final Rule would prohibit the provider from providing her with a specific list of healthcare entities that perform abortions; at most, the healthcare provider may provide a list of "comprehensive primary health care providers (including providers of prenatal care)." *Id*. §§ 59.14(a), 59.14(b)(ii). Title X provider may choose to exclude providers that perform abortion entirely from the list. *Id*. § 59.14(c)(2). Provider lists given to women seeking an abortion may

[3] Unless indicated by an earlier date, all citations in Plaintiff's brief to the Code of Federal Regulations refer to the regulations published in the Final Rule on March 4, 2019.

only include providers that also offer comprehensive primary care, which means that a specialty clinic or individual provider who provides abortions and other healthcare services, but not "comprehensive" care, would be ineligible to be placed on a list, even if the clinic or provider were the most convenient, qualified, and/or affordable provider offering the abortion care services that the Title X patient seeks. The Final Rule not only authorizes this misleading provider list, it also prohibits Title X clinicians from informing their patient—who has requested a referral for an abortion (a time sensitive medical procedure)—that only some or none of the healthcare facilities on the list they receive provide the abortion services they seek. *Id*. § 59.14(c)(2). In addition, the Final Rule adds further barriers to accessing information by providing that only doctors and nurses with advanced degrees may discuss reproductive options with pregnant women, or give the provider list. *See id*. §§ 59.2 (defining "advanced practice provider"), 59.14 (b)(1)(ii) (limiting who may give pregnancy counseling).

Furthermore, the Final Rule eliminates the requirement that Title X providers offer a broad range of "medically approved" family planning methods. 84 Fed. Reg. at 7740. And, contrary to the QFP recommendations, the Final Rule removes the requirement that Title X providers offer nondirective pregnancy options counseling that includes information about prenatal care and delivery, adoption, and pregnancy termination, if requested. *Id*. at 7716.

The Final Rule also impedes provision of care to adolescents. Minors may be found to be financially eligible for subsidized Title X services only after documentation of "specific actions taken to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services."[4] 42 C.F.R. § 59.2. Even for minors who manage to pay for Title X services out of pocket, the Rule requires that providers document in the medical record the specific actions taken to encourage family participation or any specific reason why family participation was not encouraged. *Id*.

Finally, the Rule also includes a new ban on use of Title X funds to "build infrastructure

[4] The only exception to this family involvement requirement is when the provider suspects child abuse or incest, has reported the situation to State or local authorities, and has documented that reporting in the record.

for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient." 42 C.F.R. § 59.18(a). HHS's sole example of prohibited "infrastructure building" is the Los Angeles, California-based Venice Family Clinic's use of health educators wearing backpacks with condoms and educational materials to promote sexual and reproductive health in the community, and visiting homeless shelters. 84 Fed. Reg. at 7774.

For the reasons described below, this Final Rule violates the APA, and will cause imminent and irreparable harm to California and its residents.

LEGAL STANDARD

To obtain a preliminary injunction, the plaintiff must demonstrate that (1) it "is likely to succeed on the merits," (2) it "is likely to suffer irreparable harm in the absence of preliminary relief," (3) "the balance of equities tips in [its] favor," and (4) "an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Courts evaluate these factors on a "'sliding scale,'" such that serious questions on the merits and a balance of hardships that tip sharply towards the plaintiff can support a preliminary injunction, so long as the plaintiff also shows a likelihood of irreparable injury and that the injunction is in the public interest. *Arc of Cal. v. Douglas*, 757 F.3d 975, 983 (9th Cir. 2014).

Similarly, the APA provides that "the reviewing court […] may issue all necessary and appropriate process to postpone the effective date of an agency action." 5 U.S.C. § 705. This remedy is available "to the extent necessary to prevent irreparable injury" and to preserve the status quo pending judicial review proceedings. *Id.*; *see Nken v. Holder*, 556 U.S. 418, 425 (2009) (applying traditional preliminary injunction factors to request for stay pending review).

ARGUMENT

I. CALIFORNIA IS LIKELY TO SUCCEED ON THE MERITS

A. The Final Rule is Invalid Under the APA Because it is Not in Accordance with the Law and is in Excess of Statutory Authority

The Final Rule must be held "unlawful and set aside" under the APA because it is "not in accordance with the law" and is "in excess of statutory jurisdiction." 5 U.S.C. §§ 706(2)(A), 706(2)(C). Here, Congress has required that options counseling be "nondirective," and forbids

Defendants from issuing regulations that interfere with the delivery of health care as the Final Rule does. And Congress delegated to Defendants only the authority to promulgate rules consistent with that authority, but the Final Rule is inconsistent with Title X and Congress' subsequent mandates because it undermines the availability and effectiveness of family planning services. *See Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001) (noting agency's power to promulgate legislative regulations is limited to the authority delegated to it by Congress) (citing *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988)).

