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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 PARTIAL SUMMARY JUDGMENT** Filed concurrently with: 1. Appendix of Evidence 2. Declaration of Ketakee Kane 3. Declaration of Julie Rabinovitz 4. Request for Judicial Notice; and 5. [Proposed] Order Date: February 20, 2020 Time: 1:30 p.m. Dept: Courtroom 5, 17th floor Judge: Hon. Edward M. Chen Date Filed: March 4, 2019 Trial Date: None Set

TO THE COURT, ALL PARTIES, AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on February 20, 2020 at 1:30 p.m. in Courtroom 5 of the above-entitled court, at 450 Golden Gate Avenue, San Francisco, California, Plaintiff State of California, by and through Attorney General Xavier Becerra (California), will and does move the Court for an order granting partial summary judgment under Federal Rule of Civil Procedure 56(a).

The grounds for this relief are that the undisputed facts demonstrate that California is entitled to judgment on its first, second, and third cause of action because the Rule, 84 Fed. Reg. 7714 (Mar. 4, 2019), codified at 42 C.F.R. pt. 59, violates the Administrative Procedure Act, 5 U.S.C. § 706.

This motion is based on this notice of motion and motion, the memorandum of points and authorities, the concurrently filed appendix of evidence, all records, documents, and papers in the Court's file, and any written and oral argument presented at the hearing in this matter.

Dated: January 23, 2020

Respectfully Submitted,

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INTRODUCTION

Title X of the Public Health Service Act (Title X) is our nation's sole federally funded program devoted to family planning. For decades, Title X has provided critical, evidence-based healthcare services to women, men, and families in California, contributing to Californians' overall health and well-being, and furthering the State's objectives of promoting public health and broad-based access to contraceptive and other preventive care.

But Defendants' March 4, 2019 Rule "Compliance with Statutory Program Integrity Requirements" imposed new, onerous, and unnecessary requirements for healthcare providers, including: "gag" rules that prevent Title X healthcare providers from giving comprehensive, accurate and nondirective healthcare information to their patients; and mandating physical and financial separation between family planning programs and facilities that provide either abortion services or referrals to such services. 84 Fed. Reg. 7714 (Mar. 4, 2019) (the "Rule"). The Rule undermines clinically established standards of care, interferes with the patient-provider relationship, and contradicts the core purpose of the Title X program. As this Court and others recognized, absent a preliminary injunction, the Rule would decimate California's Title X program because it would reduce Californians' access to needed reproductive care and cause harm to public health in California and the public fisc. And this worst case scenario is coming true. Ever since the Rule became effective, 375,000 fewer patients in California received care than in the year previous. Rabinovitz Decl., ¶ 10.

At the crux of the illegality of this rule is Defendants' failure to comply with the Administrative Procedures Act. As stated in California's complaint, Defendants did not respond to countless comments stating that the Rule harms state residents by interfering with the provider-patient relationship, presenting women seeking or considering an abortion with illusory healthcare options, and creating barriers for people seeking care, among many other negative impacts. Defendants were also told that the Rule, if finalized, would decrease access to care, with an especially negative impact on low-income families, women (particularly women of color), and rural communities, as well as harm public health and the public fisc. As predicted, droves of

providers have left the program, and HHS's prediction that new providers would emerge to join the program has not come true. As such, the Rule must be vacated because it is arbitrary and capricious, contrary to law, and in excess of statutory authority.

First, the Rule is arbitrary and capricious because the U.S. Department of Health and Human Services (HHS) failed to provide a reasoned explanation and justification for why it gutted the Title X program and dramatically reversed course after thirty years of established regulations implementing and enforcing the Title X program. HHS either ignored or offered conclusory responses to hundreds of expert commenters informing HHS that restrictions on counseling or mandating physical separation would have catastrophic impacts on Title X grantees, Title X providers, and—mostly importantly—Title X patients.

Second, the Rule is contrary to law. The Rule is invalid under two Congressional statutes: the nondirective mandate and the Affordable Care Act (ACA). Since 1996, Congress has mandated that all Title X pregnancy counseling "shall be nondirective." That language means what it says: Title X counseling may not direct patients toward or away from any option, be it abortion or childbirth. The Rule is also invalid under Section 1554 of the ACA, which prohibits the Secretary from promulgating any regulation that, among other things, interferes with provider–patient communications or impedes access to care. Congress has mandated that Title X counseling focus on the patient's preferences, not those of the Executive Branch.

The Rule is also in excess of statutory authority. Title X has specific delegations of authority to the Secretary to increase access to effective, comprehensive reproductive healthcare. The Rule is in excess of this authority because it instead works to undermine the Title X program.

HHS has imposed an unworkable, ill-supported Rule on the States. This Rule should and must be vacated. California respectfully asks the Court to grant this motion and issue summary judgment on California's first, second, and third causes of action.

BACKGROUND

As the Court is already familiar with Title X program, its history, the Rule, and the procedural history of this litigation, this section highlights key factual and procedural points relevant to the instant motion. ECF 103 (PI Ord.) at 3-13; *see also* ECF (Cal. PI Mot.) 26 at 2-10.

I. FACTUAL BACKGROUND

A. The Historical Title X Program Brought Significant Benefits to Californians.

Title X is the nation's family planning program. 42 U.S.C. § 300(a). It was passed on a bipartisan basis and continues to be supported as such. The statute authorizes the Secretary of HHS "to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services." *Id*. Title X's purpose is, *inter alia*, to: (1) assist in making comprehensive family planning services readily available to all persons desiring such services; (2) improve the administrative and operational supervision of domestic family planning services; and (3) to enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services. *Id*.; Pub. L. No. 91-572 § 2, 84 Stat. 1504 (1970); ECF No. 103 (PI Ord.) at 3-4.[1]

The Title X program is considered the gold standard for family planning care and has been successful in "improve[ing] the lives of women and their families." American College of Obstetricians and Gynecologists (ACOG) AR 268837; Brindis AR 388054-388063; Nat'l Council of Jewish Women (NCJW) AR 102349. HHS's Office of Population Affairs (OPA) 2016 and 2017 Family Planning Annual Reports commended the success of the Title X program and stated that Title X providers are a critical source of high-quality and affordable reproductive healthcare for individuals with and without health insurance. AR 407030; AR 406191.

California's primary 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.[2]

[1] Prior to the enactment of Title X, Congress found that low income individuals were "forced to do without, or rely heavily on the least effective nonmedical techniques for fertility control unless they happen to reside in an area where family planning services are made readily available by public health services or voluntary agencies." S. Rep. No. 91-1004, at 9 (1970).

[2] In 2019, the OPA awarded Essential Access $21 million dollars to support access to high-quality family planning and sexual healthcare. https://www.hhs.gov/opa/grants-and-funding/recent-grant-awards/index.html, last accessed on January 22, 2020.

B. Historical Background

Section 1008 of the Public Health Service Act prohibits the funding of "programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. HHS initially construed this language to allow Title X providers to provide neutral, unbiased counseling to pregnant women about their options, including referrals to other providers for prenatal care, adoption, or abortion, so long as no program funds were used for abortions. *See* ECF 103 at 4; 53 Fed. Reg. 2922, 2923 (Feb. 2, 1988); *see also Nat'l Family Planning & Reprod. Health Ass'n, Inc., v. Sullivan*, 979 F.2d 227, 229 (D.C. Cir. 1992) (noting that agency memoranda from the 1970s distinguished between permissible nondirective counseling on abortion and impermissible "directive" counseling).

In 1988, 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. at 2923-2924; ECF 103 at 5. The Supreme Court afforded *Chevron* deference to HHS's interpretation of Section 1008, concluding, "we are unable to say that the Secretary's construction of the prohibition in § 1008 to require a ban on counseling, referral, and advocacy [regarding abortion] within the Title X project is impermissible." *Rust v. Sullivan*, 500 U.S. 173, 184 (1991). The Court also upheld the separation requirements and rejected constitutional challenges to the regulations. *Id.* at 187-203. Despite the *Rust* decision, the 1988 rule was never fully implemented and was completely rescinded in 1993. 58 Fed. Reg. 7462, 7462 (Feb. 5, 1993) (rescinding the 1988 rule); ECF 103 at 7-8.

In the decades after *Rust*, the governing law has changed in two significant ways. First, starting in 1996, Congress has mandated that "all pregnancy counseling shall be nondirective." Omnibus Consolidated Rescissions and Appropriations Act of 1996, PL 104–134, April 26, 1996, 110 Stat 1321; *see, e.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, PL 115-245, September 28, 2018, 132 Stat 2981, Div. B, Tit. II, 132 Stat 2981, 3070–71 (2018); Further Consolidated Appropriations Act, 2020, PL 116-94, 133 Stat 2534 (2019) (Nondirective Mandate).

