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10 IN THE UNITED STATES DISTRICT COURT
 11 FOR THE NORTHERN DISTRICT OF CALIFORNIA

13 **STATE OF CALIFORNIA, by and through**
ATTORNEY GENERAL XAVIER
BECCERRA,

15 Plaintiff,

16 v.

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

20 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

23 **TO THE DEFENDANTS AND THEIR COUNSELS OF RECORD:**

24 **PLEASE TAKE NOTICE** that on April 18, 2019, at 12:30 p.m., in Courtroom 5 of the
 25 above-entitled court, at 450 Golden Gate Avenue, San Francisco, California, Plaintiff State of
 26 California will move under Local Rule 7-2 for a preliminary injunction enjoining implementation
 27 of the Final Rule, “Compliance with Statutory Program Integrity Requirements,” 84 Fed. Reg.
 28 7714 (Mar. 4, 2019) (to be codified at 42 C.F.R. pt. 59).

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

7 This motion is based on this notice, the Memorandum of Points and Authorities, the
8 Declarations of Claire Brindis, Ph.D., Mari Cantwell, Carmela Castellano-Garcia, Barbara Ferrer,
9 Ph.D., Elizabeth Forer, Kathryn Kost, Ph.D., Melissa Marshall, M.D., Louise McCarthy, Marie
10 McKinney, Joseph Morris, Ph.D., M.S.N., R.N., Shivaun M. Nestor, Julie Rabinovitz, Anna
11 Rich, Tatiana W. Spirtos, M.D., Jane Thomas, Jenna Tosh, Ph.D., Henry N. Tuttle, Kayla
12 Wilburn, this Court's file, and any matters properly before the Court. Where declarations are
13 offered in support of both California and Essential Access Health's related motions, those
14 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).

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

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

20 **II. TITLE X LAW AND PRIOR REGULATIONS**

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

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

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

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

17 Section 1008 of the PHSA prohibits Title X funds from being “used in programs where
18 abortion is a method of family planning.”¹ 42 U.S.C. § 300a-6 (hereinafter referred to as “Section
19 1008”). In 1988, in order to “preserve the distinction between Title X programs and abortion as a
20 method of family planning,” HHS issued regulations banning abortion options counseling and
21 referral and mandating strict physical and financial separation between a recipient’s Title X
22 programs and any abortion-related services. 53 Fed Reg. 1923-2924. The Supreme Court held
23 that Section 1008 of the PHSA was ambiguous, and that HHS’s regulation banning abortion
24 referral and counseling, and imposing physical and financial separation requirements, was a
25 permissible interpretation of that provision. *Rust v. Sullivan*, 500 U.S. 173, 186, 191 (1991).
26 Despite the *Rust* decision, the 1988 rule was never fully implemented, and was ultimately short-
27 lived. HHS completely rescinded the rules in 1993, concluding that they “inappropriately
28 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.”

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

19 OPA provides strict oversight of Title X-programs to ensure that federal funds are used
20 appropriately. Rabinovitz Decl. ¶ 16. Existing safeguards include: (1) careful review of grant
21 applications to ensure that the applicant understands and has the capacity to comply with all
22 requirements; (2) independent financial audits to examine whether there is a system to account for
23 program-funded activities and non-allowable program activities; (3) yearly comprehensive
24 reviews of the grantees’ financial status and budget report; and (4) periodic and comprehensive
25 program reviews and site visits by OPA. *Id.* ¶¶ 16-18. Essential Access Health itself closely
26 monitors compliance by its sub-grantees. Rabinovitz Decl. ¶¶ 19-20. HHS did not identify a
27 single confirmed instance of inappropriate use of Title X funds for abortion services in its rule.
28