1. The Rule Violates the Requirement that Title X Services Be Nondirective and Voluntary

The Final Rule violates Congress' mandate that pregnancy counseling be nondirective. Appropriations bills since 1996, up to and including the most recent, have provided that "all pregnancy counseling" in Title X family planning projects "*shall* be nondirective."[5] Pub. L. No. 115-245, 132 Stat. 2981, 3070-71 (2018) (emphasis added). This accords with the statutory requirement that all Title X grants support only "voluntary family planning projects," 42 U.S.C. § 300, *see also* Pub. L. 115-245, 132 Stat. at 3070-71 (reiterating the "voluntary" nature of services in setting forth the nondirective mandate). Providing inaccurate or misleading referral lists for patients seeking abortions (but no other postconception services), 42 C.F.R. §§ 59.14(a), 59.14(b)(ii), and requiring that all pregnant women be referred for prenatal services (even if they have expressed a choice to seek an abortion), *id*. § 59.14(b)(ii, iv), is not nondirective. It is coercive, steering patients into prenatal care regardless of their preference.

Moreover, the Final Rule effectively prohibits nondirective counseling by prohibiting referrals for abortion, by issuing a vague prohibition on providers who "encourage" or "promote" abortion (inhibiting providers' ability to provide respectful, client-centered counseling), *id*. § 59.16, and by banning referrals for abortion, but not other post-conception care, *id*. § 59.14(a, c). None of these limitations can be squared with the requirement for nondirective options

[5] When Congress enacted the nondirective requirement, it did so against the backdrop of HHS's regulation defining "nondirective counseling" to include "counseling to the patient on options relating to her pregnancy, including abortion" and a requirement to "refer her for abortion, if that is the option she selects." *See* Standards for Compliance for Abortion-Related Services in Family Planning Service Projects, 58 Fed. Reg. 7464, 7464 (Feb. 5, 1993).

counseling. *See supra* pp. 9-10. Such unclear guidance will likely cause providers to forgo discussions altogether for fear of violating the Rule. *See, e.g.*, Rich Decl. Ex. B, Cal. Med. Asso.; Ex. C, Ctr. Reprod. Rts. at 9; Ex. D, Am. Acad. Nursing; Ex. E, Guttmacher Inst.

In opposing this Motion, Defendants may attempt to rely on *Rust* to suggest that the Final Rule is a permissible interpretation of Section 1008. However, *Rust* has been superseded by subsequent Congressional action. In 1991, the Supreme Court examined the statutory language and legislative history surrounding Section 1008, and found that "the plain language and legislative history are ambiguous as to Congress' intent in enacting Title X." *Rust*, 500 U.S. at 187. The Court held that the Secretary's interpretation of Title X permitting a gag rule that prohibited counseling and referral regarding abortion was a permissible interpretation of the statute because it was merely "a prohibition on a project grantee or its employees from engaging in activities outside of the project's scope." *Id*. at 194. But *Rust* was decided five years before Congress enacted the requirement that "all pregnancy counseling shall be nondirective." The ambiguity regarding the scope of Title X projects that was a central issue in *Rust* has now been resolved by Congress' subsequent laws establishing that non-directive counseling, including provision of information and referrals regarding abortion, is not only within the scope of Title X projects, but the standard when counseling pregnant women on their options.[6]

2. The Rule Violates Section 1554 of the ACA

The Final Rule also conflicts directly with Section 1554, which forbids the HHS Secretary from promulgating "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 provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; [or] (5) violates the

[6] Defendants' assertion that the 2000 regulations were "inconsistent with a number of federal conscience protection[s]," 84 Fed. Reg. at 7745, specifically the Church, Coats-Snowe, and Weldon Amendments (respectively, 42 U.S.C. § 300a-7, 42 U.S.C. § 238n(a), and Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, Div. H, § 507(d)) is meritless. Those laws pertain to specific circumstances in which healthcare providers may not be required to participate in abortions or sterilizations, not the overall clinical standard for what constitutes appropriate Title X family planning services. The latter is not a matter appropriately left to individual conscience, and Congress' nondirective mandate shows that it did not intend to do so.

principles of informed consent and the ethical standards of health care professionals.