Second, Congress passed Section 1554 of the Affordable Care Act (ACA). 42 U.S.C. § 18114 (Section 1554). Section 1554 forbids HHS from promulgating "any regulation" that: (1) creates unreasonable barriers to the ability of individuals to obtain medical care; (2) impedes timely access to healthcare services; (3) interferes with provider-patient communications; (4) restricts providers' ability to make full disclosure of all relevant health information; (5) violates professional or ethical standards; and (6) limits the availability of health care treatment for the full duration of a patient's medical needs. *Id*.

In 2000, to codify provider requirements under the Nondirective Mandate, HHS issued regulations requiring Title X projects to provide pregnant women with "neutral, factual information and nondirective counseling on each of [her] options, and referral on request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling." 42 C.F.R. § 59.5(a)(5)(ii) (2000); *see* 65 Fed. Reg. 41270, 41281 (July 3, 2000); ECF 103 at 8. The 2000 regulations also required Title X providers' abortion activities to be *financially* separate and distinct from their Title X activities, but allowed shared facilities (such as common waiting rooms, common staff, and a single filing system) so long as costs were properly separated and it was "possible to distinguish between the Title X supported activities and non-Title X abortion-related activities." 65 Fed. Reg. at 41282; ECF 103 at 8. The 2000 regulations remained in place for almost two decades, across multiple changes of administration.

Since 2014, HHS also 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 evidence-based standards for high-quality clinical practice for the provision of family planning services.[3] ECF 103 at 30; Ex. 137 (QFP) at 5-6; AR 406508 (Title X program requirements incorporating the QFP). The QFP recommendations are incorporated into

[3] HHS continues to refer Title X providers to the QFP recommendations. *See* HHS Office of Population Affairs, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html, last accessed January 23, 2020 ("The QFP provide recommendations for use by all reproductive health and primary care providers with patients who are in need of services related to preventing or for achieving pregnancy.").

the Title X program. *Id.* The "Pregnancy Testing and Counseling" section of the QFP recommendations instructs that "[pregnancy] test results should be presented to the client, followed by a discussion of options and appropriate referrals." QFP at 14. The QFP recommendations then advise that "[o]ptions counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG and AAP [American Academy of Pediatrics]." *Id.* ACOG and AAP have both stated that counseling should be nondirective and should not omit or restrict any medical information from the patient. ACOG AR 268839; AAP & Soc'y for Adolescent Health & Med. (SAHM) 277788-89. The American Medical Association's (AMA) comment letter to the Proposed Rule likewise states unequivocally that "[t]he inability to counsel patients about all of their options in the event of a pregnancy and to provide any and all appropriate referrals, including for abortion services, [is] contrary to the AMA's Code of Medical Ethics." AMA AR 269332.

C. The Rule

On March 4, 2019, HHS promulgated the Rule that is the subject of this suit. 84 Fed. Reg. 7714. The Rule represents a sharp break from the 2000 regulations, and a return in many respects to the 1988 regulations. Its key provisions are detailed below.

- The Rule bans any Title X provider from making a referral of a pregnant patient for an abortion, even in response to the patient's direct request. 42 C.F.R. §§ 59.5(a)(5); 59.14(a) (2019).
- In response to a patient's direct request for a referral for an abortion, a provider may offer only a "list of licensed, qualified, comprehensive primary health care providers." 42 C.F.R. § 59.14(b)(1)(ii). The list "may be limited to those that do not provide abortion," but the provider is not required to inform the patient of that fact. *Id.* § 59.14(c)(2). The list may include "some" providers who "provide abortion as part of their comprehensive health care services," but these providers may not account for a "majority" of the providers on the list. *Id.* The list cannot include any women's reproductive health specialists who do not provide "comprehensive health care services." *Id.* Even if a patient specifically asks for information regarding

providers who perform abortion, "[n]either the list nor project staff may identify which providers on the list perform abortion." *Id.* The Rule also prohibits providers from doing anything to "promote … or support abortion as a method of family planning," *id.* §§ 59.5(a)(5); 59.14(a), though it does not provide further guidance on what actions constitute promotion or support for abortion.

- The Rule requires providers to refer every pregnant patient for prenatal care, even if the patient has clearly stated her decision to obtain an abortion. *Id.* § 59.14(b)(1). The Rule also limits the presentation of information about abortion to only doctors or other providers with advanced degrees. *Id.* §§ 59.2; 59.14(b)(1)(i).
- The Rule requires costly and impracticable physical and financial separation. The Rule mandates "physical and financial separation" between a Title X program and a facility that engages in "abortion activities." 84 Fed. Reg. at 7715, 7764; *see* 42 C.F.R. § 59.15. The Rule allows Defendants to determine whether a grantee is in compliance with this requirement "based on a review of facts and circumstances." 42 C.F.R. § 59.15. "Factors relevant to this determination … include" the existence of 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 Rule deemphasizes evidence-based medicine by removing the requirement that family planning methods and services be medically approved. Previous Title X regulations required projects to "[p]rovide a broad range of acceptable and effective *medically approved* family planning methods . . . and services." 42 C.F.R. § 59.5(a)(1) (2000) (emphasis added). The Rule removes the "medically approved" language; it simply requires Title X projects to "[p]rovide a broad range of acceptable and effective family planning methods . . . and services." § 59.5(a)(1).
- The Rule generally diminishes the provision of family planning services by requiring clinics to offer or be in close physical proximity to "comprehensive primary health services," which are not Title X services. 42 C.F.R. § 59.5(a)(12).

- The Rule singles out adolescents—especially those with limited means—for even lower-quality care. 42 C.F.R. §§ 59.2, 59.5(a)(14).

Many organizations, including the nation's leading medical associations submitted comments opposing the changes contemplated by the rule, including the AMA AR 269330-269334, ACOG AR 268836-268853, the American College of Physicians (ACP) AR 28203-281211, the American Academy of Family Physicians (AAFP) AR 104075-78, the American Academy of Nursing (AAN) AR 107970-75, and the AAP & SAHM AR 277786-96.

D. Procedural History

On March 4, 2019, California filed this lawsuit alleging, *inter alia*, that the new Rule violates the Administrative Procedure Act, 5 U.S.C. §701 *et seq*. (APA). ECF 1 (Cal. Complaint). Essential Access Health and Dr. Melissa Marshall, Chief Executive Officer of CommuniCare Health Centers in Yolo County, California, a longtime Title X provider, filed a similar lawsuit (which also asserted other constitutional claims), and the two cases were related. California and the other plaintiffs moved for a preliminary injunction on their APA claims.

On April 26, 2019, prior to production of the administrative record, this Court issued a detailed 78-page order preliminarily enjoining implementation of the Rule. *See generally* ECF 103.[4] This Court made numerous well-supported factual findings—based upon many comments that constitute the administrative record—establishing that the Rule would "irreparably harm individual patients and public health in California as a whole." *Id*. at 2. The court concluded that a substantial number of existing Title X providers were likely to leave the program rather than comply with the Rule's restrictions that compromise the quality of care they provide and violate their ethical obligations. *Id*. at 15-16. Because of these departures, Title X patients would have

[4] Preliminary injunctions were also granted in Washington, Oregon, and Baltimore. *Oregon v. Azar*, 389 F. Supp. 3d 898, 902 (D. Or. 2019)("At best, the Final Rule is a solution in search of a problem. At worst, it is a ham-fisted approach to health policy that recklessly disregards the health outcomes of women, families, and communities."); *Washington v. Azar,* 376 F. Supp. 3d 1119, 1132 (E.D. Wash. 2019) ("[T]he Government's response in this case is dismissive, speculative, and not based on any evidence presented in the record before this Court."); *City Council of Baltimore v. Azar*, 392 F. Supp. 3d 602, 614-617 (D.Md. 2019) (finding the Rule is contrary to law).

more difficulty obtaining effective methods of birth control, including long-acting reversible contraceptives. *Id*. at 17-18.

This Court also concluded that California was likely to succeed on the merits of its claims that the Rule is contrary to the Nondirective Mandate and Section 1554, and that it is arbitrary and capricious in certain respects. *Id*. at 25-74. Based on its analysis of the "statute, regulations, and industry practice," the court concluded that the Rule's "categorical prohibition on providing referrals for abortion … prevents Title X projects from presenting abortion on an equal basis with other pregnancy options," in violation of the Nondirective Mandate. *Id*. at 33-34. That prohibition, combined with the Rule's "mandate[] that every pregnant patient," even those who have decided to obtain an abortion, "be referred to 'prenatal health care' … pushes patients to pursue one option over another." *Id*. at 34. This Court next held that the Rule likely violated Section 1554 of the ACA. *Id*. at 43-46. On the merits of the claim, the Court concluded that the Rule would "obstruct patients from receiving information and treatment for their pressing medical needs" and was "squarely at odds with established … standards" of medical ethics. *Id*. at 43-44.