1 OPA also routinely sets forth specific clinical standards for Title X services. Prior to the
2 Final Rule, OPA required grantees to adhere to federal Quality Family Planning (QFP)
3 recommendations issued by OPA and the Centers for Disease Control and Prevention (CDC)
4 which set forth broadly accepted, evidence-based standards for high-quality clinical practice for
5 the provision of family planning services.² See Brindis Decl. Ex. C, HHS, “Providing Quality
6 Family Planning Services: Recommendations of CDC and the U.S. [OPA].” The CDC developed
7 these nationally recognized protocols in collaboration with professional medical associations like
8 the American College of Obstetricians and Gynecologists (ACOG) and the American Academy
9 of Pediatrics. *Id.* at 13. The QFP recommendations were incorporated by OPA into their
10 standards for Title X care. See Rich Decl. Ex. A, OPA, “Program Requirements for Title X
11 Funded Family Planning Projects” (April 2014), p. 5. According to the recommendations, quality
12 family planning services should take a “client-centered approach” in which “the client’s primary
13 purpose for visiting the service site [is] respected.” Brindis Decl. Ex. C at 2. Pregnancy testing
14 and counseling services are considered a “core” part of “family planning services,” and after
15 administration of a pregnancy test, providers are instructed that the “test results should be
16 presented to the client, followed by a discussion of options *and appropriate referrals*,” which
17 “should be made *at the request of the client, as needed*.” *Id.* at 13-14 (emphasis added); *see also*
18 42 C.F.R. 59.5(a)(5)(ii) (2000) (patient who does not wish to receive information, counseling, or
19 referral about a particular option for her pregnancy cannot be forced).

20 These standards were developed to provide quality family planning services in a safe,
21 effective, and client-centered manner, Brindis Decl. Ex. C at 2, consistent with Congressional
22 intent. They help instill trust between patients and their Title X providers and ensure the delivery
23 of unbiased information regarding patients’ reproductive and sexual health. Kost Decl. ¶ 20-28.
24 This high standard of care helps patients make the best decisions for themselves and their loved
25

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

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

3 **III. California's Current Title X Provider Network**

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

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

20 **IV. The Final Rule Reverses Longstanding Agency Rules and Policies**

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

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

14 A new gag rule places restrictions on services for and communications with pregnant
15 patients, and limits who may provide those services. Title X providers may not “promote, refer
16 for, or support abortion as a method of family planning.” *Id.* §§ 59.5(a)(5), 59.14(a). The Final
17 Rule requires that when a woman is “medically verified as pregnant, she *shall* be referred” for
18 “prenatal health care,” regardless of the woman’s choices, and it permits Title X providers to
19 provide “information about maintaining the health of the mother and unborn child during
20 pregnancy” even if the woman does not wish to continue the pregnancy. *Id.* § 59.14(b)(1)(iii, iv)
21 (emphasis added). Even where a pregnant Title X patient wishes to exercise her lawful choice to
22 access an abortion, the Final Rule would prohibit the provider from providing her with a specific
23 list of healthcare entities that perform abortions; at most, the healthcare provider may provide a
24 list of “comprehensive primary health care providers (including providers of prenatal care).” *Id.*
25 §§ 59.14(a), 59.14(b)(ii). Title X provider may choose to exclude providers that perform abortion
26 entirely from the list. *Id.* § 59.14(c)(2). Provider lists given to women seeking an abortion may

27 _____
28 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.

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

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

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

25 Finally, the Rule also includes a new ban on use of Title X funds to “build infrastructure
26

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

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

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

8 LEGAL STANDARD

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

17 Similarly, the APA provides that “the reviewing court [...] may issue all necessary and
 18 appropriate process to postpone the effective date of an agency action.” 5 U.S.C. § 705. This
 19 remedy is available “to the extent necessary to prevent irreparable injury” and to preserve the
 20 status quo pending judicial review proceedings. *Id.*; see *Nken v. Holder*, 556 U.S. 418, 425
 21 (2009) (applying traditional preliminary injunction factors to request for stay pending review).

22 ARGUMENT

23 I. CALIFORNIA IS LIKELY TO SUCCEED ON THE MERITS

24 A. The Final Rule is Invalid Under the APA Because it is Not in Accordance 25 with the Law and is in Excess of Statutory Authority

26 The Final Rule must be held “unlawful and set aside” under the APA because it is “not in
 27 accordance with the law” and is “in excess of statutory jurisdiction.” 5 U.S.C. §§ 706(2)(A),
 28 706(2)(C). Here, Congress has required that options counseling be “nondirective,” and forbids