42 U.S.C. § 18114. As described in Section II below, the Final Rule constitutes a significant impediment to low-income Title X patients' access to contraceptive care and, for those who choose it, abortion services. The Final Rule vividly constructs barriers between Title X patients and reproductive healthcare; a Title X clinic cannot even place a Planned Parenthood brochure on a waiting room table without coming into violation of the Final Rule. 42 C.F.R. § 59.16(b)(1). The provision of misleading or incomplete referral lists will certainly impede timely access to abortion care services, and interfere with Title X providers' abilities to communicate with their patients regarding the full range of treatment options, to provide full disclosure of all relevant information to patients making health care decisions (such as the most convenient and high quality abortion provider), and violates basic principles of informed consent and the ethical standards of doctors, nurses, and other medical professionals. *See*, *e.g.*, Rich Decl. Ex. F, Cal. Asso. Nurse Prac.; Ex. D, Am. Acad. Nursing; Ex. C, Ctr. Reprod. Rts.

3. The Rule Is in Excess of Statutory Jurisdiction

Furthermore, these changes usurp Congressional authority by undermining the statutory mandate that Title X provide "a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a). Many aspects of the Rule that remove or weaken requirements regarding comprehensive, evidence-based reproductive care run counter to accepted principles of medical ethics and standards for clinical practice of reproductive healthcare. Rich Decl. Ex D, Am. Acad. Nursing, AMA at 3; Ex. G, ACOG at 3-6; Assoc. Am. Med Colleges at 2.

Defendants, like any federal agency, "literally [have] no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); 5 U.S.C. § 706(2)(C). In determining whether Defendants exceeded their statutory authority, this Court must undertake a two-step process. *American Library Ass'n v. FCC*, 406 F.3d 689, 698-99 (D.C. Cir. 2005). First, the Court must ascertain whether the statute "has directly spoken to the precise question at issue;" and if the statute is unambiguously clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of

Congress." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-843 (1984). Second, if the statute admits of some ambiguity, then courts must determine whether the agency's interpretation is "reasonable." *Id*. at 844. A regulation is invalid when it adopts an interpretation so unreasonable that it directly conflicts with the statute it purports to implement. *Ragsdale v. Wolverine World Wide, Inc*., 535 U.S. 81, 90-92 (2002) (holding agency interpretation unreasonable where it conflicts with law's "remedial scheme" and intent).

The Final Rule is an unreasonable exercise of Defendants' authority under the Title X statute, which requires that grants for Title X programs "shall offer a broad range of acceptable and effective family planning methods and services," and a "comprehensive program of family planning services," that "shall be voluntary." 42 U.S.C. §§ 300(a), 300a(a), 300a-5. In fact, by banning abortion referrals and effectively eliminating the provision of nondirective counseling, the Rule is directing fund recipients *not* to offer comprehensive family planning services. As ACOG explained in its comment to HHS, such a regulation "restricts the ability of physicians to provide clear, direct information to patients, and it even goes so far as to actively require physicians to withhold full and accurate information and provide referrals to providers that do not offer the service requested by the patient." Rich Decl. Ex. G, ACOG at 5. Eliminating requirements for nondirective counseling and that services be "medically approved" will result in Title X programs that offer a more limited range of effective methods and services.

Other aspects of the Final Rule similarly run counter to Congressional language and purpose. For example, Defendants' new ban on use of Title X funds to "build infrastructure for purposes prohibited by these funds" (which, according to the preamble, would include activities like "clinical training for staff" and "community outreach" (84 Fed. Reg. at 7774)) is inconsistent with the express purposes of Title X, which contemplate a wide variety of capacity-building activities. *See supra* p. 5 (quoting Pub. L. No. 91-572 § 2, 84 Stat. 1504 (1970)). Far from supporting an "abortion business," 42 C.F.R. § 59.18(a), the so-called infrastructure building activity decried in the rule is aimed to increase access to contraceptives, and thus decrease the need for abortion. Likewise, allowing only doctors and nurses with advanced degrees, but not nurses or other health professionals with bachelors or associates degrees, to provide counseling

regarding pregnancy options will make obtaining family planning services harder, not easier, to obtain, directly contradicting Title X's purposes. Rich Decl. Ex. J, Am. C. Nurse-Midwives.