Finally, this Court determined that California was likely to succeed on the merits of its claim that Defendants failed to provide a reasoned explanation for the Rule. This Court observed that the Rule represented a "sharp break from prior policy, without engaging in any reasoned decisionmaking." *Id*. at 2. The Court found that the Rule's physical separation requirement was arbitrary and capricious because Defendants had relied upon "speculative fears of theoretical abuse of Title X funds," while "turn[ing] a blind eye to voluminous evidence documenting the significant adverse impact the requirement would have on the Title X network and patient health." *Id*. at 49. The Court found other aspects of the Rule arbitrary and capricious as well, including the counseling restrictions, *id*. at 62-63; the requirement that only physicians and advanced practice providers may engage in nondirective pregnancy counseling, *id*. at 64-65; the removal of the requirement that family planning methods be "medically approved," *id*. at 65-66; and Defendants' cost-benefit analysis, *id*. at 67-68.

Based on its analysis of the preliminary injunction factors, the Court concluded that an injunction was warranted to preserve the status quo pending resolution of the litigation. *Id*. at 76.

On May 6, 2019, Defendants moved the district court to stay the preliminary injunction pending appeal. ECF 109. This Court denied Defendants' motion. ECF 115 at 3-4.

On June 20, 2019, a Ninth Circuit motions panel issued an opinion granting Defendants' motion for a stay of the preliminary injunction pending appeal (as well as related motions concerning similar preliminary injunctions issued by district courts in Oregon and Washington). *California v. Azar*, 927 F.3d 1068 (9th Cir. 2019).

On July 3, 2019, the Ninth Circuit granted rehearing *en banc* and directed that the June 20 stay order "shall not be cited as precedent by or to any court of the Ninth Circuit." *California v. Azar*, 927 F.3d 1045, 1046 (9th Cir. 2019). On July 11, 2019, the *en banc* court specified that although the stay order was no longer binding precedent, it had not been "vacate[d]" and thus it "remains in effect." *California v. Azar*, 928 F.3d 1153, 1155 (9th Cir. 2019). The Court heard e*n banc* oral argument on September 23, 2019. Defendants' underlying appeal of the PI Order and California's motion to reconsider the stay order remain pending in the Ninth Circuit.

Defendants produced the administrative record on June 24, 2019 (ECF 129) and on September 23, 2019, they certified its completeness. Kane Decl. Ex. A. The administrative record contains over 500,000 comment letters and approximately 108 legal, academic, and other materials. Kane Decl. ¶ 3.

LEGAL STANDARD

A moving party is entitled to summary judgment if that party demonstrates the absence of a genuine issue as to any material fact and that he or she is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Section 706 of the APA governs judicial review of administrative decisions. Agency actions must be set aside where they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C). "[T]he function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *City & Cty. of San Francisco v. United States*, 130 F.3d 873, 877 (9th Cir. 1997). In reviewing an administrative agency decision, "summary

judgment is an appropriate mechanism for deciding the legal question of whether the agency could reasonably have found the facts as it did." *Id.*

I. THE RULE IS ARBITRARY AND CAPRICIOUS

In enacting the Rule, HHS: (1) "entirely failed to consider an important aspect of the problem," (2) "offered an explanation for its decision that runs counter to the evidence before the agency," (3) "relied on factors which Congress has not intended it to consider," or (4) "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (*State Farm*). In reviewing Defendants' actions, this Court must engage in "a thorough, probing, in-depth review." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977).

When an agency changes its position, it must provide "good reasons." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (*Fox*) "[T]he requirement that an agency provide reasoned explanation for its action would ordinarily demand that [an agency] display awareness that it *is* changing position." *Id.* (emphasis in original). And 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." *Id*. Conclusory or bare statements that a factor was considered is inadequate. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016); *State Farm*, 463 U.S. at 52; *Beno v. Shalala*, 30 F.3d 1057, 1075 (9th Cir. 1994). Here, the record fails to include either "good reasons" or a "detailed justification." Instead, HHS's decision making is riddled with conclusory, unsupported statements.

A. The Counseling and Referral Restrictions are Arbitrary and Capricious

The counseling restrictions imposed by the Rule are unsupported by factual findings, the restrictions contradict HHS's prior findings, and HHS failed to provide a reasoned justification for its reversal. Specifically, HHS failed to provide reasoned justification for the following rule changes: elimination of the abortion counseling requirements as part of nondirective counseling; the prohibition of referrals for abortion services; the abortion referral list restrictions; and the new

limitations on who can provide nondirective counseling. And these changes contradict its findings in the 2000 regulations and its QFP recommendations.

1. The 2000 Regulations

In 2000, HHS relied heavily upon record of "medical ethics," "good medical care," and the prevailing medical policies. 65 Fed. Reg. 41270, 41273-75 (July 3, 2000). HHS determined that to be compliant with Congress's Nondirective Mandate, when a patient sought counseling, the counseling must be "nondirective" and present to the patient "all options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects." *Id.* at 41270. In fact, such counseling was a "fundamental program policy" and "options counseling was a necessary component of quality reproductive health care services." *Id.* at 41273. HHS determined that the nondirective mandate required the provision of counseling and referral for abortion upon request because "totally omitting information on a legal option or removing an option from the client's consideration necessarily steers her towards the options presented and is a directive form of counseling." *Id.*

HHS concluded that nondirective counseling was to be a patient-led process. *Id.* at 41273. As such, "if the client indicates that she does not want information and counseling on any particular option, that decision must be respected." *Id.* This process was consistent with the prevailing medical standards recommended by ACOG and the AMA. *Id.* (citing to ACOG policies and the AMA code of ethics). HHS also found that promotion of directive counseling on prenatal care was inconsistent with Congress's Nondirective Mandate. *Id.*

HHS also concluded that the "provision of a referral is the logical and appropriate outcome of the counseling process." *Id.* at 41474. As it relates to information regarding particular abortion providers, HHS noted that "it does not seem rational to restrict the provision of factual information in the referral context, when no similar restriction applies in the counseling context." And HHS concluded that mandatory prenatal referrals were inappropriate. Specifically, HHS determined that "requiring a referral for prenatal care and delivery or adoption where the client rejected those options would seem coercive and inconsistent with the concerns underlying the nondirective counseling requirement." *Id.* at 41275.

Finally, HHS recognized that the 1988 regulations (relied upon by Defendants in the Rule) were never fully implemented, and therefore, the policies from 1981 have governed the Title X program consistently since that time. *Id*. at 41271. As such, there is "no evidence that [the 1988 regulations] can and will work operationally on a national basis in the Title X program." *Id*. HHS also relied upon comment letters as evidence that the Title X grantee community found the 2000 regulations generally acceptable while the 1988 compliance standards were "generally unacceptable to the grantee community." *Id*.

As discussed below, the Rule violates the APA because it makes no reasoned or evidence-based findings to justify overhauling the 2000 regulations and abandoning the evidence underpinning those regulations.

2. HHS's QFP Recommendations

The Rule also contradicts HHS's own QFP recommendations. The QFP recommendations, which are incorporated into Title X, state that quality family planning is to be "client centered" by "highlighting the client's primary purpose for visiting the service site," and encouraging clients to make contraceptive choices based upon "their individual needs and preferences." QFP at 2. The recommendations state that "client values guide all clinical decisions" while "[c]are is responsive to, individual client preferences, needs, and values." *Id*. at 4

The QFP recommendations also state that "[o]ptions counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG and AAP." *Id*. at 13. The guidelines further state that

> Referral to appropriate providers of follow-up care should be made at the request of the client, as needed. Every effort should be made to expedite and follow through on all referrals. For example, providers might provide a resource listing or directory of providers to help the client identify options for care. Depending upon a client's needs, the provider may make an appointment for the client, or call the referral site to let them know the client was referred.

QFP at 14.

Regarding prenatal care, the QFP recommendations only discuss prenatal services in the context of "clients who are considering or choose to continue the pregnancy." *Id.* at 14. There is

no discussion of requiring clients to receive prenatal care upon a positive pregnancy test, regardless of her wishes or choice.

3. HHS Abandoned 35 Years of Title X Regulations Without a Reasoned Explanation

In adopting the Rule, HHS implemented a significant policy change that is so "unclear or contradictory that we are left in doubt as to the reason for the change in direction." *Int'l Rehab. Scis. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012). And in many instances, HHS did not acknowledge that it was contradicting its own findings on the necessary components of family planning. *See Fox*, 556 U.S. at 515-516 (holding that it is arbitrary and capricious for an agency to ignore that it is disregarding facts and circumstances that underlay or were engendered by the prior policy).