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

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

10 The Final Rule violates Congress' mandate that pregnancy counseling be nondirective.
 11 Appropriations bills since 1996, up to and including the most recent, have provided that "all
 12 pregnancy counseling" in Title X family planning projects "*shall be nondirective.*"⁵ Pub. L. No.
 13 115-245, 132 Stat. 2981, 3070-71 (2018) (emphasis added). This accords with the statutory
 14 requirement that all Title X grants support only "voluntary family planning projects," 42 U.S.C. §
 15 300, *see also* Pub. L. 115-245, 132 Stat. at 3070-71 (reiterating the "voluntary" nature of services
 16 in setting forth the nondirective mandate). Providing inaccurate or misleading referral lists for
 17 patients seeking abortions (but no other postconception services), 42 C.F.R. §§ 59.14(a),
 18 59.14(b)(ii), and requiring that all pregnant women be referred for prenatal services (even if they
 19 have expressed a choice to seek an abortion), *id.* § 59.14(b)(ii, iv), is not nondirective. It is
 20 coercive, steering patients into prenatal care regardless of their preference.

21 Moreover, the Final Rule effectively prohibits nondirective counseling by prohibiting
 22 referrals for abortion, by issuing a vague prohibition on providers who "encourage" or "promote"
 23 abortion (inhibiting providers' ability to provide respectful, client-centered counseling), *id.* §
 24 59.16, and by banning referrals for abortion, but not other post-conception care, *id.* § 59.14(a, c).
 25 None of these limitations can be squared with the requirement for nondirective options

26 ⁵ When Congress enacted the nondirective requirement, it did so against the backdrop of HHS's
 27 regulation defining "nondirective counseling" to include "counseling to the patient on options
 28 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).

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

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

18 **2. The Rule Violates Section 1554 of the ACA**

19 The Final Rule also conflicts directly with Section 1554, which forbids the HHS Secretary from
 20 promulgating “any regulation” that:

21 (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate
 22 medical care; (2) impedes timely access to health care services; (3) interferes with
 23 communications regarding a full range of treatment options between the patient and
 24 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

25 ⁶ Defendants’ assertion that the 2000 regulations were “inconsistent with a number of federal
 26 conscience protection[s],” 84 Fed. Reg. at 7745, specifically the Church, Coats-Snowe, and
 27 Weldon Amendments (respectively, 42 U.S.C. § 300a-7, 42 U.S.C. § 238n(a), and Consolidated
 28 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.

1 principles of informed consent and the ethical standards of health care professionals.
2
3 42 U.S.C. § 18114. As described in Section II below, the Final Rule constitutes a significant
4 impediment to low-income Title X patients’ access to contraceptive care and, for those who
5 choose it, abortion services. The Final Rule vividly constructs barriers between Title X patients
6 and reproductive healthcare; a Title X clinic cannot even place a Planned Parenthood brochure on
7 a waiting room table without coming into violation of the Final Rule. 42 C.F.R. § 59.16(b)(1).
8 The provision of misleading or incomplete referral lists will certainly impede timely access to
9 abortion care services, and interfere with Title X providers’ abilities to communicate with their
10 patients regarding the full range of treatment options, to provide full disclosure of all relevant
11 information to patients making health care decisions (such as the most convenient and high
12 quality abortion provider), and violates basic principles of informed consent and the ethical
13 standards of doctors, nurses, and other medical professionals. *See, e.g.*, Rich Decl. Ex. F, Cal.
14 Asso. Nurse Prac.; Ex. D, Am. Acad. Nursing; Ex. C, Ctr. Reprod. Rts.

15 **3. The Rule Is in Excess of Statutory Jurisdiction**

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

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

1 Congress.” *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-843 (1984).

2 Second, if the statute admits of some ambiguity, then courts must determine whether the agency’s
3 interpretation is “reasonable.” *Id.* at 844. A regulation is invalid when it adopts an interpretation
4 so unreasonable that it directly conflicts with the statute it purports to implement. *Ragsdale v.*
5 *Wolverine World Wide, Inc.*, 535 U.S. 81, 90-92 (2002) (holding agency interpretation
6 unreasonable where it conflicts with law’s “remedial scheme” and intent).