4. The Rule is Arbitrary and Capricious Because Defendants Failed to Provide an Adequate Justification for Their Policy Reversal

In issuing the Rule, Defendants ignored impacts of the Rule that were raised by California and others in public comments. Rich Decl. Ex. H, Multistate Comment. Defendants' explanation for their decision "runs counter to the evidence before the agency"; it is "so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Veh. Mfrs. Ass'n v. State Farm Ins*., 463 U.S. 29, 43 (1983). Indeed, Defendants ignored evidence that the impact of the Rule will undermine the very purposes of the Title X statute.

An agency must provide a "concise general statement of [a regulation's] basis or purpose". 5 U.S.C. 553(c). "[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself." *State Farm*, 463 U.S. at 50. Where an agency departs from a prior policy, a more "detailed justification" is necessary where 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; *see also State Farm*, 463 U.S. at 47-51 (new administration's rule change was arbitrary and capricious where agency failed to address prior factual findings). A change in administration does not authorize an unreasoned reversal of course. *See Regents of the Univ. of Cal. v. U.S. State Dept*., 908 F.3d 476, 510 (9th Cir. 2018) (upholding preliminary injunction where agency change in position was arbitrary and capricious under settled law); *California v. U.S. Bureau of Land Mgmt*., 277 F.Supp.3d. 1106, 1123 (N.D. Cal. 2017) ("New presidential administrations […] must give reasoned explanations […] and address the prior factual findings underpinning a prior regulatory regime." (quotation marks omitted)). Where the agency action is "arbitrary" or "capricious," the court must invalidate it. 5 U.S.C. § 706(2)(A).

HHS stated its intent to revise existing regulations in order "to ensure compliance with, and enhance the implementation of" the provision of the PHSA which prohibits use of Title X funds from being used in "programs where abortion is a method of family planning." 84 Fed. Reg. at

7714. Defendants claim to be concerned about the "potential for…confusion and…co-mingling" or a "risk" of the "appearance and perception" of misuse of funds, 84 Fed. Reg. at 7764-65, yet fail to identify *any* evidence showing that funds appropriated for Title X were, in fact, being illegally used by recipients of those funds, or any other evidence warranting such a drastic change in regulation. HHS acknowledged that the examples it cited in the proposed rule related to improper use of funds involved Medicaid, not Title X funds. 84 Fed. Reg. at 7725. Given the number of individuals nationwide who rely on Title X funded services, the government must provide greater justification for the Final Rule. *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015) (requiring "more substantial justification" when "prior policy has engendered serious reliance interests") (quoting *Fox Television Stations, Inc*., 556 U.S. at 515). Defendants failed to do so.

Comment letters submitted by the major medical healthcare provider organizations and experts in reproductive health opposing the Final Rule all provided Defendants with substantial evidence showing that the Rule is medically misguided and contrary to best practices and medical ethics. *Id*. Rich. Decl. Ex. G, ACOG; Ex. I, Am. Med. Asso.; Ex. B, Cal. Med. Asso.; Ex. D, Am. Acad. Nursing; Ex. E, Guttmacher Inst.; Ex. F, Cal. Asso. Nurse Prac.; Ex. D, Am. Acad. Nursing; Ex. K, Am. Pub. Health Asso. Yet in explaining the reasoning behind the Final Rule, Defendants fail to acknowledge how expert opinion weighs against the Final Rule, frequently and misleadingly suggesting that expert opinion is split and ignoring widespread norms. For example, in justifying their decision to remove the requirement that family planning methods be "medically approved," Defendants claim that "different medical doctors and professional organizations may differ on which methods of health care they approve, including different methods of family planning," and selectively rely upon ACOG's support for inclusion of natural family planning as a method of contraception in order to misleadingly support their assertion that the "medically approved" requirement is confusing and unnecessary. 84 Fed. Reg. at 7741, & n.70. In fact, ACOG told Defendants in no uncertain terms that the proposed rule "appears to be diluting long-standing Title X program requirements, lowering the standards governing the services that must be offered," "threaten[ing] the quality of family planning available to Title X patients," and

"prioritizing ideology over scientific evidence." Rich Decl. Ex. G, ACOG at 2, 9.