Here, HHS did not explain why it changed its mind from the 2000 regulations regarding: (1) why it no longer believes "options counseling [is] a necessary component of quality reproductive health care services"; (2) why requiring prenatal care referrals or promotion of options that the client does not want is not directive; and (3) why it decided to restrict abortion referrals.[5] 65 Fed. Reg. at 41273-74. HHS also does not explain why it believes implementation of the Rule is feasible when, as discussed in the 2000 regulations, no similar regulations have ever been implemented. *Id*. at 41271; *Organized Vill. of Kake v. U.S. Dep't of Agriculture*, 795 F.3d 956, 966 (9th Cir. 2015) ("The absence of reasoned explanation for disregarding previous factual findings violates the APA); *Fox*, 556 U.S. at 515-16.

Confusingly, HHS also did not discuss its agency's own QFP recommendations in any capacity—despite the fact these are HHS's own recommendations for best practices and several commenters noted that the Rule did not align with these guidelines. *See* ACOG AR 268843-44; Nat'l Family Planning & Reprod. Health Ass'n (NFPRHA) AR 308016 (stating that the QFP

[5] HHS also did not address the concern of commenters that providing an incomplete list for referrals would expose women to crisis pregnancy centers which "specifically target pregnant women who are considering abortion to dissuade or outright prevent them from obtaining abortion care" and often "do not have qualified medical providers on staff and refuse to provide or refer for appropriate medical services." Ctr. for Reprod. Rights AR 315964-65; 77 ("Many of these centers also train their staff and volunteers to convince women to make an appointment, regardless of whether the center provides the services they are seeking.")

recommendations instruct that options counseling should be provided and the Rule is in "violation of these standards."); Planned Parenthood Fed'n of Am. (PPFA) AR 316412-13 ("the Department's proposed changes in this area conflict with its own clinical recommendations [the QFP recommendations]"); *Fox*, 556 U.S. at 515 ("The requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position.") (emphasis in original). The QFP recommendations are—as described by HHS—its own expert findings and are supposed to guide clinicians nationwide on "how to provide family planning services." QFP at 1-2; PPFA AR 316412-13 ("Because the process of developing the QFP recommendations was rigorous and based on the effectiveness of services, it constitutes a body of objective, research-based practices.") Multiple commenters referred and relied upon the QFP recommendations in identifying serious problems with the rule. *See* ACOG AR 268843-44; PPFA AR 316412-13; Jacobs Inst. of Women's Health (JIWH) AR 239147-49; Am. College of Nurse-Midwives (ACNM) AR 315936-37.

In fact, the Rule directly contradicts the QFP recommendations in several respects. First, the QFP recommendations state that prenatal counseling is only appropriate for clients who are considering or choose to continue their pregnancy. *Id*. at 14. And HHS has previously determined that mandatory prenatal referrals were coercive and inconsistent with the nondirective counseling limitation. 65 Fed. Reg at 41275. But now, HHS is mandating pregnancy care in spite of a patient's directive. Second, the QFP recommendations affirm that quality family planning care should take a "client-centered" approach. QFP at 4. And this approach means that providers are supposed to focus on the patients' desires—not the clinicians. But the Rule allows a provider to omit information about abortion—even if the client asks for that information—and the Rule insists that providers force potentially unwanted prenatal care on patients. The Rule places a "thumb on the scale" to prioritize a Title X *provider's* personal choices regarding the information a patient might receive and it overvalues a Title X provider's desires over the patients. *See Ctr. For Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008) (holding that an agency "cannot put a thumb on the scale by undervaluing the benefits and overvaluing the costs of more stringent standards," and doing so is arbitrary and capricious.)

HHS also did not explain—let alone acknowledge—its physician or advance practice providers (APP) requirement. This requirement hampers patient care by narrowing who can provide nondirective counseling. Under the Rule *only* physicians or APPs may provide nondirective counseling that may include a discussion of abortion. 42 C.F.R. § 59.14(b); 59.2. But the evidence before the agency shows that trained health educators, registered nurses, and other trained personnel can counsel patients in selecting contraceptive methods. ECF 103 at 64; ACOG AR 268840 ("There is no question that these non-physician providers are qualified to provide counseling and referrals to patients.") In fact, the Rule authorizes *any* clinic staff person to provide directive counseling exclusively about carrying a pregnancy to term. As discussed by multiple commenters, this reversal of who is qualified to provide counseling will further tax a burdened Title X system, leading to worse patient care. Essential Access AR 245491-92; ASTHO AR 199042; ACOG AR 268840 ("arbitrarily limiting the providers" permitted to undertake some types of pregnancy counseling, especially in a time of workforce shortages, "erects an unnecessary and unsupported barrier to care"). This Court held that the Rule never explains why advanced medical degrees, licensing, and certification requirements are necessary to provide someone with pregnancy counseling. ECF 103 at 65 ("HHS has articulated no explanation at all for the APP requirement and thus fails both tests.").[6]

As such, HHS has failed to engage in reasoned decision making and its findings are contrary to expert opinion and its own findings on compliance with Congressional mandates. *State Farm*, 463 U.S. at 43. By failing to offer any explanation—let alone reasoned explanation—for its change in position, the Rule cannot be "ascribed" as a "product of agency expertise." *Id*.

B. The Physical Separation Requirement and Infrastructure Building Limitation is Arbitrary and Capricious

Similarly, the physical separation requirement and the infrastructure building limitation are arbitrary and capricious because the requirements are unsupported by factual findings, contradict HHS's previous findings, and HHS failed to provide a reasoned justification for the change.

[6] HHS also disregarded its own recognition of the importance of non-APPs to Title X. *See* 84 Fed. Reg. at 7778 (reporting that non-APPs "were involved with 1.7 million Title X family planning encounters in 2016," approximately one-quarter of the total number of Title X family planning encounters that year).

1. The 2000 Regulations Found Physical Separation to be Unnecessary

In 2000, relying upon Title X providers and other commenters, HHS concluded that physical separation was "unnecessary, costly, and medically unwise." 65 Fed. Reg. at 41275. HHS acknowledged that "since Title X grantees are subject to rigorous financial audits, it can be determined whether program funds have been spent on permissible family planning services, without additional requirements being necessary." *Id*.

HHS also recognized that commenters argued that physical separation would be particularly unworkable for small and rural clinics, which "cannot afford to operate separate facilities or to employ separate staff for these services without substantially increasing the prices of services. Nor can they offer different services on different days of the week because so many of their patients are only able to travel to the clinic on one day." *Id*.

HHS determined that physical separation was "inconsistent with public health principals" as integrated health care was more important than an artificial separation of services. *Id*. ("[W]omen's reproductive health needs are not artificially separated between services: a woman who needs an abortion may also need contraceptive services, and may at another time require parental care.") Further, HHS stated that physical separation could lead to negative health outcomes, as the "most opportune time" to facilitate the provision of family planning counseling is at the post-abortion check-up. *Id*.

Finally, as with the counseling restrictions, HHS stated that physical separation had never been implemented and "the fundamental measure of compliance under that section remained ambiguous." *Id*. at 41276. HHS determined that if Title X grantees complied with the financial separation requirements of Title X, it was "hard to see what additional statutory protection is afforded by the imposition of a requirement for 'physical' separation." *Id*.

2. HHS Failed to Explain Its Reversal in Policy

The Rule places unworkable and illogical impositions on Title X grantees.

First, regarding physical separation, the Rule requires grantees to have, *inter alia*, separate treatment, consultation, examination and waiting rooms; separate entrances; separate personnel; and separate electronic health records. 42 C.F.R. § 59.15(b)–(d). HHS did not provide any

reasoned analysis or explanation of its reversal in policy. It did not address its previous factual findings in the 2000 regulations and it did not cite to any expert opinions in support of physical separation. As this Court previously held, there is nothing in HHS's rulemaking to show actual co-mingling or misuse of Title X funds. ECF 103 at 50.

HHS also does not discuss findings that patients benefit from immediate, onsite access to a range of contraceptive methods after an abortion. PPFA AR 316482; 65 Fed. Reg. at 41275. According to studies in the AR, two-thirds of abortion patients seek to leave their appointments with a contraceptive method. *Id*. But physical separation will necessitate visits to two separate facilities, increasing barriers to care. *Id*.

Second, regarding infrastructure building, the Rule irrationally bans Title X grants from being used to "build infrastructure for purposes prohibited by these fund" including activities like "clinical training for staff" and "community outreach" because these actions allegedly support an "abortion business." HHS again failed to provide any reasoned analysis or explanation of its reversal in policy. There is no evidence of Title X providers using Title X dollars to create an "infrastructure" for abortion services. And HHS failed to explain its reasons for the ban. 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. But, as commenters have stated, these sorts of wraparound services work to increase access to contraceptives and *decrease* actual abortions. PPFA AR 316440-41.