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

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

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

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

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

11 An agency must provide a "concise general statement of [a regulation's] basis or
12 purpose". 5 U.S.C. 553(c). "[A]n agency's action must be upheld, if at all, on the basis
13 articulated by the agency itself." *State Farm*, 463 U.S. at 50. Where an agency departs from a
14 prior policy, a more "detailed justification" is necessary where there are "serious reliance
15 interests" at stake or the new policy "rests upon factual findings that contradict those which
16 underlay its prior policy." *F.C.C. v. Fox Television Stations*, 556 U.S. 502, 515; *see also State*
17 *Farm*, 463 U.S. at 47-51 (new administration's rule change was arbitrary and capricious where
18 agency failed to address prior factual findings). A change in administration does not authorize an
19 unreasoned reversal of course. *See Regents of the Univ. of Cal. v. U.S. State Dept.*, 908 F.3d 476,
20 510 (9th Cir. 2018) (upholding preliminary injunction where agency change in position was
21 arbitrary and capricious under settled law); *California v. U.S. Bureau of Land Mgmt.*, 277
22 F.Supp.3d. 1106, 1123 (N.D. Cal. 2017) ("New presidential administrations [...] must give
23 reasoned explanations [...] and address the prior factual findings underpinning a prior regulatory
24 regime." (quotation marks omitted)). Where the agency action is "arbitrary" or "capricious," the
25 court must invalidate it. 5 U.S.C. § 706(2)(A).

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

1 7714. Defendants claim to be concerned about the “potential for...confusion and...co-mingling”
2 or a “risk” of the “appearance and perception” of misuse of funds, 84 Fed. Reg. at 7764-65, yet
3 fail to identify *any* evidence showing that funds appropriated for Title X were, in fact, being
4 illegally used by recipients of those funds, or any other evidence warranting such a drastic change
5 in regulation. HHS acknowledged that the examples it cited in the proposed rule related to
6 improper use of funds involved Medicaid, not Title X funds. 84 Fed. Reg. at 7725. Given the
7 number of individuals nationwide who rely on Title X funded services, the government must
8 provide greater justification for the Final Rule. *Perez v. Mortgage Bankers Ass’n*, 135 S. Ct.
9 1199, 1209 (2015) (requiring “more substantial justification” when “prior policy has engendered
10 serious reliance interests”) (quoting *Fox Television Stations, Inc.*, 556 U.S. at 515). Defendants
11 failed to do so.

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

1 “prioritizing ideology over scientific evidence.” Rich Decl. Ex. G, ACOG at 2, 9.

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

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

25 ⁷ Defendants’ blithe assertion that nondirective counseling and referrals about abortion services
26 are not needed for women’s health because information is “widely available and easily accessible,
27 including on the internet,” 84 Fed. Reg. at 7746, belies the importance of these services to
28 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.).

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

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

19 In promulgating the new requirement that only doctors and nurses with graduate degrees
20 may provide patients with options counseling or refer them to primary care services, HHS
21 likewise ignored evidence that such a provision would impede women’s access to reproductive
22 health services. “[H]ealth care professionals at Title X-funded health centers must be able to
23 continue to work to the ceiling of their scope and training,” otherwise the Rule will “interfere
24 with the progress made in California and other states across the country to address workforce
25 shortages.” Rich Decl. Ex. O, Northeast Valley Health Corp. Counseling regarding medical
26 options is safely and effectively provided by clinicians with a variety of credentials, subject to
27 appropriate training and supervision. Moreover, the decision to limit counseling for pregnant
28

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

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

4 **II. ABSENT AN INJUNCTION, CALIFORNIA WILL SUFFER IRREPARABLE HARM**

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

11 **A. Harm to the Patient-Provider Relationship**

12 The Final Rule’s new strictures will harm patient-provider relationships. According to the
13 American Medical Association (AMA), truthful and open communication between physician and
14 patient is essential for trust in the relationship and for respect for autonomy; in fact, withholding
15 information without a patient’s knowledge or consent is contrary to medical ethics. *Spirtos Decl.*
16 ¶ 18; *Marshall Decl.* ¶ 23. Yet the Rule requires physicians to tailor their counseling when
17 providing a patient with requested, time sensitive medical information. *Spirtos Decl.* ¶ 17. In
18 addition, the Rule invites intrusive federal scrutiny into the subjective motivations of Title X
19 providers by prohibiting any conversations between doctors or nurses and their patients that
20 Defendants deem to be “promoting” or “supporting” access to abortion. *Id.* ¶ 15.