In promulgating the Rule, Defendants ignored the views of the American Medical Association, ACOG, the American College of Physicians, and the American Academy of Family Physicians endorsing nondirective options counseling, including referral to appropriate providers, as the most clinically appropriate role for providers caring for a patient facing an unexpected pregnancy.[7] Rich Decl. Ex. I, Am. Med. Asso.; Ex. G, ACOG; Ex. P, Am. C. Physicians; Ex. Q, Am. Acad. Fam. Physicians. And Defendants ignored the weight of the medical community's consensus that the Rule would interfere with the relationships between health providers and their patients, and violate accepted principles of medical ethics, which require doctors and other health professionals to put patients' needs first, and undermines doctors and other health professionals' ability to provide high quality, evidence-based medical care. *Id*. Ex. G; Rich Decl. Ex. G, ACOG; Ex. I, AMA; Ex. J, Am. C. Nurse Mid-wives (ACNM); Ex. K, Am. Pub. Health Assoc. (APHA); Ex. L, Nat'l Fam. Planning Repro. Health Assoc. Defendants mention the CDC's Quality Family Planning recommendations for high quality, evidence-based clinical practice regarding the provision of family planning services only in passing. *See* 84 Fed. Reg. at 7740.

Defendants do not acknowledge or address the weight of provider and public health experts' evidence that the Final Rule would have perverse consequences, including likely reducing access to contraceptive care and increasing unintended pregnancies and abortions. Among Defendants' many unfounded assumptions are that the quality of Title X providers will improve as entities that cannot abide by the financial and physical separation requirements are excluded; that more clients will be served, and gaps in service reduced; and that unintended pregnancies will not increase. 84 Fed. Reg. at 7718, 7723, and 7741. In fact, none of these assumptions are reasonable in light of the evidence before the agency that the Final Rule will reduce access to contraceptive care and increase unintended pregnancies and abortions. *See*, *e.g.*,

[7] Defendants' blithe assertion that nondirective counseling and referrals about abortion services are not needed for women's health because information is "widely available and easily accessible, including on the internet," 84 Fed. Reg. at 7746, belies the importance of these services to women's health and healthcare and demeans the relationship between patient and provider. Indeed, counseling and referrals about pregnancy options help women to take control of their most "intimate and personal choices . . . central to personal dignity and autonomy." *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992) (plurality op.).

Rich Decl., Ex. Ex. M, Planned Parenthood Fed'n Am. (PPFA) at 18; Ex. I, AMA at 4. Defendants have not "offered a satisfactory explanation for [their] action." *Humane Soc. of U.S. v. Locke*, 626 F.3d 1040, 1048 (9th Cir. 2010). And to the extent that facts have changed since the 2000 regulations were promulgated, those new facts weigh against adoption of the Rule. *See*, *e.g.*, Brindis Decl. Ex. B at 4, 12 (noting 2016 finding that Texas exclusion of Planned Parenthood led to decline in use of more effective contraception and increase in Medicaid-covered births). As the American Public Health Association explained, in states that have eliminated Planned Parenthood from their family planning programs, the "public health results have been disastrous." Rich Decl. Ex. K, APHA at 4.

Providers who specialize in the treatment of adolescents overwhelmingly believe that the new requirements will create barriers to access to care for adolescents in need of reproductive health services. As the American Academy of Pediatrics and Society for Adolescent Health and Medicine's comment on the Rule, requiring clinicians to take "specific actions" to encourage family participation, even after they have learned that this involvement is not practicable, "is not only contrary to medical ethics, but it also undermines the relationship between the minor and the health care professional and is likely to drive some minors away from returning for critical health care services, including contraception and testing and treatment for sexually transmitted infections." Rich Decl. Ex N, Am. Acad. of Pediatrics and Soc'y Adolescent Health Med. at 6.

In promulgating the new requirement that only doctors and nurses with graduate degrees may provide patients with options counseling or refer them to primary care services, HHS likewise ignored evidence that such a provision would impede women's access to reproductive health services. "[H]ealth care professionals at Title X-funded health centers must be able to continue to work to the ceiling of their scope and training," otherwise the Rule will "interfere with the progress made in California and other states across the country to address workforce shortages." Rich Decl. Ex. O, Northeast Valley Health Corp. Counseling regarding medical options is safely and effectively provided by clinicians with a variety of credentials, subject to appropriate training and supervision. Moreover, the decision to limit counseling for pregnant

patients to doctors and nurses with graduate degrees is not a logical outgrowth of the proposed rule, which allowed only "doctors" to provide this service.

Plaintiff is likely to prevail on its claim that the Final Rule is arbitrary and capricious.

II. ABSENT AN INJUNCTION, CALIFORNIA WILL SUFFER IRREPARABLE HARM

The Final Rule will inflict irreparable harm upon California. *Winter*, 555 U.S. at 22; *California v. Azar*, 911 F.3d 558, 582 (9th Cir. 2018), petition for cert. filed (U.S. Mar. 13, 2019) (No. 18-1192) (affirming district court conclusion that "potentially dire public health and fiscal consequences" will result without an injunction blocking federal rule that reduced access to contraception). The threat of harm here is imminent. *Caribbean Marine Servs. Co., Inc. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988).