The Rule is fixated on addressing the *perception* of a problem, but does not actually identify a problem. The Rule states that HHS was concerned that there was a "perception" that Title X funds were being used for prohibited abortion activities. 84 Fed. Reg. at 7729, 7764.[7] But there are no comments which demonstrate actual evidence that Title X providers are misusing

[7] In comparison, in the 1988 regulations, HHS had evidence in the form of reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG) that stated the previous policy failed to implement properly the distinction between Title X programs and abortion as a method of family planning. 53 Fed. Reg. at 2923-2927; *Rust*, 500 U.S. at 187. Now, in contrast, there is no evidence or discussion of any confusion or comingling of funds.

funds. ECF 103 at 50. And, as this Court held, comments sent to HHS demonstrate that "commenters understand Title X funds *cannot* currently be used for abortion" *Id.* at 51.

In fact, as recently as 2018 HHS reported that "family planning projects that receive Title X funds are closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities, such as abortion." Angela Napili, Congressional Research Service Report for Congress: Family Planning Program Under Title X of the Public Health Service Act, at 14 (Oct. 15, 2018), https://fas.org/sgp/crs/misc/R45181.pdf.[8] HHS provides no explanation for its reversal from 18 years of finding that Title X programs do not inappropriately use funds to sudden, unsupported claims that Title X funds are being misused.

HHS's determination that Title X providers are benefitting from alleged economies of scale is "illogical on its own terms." ECF 103 at 52; *Am. Fed'n of Gov't Emps., Local 2924 v. Fed. Labor Relations Auth.*, 470 F.3d 375, 380 (D.C. Cir. 2006). First, a Title X provider cannot use Title X to "subsidize" its non-Title X activities because Title X cannot make up 100% of a program's budget. 42 U.S.C. § 300.[9] Providers must have other funds sources to run a clinic. The agency already provides very specific guidelines grantees must follow to ensure that Title X grants are not misused. Second, a grantee that, pursuant to the Rule, maintains separate facilities and medical records between its Title X services and abortion services can still benefit from economies of scale in rent, bulk purchasing, etc. Third, as discussed in Section I.E.1, HHS fails to provide guidance on how to reconcile its emphasis on primary care, which may include abortion referrals, with the physical separation requirement.

[8] Napili, Title X (Public Health Service Act) Family Planning Program at 22 (noting that existing "[s]afeguards to maintain this separation include (1) careful review of grant applications to ensure that the applicant understands the requirements 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 nonallowable 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 regional offices.")

[9] *New Title X Regulations: Implications for Women and Family Planning Providers* (Mar. 8, 2018), https://www.kff.org/womens-health-policy/issue-brief/new-title-x-regulations-implications-for-women-and-family-planning-providers/ ("Title X grants made up about 19% of revenue for family planning services for participating clinics in 2017, providing funds to not only cover the direct costs of family planning services, but also pay for general operating costs such as staff salaries, staff training, rent, and health information technology.")

3. HHS Failed to Rationally Evaluate Compliance Costs

HHS's physical separation compliance cost estimates are also arbitrary and capricious. HHS estimated that compliance costs would be somewhere between $20,000 to $40,00 at each service site. 84 Fed. Reg. 7781-82. But, as this Court found, this estimate is seemingly "pulled from thin air" and does not address ongoing compliance costs. ECF 103 at 59. Various commenters have stated that compliance would cost hundreds of thousands of dollars to locate a new facility, staff it, purchase separate workstations, etc. Planned Parenthood AR 316484-87 ("We estimate that, even based on these conservative assumptions. . . building and renovation costs alone would total $1.2 billion in the first year after the regulation is finalized"; NFPRHA AR 308046-47 (estimating $60 million in compliance costs); Essential Access AR 245494 ("These estimates are unrealistically low, and could feasibly amount to hundreds of thousands of dollars.") HHS simply disregarded this evidence. *See McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1186–87 (D.C. Cir. 2004) (holding that courts "do not defer to the agency's conclusory or unsupported suppositions.")

HHS ignored critical facts to conclude that physical separation is feasible. *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017) (holding that an agency may not brush aside critical facts.) As such, the physical separation requirement and infrastructure building limitation is arbitrary and capricious.

C. HHS Failed to Consider the Rules Devastating Impacts on Title X Providers and Title X Recipients

The Rule is arbitrary and capricious because HHS does not give reasoned explanation for its dismissal of the documented impacts on Title X grantees, providers, and recipients.

1. Impacts on Title X Programs

a. The Rule will Result in Title X Programs Leaving the Program

Numerous commenters have informed HHS that the counseling restrictions, physical-separation requirements, and other aspects of the Rule discussed in Sections I.A-B will cause grantees to leave the program. PPFA AR 316476-77; 316414; *see also* NFPRHA AR 308014-21 (explaining in detail why the counseling changes, "if adopted, will drive a number of Title X

providers from the program" and "shrink and diminish the effectiveness of the Title X network"); Guttmacher AR 264118 (showing that "it is clear that by dissuading dedicated, high-quality family planning providers from participating in Title X, these [counseling] restrictions would make it more difficult for patients to receive the family planning care they need"); Minn. AR 243717-18; AUCH AR 84165-66.

Loss of Title X providers "will undermine the quality and standard of care upon which millions of women depend" and "put[] at risk access to quality family planning services." AMA AR 269333; ACOG AR 268846–48 ("Eliminating specialized reproductive health-focused providers will result in a significant gap in access that the health care system is not equipped to handle"); AccessMatters AR 256454 (loss of Title X providers will lead to patients "with nowhere to turn for high-quality, unbiased, comprehensive family planning information and care."); Ctr. for Biological Diversity (CBD) AR 54193–95; NCJW AR 102349; Nat'l Inst. for Reprod. Health (NIRH) AR 106457; Miliken Inst. AR 106800–01; AAN AR 107973; JIWH AR 2239147–50; Am. Pub. Health Ass'n (APHA) AR 239897; Wash. AR 278573; Nat'l Women's Law Ctr. (NWLC) AR 280767–68; Nat'l Ass'n of County & City Health Officials (NACCHO) AR 294047; NFPRHA AR 308042–45 (rule will "radically change the makeup of the Title X network, leaving patients without access to critical care in many instances and requiring subpar, ineffective care in others"); PPFA AR 316419 (describing the "negative effects on the quality of patient care at Title X-funded sites that attempt to adhere" to the rule); Physicians for Reprod. Health (PRH) AR 317926.

HHS dismisses these concerns. HHS argues that it "does not believe" the Rule will impact patients' access to care. 84 Fed. Reg. 7725, 7769, 7781. This is a "generalized conclusion" that does not satisfy the agency's obligation to consider "important aspect[s] of the problem." *AEP Texas N. Co. v. Surface Transp. Bd.*, 609 F.3d 432, 441 (D.C. Cir. 2010); *State Farm*, 463 U.S. at 43. HHS further claimed that it did not anticipate a decrease in overall facilities offering care because it anticipates new entities will apply for funds, or seek to participate as subrecipients, as a result of the Rule. 84 Fed. Reg. at 7782. But, as this Court held, this pronouncement is "wholly conclusory and unsupported." ECF 103 at 68. Upon review of the entire administrative record, the

Court's preliminary holding is confirmed. There is nothing to support the claim that new providers are waiting to join the program.

b. HHS Failed to Address Title X Programs' Reliance upon the 2000 Regulations

The Rule also fails to evaluate Title X program's longstanding reliance upon the existing Title X structure. Title X grantees and providers long relied upon pre-Rule parameters to structure their facilities and Title X programs. *See Fox*, 556 U.S. at 515 (holding that one purpose of arbitrary and capricious review is to safeguard reliance interests from being upended by erratic policy shifts by administrative agencies). And patients have understandably relied upon access to these facilities and programs.

As this Court recognized, various providers discussed the extensive investment they made with respect to its physical infrastructure, programming, and records systems over the years in reliance on the 2000 regulations. ECF 103 at 55-56; VTDOH AR 198208 (relying on those regulations, the Title X network has been enhancing its infrastructure and opening new facilities)[10]; Guttmacher AR 264117 ("These investments include activities such as stocking contraceptive methods, training and paying staff, modernizing patient health records, covering brick-and-mortar costs, and engaging in outreach and education activities—all in direct service of sustaining the delivery of family planning care provided for under the statute, regulations and legislative mandates governing Title X."). And these investments in integrated staff and systems means that a reversal of course by the agency engenders significantly higher costs than if the separation requirement had always been in effect. ECF 103 at 56. Moreover, Title X projects create budgets based upon past fund grants, and use these budgets in support of their requests for *three-year Title X grants*.[11]

As this Court held, the reliance interests these Title X grantees demonstrated are similar to those the Supreme Court recognized as warranting a more detailed explanation of an agency's

[10] VTDOH AR 198208 ("These conditions would undermine, if not negate, the significant investments made to develop this robust system. Health care delivery is extremely costly, and the cost of care is often associated with the overhead investment in medical facilities.")
[11] HHS Office of Population Affairs, https://www.hhs.gov/opa/grants-and-funding/recent-grant-awards/index.html last accessed January 20, 2020.

change in policy. *See Encino Motorcars, LLC*, 136 S. Ct. at 2126–27 (holding that automobile dealerships had established "decades of industry reliance" on prior Department of Labor policy exempting dealerships from paying overtime compensation to "service advisors," because "[d]ealerships and service advisors negotiated and structured their compensation plans against this background understanding," and eliminating the exemption "could necessitate systemic, significant changes to the dealerships' compensation arrangements"); ECF 103 at 56.