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

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

3 **B. Decreased Access to Reproductive Healthcare**

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

23 Restricting options counseling only to doctors and nurses with graduate degrees will further
24 limit services. Kost Decl. ¶ 86. This restriction will make it harder to staff Title X clinics.
25 Castellano-Garcia Decl. ¶ 11; McKinney Decl. ¶ 11. If a well-qualified and trained registered
26 nurse with a baccalaureate degree, but no master's degree, is present in a family planning clinic,
27 the Final Rule denies a patient in need any pregnancy options counseling. Forer Decl. ¶¶ 29-30.
28

1 Because the Rule will cause many facilities in California to exit the Title X program,
2 remaining clinics, already stretched thin, will be forced to serve even more Title X patients,
3 increasing wait times and reducing accessibility of family planning services. Kost Decl. ¶ 113-
4 118. In less populous regions, the Rule will create “contraceptive deserts” where women in need
5 of Title X-funded contraceptive services will be unable to find an affordable, well-qualified
6 provider within their county. *Id.* ¶ 78. Traveling to a reproductive health clinic requires taking
7 time off work, incurring lost income, transportation and/or lodging costs. The Rule will
8 exacerbate those burdens on low-income patients.

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

14 **C. Disproportionate Impact on Vulnerable Populations**

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

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

27
28

1 **D. Delayed Access to Contraception and Abortion Harms Women**

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

14 **E. The Rule Will Encourage Poorer Quality Title X Service**

15 The Rule will make the family planning services provided by Title X programs less
16 effective, because they will permit and, in some respects, mandate the provision of services that
17 do not meet accepted clinical standards. Just as the Rule will cause the flight of high quality
18 family planning providers from the Title X program, it may encourage new, lower-quality
19 providers to apply for and obtain Title X funding. Kost Decl. ¶ 79. Some clinics that do not
20 adhere to the Quality Family Planning Guidelines have expressed interest in obtaining Title X
21 funds if the Rule takes effect and are now more likely to qualify for Title X funding; these lower-
22 quality providers do not offer comprehensive contraception services, and staff at these facilities
23 are often trained to delay women’s decisions so that abortion becomes a less safe and accessible
24 alternative. Rabinovitz Decl. ¶ 46. To the extent that the Final Rule directs funds to providers
25 that do not qualify or are not willing to accept the terms of participation to be Family PACT
26

27 ⁸ The consequences of the Rule will be particularly severe in circumstances where an abortion
28 may not qualify as an “emergency service” under the Rule’s narrow definition, but a woman’s
health is nevertheless at risk.

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

3 **F. Harm to California’s Well-Established Title X Network**

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

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

19 **G. Harm to State Public Health and Public Fisc**

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

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

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

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

14 Finally, if women experience delays in access to contraception and abortion, and all the
15 concomitant harms, the State of California will be forced to absorb financial and administrative
16 burdens as a result. California funds a significant portion of the costs of medical procedures
17 associated with unintended pregnancies and their aftermath, and all of the costs associated with
18 abortions for Medicaid recipients.⁹ Tosh Decl. ¶ 44; Cantwell Decl. ¶¶ 27-30. Furthermore,
19 California will bear the primary responsibility for the increased costs of treating health conditions
20 wholly unrelated to abortions, ranging from cervical cancer to STIs, due to delays in diagnosis
21 and treatment. Cantwell Decl. ¶ 30. Even a slight uptick in such costs will cause irreparable
22 harm to the State. *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 724 (9th Cir. 1999) (“magnitude of
23 the injury” is not determinative); *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1068 (9th Cir.
24 2014) (district court erred by evaluating severity, not irreparability, of harm). State agencies will
25 be harmed by this Rule as they seek to implement California laws relating to nondiscrimination
26 and access to state family planning programs. Cantwell Decl. ¶ 25; Morris Decl. ¶ 8-9.

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

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

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

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

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

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

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

27 **CONCLUSION**

28 The Court should enjoin implementation of the Final Rule.

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Dated: March 21, 2019

Respectfully submitted,

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