A. Harm to the Patient-Provider Relationship

The Final Rule's new strictures will harm patient-provider relationships. According to the American Medical Association (AMA), truthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy; in fact, withholding information without a patient's knowledge or consent is contrary to medical ethics. Spirtos Decl. ¶ 18; Marshall Decl. ¶ 23. Yet the Rule requires physicians to tailor their counseling when providing a patient with requested, time sensitive medical information. Spirtos Decl. ¶ 17. In addition, the Rule invites intrusive federal scrutiny into the subjective motivations of Title X providers by prohibiting any conversations between doctors or nurses and their patients that Defendants deem to be "promoting" or "supporting" access to abortion. *Id*. ¶ 15.

The Rule's impact on provider-patient relationships will have other serious negative consequences. Some women will lack the necessary information and support to effectuate their decisions about their reproductive healthcare options. Lack of reliable information from trusted providers will delay access to abortion for some women, causing further harms described in section II(D) below. Furthermore, the requirement that lists of local providers contain only providers that also offer "comprehensive primary care" will exclude many qualified abortion providers, including many Planned Parenthood clinics, leaving women with even less information and awareness of fewer choices. Kost Decl. ¶ 88-89; Marshall Decl. ¶ 20. Omitting these

providers from reference lists will leave Title X patients who wish to terminate their pregnancy unable to obtain any local referral**.**

B. Decreased Access to Reproductive Healthcare

The Rule will dramatically reduce the number of high quality providers participating in California's Title X program, impeding access to care and disproportionately harming individuals with limited incomes. Providers who choose not to accept the Rule's mandates to compromise their high clinical standards of care will lose critical funding, rendering former Title X providers unable to provide the same breadth and quality of services to low-income and under-served populations. Rabinovitz Decl. ¶ 40, 42-46; Nestor ¶¶ 11-13. Other providers will have to exit Title X or divert resources to comply with the extraordinary physical and financial separation requirements. Rabinovitz Decl. ¶ 69; Tuttle Decl. ¶ 11. With less funding for outreach (and limits on "infrastructure building" for providers who remain in Title X), fewer individuals will be linked to the services they need. McCarthy Decl. ¶ 5; Rabinovitz Decl. ¶ 44. Loss of Title X funding will cause clinics to reduce hours of operation, eliminate transportation or off-site locations currently offering services at times and places convenient to certain patients, and undermine the long-term financial stability of some family planning clinics, especially in rural communities. *Id*. ¶ 45; Wilburn Decl ¶ 16-17; Thomas Decl. ¶ 11. Individuals with incomes between 200 and 250% of the federal poverty level who are eligible for Title-X funded services, but not California's Medicaid family planning program, Family PACT, will lose access to publicly funded family planning services. Cantwell Decl. ¶ 15-16, 21. This poses a high risk to low-income rural residents, such as those California counties where a Title X-funded clinic is the only publicly funded site offering a full range of contraceptive methods. Tosh Decl. ¶ 49.

Restricting options counseling only to doctors and nurses with graduate degrees will further limit services. Kost Decl. ¶ 86. This restriction will make it harder to staff Title X clinics. Castellano-Garcia Decl. ¶ 11; McKinney Decl. ¶ 11. If a well-qualified and trained registered nurse with a baccalaureate degree, but no master's degree, is present in a family planning clinic, the Final Rule denies a patient in need any pregnancy options counseling. Forer Decl. ¶¶ 29-30.

Because the Rule will cause many facilities in California to exit the Title X program, remaining clinics, already stretched thin, will be forced to serve even more Title X patients, increasing wait times and reducing accessibility of family planning services. Kost Decl. ¶ 113-118. In less populous regions, the Rule will create "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*. ¶ 78. Traveling to a reproductive health clinic requires taking time off work, incurring lost income, transportation and/or lodging costs. The Rule will exacerbate those burdens on low-income patients.

Reductions in access will, in turn, cause patients to reduce utilization of family planning services, and to reduce utilization of contraceptive methods that are the best personal or medical choice. Brindis Decl. ¶ 31-33; Kost Decl. ¶ 120-122. When access to the full range of contraceptive methods become less available, convenient, or affordable, patients will resort to less effective methods, or simply go without.