HHS did not meaningfully address these problems. Instead, HHS merely "disagree[s]" with commenters who protested "that the physical and financial separation requirements will destabilize the network of Title X providers" by imposing significant compliance costs. 84 Fed. Reg. at 7766. Instead, the agency "believes that, overall, the Rule will contribute to more clients being served, gaps in services being closed, and improved client care that better focuses on the family planning mission of the Title X program." *Id*. But these speculations have no justification, support, or reasoned explanation.

2. Impacts on Title X patients

a. The Rule Imposes Negative Health Outcomes on Title X Patients

Title X patients will be the most impacted by the Rule. The Rule will lead to an increase in the pregnancy rate, which will result in increased maternal mortality and an increase in abortions (the opposite of what HHS's rulemaking is intended to do). ECF 103 at 69-70. *See* APHA AR239895 ("Limiting support for comprehensive reproductive health services takes us back to failed policies that harm women's health," including "an increase in maternal deaths and encouraging unsafe abortions"); AAN AR 107972 (citing evidence that removing specialized reproductive health care providers from family planning networks "is linked with increased pregnancy rates that differ substantially from rates of unaffected populations"); Brindis AR 388056 ("The proposed rule will also cause more abortions. . .by encouraging low-efficacy methods of family planning and reducing access to contraceptives."); Ass'n of Am. Med. Colleges (AAMC) AR 264536-38 (rule will "reverse" Title X's contribution to the "dramatic decline in the unintended pregnancy rate in the United States, now at a 30-year low" and "harm

lower income Americans and patients in rural areas"); Ass'n of Women's Health, Obstetric & Neonatal Nurses AR 278750, Int'l Women's Health Coalition (IWHC) AR 308089-90, Johns Hopkins Med. Depts. AR 285353, Nat'l Ass'n of Social Workers (NASW) AR 107240-41, NCJW AR 102351, PRH AR 317926–27; Cal. AR 245691, 702-03 ("less access to critical preventive care" leads to "increased unintended pregnancies" and "increased maternal mortality outcomes," which are already higher in the U.S. than any developed nation.)[12]

Researchers have also stated that women experiencing an unintended pregnancy are less likely to receive prenatal care, more likely to engage in risky behaviors, and "children from unintended pregnancies are more likely to experience poor mental and physical health during childhood, and they have lower educational attainment and more behavioral issues in their teen years." Brindis AR 388056-57. Further, the Rule will lead to reduced Sexually Transmitted Infections (STI) testing, which may lead to adverse health outcomes, infertility, or endanger the ability to carry a child to term. Brindis AR 388057; Guttmacher AR 264125 (rule will cause significant numbers of patients to "los[e] access to the comprehensive, high-quality services they need to avoid unintended pregnancies, STIs, cervical cancer, and other negative and potentially costly health outcomes"); Wash. AR 278576–77 (patients will lose access to contraception and other critical health services like STI and HIV testing and cancer screening, which can be lifesaving). These impacts will particularly be felt in California, where the Title X program has historically served more than one million patients annually and been highly effective in reducing unintended pregnancies and maternal mortality. Cal. AR 245689; 245700.

For many patients, the loss of reproductive healthcare results in the loss of primary care altogether. Inst. for Policy Integrity AR 308573 (when Title X recipient programs close, almost half the patients dependent on those services lose their only access to health care"); ACOG AR 268847–48; NACCHO AR 294047–48; NWLC AR280772-73; Brindis AR 388055 ("[F]or many low-income women, visits to a family planning provider are their only interaction with the health care system at all—including those with health insurance coverage.")

[12] *See also* Cal. Assoc. for Nurse Pract. AR 331394 (The Rule "could very likely result in unplanned teen pregnancies, untreated [STIs] and cancers, and significant costs to California's healthcare system.")

The administrative record is replete with concrete evidence of the negative health impacts of reduced reproductive healthcare. *See* NCJW AR 102349–50; NASW AR 107239; JIWH AR 239148; AMA AR 269333; ACP AR 281210; Ass'n of Maternal & Child Health Progs. AR 295491, Am. Ass'n of Univ. Women (AAUW) AR 307784, IWHC AR 308086–87, PPFA AR 316480, PRH AR317925; ACOG AR 268847 (each citing a study published in the New England Journal of Medicine showing that 2013 Texas regulations excluding Planned Parenthood from its state-funded network caused a 35% decline in the use of the most effective methods of contraception, and a corresponding increase in unintended pregnancy which led to a 27% increase in childbirth covered by Medicaid); Miliken Inst. AR106796–97, 801 (citing additional studies on the Texas rule); AAP & SAHM AR 277794–95 ("When qualified providers are excluded from publicly funded programs serving low-income patients, other providers are unable to fill the gap"); AAMC AR 264538 (citing research showing that community health center participants in Title X lack capacity to accept new patients when other providers leave the network); IWHC AR 308087-91 (discussing clinic closure caused by global gag rule, which deprived patients of "access to essential services well beyond abortion care, including cervical cancer screenings, STI testing, HIV testing and treatment, and pre-natal and postpartum care.")[13]

Further, these harms will disproportionately impact those low-income women, who are most in need of the services Title X provides. *See* Cal. AR 245698-01 (stating that the rule would most harm low-income women, have a disparate impact on communities of color, and a disparate impact on rural, non-urban communities); ACP AR281210–11; AAP & SAHM AR 277795 (rule would "exacerbate racial and socioeconomic disparities in access to care by leaving Title X patients, who are disproportionately black and Latinx, without alternate sources of care"); IWHC AR 308089-90 (rule will "deny people who already face health disparities access to care," including people of color and people with language barriers); Black Women for Wellness AR 248191 ("Women of color will be disproportionately impacted" by the rule and "stand to lose the

[13] Cal. Primary Care Assoc. AR 252300 ("If all qualified family planning providers that also provide abortion services were to be eliminated from the Title X family planning program in California. . . [m]any local health systems will have difficulty absorbing the additional patients, leaving gaps in timely access to care for low-income patients across California.")

most."); Nat'l Council of Asian Pacific Americans AR 305328–29 (rule will disproportionately impact Asian American Pacific Islander women, who experience higher cervical cancer rates and are more at risk for unintended pregnancy than other racial groups); Nat'l Health Care for the Homeless Council AR 308420 (reduced access "worsens homelessness and poverty"); Am. Psychol. Ass'n AR 280243–44 (rule "endangers a patient population that has an unmet need for services and high risk for mental health problems"); NCJW AR AR102351–52; NASW AR107240–41; ACLU AR 305735–36; Nat'l Latina Inst. for Reprod. Health AR 307453–54; PRH AR 317927; Nat'l Women's Health Network (NWHN) AR372640. This impact will particularly be felt in California. The Title X program serves more than one million patients annually, and the program has been highly effective in reducing unintended pregnancies and maternal mortality. Cal. AR 245689; 245700.

b. HHS Ignored These Comments

HHS did not address these patient impacts. HHS also did not address any comments pointing out that diminished access to Title X providers will lead to an increase in Medicaid spending—directly affecting the state. *See* Miliken Inst. AR 106801 (Medicaid covers almost half of U.S. births; a "spike in unintended pregnancy and childbearing" caused by the rule will raise Medicaid spending nationwide); PPFA AR 316480 (childbirth covered by Medicaid increased by 27% after enactment of similar regulations in Texas); AccessMatters AR 256454 (predicting taxpayer cost of $80 million per year based on conservative estimate of only 10,000 more Medicaid-funded births resulting from loss of access to Title X services); NCJW AR102349 (in 2010, Title X-funded health centers saved state and federal governments $7 billion); AAFP AR 1040786 ("Universal coverage of contraceptives is cost effective and reduces unintended pregnancy and abortion rates."); NACCHO AR 294046 ("Ultimately, increased taxpayer contributions will be required" to address the "long-term cyclical impacts of this rule."); *compare* Cal Acad. of Fam. Phys. AR 240313 ("In California $ 1.3 billion is saved annually [due to] public investment in family planning and related services provided at Title X funded health centers). These costs, "in terms of both public health outcomes and taxpayer dollars," are "exactly the costs

that Congress sought to avoid when creating the Title X program in the first instance[.]" NFPRHA AR 308044–45.