C. Disproportionate Impact on Vulnerable Populations

The Rule will disproportionately harm marginalized groups in California. The risk of unintended pregnancy is already greatest for women who are young, women of color, those who have low incomes, live in rural communities, and those who have limited education. Loss of Title X funding will have a disproportionate impact on the most vulnerable patients by reducing funds available for services that connect hard-to-reach patients with healthcare, such as individuals experiencing homelessness or adolescents. Rabinovitz Decl. ¶ 43; Forer Decl. ¶¶ 22, 39.

California adolescents will also be particularly hard hit by the Final Rule. Family participation is often not practicable for adolescents, for reasons other than abuse or incest. New requirements that necessitate intrusive questioning and unnecessary documentation will prevent Title X providers from offering the highest quality care to these patients, and reduce this population's willingness to access needed sexual and STD education and testing, and contraceptive services. Thomas Decl. ¶ 14.

D. Delayed Access to Contraception and Abortion Harms Women

As California women resort to less effective contraceptive methods, or go without contraceptives altogether, the result of the Rule will be an increase in unintended pregnancies. Brindis Decl. ¶¶ 51-57. Some pregnant women who receive incomplete or misleading referral information will experience delays in accessing desired abortion services, or will be prevented altogether from accessing these services even if medically necessary for the women's health. In the context of a woman's decision about whether to continue or terminate a pregnancy, obtaining complete and honest healthcare information and access to a full range of services is important *and* urgent. Any delay in obtaining information or services is harmful to the patient and results in increased potential for complications and poor health outcomes.[8] Kost Decl. ¶ 93. An increase in unwanted pregnancy has larger ramifications, because "[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives." *Casey*, 505 U.S. at 856 (plurality op.).

E. The Rule Will Encourage Poorer Quality Title X Service

The Rule will make the family planning services provided by Title X programs less effective, because they will permit and, in some respects, mandate the provision of services that do not meet accepted clinical standards. Just as the Rule will cause the flight of high quality family planning providers from the Title X program, it may encourage new, lower-quality providers to apply for and obtain Title X funding. Kost Decl. ¶ 79. Some clinics that do not adhere to the Quality Family Planning Guidelines have expressed interest in obtaining Title X funds if the Rule takes effect and are now more likely to quality for Title X funding; these lower-quality providers do not offer comprehensive contraception services, and staff at these facilities are often trained to delay women's decisions so that abortion becomes a less safe and accessible alternative. Rabinovitz Decl. ¶ 46. To the extent that the Final Rule directs funds to providers that do not qualify or are not willing to accept the terms of participation to be Family PACT

[8] The consequences of the Rule will be particularly severe in circumstances where an abortion may not qualify as an "emergency service" under the Rule's narrow definition, but a woman's health is nevertheless at risk.

providers (California's Medicaid family planning program), that will further weaken overall provider quality in California. Cantwell Decl. ¶ 25-26.

F. Harm to California's Well-Established Title X Network

The Final Rule will harm California's concrete and proprietary interest in ensuring access to healthcare and maintaining a stable network of healthcare providers. Over the years, Essential Access Health has made substantial investments in training and supporting the existing Title X provider network. The Rule will undermine years of investments that have raised the overall level of clinical practice for California's Title X providers as a group. The restriction on "infrastructure building" activities will also inhibit Title X training and other highly valuable activities that do not involve direct provision of services.

Likewise, the State of California has invested a great deal of time and resources into a "no wrong door" approach to reproductive healthcare, with the objective of a seamless system of care that connects women with needed healthcare regardless of their particular eligibility category or where or how they first seek healthcare. Cantwell Decl. ¶ 23; Rabinovitz Decl. ¶ 54. The expectation that any Title X providers will provide high quality, comprehensive referrals to all needed reproductive healthcare is an integral part of that approach. *Id*. ¶ 26; Kost Decl. ¶ 59-60. The Final Rule and the resulting exit of many of California's well-established providers from Title X will undermine the effectiveness of this policy. Ferrer Decl. ¶ 13.

G. Harm to State Public Health and Public Fisc

Decreases in access to contraceptive services and/or quality of those services will likely cause unintended pregnancies to rise, with resulting increased costs and other impacts to the state and its residents. Cantwell Decl. ¶ 27; Brindis Decl. ¶ 52-53.