Instead, HHS made three different, conflicting responses to this evidence. HHS first claimed that the Rule will decrease unintended pregnancies (but offers no evidence supporting this assertion); then HHS claimed that commenters offer no compelling evidence that the rule will increase unintended pregnancies (ignoring the research cited above); and then HHS determined that an increase in pregnancy and resultant costs are speculative. 84 Fed. Reg. at 7743, 75, 85. As this Court held, "[t]his rationale does not withstand even deferential scrutiny." ECF 103 at 70. HHS cannot simply disregard evidence it finds inconvenient. *Id.*; *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004).

3. Impact on Providers

Finally, as discussed above, the Rule's limits on pregnancy counseling fails to satisfy the clinical practice recommendations of ACOG and AAP, which HHS incorporated into the QFP recommendations. *See* ACOG 268838-41 (referencing ACOG policies and opinions); AAP Cmt 277788-89 (counseling changes "conflict [] with medical practice guidelines, including those of the American Academy of Pediatrics"); Fam. Planning Councils of Am. AR 385053 (the Rule, including in changes to pregnancy counseling, "undermine[s] the evidence-based standard of care" in the QFP recommendations, set after extensive review by HHS of "best practices and current research").

Governing ethical bodies explained in their comments that the Rule was contrary to prevailing ethical standards. The AMA, which wrote and interprets the Code of Medical Ethics, emphasized that the Rule "would force physicians to violate their ethical obligations," by prohibiting referrals upon patient request. AMA AR 269332; *see also* Am. Acad. of Phys. Asst. AR 106281 (to comply with its ethical principles, physician assistants "must … be able to provide referrals" for the care that is desired by their patients and "have an ethical obligation to provide… unbiased clinical information"); NASW AR 107236-37 (NASW Code of Ethics).

Providers also commented that the restrictions on counseling and referral information may place them at increased risk of medical liability. AAP & SAHM AR 277789. Specifically, the

AAP stated that restrictions on the provision of clear and direct referrals to patients may put the patient at risk of undiagnosed medical conditions, placing Title X providers at elevated risk of liability. *Id.*

However, HHS offered only conclusory assertions that it "disagrees with commenters who contend" that the Rule infringes on "ethical[] or professional obligations of medical professionals." HHS's "conclusory statements do not suffice to explain" HHS's decision-making, *Encino Motorcars*, 136 S. Ct. at 2127, and "offer[ing] an explanation for its decision that runs counter to the evidence before the agency" is arbitrary and capricious, *State Farm*, 463 U.S. at 43.

In the Rule, HHS stated that the new restrictions are intended to ensure that "the 2000 regulations are not consistent with federal conscience laws," including "the Church Amendment, Coats-Snowe Amendment and the Weldon Amendment." 84 Fed. Reg. at 7746. But in 2011, the agency affirmed that there were protections for conscience protections and the HHS Office for Civil Rights addresses any complaints of discrimination under the conscience laws. 76 Fed. Reg. 9968, 9969 (Feb. 23, 2011). HHS does not discuss why the existing conscience statutes are inadequate to protect providers. *See Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 50 (D.D.C. 2019) (holding that an agency rule is arbitrary and capricious where "the government failed to explain why the [existing] safeguards as a whole would not prevent against the risk" the rule purported to address).[14]

Further, the pregnancy counseling restrictions discussed in Section I.A undermine the patient-provider trust that is essential for patients' willingness to seek help from their provider and trust that their provider is offering them accurate information. *See, e.g.,* ACOG AR 268838-41; AMA AR 269330-32; AAP & SAHM 277788-89; AAMC 264536-37; NLIRH 307455-56; NFPRHA 308018-20 (explaining that misleading and incomplete counseling under the Rule will destroy trust in the provider); Health Care Partners of Southern. Cal. AR 107219 ("It could cause irreparable harm to the patient/doctor relationship if the patient learns that their physician

[14] HHS has limited to no statutory authority to implement regulations under the Church Amendment, the Coats-Snowe Amendment, and the Weldon Amendment. *New York v. United States Dep't of Health & Human Servs.*, 2019 WL 5781789, at *32 (S.D.N.Y. Nov. 6, 2019); *City & Cty. of San Francisco v. Azar*, 2019 WL 6139750, at *16-17 (N.D. Cal. Nov. 19, 2019).

purposefully withheld information from them."). HHS admits "quality of communication" affects health care outcomes (84 Fed. Reg. at 7783) but does not discuss the impact of forcing clinicians to state misleading or ideological information.

HHS failed to consider any professional, reputational, or ethical harm to providers. *See Ctr. For Biological Diversity*, 538 F.3d at 1200 (agency acted arbitrarily by assigning zero value to a relevant factor reflected in the record); *Make the Road New York v. McAleenan*, 405 F.Supp.3d 1, 55 (D.D.C. 2019) ("An agency cannot possibly conduct reasoned, non-arbitrary decision making concerning policies that might impact *real* people and not take *real life circumstances* into account.")

D. Removal of the Medically Approved Requirement is Arbitrary and Capricious

HHS's removal of the "medically approved" requirement is arbitrary and capricious and serves to prioritize an untested and unreliable form of family planning. The 2000 regulations required Title X projects to "[p]rovide a broad range of acceptable and effective medically approved family planning methods . . . and services." 42 C.F.R. § 59.5(a)(1) (2000) (emphasis added). The Rule removes the "medically approved" language; it simply requires Title X projects to "[p]rovide a broad range of acceptable and effective family planning methods . . . and services." § 59.5(a)(1). HHS failed to provide a reasoned basis for this change.

HHS stated that the requirement "risked creating confusion about what kind of approval is required," 84 Fed. Reg. at 7774, but as this Court noted, there is no evidence that any provider had expressed any confusion. ECF 103 at 65; QFP at 7. It was widely understood that "medically approved" means "contraceptive methods that have been approved by the Food and Drug Administration," as discussed by the QFP recommendations. *Id.*; Guttmacher AR 264107-08; ACOG AR 268843; AMA AR 269332-33; PPFA AR 316467. HHS's explanation of its decision to remove the medically approved language "runs counter to the evidence before the agency."[15]

[15] HHS seems to be encouraging providers who will not offer the "full range" of contraceptive choices in accordance with the QFP recommendations. QFP at 1, 2, 7, 24; *see* NACCHO AR 294043–44 (rule permits clinics to provide "calendar-based methods relying on abstinence during fertile windows" that "have not been regulated, approved, or certified by any particular agency or accreditation body"); ACOG AR 268843–44; AMA AR 269332–33; AAP & SAHM AR277793–

State Farm, 463 U.S. at 43.

E. HHS Arbitrarily Interfered with an Effective Title X Network

1. Section 59.5 (a)(12) Irrationally Blocks Isolated Title X Sites

The Rule irrationally blocks Title X providers without primary care onsite. Section 59.5 requires each supported project to either have comprehensive primary health services onsite or have a "robust referral linkage with primary health providers who are in close physical proximity[] to the Title X site." 42 C.F.R. § 59.5(a); 84 Fed. Reg. 7787-88. But multiple commenters informed HHS that this proximity requirement would block existing or future Title X sites in areas where Title X sites offer the *only* care. See Guttmacher AR 264118-19; PPFA AR 316468-70; ACP AR 281210-11; Cal. AR 245699. The Association of State and Territorial Health Officials specifically warned HHS that in "primary care health professional shortage areas," this provision would harm patient access to care. ASTHO AR 199037. The association emphasized that "most state and local health agencies do not provide direct primary care," and that this provision would interfere with maintaining existing Title X sites. *Id*.

HHS offered only conclusory statements that linkages to primary care are important. 84 Fed. Reg. 7787-88. But it did not address evidence in the record regarding the impact of clinic closures due to an inability to provide access to primary care—which is arguably a worse scenario for patients, nor did it define close physical proximity. HHS also does not acknowledge that since the purpose of Title X is reproductive healthcare, and mandating increased primary care to the detriment of the Title X network undermines the purpose of the statute. Further, HHS does not explain how to reconcile the need for primary care—which may involve a primary care provider giving a referral for abortion—with the physical separation requirement.

2. The Rule Further Harms Minors Who Seek Free Services

The Rule applies an illogical differential standard to minors seeking services and does not

94; Guttmacher AR 264110 ("The federal government promoting [fertility awareness-based methods] within Title X would actively undermine the program's mandate to ensure patients' choices are wholly voluntary and free from coercion."). ACOG told HHS that this aspect of 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." ACOG AR 268837; *see also* NFPRHA 308022; Cal. Women's Law Ctr. AR 315624-29.

rationally explain the new restrictions. Title X covers services to minors. 42 U.S.C. § 300(a). The Rule now requires that providers must encourage the involvement of the minor's parents or guardian, regardless of the specifics of the minor's family circumstances, if the minor is seeking free or reduced fee services. Section 59.2. But if the minor is not seeking free or reduced-fee services, the Rule permits a provider to meet the less exacting standard of documenting any reason by family participation might not be encouraged. 84 Fed. Reg. 7788. HHS did not meaningfully explain the discrepancy in treatment. And HHS did not address commenters who noted that there are many reasons why parental involvement should not be encouraged when a minor might be at risk from dangerous family members. NFPRHA AR 308031-32; ACOG AR 268848; Ctr. Reprod. Rts. AR 315972-73. These failures violate the APA's requirement that the agency provide a rational explanation for its approach.

F. *Rust* Does Not Foreclose California's Arbitrary and Capricious Claims.

Defendants relied heavily upon *Rust* in the Rule, the parties' preliminary injunction briefing, and the parties' motion to dismiss briefing to argue that the Rule is valid. But California's arbitrary and capricious claims are not foreclosed by *Rust*. *See* ECF 103 at 48.

The justifications supporting the 1988 regulations upheld in *Rust* cannot insulate the Rule from review now. *See Michigan v. E.P.A.*, 135 S. Ct. 2699, 2710 (2015) (It is a "foundational principle of administrative law that a court may uphold agency action only on the grounds that the agency invoked when it took the action.") Nor can HHS rely on the factual bases justifying the 1988 regulations. *See Sierra Club v. U.S. E.P.A.*, 671 F.3d 955, 966 (9th Cir. 2012) ("[An agency] stands on shaky legal ground relying on significantly outdated data" to justify its actions.); *Ctr. for Biological Diversity*, 538 F.3d at 1198 ("What was a reasonable balancing of competing statutory priorities twenty years ago may not be a reasonable balancing of those priorities today.")

HHS has failed to provide reasoned analysis for its reversal in the Rule. *Rust* does not save the Rule from being found to be arbitrary and capricious.

II. THE RULE IS CONTRARY TO LAW

The APA requires a reviewing court to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C.

§ 706(2)(A). "'[N]ot in accordance with law' . . . means, of course, *any* law, and not merely those laws that the agency itself is charged with administering." *F.C.C. v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003) (emphasis in original); *see Michigan v. E.P.A.*, 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).

A. The Rule Is Inconsistent with the Nondirective Mandate

As this Court held in its PI order, the Rule violates the Nondirective Mandate. ECF 103 at 26-35. In appropriations bills since 1996, Congress has mandated that "all pregnancy counseling" in Title X family planning projects "shall be nondirective." Pub. L. No. 115-245, 132 Stat. 2981, 3070-71 (2018). 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).

Here, the Rule acts to steer patients. By omitting information, 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), HHS acts to steer patients towards a limited set of options. This results in directive counseling and conflicts with the Nondirective Mandate.[16]

Moreover, the Rule also requires that providers refrain from "encourage[ing]" or "promot[ing]" abortion. *Id.* § 59.16. But this requirement—and unclear guidance as to what constitutes encouragement—will only result in providers omitting in-depth discussions for fear of violating the Rule. ECF 103 at 34-35; ACOG AR 268839 ("Without additional guidance, grantees may interpret this language as a complete prohibition on any conversation with their patients that

[16] Defendants have previously argued that referrals are separate from counseling. ECF 103 at 28. But as this Court held, statute, regulations, industry practice, and HHS's own QFP recommendations all state that referrals are part of counseling. *Id.* at 28-33. *See Louisiana Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 357 (1986) (articulating "the rule of construction that technical terms of art should be interpreted by reference to the trade or industry to which they apply") (citing *Corning Glass Works v. Brennan*, 417 U.S. 188, 201–02 (1974)); *Alabama Power Co. v. E.P.A.*, 40 F.3d 450, 454 (D.C. Cir. 1994) ("[W]here Congress has used technical words or terms of art, it is proper to explain them by referring to the art or science to which they are appropriate.").

references abortion."); Cal. Med. Assoc. AR 308370-71; AAN AR 107973; Guttmacher Inst. AR 264112-13; Cal. Med. Assoc. AR 30868-69 ("These changes would have a chilling effect on physicians who could fear even mentioning the word abortion.") Counseling is only nondirective if the medical professional is not suggesting or advising one option over another. 84 Fed. Reg. at 7716. The complete omission of a safe, legal, and relevant medical option cannot be nondirective.

B. The Rule Violates Section 1554.

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

42 U.S.C. § 18114.

Here, the Rule violates multiple parts of Section 1554. ECF 103 at 43-46.

First, as discussed in Section I.A, the restrictions on pregnancy counseling, including the referral restrictions, obfuscate and obstruct patients from receiving information and treatment for their medical needs. This "creates [an] unreasonable barriers to the ability of individuals to obtain appropriate medical care" and "impedes timely access to health care services," "interferes with communications regarding a full range of treatment options between the patient and the provider," and "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions." 42 U.S.C. § 18114 (1)-(4).

Second, as discussed in Section I.A, the Rule's prohibition on providing abortion referrals, restrictions on the content of referral lists, and mandate for referrals for prenatal care, even if a woman does not seek a referral, are also squarely at odds with established ethical standards and therefore violate Section 1554(5). ECF 103 at 44.

Third, as held by this Court, the Rule's family participation requirement violates ethical standards. ECF 103 at 46. Title X itself only asks grantees to "encourage family participation" in Title X projects "[t]o the extent practical." 42 U.S.C. § 300(a). But Section 59.5(a)(14) directs

Title X grantees to "[e]ncourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged)." The new requirement for "clinicians to take 'specific actions' to encourage family participation, even after they have learned that this involvement is not practicable," is "contrary to medical ethics." ECF 103 at 46.

C. *Rust* Does Not Foreclose California's Claims

As discussed in Section I.F, Defendants will likely rely upon *Rust* to argue that the Rule is valid. But in light of the enactment of Section 1554 and the nondirective counseling mandate, *Rust* alone does not give HHS the greenlight to enact the Rule. *See Vance v. Hegstrom*, 793 F.2d 1018, 1024 (9th Cir. 1986) (in issuing regulations, "the Secretary may not read [one] subsection … independently of" others). As discussed above, the Rule is incompatible.

III. THE RULE IS IN EXCESS OF STATUTORY AUTHORITY

Agency action in excess of statutory authority must be set aside. 5 U.S.C. § 706(2)(C). "[A]n agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Utility Air Regulatory Grp. v. E.P.A.*, 573 U.S. 302, 328 (2014). HHS's policy preferences cannot conflict with congressional directives. *City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 296–97 (2013) (agency discretion is cabined by scope of authority as delegated by Congress).

Here, Title X's central purpose is to increase access to comprehensive, evidence-based, voluntary family planning services. ECF 103 at 3-4; Pub. L. No. 91-572 § 2, 84 Stat. 1504. But, as discussed above in Section II.C, the Rule serves to force qualified providers out of the program, impede access to comprehensive care, and decrease the availability of family planning services. This "allow[s] the exception to swallow the rule, thereby undermining the purpose of the statute itself." *Nat'l Fed'n of Fed. Emps. v. McDonald*, 128 F. Supp. 3d 159, 172 (D.D.C. 2015); *see also Stewart v. Azar*, 366 F. Supp. 3d 125, 138 (D.D.C. 2019) (rejecting HHS regulation that was not "reasonably approximated toward enhancing the provision" of medical services per statute's "central objective"). As such, HHS is acting contrary to the purpose—and outside the

permissible scope—of Congressional authority.

The Court held that the Rule would result in a reduction of access to contraceptive reproductive health services. ECF 103 at 15-16. This is the opposite of what Congress wanted in enacting Title X. "'In order to be valid regulations must be consistent with the statute under which they are promulgated.'" *E. Bay Sanctuary Covenant v. Trump*, 909 F.3d 1219, 1248 (9th Cir. 2018) *superseded,* 932 F.3d 742 (9th Cir. 2018) (brackets omitted) (quoting *United States v. Larionoff*, 431 U.S. 864, 873 (1977)). This court should not "rubber-stamp" rules "inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *A.T.F. v. Fed. Labor Relations Auth.*, 464 U.S. 89, 97 (1983). As such, the Court should find the Rule in excess of statutory authority.

IV. THE VACATUR IS THE CORRECT REMEDY

A court must set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law." 5 U.S.C. § 706(2). A finding on any one of these three prongs is sufficient to mandate vacatur. As discussed in Sections I-III, the Rule is fatally defective and must be vacated.

CONCLUSION

For the reasons discussed above, and for those in Essential Access' brief, California respectfully requests that the Court grant California's motion in full, enter summary judgment in California's counts I-III, and vacate the Rule.

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