The consequences are both immediate and far-reaching. Unintended pregnancies are associated with risks to maternal health and adverse birth outcomes, including preterm birth, low birth weight, still birth; and negative psychological outcomes for both mothers and children. Cantwell Decl. ¶ 29. Over half of unintended pregnancies end in miscarriage or abortion. For pregnancies carried to term, intervals between pregnancies of less than 18 months are associated with poor outcomes, including maternal health problems, premature birth, birth defects, low birth

weight, and low mental and physical functioning in early childhood. Kost Decl. ¶ 49-51. These types of outcomes cost the State in the short and long term, and in tangible and intangible ways.

As described above, California's existing Title X providers play an essential role in providing a number of other vital health services for low-income residents. Brindis Decl. ¶ 59-66. They provide screenings and treatment or referrals for infectious disease, and act as a trusted entry point for medical care generally. Reduced access to Title X services will delay the diagnosis and treatment of serious diseases. Brindis Decl. ¶ 67. When communicable diseases spread, the effects are felt broadly, especially among individuals with compromised immune systems, such as newborns and persons with chronic illnesses. For example, syphilis is a highly preventable disease that infects infants born to mothers with untreated or insufficiently treated syphilis, causing miscarriages, prematurity, and low birth weights, and many serious health consequences for children. Brindis Decl. ¶ 62. If fewer women are able to access Title X services, including screening and prevention of STIs, then more children will suffer as a result.

Finally, if women experience delays in access to contraception and abortion, and all the concomitant harms, the State of California will be forced to absorb financial and administrative burdens as a result. California funds a significant portion of the costs of medical procedures associated with unintended pregnancies and their aftermath, and all of the costs associated with abortions for Medicaid recipients.[9] Tosh Decl. ¶ 44; Cantwell Decl. ¶¶ 27-30. Furthermore, California will bear the primary responsibility for the increased costs of treating health conditions wholly unrelated to abortions, ranging from cervical cancer to STIs, due to delays in diagnosis and treatment. Cantwell Decl. ¶ 30. Even a slight uptick in such costs will cause irreparable harm to the State. *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 724 (9th Cir. 1999) ("magnitude of the injury" is not determinative); *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014) (district court erred by evaluating severity, not irreparability, of harm). State agencies will be harmed by this Rule as they seek to implement California laws relating to nondiscrimination and access to state family planning programs. Cantwell Decl. ¶ 25; Morris Decl. ¶ 8-9.

[9] Harms will be worsened "if [HHS's] recent final rules that allow certain employers to claim a religious or moral objection to providing contraceptive coverage and leave their employees without access to 'no cost' contraceptive coverage are implemented." Cantwell Decl. ¶ 31.

Unless the Rule is enjoined, California and its residents will suffer irreparable injury.

III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST FAVOR ISSUING AN INJUNCTION TO PRESERVE THE STATUS QUO

The balance of the equities and the public interest support issuing a preliminary injunction. *See Winter*, 555 U.S. at 24. Particular attention should be given to preserving the status quo, "the last uncontested status that preceded the parties' controversy." *Dep't of Parks & Recreation for State of Cal. v. Bazaar Del Mundo Inc.*, 448 F.3d 1118, 1124 (9th Cir. 2006). Here, the status quo is administration of the Title X program according to the rules and funding criteria that have resulted in today's high quality family planning provider network.

In upholding a recent preliminary injunction prohibiting other federal regulations that would have reduced access to contraception, the Ninth Circuit found that an injunction was appropriate given the "potentially dire public health and fiscal consequences" and highlighted the public interest in access to contraceptive care. *California*, 911 F.3d at 582. A preliminary injunction is merited here for the same reasons.

IV. THE COURT SHOULD POSTPONE THE EFFECTIVE DATE OF THE REGULATION PENDING JUDICIAL REVIEW OR ISSUE A NATIONWIDE INJUNCTION

Given the equities at issue, the Court should stay the effective date of this regulation until a determination on the merits, pursuant to 5 U.S.C. § 705, or issue a preliminary injunction enjoining the regulation from taking effect. This Court cannot simply draw a line around California and impose an injunction here to ensure complete relief; reductions in access to Title X services outside the state will likely impact California as patients cross state lines in search of reproductive healthcare, Tosh Decl. ¶ 52, and California's existing Title X network will be affected by grant-making decisions at a national level. And absent a nationwide injunction, irreparable harms will be felt nationwide. Kost Decl. ¶ 78; Brindis Decl. ¶¶ 80-93; Cantwell Decl. ¶ 32. *See California*, 911 F.3d at 584 (nationwide injunctive relief appropriate where evidence shows "nationwide impact").

CONCLUSION

The Court should enjoin implementation of the Final Rule.

Dated: March 21, 2019

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